123920
~~27985~~

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

HUMAN RESOURCES
DIVISION

APRIL 16, 1984

B-214802


123920

The Honorable Harry N. Walters
Administrator of Veterans Affairs

Dear Mr. Walters:

Subject: VA Central Office Needs to Exercise Better Oversight of Cardiac Pacemaker Recalls (GAO/HRD-84-33)

This report summarizes the results of our review of Veterans Administration (VA) actions taken in response to recalls of defective pacemakers. While VA medical centers receive notification of recalls from several sources, stronger central office oversight is needed to insure that (1) patients are informed of pacemaker recalls or the reasons for not informing them are documented in their medical records and (2) actions taken in response to recalls are in accordance with central office guidance and documented in the patients' medical records.

BACKGROUND

A cardiac pacemaker is an internal or external electronic device used to regulate the action of the heart. An external pacemaker remains outside the body, and its use is temporary until the patient's heart rhythm stabilizes or until a permanent pacemaker is implanted. An internal pacemaker is one in which the pulse generator is implanted permanently under the skin with the electrical leads guided to the heart.

According to VA's Program Chief, Cardiovascular Diseases, a patient is considered pacemaker dependent if the pacemaker is necessary for maintaining the patient's life and nondependent if the pacemaker is used to make the patient "feel better" but is not necessary for maintaining life. He said that a nondependent patient may experience such symptoms as fainting or palpitations without a pacemaker.

028581

(401933)

VA policies on pacemaker implantation

In a May 1982 circular (10-82-72), VA designated 99 of its 172 medical centers as Cardiac Pacemaker Prosthesis Referral Centers for pacemaker implantation and expert professional followup. All VA medical centers are, however, directly involved with followup care of cardiac patients, either through telephone monitoring of pacemaker patients or by adjusting implanted pacemakers. The principal distinction between the referral centers and other VA medical centers is the ability to implant or remove pacemakers.

After implantation, a complete pacemaker record is to be maintained for each veteran. According to VA Department of Medicine and Surgery guidance, all veterans who have received pacemakers must have adequate followup and monitoring to ensure that the pacemaker is functioning properly.

FDA can order recall of defective pacemakers

Cardiac pacemakers can experience a number of significant malfunctions, including battery failure and disconnection of the electrical leads connecting the pulse generator to the heart. Depletion of the pacemaker battery before the anticipated 5- to 10-year battery life not only necessitates battery replacement, but may hint at possible failure of other components.

The Food and Drug Administration (FDA) has the authority to ban or recall medical devices, including pacemakers, that present "unreasonable risks or substantial harm." When FDA or a manufacturer recognizes that a product is potentially hazardous, action must be taken by the manufacturer to notify customers of the defect and to provide instructions for its removal and/or recall from stock. FDA classifies recalls into three categories:

Class I - There is a reasonable probability that the use of, or exposure to, a hazardous product will cause serious adverse health consequences or death.

Class II - The use of, or exposure to, a hazardous product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences is remote.

Class III- The use of, or exposure to, a hazardous product is not likely to cause adverse health consequences.

According to the Director of FDA's Division of Compliance Operations, Bureau of Medical Devices, FDA recalls are directed at removing the defective product from stock. He said that FDA does not tell doctors whether to remove recalled pacemakers from patients because such decisions involve medical judgment based on the patients' conditions and the nature of the pacemaker defect.

VA recall policies

VA's Department of Medicine and Surgery Manual (MP-2) requires that each VA medical center subscribe to the FDA Enforcement Report, a weekly summary of recalls and other FDA actions. Medical centers are also notified of recalls through (1) direct correspondence from the manufacturer and (2) letters and monthly recall summaries issued by VA's Marketing Center at Hines, Illinois.

In May 1982, VA's Department of Medicine and Surgery issued a circular (10-82-72) which required, among other things, that

--each VA medical center establish and implement a written operating procedure for identifying and removing from stock potentially hazardous medical devices, including pacemakers;

--whenever a pacemaker is judged critically unreliable, it will be removed from the patient and replaced with a new pacemaker;

--long-range patient monitoring conform to an individualized plan which will ensure that the pacemaker's functional status will be checked as frequently as indicated, but at least twice per year; and

--information on pacemakers implanted or replaced be recorded in the patients' medical records.

Pacemaker registry

VA established an automated cardiac pacemaker registry in December 1979 to provide specific information on patients who have received permanent cardiac pacemakers. The registry contains such data as the make, model, and serial number of the pacemaker; the date it was implanted; and the VA medical center that implanted it. According to the VA manual, the information provided in the registry serves to identify, follow up, and monitor pacemaker recipients and the performance of their pacemakers.

OBJECTIVES, SCOPE, AND METHODOLOGY

During a survey of VA's handling of FDA recalls, we noted that VA's computerized pacemaker registry indicated that some recalled pacemakers were still implanted in VA patients. We followed up to determine whether (1) the information contained in the registry was accurate and used to monitor recalls, (2) actions taken by the medical centers in response to the recalls were documented in the patients' medical records and were in accordance with VA guidance, and (3) the patients had been informed of the recalls.

To accomplish this we-

--reviewed VA's computerized pacemaker registry for January 25, 1983, to identify patients who were still using pacemakers classified by FDA as Class I recalls during fiscal year 1982;

--obtained from VA's Program Chief, Cardiovascular Diseases, data on the current status of the patients identified;

--visited the Albuquerque and Buffalo medical centers in the fall of 1983 to (1) review, with the assistance of our medical advisor, the records of the patients whose pacemakers were implanted by those medical centers and (2) determine, through discussions with medical center personnel, what actions they had taken in response to the recall;

--reviewed central office guidance on pacemakers and discussed that guidance with the program chief to determine what documentation should be present in patients' medical records; and

—reviewed VA Inspector General reports on pacemaker recalls.

The Albuquerque and Buffalo medical centers were selected for review because over half of the recalled pacemakers had been implanted there.

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

FURTHER VA GUIDANCE NEEDED ON PACEMAKER RECALLS

According to the Program Chief, Cardiovascular Diseases, VA guidance deals primarily with the removal of recalled pacemakers from stock. Although the guidance requires that critically unreliable pacemakers be removed from pacemaker-dependent patients, it does not establish criteria to define when a recalled pacemaker should be considered critically unreliable. VA officials differ on whether all Class I recalled pacemakers are critically unreliable. Further, VA guidance does not establish specific requirements for informing patients of recalls or documenting in patients' medical records the decisions made on actions to be taken in response to the recalls (such as increased monitoring or removal).

According to VA's Program Chief, Cardiovascular Diseases, a pacemaker is critically unreliable if it has a likelihood of failing and failure would be fatal to the patient. He said that all Class I recalled pacemakers are critically unreliable for pacemaker-dependent patients and should be immediately removed except under very rare circumstances. However, VA's Director, Medical Service, did not agree. He said that a Class I recalled pacemaker is critically unreliable if it is subject to unpredictable failure and should be removed from a pacemaker-dependent patient. He said, however, that pacemakers subject to predictable failure, such as battery depletion, do not have to be immediately replaced because there is sufficient warning before failure to permit replacement.

Failure to (1) inform patients that their pacemakers had been recalled or document the reasons for not informing patients in their medical records and (2) document the decisions made on actions to be taken in response to the recall in the patients'

medical records could increase the probability that VA would be found liable if the pacemaker later failed.[1] The program chief told us that although the circular does not require that patients be informed that they have a recalled pacemaker, medical ethics require that patients be told.

VA's Director, Medical Service, said that all of VA's cardiology consultants agreed that medical ethics require that patients be told if their pacemakers are critically unreliable. He said that if a pacemaker is not critically unreliable, and the decision is made not to take it out, then the patient does not have to be informed. He agreed, however, that both the decision not to remove the pacemaker and the reasons for not informing the patient should be documented in the medical record.

ACTIONS NEEDED TO ASSURE THAT VA PATIENTS ARE PROTECTED FROM CRITICALLY UNRELIABLE PACEMAKERS

The VA medical centers we visited were not effectively managing pacemaker recalls. The medical centers had not

--removed critically unreliable pacemakers from some pacemaker-dependent patients,

--recorded information about the recalls in the patients' medical records, or

--informed the patients that their pacemakers had been recalled or documented reasons why they did not inform patients.

In fiscal year 1982, FDA issued three Class I pacemaker recalls affecting 19 pacemaker models manufactured by ARCO Medical Products Company and Synthemed Corporation that were subject to unpredictable failure. The recalls were issued in November 1981, April 1982, and July 1982. We identified 44 patients who, according to VA's pacemaker registry, may have been using one of the recalled pacemakers as of January 25, 1983. The 44 patients' pacemakers were implanted at 15 VA medical centers.

---

[1]In a recent case involving a birth control device, a California court of appeals found a doctor liable for a patient's injuries because he had failed to notify the patient that the device had been recalled. (86 Cal. App. 3d 656 (1978), 150 Cal. Rptr. 384)

At our request, the Program Chief, Cardiovascular Diseases, contacted the 15 medical centers in April 1983 to determine the status of the 44 patients. He told us that of the 44 patients

--28 were still using the recalled pacemaker and were being monitored by VA,

--6 had had their pacemakers replaced,

--4 had died, and

--6 could not be located.

Our medical advisor visited the Albuquerque and Buffalo medical centers in the fall of 1983 to obtain further information on the actions taken in response to the recall.

Albuquerque

Our medical advisor reviewed the medical records of 8 of 11 patients whose recalled pacemakers were implanted by the Albuquerque VA medical center. The medical records of the other three patients had been transferred to other VA medical centers and were not available for review at the time of our visit. None of the eight medical records contained documentation showing that the physician was aware of and responded to the recall or that the patient had been advised of the recall. Of the eight patients

--two were, according to our medical advisor, probably pacemaker dependent[2] and

--four of the nondependent patients had had their pacemakers from 8 to 13 months beyond the manufacturers' recommended replacement period (24 months).

The recalled pacemaker was removed from one of the nondependent patients in January 1983, but there was no indication in the patient's medical record that the replacement was related to

---

[2]The medical record of one patient indicated that he had a complete heart block at the time the pacemaker was implanted. The other patient's medical record indicated that the patient had a very slow heart rate and that the heart rate dropped significantly when the patient was taken off the pacemaker.

the recall. One of the seven patients still using a recalled pacemaker had not had his pacemaker monitored for 2 years. The other six patients' (including the two pacemaker-dependent patients) pacemakers were being monitored every 2 to 3 months.

An official at the Albuquerque VA medical center told us that the medical center had not effectively handled pacemaker recalls in the past. He said that the medical center did not have written procedures for handling patients with recalled pacemakers, and no official had been designated to receive and act on notifications of pacemaker recalls. However, he told us that, as a result of our review, the medical center had appointed him director of pacemaker services responsible for handling pacemaker recalls. He said that he has been reviewing medical records of patients with recalled pacemakers and has begun scheduling both dependent and nondependent patients for replacement operations.

Buffalo

Our medical advisor reviewed the medical records of 13 patients whose recalled pacemakers were implanted by the Buffalo medical center. The medical records of 9 of the 13 patients indicated that they were pacemaker dependent. Two of the patients had transferred to other VA facilities, and the Buffalo medical center did not have records on the patients after their transfer. A third patient died of kidney failure shortly after the pacemaker was implanted. Of the remaining 10 patients

--7 had had their pacemakers monitored every 2 to 3 months,

--1 pacemaker-dependent patient was in a nursing home and had not been monitored since August 1982,

--1 pacemaker-dependent patient had not been monitored since the pacemaker was implanted in September 1981 (according to the medical center's chief of staff, the patient had refused to come to the medical center for monitoring), and

--1 nondependent patient had been monitored only once (in January 1983) between the implant date (June 1981) and his death (in February 1983) of causes not related to his pacemaker.

Pacemakers in two of the seven patients who were being monitored malfunctioned and were replaced in June and September 1983. According to the Buffalo medical center's chief of staff, the malfunctions were probably caused by the development of scar tissue around the leads from the pacemakers to the patients' heart rather than by a defect in the pacemaker.

The medical record of one patient who had transferred to the Bay Pines VA medical center contained a copy of a June 2, 1982, letter from the Buffalo medical center's chief of staff advising Bay Pines that the patient had a potentially defective pacemaker. The letter stated that the manufacturer could not predict the ultimate failure rate or average service life of the pacemaker but advised that

> "Since we have had no problem with these units and since all patients are satisfactorily pacemade, I intend to leave these units in place functioning until end-of-life indicators indicate the need for replacement.
>
> ". . . For the present I intend to follow the patients at three-month intervals. There is always the chance of random failure, of course."

The letter did not mention the FDA recall of the pacemaker issued 3 months earlier. None of the other medical records contained mention of the pacemaker defect. None of the 13 records we reviewed indicated that the patients were notified of the recall.

The chief of staff at the Buffalo medical center told us that he had received information on the pacemaker problem from the manufacturer but was not aware of the FDA recall. He said that based on the information he received from the manufacturer, he decided that the problem with the pacemaker did not warrant making the patients go through a replacement operation. He said that he had decided to replace the pacemakers after they had been implanted about 5 years although the predicted life is normally 10 years.

According to the chief of staff, the medical center has no written procedures for handling patients with recalled pacemakers. He said that had he been aware of the FDA recall, he would have informed his patients of the recall, advised them not to have a replacement operation, and noted the actions taken in the patients' records.

The chief of staff said that he would find it difficult to advise a patient to have an operation to remove a pacemaker that was working perfectly. He said that many of his patients are elderly and should not be needlessly subjected to the risk of an operation. He said that almost all pacemaker patients, even those with complete heart block, have their own heartbeat that would "kick in" if their pacemakers failed. However, he estimated that 50 percent of pacemaker patients are so dependent that they could not survive a year without a pacemaker.

In discussing with us the chief of staff's views, VA's Program Chief, Cardiovascular Diseases, emphasized that it is VA policy that critically unreliable pacemakers be replaced in pacemaker-dependent patients. He said although most pacemaker-dependent patients, as the Buffalo chief of staff stated, have an underlying heartbeat, they still risk severe physical damage (such as kidney or brain damage) if their pacemakers fail. He said that even a day without a pacemaker could cause serious damage in a pacemaker-dependent patient and that such damage might kill the patient.

IMPROVEMENTS NEEDED IN PACEMAKER REGISTRY

An August 25, 1981, VA Inspector General report stated that the pacemaker registry did not accurately reflect the VA pacemaker patient population because

--13 percent of the "events" (implantations, replacements, repairs, and adjustments) that should have been recorded in the registry were not and

--28 percent of the records in the registry contained significant inaccuracies, including incorrect pacemaker model and serial numbers, incorrect implant dates, unreported deaths, and unrecorded replacement pacemaker implants.

The Inspector General noted that none of the medical centers used the registry as a source in screening patients who might be affected by recalls.

The program chief told us that before the registry was established, some VA physicians were not keeping records of patients with pacemakers. He said that this created a problem when manufacturers notified VA of defective pacemakers. The

chief said that the registry forces VA physicians to keep records and provides the central office with information on the number and types of pacemakers implanted.

An official from VA's Medical Records Information staff said that the registry could give VA an effective way to handle pacemaker recalls. She said that VA's Data Processing Center at St. Paul, Minnesota, could generate a report identifying patients who have a recalled pacemaker within about 2 weeks after receiving notification of the recall.

The program chief told us he has proposed that a new clinical pacemaker registry be established which could be used to ensure that medical centers respond appropriately to the pacemaker recalls. He said that the proposed clinical registry would expand the current registry to include data on patients' heart rates without pacemakers (to show whether they are pacemaker dependent) and pacemaker performance.

The program chief said that the clinical registry would be used to identify all pacemaker-dependent patients with recalled pacemakers and that their doctors would be alerted to replace the recalled pacemakers. He said that a circular establishing the new clinical registry will soon be finalized. The Director, Medical Service, advised us on February 24, 1984, that the new clinical registry is being delayed by funding problems. However, he agreed that the development of the registry should be hastened.

The reliability of registry data continues to be questionable. For example, the registry

--did not, according to the director of pacemaker services at the Albuquerque medical center, include 7 of the medical center's 18 patients with recalled pacemakers;

--did not report the death of 4 of the 44 patients identified in the registry as having recalled pacemakers (according to the Buffalo medical center's chief of staff, 1 of the patients at the medical center had died in October 1981);

--did not report that the recalled pacemakers had been replaced for 6 of the 44 patients;

--indicated that one patient had a recalled pacemaker implanted after the date of the recall when it should have indicated that the recalled pacemaker had been replaced on that date; and

--contained inaccurate or no model numbers for implanted pacemakers.

RECOMMENDATIONS TO THE ADMINISTRATOR OF VETERANS AFFAIRS

We recommend that you, through the Chief Medical Director,

--establish criteria, as part of program guidance, to define when a recalled pacemaker should be considered critically unreliable;

--revise program guidance to require that medical centers (1) inform patients of pacemaker recalls unless the reasons for not informing the patient are documented in the medical record and (2) document the actions taken in response to the recall (i.e., increased monitoring, removal, etc.) in the patients' medical records;

--identify all VA patients using recalled pacemakers and assure that (1) they have been informed of the recall (or that the reasons for not informing the patient are documented in the patients' medical records) and (2) all actions taken in response to the recalls are documented in affected patients' medical records,

--establish a timetable for development of the clinical pacemaker registry and, in the interim, take steps to improve the completeness and reliability of data contained in the existing registry, and

--establish a program to monitor the actions taken by medical centers in response to pacemaker recalls.

As you know, 31 U.S.C. 720 requires that the head of a federal agency submit a written statement on the actions taken on our recommendations to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We are sending copies of this report to the Chairmen of the four above-mentioned Committees and the House and Senate Committees on Veterans' Affairs; the Director, Office of Management and Budget; and other interested parties.

Sincerely yours,

Richard L. Fogel
Director