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Report to the Ranking Minority Member, Committee on Veterans' Affairs, U.S. Senate

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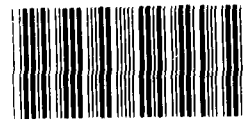
VA HEALTH CARE

VA's Patient Injury Control Program Not Effective



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GAO

United States
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Washington, D.C. 20548

Human Resources Division

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May 18, 1987

The Honorable Frank H. Murkowski
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate

Dear Senator Murkowski:

In response to your August 30, 1985, request, we have reviewed the effectiveness of the patient injury control function of the Veterans Administration (VA) quality assurance program. The report discusses the (1) reporting of incidents at VA medical centers, (2) investigating of specified incidents, and (3) trending and analysis of patient incidents by VA's medical centers and central office.

Copies of this report are being sent to the appropriate congressional committees; the Administrator of Veteran Affairs; the Director, Office of Management and Budget; and other interested parties.

Sincerely yours,

for

Richard L. Fogel
Assistant Comptroller General

Executive Summary

Purpose

Providing high quality medical care to patients is a major goal of the Veterans Administration (VA). In 1985, GAO reported that VA had not fully implemented important systems to assess the quality of care provided in its medical centers. Subsequently, the former Chairman, Senate Committee on Veterans' Affairs, asked GAO to evaluate the effectiveness of a key quality assurance program at VA—patient injury control. Accordingly, GAO sought to learn if incidents of patient injury were being reported, reported incidents investigated, trends identified, data analyzed, and corrective actions taken.

Background

VA requires each of its 160 medical centers to establish a patient injury control program to prevent the recurrence of patient injuries, such as falls, surgical complications, and unexpected deaths. VA's medical inspector oversees this program.

The patient injury control program involves (1) reporting incidents that would not be considered a natural consequence of a patient's disease process or illness, (2) investigating certain incidents to determine why they happened and whether they can be prevented from recurring, and (3) analyzing patient incident trends that may indicate problems requiring further study or corrective actions.

Incident reporting is the cornerstone of an effective program. Without it, quality of care problems cannot be identified and investigated; trending and analysis of incidents cannot be done; and recommendations to correct problems cannot be made.

For this study, GAO analyzed patient injury control programs at nine VA medical centers between August 1985 and November 1986. GAO also obtained information on similar programs in non-VA hospitals or hospital systems.

Results in Brief

VA's patient injury control program has not been effective in preventing the recurrence of more serious incidents, e.g., unexpected deaths and surgical complications. These incidents have been underreported principally due to disincentives for staff to report them and lack of reporting guidance from and oversight by VA's central office.

Also, VA medical centers did not (1) conduct all required investigations, (2) forward all investigation reports to the medical inspector for review, (3) forward investigation reports in a timely manner, or (4) always

trend and analyze available data. GAO's work showed that proper reporting, investigating, trending, and analysis of serious incidents reduces quality of care problems.

A system used by many hospitals to identify incidents—occurrence screening—overcomes many of the reporting problems experienced by VA. VA intends to implement an occurrence screening system in all its medical centers in October 1987. This should help overcome the reporting disincentives.

Principal Finding

Serious Incidents Underreported

In fiscal year 1985, VA medical centers reported about 85,000 incidents through the patient injury control program. But the more serious incidents generally were not reported. At the nine centers reviewed, GAO found 613 unreported incidents (86 percent) in 714 cases specifically selected because of the likelihood that an incident had occurred. For example, a 69-year-old patient experienced excessive bleeding because of an aneurysm that ruptured during surgery. The bleeding could not be controlled, and the patient died. According to the VA medical inspector, this incident, which was not an expected outcome of the surgery, should have been reported through the patient injury control program but was not.

Among the reasons for underreporting were disincentives to report incidents, such as the negative connotations of such reporting; the nonconfidentiality of incident reports; and lack of clear guidance on what was to be reported and how. (See pp. 20 to 25.)

Problems With Investigation Process

By analyzing fiscal year 1984 information reported by VA's 160 medical centers, GAO found that only 266 investigation reports for 1,344 incidents requiring an investigation were forwarded to the medical inspector. At the nine centers GAO visited, about 36 percent of incidents requiring investigation were investigated. The staff either saw no need to investigate or felt that VA's investigations took too long. Additionally, only 20 percent of investigations that were reported to the medical inspector in fiscal year 1984 were reported within the required 30-day time frame. (See p. 34.)

Compared with non-VA hospitals, VA's investigative process is cumbersome. It requires that every investigation be conducted by a three-member board, which takes testimony under oath.

Analysis of Incident Data Limited

Despite the generally recognized advantages of trending data on patient incidents over time and comparing them among hospitals in a system, VA did little such analysis. The medical inspector performed very limited analysis because he considered the data reported to him to be unreliable. At the centers, trending was done mainly by nursing staff and involved mostly nursing-related incidents. Center officials saw no need to trend other data because they thought incidents would be taken care of on a case-by-case basis or by other quality assurance activities. (See pp. 44 and 45.)

GAO's analyses of incidents at several medical centers showed the value of trending as part of the patient injury control program. For example, at one center, GAO's analysis of surgical complications and unexpected deaths prompted a review by the center's chief of staff and other medical officials that resulted in corrective actions. GAO believes that, had the center properly reported, investigated, and trended those incidents, it could have taken the corrective actions much earlier than it did. (See pp. 45 and 46.)

Occurrence Screening May Be Answer

Several hospital insurance companies and non-VA hospital chains recommend occurrence screening as an addition to a facility's incident-reporting system. Under occurrence screening, trained personnel review each patient's chart at various points during and after the hospital stay. Certain criteria, such as whether the patient had been readmitted to the facility because of complications from a previous admission, are used to identify possible incidents.

GAO supports VA's planned establishment of an occurrence screening program in all VA medical centers as a complement to the incident-reporting program.

Recommendations

GAO recommends that VA improve its patient injury control system by (1) reinforcing both the importance of the patient injury control program as

a quality assurance mechanism and the need to comply with federal regulations, (2) clarifying what incidents are to be reported and investigated, (3) simplifying the investigation process, and (4) improving central office oversight of centers' programs.

Agency Comments

VA concurred with the recommendations and said that implementation of them was in progress. Publication of a revised manual is expected in October 1987.

VA did not agree with GAO's description of its patient injury control program as ineffective and stated that it would be more accurate to say that improvements were needed in the program. GAO believes that a program that does not identify 86 percent of serious incidents is not effective. The actions being taken or planned by VA should make the program more effective.

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Abbreviations

AHA	American Hospital Association
GAO	General Accounting Office
JCAH	Joint Commission on Accreditation of Hospitals
VA	Veterans Administration

Introduction

The Veterans Administration (VA) operates one of the largest health care delivery systems in the United States. In fiscal year 1985, VA's system included 172 hospitals, 226 outpatient clinics, 105 nursing care units, and 16 domiciliaries. Most of the VA's health care facilities are organized into 160 medical centers. A medical center may consist of one or more hospitals, one or more outpatient clinics, a nursing home, and a domiciliary. VA's Department of Medicine and Surgery, headed by the chief medical director, is responsible for all the facilities.

VA's goal is to provide high quality, timely health care to all eligible veterans. To help determine if veterans are receiving such care, the agency has instituted a quality assurance program.[1] Focusing on patterns of care rather than individual cases or clinicians, this program is designed to objectively and systematically review VA's total health care activities.

The program provides a process by which VA evaluates the (1) appropriateness of patient care and service provided, (2) utilization of resources, (3) safety of patients, and (4) conduct and performance of VA employees and others providing patient care. It is expected to lead to better patient care by providing recommendations to health care providers and managers for improving such activities as staff performance and productivity as well as the quality and timeliness of service.

The quality assurance process consists of an in-hospital and an external review component. Internally, each medical center is required to have an integrated quality assurance process comprising five mandatory functions:

- Continuous monitoring reviews,
- Patient injury control,
- Utilization reviews,
- Problem-focused health care evaluation studies, and
- Credentialing and delineation of clinical privileges.

Externally, there is a peer review mechanism for periodically evaluating the quality of care in each medical center and the effectiveness of its internal quality assurance process. This mechanism, called the systematic external review program, involves a week-long evaluation of medical care and related services by a team of health care and administrative personnel from other VA medical centers.

[1]The program is defined in the Code of Federal Regulations at 38 C.F.R. 17.500 (1986).

In a 1985 report[2] to the chairman and ranking minority member of the Senate Veterans' Affairs Committee, as well as testimony before it, we concluded that 13 VA medical centers had not fully implemented the internal functions listed above, nor had the external peer review mechanism evaluated the effectiveness of the centers' internal functions. We did not address the effectiveness of the quality assurance programs those centers had implemented but concentrated on the centers' compliance with VA quality assurance regulations. That report laid the groundwork for our review of the effectiveness of VA's patient injury control program at the individual medical center, regional, and central office levels and our determination of whether it is an effective quality assurance function. In a letter dated August 30, 1985, the then chairman of the Senate Veterans' Affairs Committee endorsed our efforts to examine VA's program. (See app. I.)

VA's Patient Injury Control Program

VA's patient injury control program requires each medical center to report, analyze, review, and investigate any unusual, unexpected, or unfavorable incident a patient may experience. Examples of such incidents include falls, assaults, patient abuse or neglect, unexpected deaths, surgical complications, suicides, and suicide attempts.

Roles and Responsibilities

VA's chief medical director has overall responsibility for implementing and enforcing VA's quality assurance requirements, which includes the patient injury control program. That official relies on the medical center directors, seven regional directors, the medical inspector, and the Office of Quality Assurance to meet the objective of providing high quality health care to veterans. Also, the Office of the Inspector General reviews quality assurance activities.

At each facility, the medical center director is responsible for the patient injury control program. The authority for coordinating and conducting day-to-day supervision of patient injury control activities, however, is generally delegated to such staff members as the chief of staff and the quality assurance coordinator.

In addition to exercising direct line supervision of medical center directors in their regions, regional directors receive such patient injury control program data as 6-month summaries of reported incidents, certain

[2]VA Has Not Fully Implemented Its Health Care Quality Assurance Systems (GAO/HRD-86-57, June 27, 1985).

incident reports, and investigations from the medical centers. Also, regional directors conduct peer review site visits at the medical centers within their regions.

The medical inspector is the key VA Central Office official responsible for VA's patient injury control program. Until March 3, 1985, the medical inspector developed policies and procedures and provided guidance and oversight for medical center quality assurance programs. He also was responsible for systematic external reviews and investigation of selected quality-of-care incidents. On that date, all but the patient injury control function was incorporated in the newly created Office of Quality Assurance in the Department of Medicine and Surgery. According to the chief medical director, this was done to place additional emphasis on VA's quality assurance program. The medical inspector remains responsible for patient injury control.

Program Mechanisms

The purpose of VA's patient injury control program is to prevent and limit patient injuries. This is to be done by reporting and investigating incidents, trending and analyzing data, taking corrective action on problems, and following up to see if problems have been corrected.

Any medical center employee who observes or is aware of an incident must report it. Incident reports are reviewed by the patient's attending physician, the chief of the particular medical center service affected, the chief of staff, and the medical center director. Whether or not an investigation of an incident is needed is determined by VA regulations, the chief of staff's recommendations, or the request of the medical center director or medical inspector.

Trending and analysis of data, generally done by VA quality assurance coordinators, provides a regular statistical or descriptive summary of incidents. Also, trends are analyzed to determine if there is a need for further study, policy changes, enforcement, or investigation.

Corrective actions to prevent recurrence of a problem may be proposed by the veteran's attending physician, nurses, the chief of staff, the medical center director, or VA's medical inspector.

An example of the program at work is the review of patient falls from beds at one medical center. An analysis by the center's nursing service of reported incidents indicated an increase in falls. The center determined that a structural defect—collapsing bed rails—was the cause and

replaced the defective parts. According to the quality assurance coordinator, this reduced the number of falls due to collapsing bed rails.

Additionally, VA's Central Office may propose, through VA circulars or information letters, corrections to the entire VA health care system. For instance, when the medical inspector circulated an incident investigation for comments, Radiology Service felt the incident warranted notification of all VA health care facilities. As a result, VA issued a circular that warned of the dangers of pumping air into bottles of contrast liquid when performing computerized tomography[3] procedures.

Patient Injury Control Programs in Non-VA Hospitals

Patient injury control programs are not unique to VA medical centers. The increase in malpractice claims during the 1970's, coupled with court decisions holding that hospitals were liable for hospital-based patient care, created a need for mechanisms for managing or reducing the impact of the claims. By 1963, according to the American Hospital Association (AHA), more than 4,000 hospitals had established mechanisms to reduce patient risks. For many hospitals, AHA reports, this mechanism was incident reporting.

Increased malpractice[4] claims, as would be expected, increased the cost of commercial malpractice insurance, forcingmedical facilities to seek ways to avoid incurring such increases. One method was to incorporate, internally, functions that previously had been delegated to insurance companies, e.g., risk management.[5] For example, the St. Paul Fire and Marine Insurance Company[6] stated that, "In fulfilling their obligation to provide a safe environment and a high quality of patient care, hospitals have implemented formal quality assurance and risk management programs." The company defined quality assurance as an assessment of patient care processes and outcomes to improve them where indicated,

[3]A diagnostic technique using x-ray photographs in which the shadows of structures before and behind the section under scrutiny do not show. Also known as "CAT" or "CT" scanning.

[4]GAO currently is completing work on a series of reports concerning medical malpractice in the private sector. Five reports have been or will be issued on such subjects as the nature of the current malpractice situation, alternative ways to resolve malpractice claims, and the malpractice situation in selected states.

[5]Orlikoff and Lanham ("Quality Assurance and Risk Management: Learning to Live Together," Journal of Quality Assurance, Vol. 2, No. 8, 1980) stated that "risk management" encompasses prediction of risk of patient injury, avoidance of exposure to predicted risk, and minimization of malpractice claims loss.

[6]Insures about 55,000 physicians and 1,500 hospitals.

while calling risk management a loss prevention program whose primary goal is preserving the hospital's and its professionals' resources from avoidable loss due to claims.

All of the above systems, whether quality assurance or risk management, have common goals—preventing patient injuries, improving the quality of patient care, and reducing malpractice losses. Additionally, all of these systems incorporate or have mechanisms that identify actual problems or potential risk circumstances that should be eliminated or reduced to prevent patient injuries.

Objective, Scope, and Methodology

Our overall objective was to determine whether VA had an effective patient injury control program. We visited VA's Central Office and nine VA medical centers (see app. II) throughout the United States to learn if (1) incidents were being reported, (2) reported incidents were being investigated, (3) trends were being identified, (4) available data were being analyzed, and (5) corrective actions were being taken.

Because of their expertise in such hospital programs as patient injury control, risk management, and occurrence screening,[7] we visited the Joint Commission on Accreditation of Hospitals (JCAH), AHA, and several hospital insurance companies to help us decide whether VA's patient injury control program, if implemented properly, would produce the desired results. Finally, we visited two hospital corporations and two nongovernmental hospitals to see how they operated patient injury control or similar programs.

In selecting eight of the nine medical centers, we took into consideration the following factors: geographical dispersion, variety of and mix of services, medical school affiliation status, and range of incidents reported. We visited the medical center in New York City at the request of the Senate Veterans' Affairs Committee staff. At each medical center, we

- examined the facility's policies and guidance regarding patient injury control;
- reviewed selected medical records and reports and incident and investigation reports;
- talked to the medical center director, the chief of staff, quality assurance coordinators, nurses, and chiefs of various services;

[7]Occurrence screening is a comprehensive system used to identify patient management events that could potentially result in liability for the hospital or its professionals (see ch. 3).

- analyzed trending and analysis conducted by quality assurance personnel;
- reviewed malpractice cases; and
- conducted trending and analysis of both reported and unreported incidents to see if incidents were recurring.

The criterion we used was VA's quality assurance regulations at 38 CFR 17.508. These regulations have not been revised since they were published on October 12, 1982.

Our analysis of VA's incident reporting system was not based on a review of all incident categories. Rather, we concentrated on categories where we believed an incident had occurred and should have been reported. To identify incidents not reported, we used nonpatient injury control sources, such as cases reported to medical examiners, reports of surgical complications,[8] and patient treatment file[9] categories closely related to incident reporting categories. For example, from the patient treatment file, we identified patients who died within 1 day of care[10] or on the day of surgery. We then reviewed medical records to determine if the patient had died within 24 hours of admission, during surgery, or under anesthesia. Such deaths are required to be reported as incidents.

At VA's Central Office, we interviewed the medical inspector and reviewed relevant documents to determine how the program was administered and operated. Also, we talked to the chief of surgical services, the director of quality assurance, and the chief of mental health and behavioral sciences to determine what data they received on patient incidents and whether they shared that information with the medical inspector. We analyzed Central Office data to determine how it could be used to identify nonreporting of incidents or potential problems at medical centers. We interviewed regional office officials concerning their roles in the patient injury control program.

Our audit was done between August 1985 and November 1986, in accordance with generally accepted government audit standards.

[8]A complication following or resulting from surgery.

[9]The patient treatment file, a computerized system, is VA's primary demographic, clinical, and workload data base for inpatients.

[10]The patient treatment file category—deaths within 1 day of care—may include some deaths that occurred after 24 hours of admission. According to federal regulations, deaths within 24 hours of admission are included in the category of "unexpected deaths" and are required to be reported as incidents.

VA Medical Centers Underreported Patient Incidents

Incident reporting is the first step in VA's patient injury control process. Without incident reporting, subsequent steps, which lead to the correction of problems that cause injuries and deaths, cannot occur. VA gives its medical centers guidelines for such reporting.

VA medical center personnel were not reporting all appropriate incidents through the patient injury control program as required. While medical centers reported 85,357 incidents during fiscal year 1985, more serious incidents, such as surgical complications or unexpected deaths, generally were not reported. In fact, of 714 patient cases we selected for review, 613 (86 percent) included unreported incidents, such as surgical complications and unexpected deaths.

The major reasons patient incidents were not being reported were twofold: (1) VA's system contains disincentives for reporting incidents, and (2) the medical inspector did not provide adequate guidance or oversight to the centers on what should have been reported.

Criteria for Incident Reporting

Incident reporting provides the foundation upon which an effective patient injury control program is based. If medical center management does not know that an event has happened, it cannot take action to prevent its reoccurrence.

VA's patient injury control program requires medical centers to monitor, report, analyze, review, and investigate any unusual, unexpected, or unfavorable incident a patient may experience. Such an incident would not be considered a natural consequence of a patient's disease process or illness. The incident could be an illness or injury resulting from either omission or action by a health care provider or the direct result of medical intervention during the course of inpatient or outpatient care.

Following are the types of incidents required by federal regulations to be reported narratively on VA form 10-2633, "Report of Special Incident Involving a Beneficiary," or other appropriate document:

- Suicides, suicide attempts, and self-inflicted wounds;
- Homicides;
- Falls;
- Assaults and patient abuse/neglect;
- Allergic or idiosyncratic[1] reaction to anesthesia, blood, or medications;

[1]Individual hypersensitivity (as to a drug or food).

- Unexpected deaths, including those under anesthesia and during the performance of a procedure, and deaths within 24 hours of admission;
- Transfusion, medication, diagnostic, and therapeutic errors;
- Surgical complications; and
- Other incidents that result or may result in injury, harm, disability, disfigurement, or death to a patient.

It should be noted that there are inconsistencies among the various requirements for reporting incidents under VA's patient injury control program. (See p. 50 and table 5.1.)

To determine if VA's program as described both in the federal regulations (38 C.F.R. 17.508) and VA's manual would produce the desired results—preventing patient injuries—we asked several organizations associated with the delivery of health care to critique it. The organizations were (1) the Joint Commission on the Accreditation of Hospitals, (2) the American Hospital Association, (3) the St. Paul Fire and Marine Insurance Company, and (4) the Pennsylvania Health Insurance Corporation. They were chosen because of their incident reporting or quality assurance expertise.

For instance, the St. Paul Fire and Marine Insurance Company underwrites malpractice insurance for 55,000 physicians and 1,500 hospitals; Pennsylvania Health Insurance Corporation officials stated they underwrite malpractice insurance for 400 hospitals in Pennsylvania, Indiana, Maryland, and Virginia; JCAH inspects and accredits health care facilities nationwide; and AHA is an association of member hospitals that has addressed the patient injury control issue.

Generally, officials from these organizations believed that VA's regulations provided an adequate basis for initiating a patient injury control program. But VA needed to provide its medical centers with additional implementation guidance, according to all officials with whom we spoke. For example, a JCAH official said the regulations provided information about the patient injury control program but gave no instructions on how to implement it. Some of the incident definitions, according to a Pennsylvania Health Insurance Corporation official, were too general, leading to differing interpretations by the facilities as to what was reportable. An AHA official echoed that statement. Data being reported by the facilities should be standardized, he said, so that summary data can be trended and analyzed. The need to standardize reporting criteria also was mentioned by an official of the St. Paul Fire and Marine Insurance Company. Further, that official said the VA Central Office should

emphasize that reporting is mainly for patient care purposes and should avoid negative connotations. To encourage reporting, all of the officials with whom we talked believed incident reports should be confidential.

Patient Incidents Not Reported as Required

All told, VA's medical facilities reported about 80,000 incidents in fiscal year 1984 and about 85,000 in fiscal year 1985, as shown in table 2.1.

Table 2.1: VA-Reported Patient Incidents (Fiscal Years 1984 and 1985)

	Reported incidents	
Incident categories	**Fiscal year 1984**	**Fiscal year 1985**
Suicide gestures	615	613
Suicide attempts	480	323
Suicides	93	119
Alleged patient abuse	537	434
Sustained patient abuse	121	91
Falls	40,030	42,320
Transfusion errors	114	41
Medication errors	10,530	12,983
Patient injury other than falls	11,498	12,045
Unexpected death related to surgery	103	88
Unexpected death not related to surgery	590	492
Fire	161	142
Other[a]	15,499	15,666
Totals	**80,371**	**85,357**

[a]Includes such incidents as burns, equipment failures, choking on food, and incorrect operating room counts

To determine whether more serious incidents, such as surgical complications and unexpected deaths, were reported during fiscal year 1984 at the nine centers we visited, we reviewed case information from sources other than VA's patient injury control system. These cases and our reasons for selecting them were

- cases referred to medical examiners, as reporting criteria used by medical examiners and VA were similar, i.e., unexpected death and death within 24 hours of admission;
- surgical complication cases, as the medical centers already had identified specific surgical complications, obviating our need to make a medical judgment;

- deaths on the day of surgery, as VA's reporting criteria of deaths during surgery or under anesthesia would be included;
- deaths within 1 day of care, as VA's reporting criteria for death within 24 hours of admission reporting criteria would be included; and
- deaths following multiple surgeries, because we believed that these cases would be more likely to reveal any surgical complications that may have occurred.

Except for surgical complications, we reviewed a judgmental sample of the cases. In addition, several categories overlapped, which reduced the number of cases examined. We reviewed all surgical complications because the medical centers had already determined that these cases belonged in this category.

From our review of a total of 714 cases for patients discharged during fiscal year 1984, we identified 613 incidents that according to the regulations should have been reported but were not.

The universe from which the cases were selected, the number reviewed, and the number of incidents that occurred but were not reported are shown in table 2.2.

Table 2.2: Number of Unreported Patient Incidents in Cases Reviewed by GAO (Fiscal Year 1984)

Review categories	Universe	No. of cases reviewed	No. of unreported incidents
Medical examiner's cases	232	59	26
Surgical complications	397	397	397
Deaths on day of surgery	59	52	35
Deaths within 1 day of care	547	138	112
Deaths following multiple surgeries	219	68	43
Totals	**1,454**	**714**	**613**

At these nine centers, we also reviewed other quality assurance monitors for other incidents not reported in the patient injury control program. Of 153 such cases, we identified 64 more that should have been reported but were not. The following are examples of incidents not reported:

- A 69-year-old patient was undergoing surgery for a leaking aortic aneurysm.[2] When given anesthesia, the patient exhibited conditions associated with high blood pressure. Shortly after the patient received the anesthesia, the aneurysm ruptured. The surgeon tried unsuccessfully to control the bleeding, but the patient progressively deteriorated and died. This should have been reported as an unexpected death and investigated by the medical center, the medical inspector stated.
- Medical center staff observed a 71-year-old patient "constantly playing with his tracheostomy tube,"[3] according to a medical record notation. Approximately 4 hours following his admission and after the above observation, he was pronounced dead. The cause, according to the death certificate, was a dislodged tracheostomy tube. Because the patient died within 24 hours after admission, the incident should have been reported. The chief of staff of this medical center said that had he known about this case, he would have formally investigated it.
- A physician found a 65-year-old patient disconnected from his ventilator. No alarm was on, the patient was perspiring, and his skin was dark blue due to lack of oxygen. The nurses responsible for caring for the patient did not know how to work the alarm, they told the treating physician. According to the medical inspector, this was reportable as an incident and should have been investigated.
- Medical staff recommended withholding oral feedings in favor of intravenous feedings for a 65-year-old patient experiencing massive diarrhea. This recommendation was not followed, and the patient was constantly lying in a pool of his own excrement. As a result, an abscess requiring surgical removal developed.

Why Medical Centers Did Not Report Incidents

VA medical center personnel were not reporting all incidents as required by federal regulations because (1) the system as established by VA contains disincentives for reporting incidents, and (2) the medical inspector did not provide adequate guidance or oversight to the medical centers on what should have been reported.

Disincentives Associated With Reporting

VA's patient injury control program relies on the individuals involved with patient treatment to report medically related incidents. Such individuals often are placed in the predicament of having to report on themselves, a peer, a subordinate, or a superior. Following are the

[2]Blood-filled expansion of the aorta resulting from a disease of the vessel wall.

[3]A tube inserted in the surgical formation of an opening into the trachea through the neck to allow the passage of air.

disincentives associated with self-reporting that we identified during our review of the nine medical centers:

- Nurses were reluctant to report physician-related incidents,
- Medical center staff viewed incident reporting as negative, and
- As incident reports were not confidential, reporting incidents might lead to litigation.

Nurses Reluctant to Report Physician-Related Incidents

In analyzing VA medical malpractice claims during fiscal year 1985, the VA inspector general noted that nursing staff almost always reported incidents that occurred in patient areas as opposed to clinical areas. Incidents involving physicians that led to malpractice claims, however, generally were not reported. Of 242 cases involving procedural misadventures, diagnostic errors, or treatment errors, only 34 (14 percent) were reported as incidents, the inspector general pointed out.

At three of the centers we reviewed, nurses involved with the patient injury control program told us they were reluctant to report medically related incidents because to do so might require medical judgment for which they were not trained. Their reluctance is normal, according to the American College of Surgeons' Patient Safety Manual. The manual further states that generally nonphysicians do not report incidents that directly involve a physician's care, leaving this responsibility to physicians.

Reporting of Incidents Viewed as Negative

At three medical centers we reviewed, program officials stated that incident reporting was viewed negatively by staff and often was equated with wrongdoing, i.e., someone committed an error. This often valid perception inhibits the reporting of patient incidents, according to a quality assurance nurse. For example, she suspected that medication errors were underreported at her center because the supervisory response was punishment in the form of written admonishments or other disciplinary actions for the incident.

At another medical center, the quality assurance coordinator stated that its accurate reporting of patient abuse incidents resulted in the center's director being questioned by the medical inspector. The director believed that even minor patient abuse incidents should be investigated. Now, as a result of the director's stance, the center is questioned every time a patient abuse incident occurs, according to the coordinator. This

caused her to wonder if accurately reporting all incidents was worth the resulting questioning.

Incident Reports Not Confidential

Lack of confidentiality was one reason for their underreporting of physician-related incidents, according to medical center staff. Incident reports for surgical complications might be used in legal actions by some patients, the chief of staff at one medical center said. He added that any problems associated with surgery could be discussed among physicians without involving paperwork that might be used in litigation. At another facility, the assistant chief of staff informed us that physicians were hesitant to use incident reports because they are not confidential. Physicians were unwilling to prepare documents, he said, that would disclose their errors to individuals outside of the medical profession.

Furthermore, in a 1985 publication[4] the American College of Surgeons stated that the concern that incident reporting exposes hospital staff to liability and could be discoverable in court is a reason hospital staffs do not report incidents.

In a 1981 publication,[5] however, AHA noted that

> ". . . hospitals are concerned with the possibility that, in their states, incident reports may be both legally discoverable and admissible as evidence against that hospital in a malpractice liability lawsuit. This issue is often conjured up by administrators and members of medical staffs as reason not to engage in meaningful incident reporting. The argument that incident reports can be legally used against physicians and hospitals and therefore should not be completed is specious. Dixon points out that incident reports should reproduce only information that is contained, or should be contained, in the medical record."

In its quality assurance regulations, VA excludes its incident reporting form or other documents used in describing an incident from the category of confidential quality assurance documents. According to an official in the Office of the Medical Inspector, the reports should contain only facts, thus should not be confidential; further they were not designated confidential at the urging of VA's general counsel.

[4]Patient Safety Manual, 2nd ed.

[5]James E. Orlikoff, William R. Fifer, M.D., and Hugh P. Greeley, Malpractice Prevention and Liability Control for Hospitals.

Medical Inspector Guidance, Oversight Lacking

VA's medical inspector, according to federal regulations, is responsible for providing guidance, oversight, and recommendations to improve the patient injury control program. Our review of incident reporting, however, indicated that inadequate guidance and limited oversight contributed to the underreporting of patient incidents.

Regulations establishing the VA's quality assurance program, which includes the patient injury control program, were developed by VA and published October 22, 1982. They are binding on all VA medical centers. However, the medical inspector had not issued any implementing guidance. He thought the regulations were self-explanatory and further believed they were not mandatory. Consequently, the only guidance available to the centers other than the regulations was a VA manual, issued a month before the regulations. The manual did not require the centers to report such incidents as surgical complications and certain categories of reportable deaths, both of which were reportable under the regulations. The manual therefore does not adequately reflect VA requirements.

We found a lack of uniformity in incident reporting among the nine centers we visited. Only two centers had incident-reporting criteria based on the federal regulations. Five centers had adopted the criteria published in the VA manual; two others had developed their own. Centers using the VA manual told us that the federal regulations were not mandatory. The other two centers developed their own criteria to avoid paperwork or eliminate the reporting of what they defined as insignificant incidents—those that did not result in a severe patient injury. This interpretation put them further from what was required by the federal regulations.

Incident Definitions Unclear

The medical inspector had been aware since receiving the 6-month incident summaries in fiscal year 1983, he said, that incident reporting data were not reliable. Not until August 1985, however, did he institute formal corrective action, i.e., a change to the VA manual. Before then, each medical center defined for itself what was a reportable incident.

The definition of a patient incident differed at each of the nine centers we visited. For instance, centers are required by federal regulations, but not the VA manual, to report as incidents deaths within 24 hours of admission. But none of the staff responsible for incident reporting at the medical centers we visited considered this type of incident reportable. Medical center program officials considered such deaths reportable only

when the death was unexplainable. The definition of an explainable death may differ with each VA physician. Examples of two deaths considered explainable and not reportable included:

- A 61-year-old patient released from a VA emergency room after complaining of shortness of breath was found unresponsive at the ambulance entrance 1-1/2 hours later. The patient was admitted to the hospital, but died 1 hour later. This medical center followed VA Manual MP-1, which does not require such deaths to be reported as incidents. Mandatory federal regulations, however, require that this be reported as a death within 24 hours of admission.
- A 50-year-old patient was transferred by taxi about 300 miles from one VA center to another for radiation treatment. Upon arrival, the patient was found dead in the cab. No autopsy was performed and the cause of death was listed as lung cancer. According to the medical inspector, this patient's death should have been reported by the receiving center as unexpected and investigated.

A second incident category, surgical complications, has also been defined differently. Medical center staffs are required by federal regulations, but not the VA manual, to report surgical complications as incidents for purposes of patient injury control. Another section of the manual requires monthly surgical complication reports to VA's Central Office Surgical Service. While seven of the nine facilities submitted monthly reports, none had routinely reported surgical complications as incidents during fiscal year 1984. The chiefs of surgery at these centers stated that tears, perforations, and lacerations are considered normal risks of surgery; consequently, they did not consider such incidents reportable. Nevertheless, federal regulations require that any surgical complication be reported as a patient incident, and VA's Central Office considers tears, perforations, and lacerations to be complications. Furthermore, data in surgical complication reports is insufficient for the medical center to determine whether or not to investigate the incident.

Surgical complications not reported by the medical centers' staff as incidents included:

- A 56-year-old veteran underwent five successive surgeries—four at a VA medical center and one at a private hospital—in an attempt to repair a colon perforation resulting from previous VA surgery. The perforation could not be repaired, and the veteran subsequently filed a malpractice

claim. The chief of staff told us this case had been reported to VA's Surgical Service as a surgical complication and agreed it also should have been reported as an incident under the patient injury control program.

- Following bypass surgery, a 68-year-old patient lost considerable blood and was returned to the operating room. During the return, he suffered cardiac arrest and could not be resuscitated. His abdomen was quickly opened, and about 2,000 cc of blood and a tear in a vein were noted. The patient subsequently died. The medical inspector, upon reviewing this case, stated it should have been reported as an incident because the tear in the vein could have been a complication of the bypass surgery.

Medical Inspector Unaware of the Extent of Nonreporting

VA's Office of the Medical Inspector has done limited analysis of individual medical centers' incident reporting patterns. The medical inspector considered the data unreliable, he said, because the medical centers were not consistently reporting incidents.

While we agree the data are not necessarily reliable, we believe they could be analyzed to at least determine if there is a basis for questioning the reporting practices of individual medical centers. For instance, the medical inspector could use centrally analyzed data to identify a center that might not be reporting all required incidents. An example is our analysis of patient treatment file data, which revealed that 5,424 veterans died on their initial day of care in VA medical facilities during fiscal year 1984. Comparing that figure to the type of unexpected deaths reported via the semiannual report, which showed a total of 693 deaths, would have indicated to the medical inspector that centers were not reporting all deaths within 24 hours of admission.

Deaths within 1 day of care are compared with the unexpected deaths reported by the nine facilities we reviewed for fiscal year 1984 and 1985, as shown in table 2.3.

Table 2.3: Deaths Within 1 Day of Care and Unexpected Deaths Reported by Nine VA Medical Centers Reviewed
(Fiscal Years 1984 and 1985)

	Fiscal year 1984		Fiscal year 1985	
VA medical center	Deaths within 1 day of care	Unexpected deaths reported by each facility	Deaths within 1 day of care	Unexpected deaths reported by each facility
Dallas, TX	147	7	159	9
Houston, TX	93	0	79	4
New Orleans, LA	75	0	84	7
West Los Angeles, CA	55	8	57	11
Washington, DC	47	0	48	11
Pittsburgh, PA	46	0	51	3
Tucson, AZ	43	2	46	2
New York, NY	21	1	26	0
Altoona, PA	20	1	22	0
Totals	**547[a]**	**19**	**572**	**47**

[a]viewed 138 of the 547 cases and verified that 112 should have been reported as unexpected deaths.

Furthermore, by comparing medical centers of similar size and function, the medical inspector could have determined if the reporting statistics for a particular center were out of line with the rest of VA. While deviation from the norm does not necessarily mean a medical center is over- or underreporting, a high or low patient-incident ratio can be the basis for questioning the center's reporting practices. A listing of VA medical center patient-incident ratios appears in appendix III.

The medical inspector's office did not consider the data reliable until fiscal year 1984, and therefore believed trending and analyzing these reports would have provided no useful results. But, our analysis of that data indicated that some large medical centers were reporting a small number of incidents. Not analyzing the data limited the medical inspector's ability to assess the incident reporting patterns of individual centers.

Actions Taken by Medical Inspector to Improve Reporting

The VA Central Office and individual centers have taken actions to correct some of their incident-reporting problems. In August 1985, the medical inspector revised the VA manual to clarify some incident definitions. The revised manual did not, however, fully incorporate all aspects of the federal regulations, e.g., all categories of reportable deaths or the requirement that surgical complications be reported as incidents. Also, the inspector's office has conducted two regional training seminars on patient injury control attended by approximately 125 health care staff,

including quality assurance coordinators, physicians, and other medical center staff.

Additionally, the medical inspector took specific actions following his review of cases referred by us during our evaluation. He individually notified two centers that they had misinterpreted the criteria and gave them a copy of the revised manual to aid them in establishing an accurate and uniform patient injury control system. Subsequently, the revised manual was distributed to all centers through normal VA distribution procedures.

Conclusions

Accurate incident reporting is the cornerstone of an effective patient injury control program, yet about 86 percent of serious incidents we reviewed at the nine centers were not reported.

Some causes of this underreporting can be corrected: VA can clarify what are reportable incidents and reinforce to its employees (1) the need for and value of reporting all incidents and (2) that federal regulations are mandatory and must be followed.

The disincentives to reporting that the staff perceive cannot be overcome easily under VA's current system. In chapter 3, we discuss a system, occurrence screening, that is recognized by the medical community as being effective in identifying the types of incidents VA's patient injury control program has failed to capture. Occurrence screening, in conjunction with improved incident reporting in VA medical centers, should enable VA's patient injury control program to become more effective.

Recommendations

We recommend that the administrator of veterans affairs direct the chief medical director to

- emphasize to all medical center staff (1) the importance of incident reporting as a means to assure that VA provides quality health care and (2) that federal regulations must be followed; and
- clarify which incidents are reportable by revising the VA manual (MP-1, pt. I, ch. 2) to incorporate all reportable incidents listed in the applicable federal regulations (38 C.F.R. 17.508).

Agency Comments and Our Evaluation

In an April 10, 1987, letter commenting on a draft of this report (see app. IV), the administrator agreed with our recommendations and said that implementation of them was in progress. The manual was being revised and would serve as a program guide, he said. The manual should be ready for publication by October 1987, according to the administrator.

The administrator stated that, while VA recognizes its program can be improved and agrees with our recommendations, VA can not accept our statement, as indicated by the report title, that its program is not effective. He suggested that a more accurate description of the program and report title would be Improvements Needed in the VA's Patient Injury Control Program.

We believe that our description accurately characterizes the program at the time of our review. A patient injury control program based on incident reporting that does not identify 86 percent of serious incidents, in our opinion, is not effective.

Use of Occurrence Screening Would Make VA's Program More Effective

Incident reporting and its problems are not unique to the VA medical care system. Nonfederal hospitals and hospital systems, responding to the increase in malpractice claims, have undertaken new techniques to reduce the risk of patient injuries and the financial loss often associated with them.

One technique believed by the American College of Surgeons and others to be effective in identifying patient injuries—and acknowledged by VA—is occurrence screening. Using agreed-upon criteria, quality assurance staff routinely review patients' medical files to identify incidents. This method overcomes many of the disincentives that exist in the current VA patient injury control program and, if properly implemented system-wide, should make the VA program more effective.

Incident Reporting at Nonfederal Hospitals

About 4,000 nonfederal hospitals have mechanisms that identify actual patient problems or potential risks, AHA reports. These mechanisms have generally taken the form of incident reporting.

No one incident reporting system could achieve 100-percent reporting, the major groups we contacted (JCAH, AHA, Hospital Corporation of America, and Humana) agreed. To be effective, a patient injury control system should combine data collected through several hospital systems, including incident reports, oral communication, and other routine quality assurance reports.

In its 1985 manual on patient safety, the American College of Surgeons said that existing incident reporting systems were not particularly effective in identifying physician-related incidents because, as with the VA medical centers we reviewed, staff feared punitive actions, were reluctant to report incidents involving physicians, and were unsure what the system required. Occurrence screening is, however, believed to be effective at overcoming these reporting obstacles. For example, one hospital corporation official said that because no operating room incidents were being reported; the corporation therefore established a screening process for identifying such occurrences.

Finally, traditional reporting systems generally concentrate on safety issues, not clinical ones, a St. Paul Fire and Marine Insurance Company official said. He recommended occurrence screening as an effective method for focusing on clinical problems. Both non-VA hospitals we visited used occurrence screening and found it effective.

report physician-related incidents. It also establishes reporting criteria that minimize the amount of interpretation by nonphysicians.

Part of the methodology we used to identify incidents that should have been reported involved screening VA's patient treatment files to determine deaths on the same day as surgery, within 1 day of care, and following multiple surgeries. Our use of these screens, which we found effective, was somewhat similar to the occurrence screening process used by some individual hospitals and corporations and promoted by several hospital-associated organizations. As a result of our work, we believe that establishing an occurrence-screening process in VA medical centers to supplement the incident-reporting system should lead to better incident identification. Because VA is in the process of implementing an occurrence screening system, we are making no recommendations.

VA should require its medical centers to implement occurrence screening systems that meet their quality assurance needs and budgets. Effective implementation of the occurrence screening process will require medical staff approval, training of data screeners, and clear guidance and monitoring by VA Central Office. In his April 10, 1987, comments on this report, the VA administrator said he was studying ways the process will be structured within existing quality assurance activities.

Improvements Needed in VA's Investigative Process

VA's medical inspector, who is responsible for the agency's quality assurance investigative process, generally relies on the medical centers to investigate incidents that may have adversely affected the quality of patient care. While VA requires investigations of certain incidents, such as transfusion errors or alleged patient abuse, they are optional for others. We found that centers did not conduct all required investigations, routinely forward investigation results to the medical inspector, or report investigations in a timely manner. But when investigations were conducted and reports forwarded, they were usually deemed adequate by the medical inspector.

VA's Investigative Process

VA's investigations are of two types—quality assurance and administrative. An inquiry into any incident involving a patient, a quality assurance investigation, is optional and focuses on improving the quality of patient care. The results are confidential and are used only to address quality of patient care. An administrative investigation is conducted prior to, concurrently with, or upon completion of a quality assurance investigation and is a requirement set forth in VA's manual. The results, which are not confidential, can be used for purposes other than addressing patient care, e.g., to obtain facts to determine if disciplinary action should be taken against an employee.

According to the VA manual, a board of investigation consisting of at least three people appointed by the medical center director is to be convened in the following cases:

- Unexpected death of a patient;
- Medication errors that result in the death of a patient, a new medical problem, or significantly aggravate the patient's existing problem(s);
- Homicides;
- Alleged patient abuse by another patient where, as a result of the incident, the victim's condition (burns, slashing, stabbing, etc.) requires surgery or an extension of hospital stay beyond that otherwise anticipated;
- Rape;
- Serious injury and/or death by fire;
- Alleged patient abuse by staff;
- Transfusion error;
- Incidents resulting in permanent disfigurement or disability; and
- Other incidents the director believes should be investigated.

While the screening process may vary, it generally includes a review by trained data screeners, usually quality assurance nurses or medical record analysts, of each medical chart shortly after the patient's admission, at specified intervals (generally 48 to 72 hours) during the patient's stay, and again at discharge. The screener reviews the patient's record using preestablished criteria to determine if there was a variation from that criteria, i.e., an incident may have occurred.

The core of an occurrence screening system is the set of objective criteria used by the initial reviewer. Examples of screening criteria are (1) admission for adverse results of outpatient management, (2) readmission for complications or incomplete management of problems during previous hospitalization, (3) unplanned removal of an organ, (4) a transfusion reaction, (5) cardiac arrest, and (6) death.

If a variation from the criteria is identified, a further review is done either by committee or individual departmental physician peer reviewers to confirm an occurrence, determine its severity, and evaluate whether quality of care was acceptable. Finally, all confirmed occurrences are trended and reviewed periodically by a quality assurance committee and department chiefs to identify potential problems in systems, procedures, and provider performance.

Occurrence Screening Proposed by VA

In February 1986, VA proposed for all of its medical centers an occurrence screening system similar to that used in some nonfederal hospitals and hospital systems. It would be an integral part of VA's quality assurance program, supplementing the existing reporting system. The screening process is being viewed as a means to improve upon traditional quality assurance methods for detecting and correcting problems. Implementation of this system has been delayed, however, while VA conducts a pilot test of the proposed occurrence screens.

Because screening uses objective criteria and relies on the medical record as the primary information source, it should facilitate VA's efforts to identify adverse events. VA expects occurrence screens to be more successful at identifying physician-related incidents than the current patient injury control program, a VA Central Office quality assurance official told us.

In conducting their occurrence screening, the centers will be instructed to use a set of hospital-wide screening criteria approved by VA Central Office. Center officials may add to the list of criteria but not subtract

from it or make substitutions. They are encouraged to develop and use other clinically valid criteria.

An Office of Quality Assurance official told us in June 1986 that occurrence screens would be implemented in all centers in October 1986. In September, however, the official said that VA expected to implement the system at all centers in March 1987, but first would conduct a pilot test at 26 centers between October 1986 and January 1987. The purpose of the pilot test was to (1) determine if the proposed set of screening criteria were appropriate and adequate and (2) identify or develop a cost-effective occurrence screening process. As of February 1987, VA's timetable had the pilot test being completed in March 1987, and implementation at all medical centers in October 1987.

One of the nine VA medical centers we visited had already instituted an occurrence screening process that included the following screens:

- Readmissions to the facility within 30 days of last discharge,
- Deaths, and
- Extended hospital stays for particular illnesses.

Under this process, once the quality assurance coordinator conducts the initial review, the raw data is provided to the appropriate functional division of the facility for its analysis, conclusions, and recommendations. Further, the implementation of corrective action is monitored through the various hospital committee minutes. Thus, the screening process is designed to facilitate surfacing and resolving patient care issues.

According to VA officials, a recently formed group met to discuss using computers for quality assurance functions, including occurrence screening.

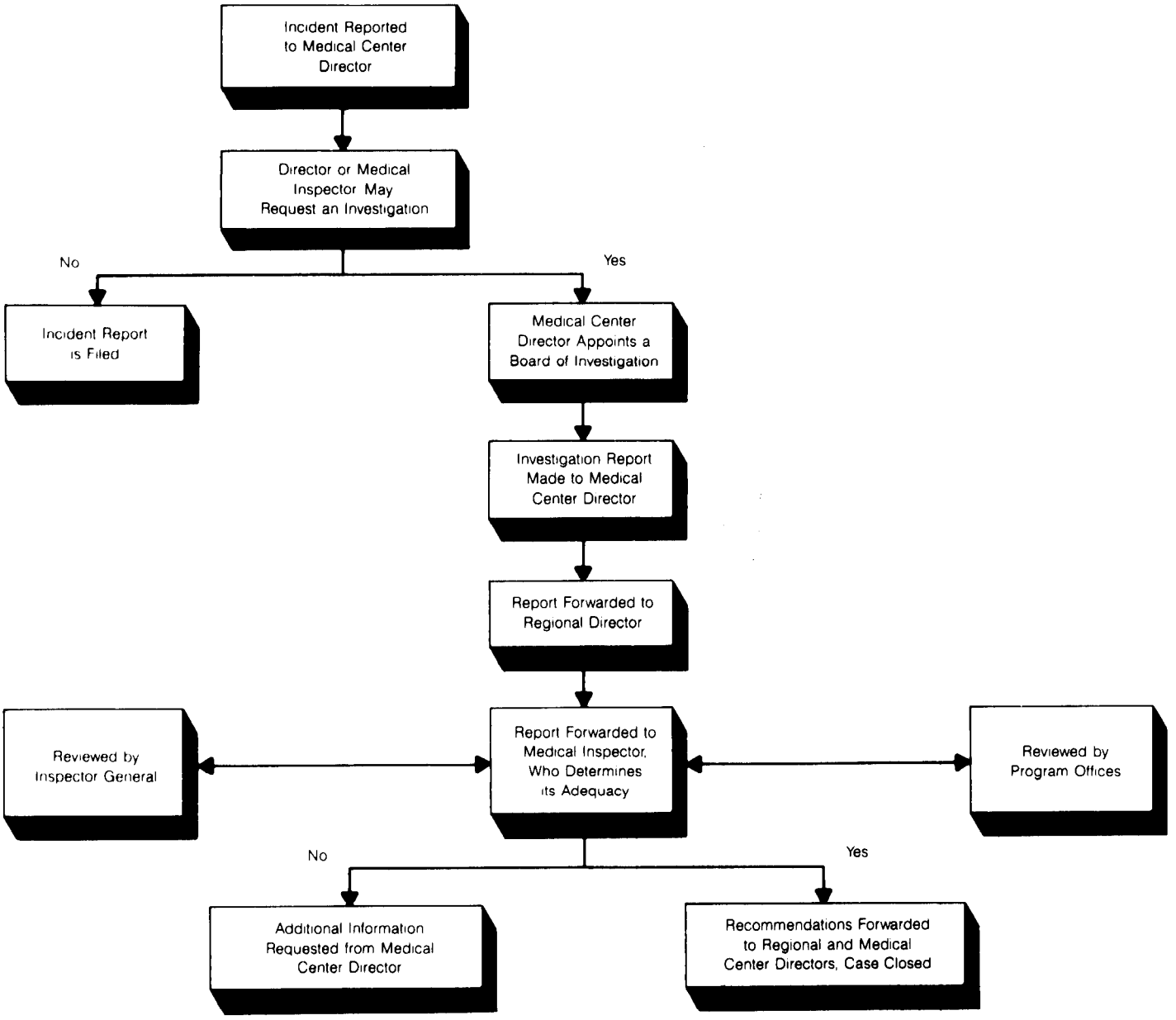
Conclusions

Incident-reporting problems experienced by VA are similar to those experienced by the non-VA medical profession. To overcome these problems, VA proposes to use the same mechanism as the non-VA hospitals and a hospital corporation we visited—occurrence screening in conjunction with incident reporting. The American College of Surgeons considers occurrence screening an effective system for identifying physician-related incidents. Occurrence screening minimizes many of the problems associated with the self-reporting concept and nurses' reluctance to

In the last four instances, an investigation report must be submitted to the medical inspector within 30 days of the incident. There is no time requirement for the other incidents requiring investigations.

Investigation results reported to the medical inspector are then forwarded to other pertinent staff within the Central Office for their review. This review helps the medical inspector to determine if the board of investigation addressed all of the issues, asked appropriate questions, and arrived at logical conclusions and recommendations. Comments must be returned to the medical inspector within 10 working days. In addition, the investigation results are forwarded to the inspector general for a similar review. Upon determining that the investigation was adequate, the medical inspector notifies the medical center through the regional director that the case is being closed—i.e., the medical inspector is satisfied with the investigation, including its conclusions and recommendations. This investigation process is diagrammed in figure 4.1.

Figure 4.1: VA's Patient Incident Investigation Process



Investigations Either Not Conducted or Not Reported to Medical Inspector

We analyzed the semiannual incident report information for abuse of patients, transfusion errors, and unexpected deaths[1] reported in fiscal year 1984 from VA's medical facilities. VA's criteria required that 1,344 of these incidents be investigated. Medical facilities, however, forwarded only 266 investigation reports to the medical inspector, leaving 1,078 incidents that were either not investigated or not reported to the medical inspector (see table 4.1).

Table 4.1: Comparison of Investigations Required and Reported for Selected Categories of Incidents (Fiscal Year 1984)

	Investigations		
		Reported to medical inspector	
Category of incident	**Required**	**Number**	**Percent**
Abuse of patients	537	183	34
Transfusion errors[a]	114	8	7
Unexpected deaths	693	75	11
Totals	**1,344**	**266**	**20**

[a]The medical inspector suggested that some incidents reported as transfusion errors actually may be transfusion reactions that do not require an investigation.

In the same fiscal year, VA medical centers conducted and reported a total of 724 investigations in all categories to the medical inspector. Of these, 266 represented incidents requiring an investigation. The remaining 458 were conducted at the request of the medical inspector or medical center officials.

Investigations Often Not Conducted

At the nine centers visited, we found that of 59 patient incidents occurring in fiscal year 1984 and requiring an investigation, 21 (36 percent) were investigated (see table 4.2).

[1]We selected these categories because we could associate them with specific categories of for which investigations were required by the VA manual.

Table 4.2: Reported Patient Incidents Requiring Investigation and Investigations at Medical Centers Visited (Fiscal Year 1984)

	Alleged patient abuse		Transfusion errors		Unexpected deaths		Total	
Medical center	**Reported**	**Investigated**	**Reported**	**Investigated**	**Reported**	**Investigated**	**Reported**	**Investigated**
Altoona	2	2	0	0	1	0	3	2
Dallas	0	0	1	0	7	1	8	1
Houston	0	0	0	0	0	0	0	0
New Orleans	3	1	3	0	2[a]	2	8	3
New York	0	0	0	0	1	0	1	0
Pittsburgh	6	6	0	0	0	0	6	6
Tucson	1	1	6	0	2	1	9	2
Washington, D.C.	1	1	1	0	2[a]	2	4	3
West Los Angeles	12	3	0	0	8	1	20	4
Total	**25**	**14**	**11**	**0**	**23**	**7**	**59**	**21**

[a]These unexpected deaths were not reported as incidents on these facilities' semiannual reports to the medical inspector. We assumed, however, that since an investigation was conducted, the medical center was aware that the incidents has occurred.

The required investigations were not conducted, according to staff at the medical centers, because the staff either saw no need to conduct an investigation once the incident was discussed informally or felt the process was too time-consuming. For example, at one medical center, the associate director told us he did not believe it would be feasible or even beneficial to investigate every death occurring within 24 hours of admission (defined by the federal regulations as unexpected death) and every allegation of patient abuse. Conducting an investigation for all such incidents would prevent the hospital from accomplishing other work, such as caring for patients, he said.

Some incidents should be screened before a board of investigation is appointed, according to an official in the Office of Medical Inspector. This is particularly applicable in the case of death within 24 hours of admission. Many such deaths are easily explainable; for example, a patient with a terminal condition may be admitted to a center and die within 24 hours. An investigation of such an incident would provide little or no useful information. Currently, the medical inspector tells the facilities to convene a board for only unexpected deaths they think should be investigated, the official said, and to submit appropriate explanatory documentation for the medical inspector's review on the other unexpected deaths. But the investigation requirements have not been officially revised, the official acknowledged, and no time frame for such a revision has been established.

Some Investigations Not Reported

The VA manual requires medical centers to submit all investigation results to the medical inspector, who determines the adequacy of the investigation. The nine centers we reviewed conducted 57 investigations (across all categories of incidents) during fiscal year 1984, but only forwarded 33 reports to the medical inspector. Reasons given by center officials for not forwarding the results to the medical inspector included (1) deaths were not unexpected, (2) officials were unaware of the policy of forwarding investigation reports, (3) functions at the center were fragmented, resulting in not all cases being forwarded as required, and (4) as no issues remained unresolved, the investigation was closed by the medical center director. In some cases, no explanation for failure to notify the medical inspector was given.

Investigations Not Reported in a Timely Manner

Some investigation reports were not submitted to the medical inspector in a timely manner. Of the 724 investigations conducted and reported by all centers in fiscal year 1984, we determined that 488 were in categories required by the VA manual to be reported within 30 days. Only 99 or 20 percent, however, were reported within this time period. The length of time taken to report on the 488 investigations ranged from 8 to 423 days, with the average being 64 days.

At the nine centers we visited, we found that of 22 investigations only 2 were reported within the required 30-day time limit. The time taken averaged 79 days and ranged from 25 to 204 days. The formality of the process, the need to convene a board, taking testimony under oath, and preparing the report all made it difficult to complete the process within 30 days, medical center officials explained.

Medical Centers' Investigations Usually Considered Adequate

The majority of the investigations conducted at the nine VA medical centers we visited were adequate, the medical inspector determined. That is, the center properly addressed the issues, and he agreed with their recommended corrective actions. In 32 of 33, or 97 percent, of the investigations, the medical inspector agreed with the medical centers' conclusions.

We asked an official in the Office of the Medical Inspector to review the adequacy of 22 investigations the medical centers conducted but did not forward to them. Of these, 14 adequately addressed the issues involved, according to the official.

But eight investigations did not adequately address the relevant issues, the official concluded. For example, one investigation was conducted because the wrong vertebrae were fused during a surgical procedure. While the report acknowledged that the attending surgeon did not use available x-rays to determine the proper location for the surgery, three of four recommendations nevertheless concerned (1) the timeliness and availability of x-ray technicians, (2) filling x-ray technician vacancies and (3) upgrading x-ray equipment. It also recommended routinely using x-rays to determine the operative site. The report was inadequate, according to the official, because it did not address why the surgeon did not use available x-rays.

Private Sector Sees Need to Improve VA Procedures

Several private sector medical organizations viewed the VA investigation process as too formal. For instance, a Pennsylvania Health Insurance Company risk management official called VA's investigative process too structured. Investigations should be performed as quickly as possible, she suggested, with someone outside the particular service reviewing the incident report and conducting the investigation. This could be a quality assurance coordinator or risk manager, she explained, either of whom should be able to raise questions to health care providers. This would facilitate the review process and provide investigative results in a more timely manner.

According to a St. Paul Fire and Marine Insurance Company Risk Management Services division manager, VA investigations are too detailed and lengthy. The required three-member board that hears required testimony is too formal and threatening, the official said, and is, in most cases, unnecessary.

VA believes, however, that its requirement for a three-member board of investigation, transcribed testimony under oath, and 30-day reporting are important and necessary to ensure complete investigation of an incident. The current investigative process was developed in October 1981 by a task force established by the chief medical director.

According to the chairperson of the task force, three-member boards improve on the past practice of assigning one person, usually a medical administration or security service staff member, to conduct an investigation. Further, three-member boards may remove any bias that might occur in a one-member board. Transcribed testimony provides a written record of what was actually said, according to the chairperson, while statement summaries reflect what the writer heard. In addition, the task

force felt that witnesses and staff would be more forthright if they testified under oath. According to the chairperson, the task force believed 30 days to be a reasonable amount of time to conduct an investigation and provide useful recommendations for preventing the recurrence of an incident.

Conclusions

For the investigation portion of VA's patient injury control system to be effective, all serious incidents must be investigated and reported to the medical inspector in a timely manner, the investigations should be properly conducted (i.e., an independent party should determine what happened, why, and what needs to be done to prevent its recurrence), and the results should be reviewed by top level officials at the center and the medical inspector. Also, corrective actions based on the investigations should be implemented as soon as possible.

Our review of VA-wide statistics and our work at the nine centers indicated that not all serious incidents were being investigated, the investigations not forwarded to the medical inspector were not always adequate, and investigations were not reported expeditiously to the medical inspector. VA's system (formal investigation, three-member board, testimony under oath) may be a barrier to timely incident investigations.

Not all unexpected deaths need to be investigated by a three-member board as is currently required. Many are easily explainable and little would be accomplished by establishing a board to investigate them. The procedure now practiced—having a the board investigate only unexpected deaths designated by the facility director and submit appropriate explanatory documentation for the medical inspector's review on the other unexpected deaths—is reasonable. The manual should be revised to reflect current practice.

Recommendations

GAO recommends that the administrator of veterans affairs direct the chief medical director to:

- reemphasize to the medical centers what incidents are required to be investigated and that all investigations reports are to be forwarded to the medical inspector, and
- revise the VA manual to reflect current practice in regard to investigating unexpected deaths, i.e., require a three-member board investigation only for deaths a facility director determines need to be investigated. For the

remaining unexpected deaths, require submission to the medical inspector of appropriate explanatory documentation so that the medical inspector will have a basis for requiring an investigation if, after reviewing the documentation, he disagrees with the facility director's decision not to investigate.

Agency Comments

In his April 10, 1987, letter the VA administrator concurred with the recommendations and said that the manual was being revised and would serve as a program guide for investigations. In addition, the revised manual, expected to be published in October 1987, is to include some simplifications in the investigative process, particularly in the areas of unexpected deaths and suicides.

Trending and Analysis of Patient Incidents by Centers and Medical Inspector Insufficient

VA requires each medical center to analyze patient incident trends that may indicate problems requiring further study, investigation, or corrective actions. Our work at nine medical centers showed that insufficient trending and analysis of patient incidents had occurred because (1) not all incidents were being reported; (2) generally, only nursing-related incidents were being trended and analyzed; and (3) medical centers had no guidance on how to analyze the data.

The medical inspector did insufficient analysis of patient incident data received from the medical centers to identify trends or reporting problems because he did not consider the data reliable.

Medical Centers' Analyses Concentrated on Nursing-Related Incidents

Trending and analysis at the nine medical centers we reviewed, when it occurred, concentrated on nursing-related incidents, particularly patient falls, which represented 50 percent of all reported incidents. At these centers, the trending and analysis generally was done manually and was successful in identifying some problems and getting corrective action, as indicated below:

- As a result of their trending and analysis of incident reports, nurses at one center recognized that falls from wheel-chairs by amputees were caused by the lack of supports to help patients balance themselves while transferring from beds to wheelchairs. After the center corrected the problem by providing needed supports, the number of falls declined.
- Seven incidents that involved patient ventilators (equipment to help patients breathe) were found when the quality assurance committee at another center analyzed incidents for the year. As a result of the committee's further investigation, the center (1) increased the frequency of checks to make sure the equipment was properly operating, (2) converted breathing alarm switches from on/off to key operations, making it more difficult to turn them off unintentionally, and (3) corrected staffing problems.

Physician-Related Incidents Not Analyzed

None of the centers we reviewed had trended or analyzed physician-related incidents, such as deaths during a procedure or surgical complications, as part of their patient injury control program. Center officials told us they saw no need to trend such incidents because problems that arose as a result of physician-related incidents were taken care of on a case-by-case basis or through other quality assurance functions.

But our case review of patients who died on the day of surgery or within 24 hours of admission at three centers showed that case-by-case analysis either was not being done or was not effective. Furthermore, other quality assurance mechanisms were either not effective or not timely.

The following cases are based on incidents that should have been reported through the centers' patient injury control programs but generally were not. We identified these cases from our analysis of other data at the centers.

Medical Center #1

While reviewing a sample of medical records of patients who died on the day of their surgery during the same fiscal year, we noted that the same surgeon had operated on three of the patients. Furthermore, all three should have been, but were not reported as unexpected deaths. Upon reviewing the cases, our chief medical advisor raised questions relating to the surgeon's performance, such as why two patients experienced excessive bleeding during the surgical procedure. Using the center's data on operations performed during the fiscal year, we identified 5 of the surgeon's other patients who died during surgery and 28 who had complications as a result of surgery.

In early 1986, we asked the center to formally review this surgeon's performance. The center's chief of staff reviewed 119 of the surgeon's cases during the year and identified 31 with unfavorable outcomes: 17 patients who died and 19 who required additional surgery for such complications as excessive bleeding and surgical wound infections (5 patients who had more than one operation died and were included in both categories).

The center concluded that some of the surgical complications appeared related to the administration of drugs used to control bleeding during the operation. Specifically, it found that postoperative tests were not performed at frequent enough intervals to recognize the need for administering additional drugs. Furthermore, the medical center stated, because some operative reports had not been completed, those cases could not be reviewed. In addition, the infection control committee, another of the center's quality assurance functions, had not monitored surgical infections, according to the center's director.

About the same time that the chief of staff was reviewing this surgeon's performance, a surgeon from a nonfederal hospital and three of this

center's other physicians reviewed this specific surgical program at the center. The examinations were prompted by the high mortality and complication rates at the center during the first part of fiscal year 1986. The reviews identified as a problem inadequate postoperative monitoring of patients, particularly in regard to complications caused by bleeding. (The surgeon about whom we were concerned performed as an assistant on the cases reviewed by this team.)

Based on these reviews, the center (1) issued a memorandum on the monitoring of certain surgery patients, (2) began conducting more frequent postoperative tests of patients' blood flow, (3) changed the dosage of the drugs used to control postoperative bleeding, and (4) now routinely monitors surgical infections. According to center officials, these actions have decreased mortality and complication rates.

The center had routinely reviewed all cases in which patients died during surgery, during the period in question, the chief of staff told us. However, we could not find any evidence that the center's quality assurance functions had documented and resolved problems with this surgeon's performance during that fiscal year.

We believe that, had the deaths during surgery and surgical complications been properly reported as incidents in the fiscal year of their occurrence, trending and analysis would have shown that (1) a particular surgeon was involved, (2) correctable problems regarding control of postoperative bleeding existed, and (3) the infection control quality assurance program was not functioning as required. Had the corrective actions later taken been implemented in a more timely fashion, some deaths and complications might have been avoided.

Medical Center #2

At another VA medical center, our analysis of deaths on the day of surgery showed that 8 of 13 patients in our sample died during or immediately after cardiac surgery. Center staff did not take corrective action until over a year after they had become aware of a potential problem in the surgical unit. A quality assurance group composed of VA and non-VA physicians created specifically to assess this type of surgical program reviewed the deaths. Their review led to the decision to make an in-depth study of the program.

Because this surgical unit experienced mortality rates more than twice the average for the entire VA, a consultants' committee reviewed "paper audits"—reports prepared by the medical center after a review of the

medical files of patients who died within 30 days of surgery or as a result of it.[1] This review process, which began with the committee's request for the medical center to review and comment on each death for this type of surgery, led to a review of the center's program by a team of VA surgeons. According to center officials, the team identified three reasons for the high mortality rates: (1) the patients had multiple problems and were high risks for that kind of surgery; (2) improvements were needed in the surgical technique of one resident; and (3) a staff surgeon had not been providing adequate supervision.

As a result of these findings, the center restricted the staff surgeon's privileges and took other actions to improve the supervision of surgical residents and the monitoring of patients undergoing this type of surgery, according to center officials. The center did not deal with the problems of the resident because he no longer worked there.

We believe that, with proper reporting, investigating, and trending under the center's patient injury control program, the center might have been able to take corrective action sooner than it did. For example, it would have seen that the resident in question had participated in the surgery of half of the patients who died.

Medical Center #3

In two cases at a third medical center, patients died while undergoing dialysis, we found in reviewing deaths within 24 hours of admission there. Later, we found that several other patients had died while on dialysis at the center. Our chief medical advisor, who reviewed these cases, called the unit's mortality rate high and questioned the patient selection procedures.

The center's end stage renal disease subcommittee[2] had reviewed 1984 and 1985 deaths but identified no specific underlying causes of these cases. The subcommittee recommended that (1) the unit improve its monitoring of dialysis patients with severe heart disease and (2) the center annually review deaths in the dialysis unit.

We brought our concerns to the attention of the VA medical inspector and the director of the Office of Quality Assurance. At our request, VA sent a

[1]Our report, Improvements Needed in Quality Assurance for Open Heart Surgery (GAO/HRD-84-22, Feb. 24, 1984), discusses the operation of this quality assurance function.

[2]One of this subcommittee's responsibilities was to monitor the quality of care provided to patients undergoing dialysis.

team of experts to review the center's dialysis program. They too concluded that the unit's mortality rates were quite high but said that the types of patients on dialysis (elderly, with multiple organ involvement and oth r serious illnesses) explained the high rates. Their review did not disc ose that the unit was providing suboptimal care, but found a number of problems, many management-related. The reviewers recommended that the center correct the problems and improve its management of the program. Some of the actions taken by the center included

- screening of prospective patients by a group of nephrologists,
- updating of patient care policies,
- improvement of record-keeping system,
- improvement of data reporting,
- recomputation of mortality statistics,
- purchase of a water treatment system, and
- development of a water-monitoring program.

We believe that had data on deaths within 24 hours of admission been reported and trended, the incidents been properly investigated, and the results forwarded to the medical inspector, officials might have been able to spot the problems in the dialysis unit without our intervention.

Guidance on Trending and Analysis Unavailable

One reason for the limited amount of trending and analysis at the nine centers is the fact, discussed in chapter 2, that many incidents were not reported. But even had most incidents been reported, the centers did not have in place the systems necessary to gather, trend, and analyze the reported data.

Federal regulations require centers to conduct a patient incident review as part of their quality assurance program. According to the regulations, this review

> ". . . provides a regular statistical and/or descriptive summary of incidents reported under the Patient Injury Control program. This summary may include such data and information as the types and frequency of incidents, hospital location where incidents occurred, age and type of patient and severity of incident. This review will analyze trends and may indicate deficiencies that require further study, policy changes, enforcement, investigation, etc." (38 C.F.R. 17.507(a)(4)(xv)).

VA includes no reference to this requirement in its operating manual. Nor has it given centers instructions regarding the data they should be trending and analyzing.

Analysis by Medical Inspector of Patient Incident Data Lacking

Under VA's patient injury control program, the medical inspector is not required to trend or analyze incident data reported by the medical centers. Data available to the medical inspector could be used, however, to identify variations in the numbers of incidents reported by centers with similar workloads, which might indicate whether the centers were reporting all incidents or were experiencing problems in providing quality care.

The two major hospital corporations, two insurance companies, and one non-VA hospital we visited used such data to identify potential problems and monitor hospital reporting performance. For example, each month a corporate office obtained and analyzed data from each of its hospitals on the numbers and types of incidents reported. Data on individual facilities were compared to current and prior corporate rates. If a facility appeared out of line, a corporate office survey team visited it to determine if it was complying with corporate reporting policies and if quality of care problems existed.

We compared the number of incidents reported for each VA medical center with the number of days of care the center provided in fiscal years 1984 and 1985 (see app. III). We obtained the data from the centers' semiannual reports to the medical inspector and VA's patient treatment file, a computerized system containing basic inpatient demographic and clinical data, including days of care.

Our analysis revealed centers with comparable days of care but vastly differing numbers of incidents reported. For example, one center that provided about 306,000 days of care in fiscal year 1985 reported 1,700 incidents, while another with about 305,000 days of care reported only 84. This could mean that the first center did a better job than the second of identifying and reporting incidents or that it was providing lower quality care. Were the medical inspector to obtain and analyze these data, he could follow up with the centers to determine which.

The medical inspector did not analyze the patient incident data reported by the medical centers because he did not consider the data reliable, he told us. He recognized that the centers were not consistently reporting patient incidents.

In addition, differing requirements on how to report patient incidents may limit the usefulness of data obtained and analyzed by VA's central office. Federal regulations require the medical centers to report 28 different types of patient incidents, VA's manual requires incidents to be

reported in 16 categories, and the medical inspector combines the incidents into 13 categories for the semiannual report. The inconsistencies among the various reporting requirements are shown in table 5.1.

Table 5.1: Varying Requirements for Reporting Incidents Under VA's Patient Injury Control Program

Federal regulations	VA Manual	Semiannual report
1. Suicides	1. Suicide	1. Suicide
2. Suicide attempts	2. Attempted suicide	2. Attempted suicide
3. Self-inflicted wounds	3. Self-injury	3. Falls
4. Falls	4. Falls	4. Alleged patient abuse
5. Patient abuse	5. Alleged patient abuse	5. Unexpected deaths related to surgery
6. Allergic reaction to anesthesia	6. Allergic reaction to anesthesia	6. Unexpected deaths not related to surgery
7. Allergic reaction to medication	7. Allergic reaction to drugs	7. Transfusion errors
8. Unexpected deaths	8. Unexpected deaths	8. Medication errors
9. Unexpected death during a procedure	9. Unexpected death during a procedure	9. Patient injury other than falls
10. Unexpected death under anesthesia	10. Transfusion errors	10. Sustained patient abuse
11. Unexpected death within 24 hours of admission	11. Medication errors	11. Patients involved in fires
12. Transfusion errors	12. Patient injury	12. Suicide gestures
13. Medication errors	13. Incident requiring a search for a individual	13. Other—define
14. Other incidents which result or may result in injury	14. Death due to surgical/ anesthesia misadventure	
15. Other incidents which result or may result in harm	15. Failure to obtain informed consent for a procedure or participating in a research project	
16. Other incidents which result or may result in disability	16. Inaccurate counts in surgery	
17. Other incidents which result or may result in disfigurement		
18. Other incidents which result or may result in death to a patient		
19. Homicides		
20. Assaults		
21. Patient neglect		
22. Allergic reaction to blood		
23. Idiosyncratic reaction to anesthesia		
24. Idiosyncratic reaction to blood		
25. Idiosyncratic reaction to medication		
26. Diagnostic errors		
27. Therapeutic errors		
28. Surgical complications		

Officials at all nine centers we reviewed said that these inconsistencies caused confusion in their reporting of incidents. Our analysis showed that 40 percent of all incidents were classified in general categories such as "other" or "patient injuries other than falls." For example, an incident classified as a surgical complication under the federal regulations might be classified as a "patient injury other than falls" in the semiannual report. (At seven of the centers we reviewed, surgical complications were not considered reportable incidents.)

Conclusions

Trending and analysis of patient incident reports can give medical centers opportunities to prevent incidents from recurring. This management process, used by a non-VA hospital, the two hospital corporations, and the insurance companies we visited, is generally recognized as an important part of a quality assurance program.

Although on some occasions trending and analysis of incidents enabled VA's centers to correct problems, we believe that the centers have missed opportunities to correct problems or to correct them sooner.

VA should take steps to improve and standardize the data to be trended and assign more specific responsibilities for analysis of these data at the centers and at the medical inspector's office. We believe there exist in non-VA hospitals several models that could be adapted to the VA system.

Recommendations

GAO recommends that the administrator of veterans affairs direct the chief medical director to

- develop for the medical centers guidelines that identify the data to be gathered and analyzed for trends and provide guidance on conducting the trending and analysis,
- revise the VA manual to reflect accurately the requirements of the federal regulations and revise statistical reporting requirements to correspond to the incident reporting categories in the revised manual, and
- require the medical inspector to analyze and trend VA program data to determine if individual medical centers are not reporting patient incidents or are having problems providing quality care.

Agency Comments

In his April letter, the administrator concurred with the above recommendations and said implementation of them was in process. Further, he said the medical inspector will be converting the trending data base to a computer system within the next 12 months. This action, according to the administrator, will give the medical inspector greater flexibility in analyzing patient incidents.

Request Letter

United States Senate

COMMITTEE ON VETERANS' AFFAIRS
WASHINGTON, DC 20510

August 30, 1985

Hon. Charles A. Bowsher
Comptroller General of the United States
General Accounting Office
General Accounting Office Building
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Bowsher:

As Chairman of the Senate Committee on Veterans' Affairs, I am writing to give my endorsement to the General Accounting Office project on the assessment of Veterans' Administration Patient Injury Control Programs. As you may know, the Committee is extremely concerned about the VA's efforts to monitor the quality of care provided to veterans at VAMC's.

The report completed by GAO in June 1985 entitled "VA Has Not Fully Implemented Its Health Care Quality Assurance Systems" stated that of the VA Medical Centers which were reviewed, none had implemented all of the VA's quality assurance requirements. 38 CFR 17.508 requires that the VA participate in a Patient Injury Control program which includes the monitoring, reporting, analysis, review and investigation of any unusual, unexpected or unfavorable incident which a patient may experience. This includes, among other things, the reporting of such incidents as suicides, homicides, falls, assaults and patient abuse and/or neglect, surgical complications, and other incidents which result or may result in injury, harm, disability, disfigurement or death to a patient. The VA further requires that such incidents be reported to the Regional Director who reports to the Medical Inspector.

GAO states that a significant number of VAMC's are failing to comply with the aforementioned regulations. Among the problems listed were failure to report certain information to the Inspector General, failure to report incidents in a timely fashion and an apparent lack of consistency regarding the need to report certain information. In light of these findings, I am extremely supportive of the GAO's study which would further examine these and other issues.

Among other things, I would be interested in learning the extent to which the failure to comply with these regulations appears to be a systemwide problem. Does the VA perceive this to be a significant problem and if not why not? Are actions being implemented to correct the deficiency in the VA's quality assurance programs? What is the general reason for the VAMC apparent underreporting? How does GAO plan to verify whether the VA is following the regulations? In cases where incidents are reported, please address the following: Who determines when an investigation is to be ordered? Do a sufficient number of investigations occur as a result of reported information? What type of information is obtained by these investigations? To what extent is the information adequately detailed? To what extent is this information useful for additional oversight in the area of quality assurance? Following the investigation, how is the information generally utilized? Are the investigations performed and reported in a timely manner? To what extent do these investigations have the potential to improve the quality of care delivered by the VA?

I thank you for your support and interest pertaining to this matter. I look forward to receiving the results of this most worthwhile project.

Sincerely,

Frank H. Murkowski
Chairman

VA Medical Centers Reviewed by GAO

Medical center	Description	Veteran population projections		
		Current	1990	1995
Altoona, Pennsylvania	A general medical and surgical nonaffiliated hospital. Currently has 143 authorized beds (108 medicine and 35 surgery) as well as 33 authorized nursing home care beds. Major buildings constructed in 1950.	95,220	89,820	84,930
Dallas, Texas	A tertiary, acute general medicine, surgery, and psychiatry facility in east-central Texas. Affiliated with the Southwestern Medical School of the University of Texas. Authorized capacity of 684 hospital and 120 nursing home care beds. Originally constructed in 1940 with a major bed addition in 1952.	447,668	449,170	438,200
Houston, Texas	A tertiary, acute general medicine, surgery, psychiatry, and nursing home care facility in southeast Texas, affiliated with the Baylor College of Medicine. Authorized capacity of 1,049 hospital and 120 nursing home care beds. Originally constructed in 1946 by the U.S. Navy, with a major psychiatric bed facility added in 1953.	484,061	488,820	478,990
New Orleans, Louisiana	A medical, surgical, and psychiatric facility in a downtown New Orleans medical complex. Affiliated with both the Louisiana State University and Tulane University Schools of Medicine. Officially opened in 1952, with a building annex added in 1957. Authorized bed capacity of 535.	200,622	194,550	187,130
New York, New York	A tertiary, acute general medical, surgical, and psychiatric facility on First Avenue, on the east side of midtown Manhattan adjacent to the New York University-Bellevue Hospital Center. Affiliated with the New York University School of Medicine. Authorized capacity, 1,030 beds. Constructed in the early 1950's and opened in 1954.	1,114,110	964,310	873,910
Pittsburgh, Pennsylvania	An acute, general medical and surgical hospital located on a 14-acre tract overlooking the University of Pittsburgh. Affiliated with the University of Pittsburgh School of Medicine and Dentistry. Authorized capacity, 536 beds. A general and intermediate bed division, built in a 50-acre tract in northeast suburban Pittsburgh and affiliated with the general medical and surgical hospital, has 204 authorized beds and a 228-bed nursing home care unit.	444,380	414,130	384,860
Tucson, Arizona	An acute general medicine, surgery, psychiatry, and nursing home care facility in south- central Arizona. Affiliated with the University of Arizona College of Medicine. Authorized capacity, 325 hospital and 41 nursing home care beds. Constructed in 1928, with new buildings added in 1930 and 1960.	123,185	130,510	130,360
Washington, D.C.	A tertiary, acute medical, surgical, and psychiatric facility in the northwest section of D.C. Affiliated with Georgetown University, George Washington University, and Howard University Schools of Medicine. Authorized capacity, 708 hospital and 120 nursing home care beds. Constructed in the early 1960's and dedicated in April 1965.	397,980	364,500	342,170
West Los Angeles, California	A tertiary, acute general medicine, surgery, nursing home care, and domiciliary facility in southern California. Affiliated with the University of California at Los Angeles Medical School. A replacement medical center opened in 1977 has 832 authorized hospital beds. Authorized also are 300 domiciliary and 357 nursing home care beds. An acute and long-term psychiatric facility is affiliated with the tertiary facility. The psychiatric facility, constructed in the 1940's, has 530 authorized beds.	1,554,857	1,452,550	1,369,090

Patient Incidents Reported to the Medical Inspector for Fiscal Years 1984-85 Ranked by the Ratio Days of Care to Incidents

		Fiscal year 1984				Fiscal year 1985			
Medical facility location	State	Rank	Total incidents	Days of care	Ratio days of care to incidents[a]	Rank	Total incidents	Days of care	Ratio days of care to incidents[a]
Waco	TX	1	4,618	281,245	164.20	2	3,794	381,043	99.57
Wichita	KS	2	441	43,764	100.77	3	477	50,873	93.76
Loma Linda	CA	3	1,145	141,042	81.18	1	1,735	143,300	121.07
Chillicothe	OH	4	1,953	269,626	72.43	14	1,700	306,564	55.45
Columbia	MO	5	639	98,879	64.62	5	813	118,037	68.88
Boise	ID	6	267	42,664	62.58	8	259	40,054	64.66
Altoona	PA	7	222	35,729	62.13	10	247	40,522	60.95
Gainesville	FL	8	941	157,693	59.67	36	714	149,373	47.80
Phoenix	AZ	9	867	149,220	58.10	15	881	161,511	54.55
Brockton/W Roxbury	MA	10	992	172,626	57.47	91	863	292,539	29.50
Fort Lyon	CO	11	598	104,422	57.27	9	839	135,036	62.13
Fort Wayne	IN	12	335	59,723	56.09	37	304	65,483	46.42
Charleston	SC	13	403	72,681	55.45	56	331	83,297	39.74
Walla Walla	WA	14	208	38,137	54.54	23	173	34,186	50.61
Fort Harrison	MT	15	209	38,799	53.87	13	203	36,550	55.54
Cincinnati	OH	16	741	138,889	53.35	60	631	162,020	38.95
Denver	CO	17	465	87,878	52.91	34	415	85,617	48.47
Poplar Bluff	MO	18	406	77,236	52.57	4	388	56,011	69.27
Wilmington	DE	19	421	81,337	51.76	12	434	74,803	58.02
Big Spring	TX	20	313	60,611	51.64	21	392	76,676	51.12
Newington	CT	21	276	53,919	51.19	20	248	48,283	51.36
San Diego	CA	22	725	149,421	48.52	7	936	141,728	66.04
Des Moines	IA	23	322	66,745	48.24	16	329	60,613	54.28
Indianapolis	IN	24	649	137,305	47.27	49	662	157,541	42.02
Martinez	CA	25	573	123,245	46.49	29	567	115,156	49.24
Seattle	WA	26	410	88,549	46.30	24	465	92,353	50.35
Wilkes-Barre	PA	27	695	150,228	46.26	65	577	154,827	37.27
San Francisco	CA	28	399	87,221	45.75	40	371	81,053	45.77
Marion	IL	29	236	51,768	45.59	19	253	48,825	51.82
Ann Arbor	MI	30	437	96,485	45.29	25	485	96,692	50.16
Louisville	KY	31	457	101,151	45.18	38	546	118,347	46.14
Fargo	ND	32	314	71,230	44.08	43	319	70,971	44.95
Kansas City	MO	33	535	124,581	42.94	63	472	123,237	38.30
Oklahoma City	OK	34	477	112,389	42.44	64	497	131,412	37.82
Livermore	CA	35	285	67,156	42.44	11	362	60,305	60.03
Providence	RI	36	340	80,472	42.25	97	255	89,175	28.60

Medical facility location	State	Fiscal year 1984				Fiscal year 1985			
		Rank	Total incidents	Days of care	Ratio days of care to incidents[a]	Rank	Total incidents	Days of care	Ratio days of care to incidents[a]
Kerrville	TX	37	324	77,365	41.88	22	411	80,709	50.92
West Haven	CT	38	826	198,775	41.55	42	766	169,841	45.10
San Antonio	TX	39	826	199,358	41.43	48	818	193,622	42.25
Sepulveda	CA	40	822	199,212	41.26	31	935	191,862	48.73
Salisbury	NC	41	1,421	346,641	40.99	32	1,433	295,172	48.55
Albuquerque	NM	42	465	114,779	40.51	68	418	116,481	35.89
Fayetteville	AR	43	200	49,582	40.34	44	197	44,040	44.73
Saginaw	MI	44	220	54,705	40.22	26	255	50,863	50.13
Spokane	WA	45	209	51,986	40.20	45	214	48,590	44.04
Erie	PA	46	182	45,471	40.03	79	171	53,194	32.15
Columbia	SC	47	636	161,143	39.47	50	696	167,902	41.45
Dallas	TX	48	753	194,220	38.77	30	976	199,568	48.91
Lincoln	NE	49	175	45,367	38.57	87	142	47,422	29.94
San Juan	PR	50	921	242,033	38.05	52	916	226,077	40.52
Fresno	CA	51	258	67,969	37.96	41	302	66,581	45.36
Iowa City	IA	52	329	86,771	37.92	18	402	77,468	51.89
Memphis	TN	53	1,075	284,174	37.83	51	1,247	304,916	40.90
East Orange	NJ	54	926	248,302	37.29	78	813	249,702	32.56
Knoxville	IA	55	874	236,040	37.03	80	821	255,956	32.08
Grand Junction	CO	56	119	32,702	36.39	82	144	46,220	31.16
Long Beach	CA	57	1,211	334,869	36.16	84	1,020	333,334	30.60
Salt Lake City	UT	58	499	138,657	35.99	6	647	97,300	66.50
Temple	TX	59	1,254	348,794	35.95	100	1,052	374,412	28.10
Salem	VA	60	1,106	312,489	35.39	27	1,235	246,609	50.08
Bay Pines	FL	61	1,255	355,080	35.34	72	1,181	339,930	34.74
Huntington	WV	62	188	53,739	34.98	28	252	51,128	49.29
Sioux Falls	SD	63	372	106,984	34.77	39	435	94,548	46.01
Manchester	NH	64	311	89,475	34.76	61	341	88,000	38.75
Togus	ME	65	749	215,794	34.71	35	784	163,394	47.98
Murfreesboro	TN	66	691	199,564	34.63	114	563	228,003	24.69
Muskogee	OK	67	166	48,336	34.34	71	177	50,422	35.10
Syracuse	NY	68	373	109,185	34.16	54	398	98,880	40.25
Alexandria	LA	69	612	183,758	33.30	17	706	131,645	53.63
Washington	DC	70	631	193,474	32.61	53	784	193,778	40.46
Butler	PA	71	311	97,877	31.77	95	323	111,364	29.00
Tucson	AZ	72	290	91,628	31.65	59	346	88,742	38.99
Northport	NY	73	967	308,054	31.39	86	870	290,300	29.97
Marlin	TX	74	228	72,658	31.38	108	205	77,673	26.39
Montrose	NY	75	1,722	554,937	31.03	115	1,235	513,597	24.05

Medical facility location	State	Fiscal year 1984				Fiscal year 1985			
		Rank	Total incidents	Days of care	Ratio days of care to incidents[a]	Rank	Total incidents	Days of care	Ratio days of care to incidents[a]
Pgh (UD)	PA	76	725	233,754	31.02	70	862	242,277	35.58
Nashville	TN	77	407	132,903	30.62	69	442	123,196	35.88
Beckley	WV	78	188	61,734	30.45	66	219	59,800	36.62
Phila.(mc/opc)	PA	79	359	119,210	30.11	75	387	112,552	34.38
Iron Mountain	MI	80	214	72,228	29.63	98	186	65,569	28.37
Amarillo	TX	81	114	38,840	29.35	124	113	55,974	20.19
Fort Howard	MD	82	248	87,037	28.49	99	261	92,213	28.30
Fort Meade	SD	83	355	125,395	28.31	58	439	111,936	39.22
White River Junction	VT	84	190	67,382	28.20	76	212	63,632	33.32
Fayetteville	NC	85	304	108,754	27.95	62	362	93,645	38.66
Baltimore	MD	86	225	82,852	27.16	57	297	75,097	39.55
Durham	NC	87	362	134,886	26.84	81	392	123,757	31.67
Reno	NV	88	193	72,085	26.77	47	268	62,304	43.01
Montgomery	AL	89	146	55,446	26.33	67	191	52,189	36.60
Portland	OR	90	421	161,431	26.08	112	400	158,282	25.27
Canandaigua	NY	91	1,035	400,418	25.85	96	860	298,639	28.80
Shreveport	LA	92	269	105,188	25.57	150	255	293,899	8.68
Battle Creek	MI	93	906	358,263	25.29	109	1,034	395,906	26.12
Decatur	GA	94	385	152,914	25.18	77	494	149,355	33.08
Tuscaloosa	AL	95	515	205,393	25.07	92	445	151,928	29.29
Boston	MA	96	498	198,943	25.03	88	563	188,341	29.89
Jackson	MS	97	410	164,509	24.92	119	354	158,790	22.29
Coatesville	PA	98	964	391,368	24.63	113	1,592	640,192	24.87
Tomah	WI	99	849	347,118	24.46	94	1,012	346,249	29.23
Lake City	FL	100	295	121,860	24.21	102	320	114,275	28.00
Castle Point	NY	101	393	162,987	24.11	93	372	127,156	29.26
Sheridan	WY	102	291	126,980	22.92	46	371	86,020	43.13
Chicago(ws)	IL	103	338	150,961	22.39	101	379	135,002	28.07
Allen Park	MI	104	337	151,898	22.19	111	440	173,102	25.42
Minneapolis	MN	105	469	212,800	22.04	103	544	195,605	27.81
Roseburg	OR	106	242	109,962	22.01	121	228	107,538	21.20
Tampa	FL	107	453	207,595	21.82	107	531	198,728	26.72
Clarksburg	WV	108	134	63,242	21.19	120	129	60,634	21.28
Martinsburg	WV	109	679	321,361	21.13	117	755	335,471	22.51
Cleveland	OH	110	751	358,516	20.95	85	1,079	354,691	30.42
Miles City	MT	111	67	32,177	20.82	33	106	21,845	48.52
Birmingham	AL	112	242	119,377	20.27	90	299	100,803	29.66
Batavia	NY	113	187	95,131	19.66	55	226	56,425	40.05
Danville	IL	114	1,054	560,101	18.82	83	1,331	432,368	30.78

Medical facility location	State	Fiscal year 1984				Fiscal year 1985			
		Rank	Total incidents	Days of care	Ratio days of care to incidents[a]	Rank	Total incidents	Days of care	Ratio days of care to incidents[a]
West LA	CA	115	823	441,697	18.63	105	1,190	436,821	27.24
Little Rock	AR	116	801	442,608	18.10	127	891	458,356	19.44
Grand Island	NE	117	103	57,806	17.82	106	163	59,901	27.21
Miami	FL	118	363	204,744	17.73	118	481	215,307	22.34
Houston	TX	119	603	346,578	17.40	123	730	347,006	21.04
Hampton	VA	120	847	496,635	17.05	116	715	306,637	23.32
Topeka	KS	121	526	310,394	16.95	125	588	293,899	20.01
Pgh.(HD)	PA	122	500	298,145	16.77	137	364	276,648	13.16
Bonham	TX	123	206	124,589	16.53	126	227	113,503	20.00
Cheyenne	WY	124	95	60,944	15.59	73	173	49,849	34.70
Prescott	AZ	125	200	128,711	15.54	104	293	106,937	27.40
Chicago(Is)	IL	126	174	117,527	14.81	156	77	111,825	6.89
Asheville	NC	127	291	201,381	14.45	147	186	196,504	9.47
Dublin	GA	128	360	249,559	14.43	138	270	209,599	12.88
Northampton	MA	129	391	278,044	14.06	130	403	241,606	16.68
Bath	MY	130	452	334,797	13.50	132	505	334,120	15.11
Augusta	GA	131	422	316,260	13.34	110	732	286,665	25.54
Lexington	KY	132	370	286,150	12.93	133	499	357,520	13.96
Buffalo	NY	133	337	261,910	12.87	74	962	279,243	34.45
Brooklyn	NY	134	430	334,875	12.84	131	452	297,752	15.18
Tacoma	WA	135	285	222,645	12.80	139	350	277,330	12.62
Mountain Home	TN	136	504	394,162	12.79	136	532	396,440	13.42
Tuskegee	AL	137	395	315,077	12.54	135	464	343,139	13.52
Wood	WI	138	651	523,532	12.43	141	628	547,037	11.48
Dayton	OH	139	623	517,110	12.05	144	527	529,111	9.96
Biloxi	MS	140	503	433,254	11.61	134	512	377,768	13.55
Hines	IL	141	446	409,944	10.88	140	457	378,071	12.09
Marion	IN	142	339	321,227	10.55	153	267	347,010	7.69
Leavenworth	KS	143	353	335,216	10.53	142	414	372,220	11.12
Hot Springs	SD	144	237	227,256	10.43	129	363	216,941	16.73
Bronx	NY	145	383	381,192	10.05	89	494	165,738	29.81
Bedford	MA	146	370	372,539	9.93	128	594	350,679	16.94
Lebanon	PA	147	444	484,502	9.16	152	469	577,377	8.12
New Orleans	LA	148	126	142,272	8.86	122	288	136,109	21.16
North Chicago	IL	149	412	501,891	8.21	151	398	468,281	8.50
White City	OR	150	250	309,544	8.08	148	252	286,015	8.81
Lyons	NJ	151	407	536,107	7.59	146	496	514,408	9.64
Albany	NY	152	174	248,785	6.99	145	212	216,931	9.77
St. Cloud	MN	153	329	479,970	6.85	149	363	413,156	8.79

Medical facility location	State	Fiscal year 1984				Fiscal year 1985			
		Rank	Total incidents	Days of care	Ratio days of care to incidents[a]	Rank	Total incidents	Days of care	Ratio days of care to incidents[a]
Perry Point	MD	154	209	310,966	6.72	143	374	356,092	10.50
Richmond	VA	155	137	218,075	6.28	155	163	236,675	6.89
Palo Alto	CA	156	201	382,691	5.25	157	161	354,133	4.55
New York	NY	157	90	243,666	3.69	154	187	250,260	7.47
St. Louis	MO	158	94	303,125	3.10	158	84	305,181	2.75
Madison	WI	159	8	75,866	1.05	160	6	72,541	0.83
Omaha	NE	160	10	108,765	0.92	159	25	102,721	2.43
Columbus(opc)	OH	161	1	0	0.00	162	12	0	0.00
El Paso(opc)	TX	162	2	0	0.00	165	7	0	0.00
Boston (opc)	MA	163	30	0	0.00	166	16	0	0.00
Brooklyn (opc)	NY	164	3	0	0.00	163	0	0	0.00
Lubbock(opc)	TX	165	5	0	0.00	161	1	0	0.00
Honolulu	HI	166	21	0	0.00	164	18	0	0.00
Las Vegas(opc)	NV	167	4	0	0.00	167	3	0	0.00
Los Angeles	CA	168	6	0	0.00	168	1	0	0.00
Total			**80,371**		**25.73**		**85,357**		**27.78**

[a]Total reported incidents multiplied by 10,000 and divided by reported days of care.

Comments From the Veterans Administration

Office of the
Administrator
of Veterans Affairs

Washington DC 20420

Veterans
Administration

APR 10 1987

Mr. Richard L. Fogel
Assistant Comptroller General
Human Resources Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Fogel:

This responds to your request that the Veterans Administration (VA) review and comment on the General Accounting Office (GAO) March 4, 1987, draft report, VA's Patient Injury Control Program Is Not Effective.

The VA recognizes that there are opportunities for improving the Patient Injury Control Program and concurs with the recommendations in this report. However, we cannot accept GAO's statement, as indicated by the report title, that the Program is not effective. We suggest that a more accurate description of the Program, and title for GAO's report, would be Improvements Needed in the VA's Patient Injury Control Program.

The enclosure describes the actions we are taking, or plan to take, to implement the recommendations.

Sincerely,

THOMAS K. TURNAGE
Administrator

Enclosure

ENCLOSURE

VETERANS ADMINISTRATION COMMENTS ON THE GAO MARCH 4, 1987, DRAFT REPORT VA'S PATIENT INJURY CONTROL PROGRAM IS NOT EFFECTIVE

Chapter 2 Recommendations:

- o Reinforce to all medical center staff the importance of incident reporting as a means to assure that VA provides quality health care and that federal regulations must be followed.

- o Clarify which incidents are reportable by revising the VA Manual (MP-1, Part I, Chapter 2) to incorporate all reportable incidents listed in the applicable federal regulations (38 CFR 17.508).

Chapter 4 Recommendations:

- o Reemphasize to the medical centers what incidents are required to be investigated and that all investigations reports are to be forwarded to the Medical Inspector.

- o Revise the VA Manual to reflect current practice in regard to investigating unexpected deaths, i.e., require a three-member board investigation only for deaths a facility director determines need to be investigated and, for the remaining unexpected deaths, submission to the Medical Inspector of appropriate explanatory documentation so that the Medical Inspector will have a basis for requiring an investigation if, after reviewing the documentation, he disagrees with the facility director's decision not to investigate.

Chapter 5 Recommendations:

- o Develop for the medical centers guidelines that identify the data to be gathered and analyzed for trends and provide guidance on conducting the trending and analysis.

- o Revise the VA Manual to reflect accurately the requirements of the federal regulations and revise statistical reporting requirements to correspond to the incident-reporting categories in the revised Manual.

Implementation of the six recommendations above is in progress. The Department of Medicine and Surgery Supplement to MP-1, Part I, Chapter 2, Change 41 is being revised and will serve both as a Manual revision and a program guide for incident reporting and investigations. The revision will include some simplifications in the investigative process, particularly in the areas of unexpected deaths and suicides. We expect the Supplement will be ready for publication by October 1987.

- o Require the Medical Inspector to analyze and trend VA program data to determine if individual medical centers are not reporting patient incidents or are having problems providing quality care.

The Medical Inspector will be converting the trending data base from a word processor to a computer system within the next 12 months. Data obtained by the Office of Inspector General during their review of malpractice claims have been incorporated into a tort claim data base using the same computer program that will be used in the trending data base conversion. These actions will give the Medical Inspector greater flexibility in the analysis of patient incidents. In addition, the Medical Inspector is working with the VA's General Counsel in establishing a claims processing data base that will be useful to both offices.

General Comment:

In Chapter 3, GAO endorses the routine review of patients' medical files to identify incidents and states this method overcomes disincentives in the current VA patient injury control program. The GAO believes implementing this occurrence screening systemwide should make the VA program more effective. We are studying the ways this process will be structured within existing Health Services Review Organization monitoring and in other quality assurance activities.

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