United States General Accounting Office

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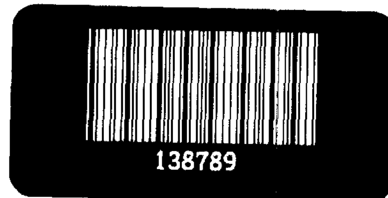
Report to the Chairman, Committee on Veterans' Affairs, U.S. Senate

May 1989

VA HEALTH CARE

Allegations Concerning VA's Patient Mortality Study



GAO/HRD-89-80

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United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-235069

May 18, 1989

The Honorable Alan Cranston
Chairman, Committee on Veterans' Affairs
United States Senate

Dear Mr. Chairman:

As requested in your October 12, 1988, letter (see app. I), we have reviewed allegations made in an October 11, 1988, Washington Post article that the Veterans Administration (VA)—now the Department of Veterans Affairs—altered the design of its patient mortality study to obtain results more favorable to VA. The article alleged that VA's Chief Medical Director ordered that the confidence level used in calculating the number of VA medical centers that had higher-than-expected mortality rates be changed from 95 to 99 percent in order to arrive at a lower number of hospitals with potential quality assurance problems. Specifically, you requested that we answer the following questions:

- Did the Chief Medical Director or any other VA official inappropriately attempt to give the appearance that VA had fewer quality assurance problems at its medical centers than actually exist?
- Why was the decision made to use a 99-percent confidence level to calculate summary hospital mortality data, who made this decision, and at what point in the study was it made?

Results in Brief

Based on information provided by VA, we cannot conclude that the Chief Medical Director or any VA official inappropriately attempted to give the appearance that VA had fewer hospitals with higher-than-expected mortality rates than actually exist. It is understandable, however, how others could have developed this perception.

The Chief Medical Director did not initially take the advice of knowledgeable staff who believed that it was inappropriate for VA to use the same methodology that the Health Care Financing Administration (HCFA) used in conducting a similar study of Medicare patients. He repeatedly maintained that if VA used HCFA's mortality study methodology, the results of the two studies would be comparable. Further, on several occasions, he expressed concern to his staff about what a high number of hospitals with high mortality rates would do to VA's public image. His insistence on using HCFA's methodology and his concern over VA's image were interpreted by some staff as instructions to assure that the studies'

results were similar. Ultimately, the Chief Medical Director approved the recommendation of VA staff to use their own methodology.

VA used both the 95-percent and the 99-percent confidence levels in its mortality study. The 95-percent level was used for determining mortality rates in individual group or diagnosis categories, and these rates were used to identify hospitals for quality assurance reviews. The 99-percent level was used for calculating summary mortality data for individual hospitals for presentation to the Chief Medical Director.

The decision to use the 99-percent confidence level was made by the research health science specialist responsible for the study methodology. She made this decision in February 1988. She used a 99-percent level because it increased VA's confidence that the hospitals identified had differences between the observed and expected mortality rates that she considered meaningful.

Scope and Methodology

In conducting this review, we interviewed VA officials who worked on, or were involved with, VA's patient mortality study, including those in VA's Offices of Quality Assurance and the Chief Medical Director. We reviewed documents and correspondence related to the study and spoke with the Washington Post reporter who wrote the article that precipitated our review. In addition, we discussed the issues with other GAO staff familiar with the VA and HCFA mortality studies, and with Office of Technology Assessment officials whom you asked to review VA's mortality study methodology.

We conducted our review in accordance with generally accepted government auditing standards. Our work was performed between November 1988 and February 1989.

Development of VA's Mortality Study

In the fall of 1987, before HCFA released its study of hospital mortality data,[1] VA's Chief Medical Director decided that VA medical center mortality rates should be analyzed to provide data for use in VA's quality assurance activities. A February 16, 1988, VA circular stated that the results of the study were intended to serve as a guide for conducting focused reviews to lead to an assessment of the quality of medical care in VA medical centers. It also cautioned that mortality rate analysis would not

[1] In December 1987, HCFA publicized hospital-specific mortality rates for Medicare patients hospitalized during 1986.

measure hospital performance and that no conclusions could be drawn about the quality of care based solely on the results of the mortality data.

The VA study compared the mortality rates in each hospital with VA systemwide patient death rates. These rates had been adjusted for patient characteristics through the use of a statistical technique called a logistic regression model. Discharged patients were divided into groups based on whether a procedure was performed during the hospital admission and, if so, what type. Patients were then placed into 1 of 14 primary diagnostic categories (e.g., cancer, severe heart disease; see app. II for complete list of groups and diagnostic categories).

A report was produced for each medical center for each patient group and primary diagnosis category. For any categories in which 10 or more deaths occurred, it was determined whether the ratio of observed mortality to expected mortality was statistically significant at the 95-percent confidence level.[2] On this basis, VA found there were 43 hospitals—25 percent of the total—that had a higher-than-expected mortality rate in at least one patient group/diagnosis category. Upon completing the comparison of the hospital mortality rates with VA systemwide rates, VA initiated additional reviews to determine whether hospitals with higher-than-expected mortality rates actually had problems in their medical care. To do so, VA's peer review organizations examined charts of patients included in the study.

According to the Chief Medical Director, his objective in initiating a mortality study was to determine whether mortality rate comparisons could be useful for quality assurance purposes. In addition, he wanted to have VA mortality data available for comparison with the HCFA mortality data released in December 1987. He wanted VA to use a study methodology as similar as possible to that used by HCFA, which he said was considered the "gold standard" at that time. He was convinced that VA hospitals provided care comparable to private sector hospitals and was initially insistent that VA hospital mortality rates be reviewed by the same methods that HCFA used for Medicare patients in private sector hospitals. He

[2]If observed and expected mortality are the same, the ratio equals one. The discrepancy between the observed and expected mortality rates indicates how much better or worse the outcomes of patients are at specific hospitals compared to those of patients treated at other hospitals. (VA Hospital Care: A Comparison of VA and HCFA Methods for Analyzing Patient Outcomes, GAO/PEMD-88-29, June 30, 1988.)

was concerned that any deviation from the HCFA standard might be criticized as an attempt to make VA hospitals appear better than private sector hospitals.

Early in the planning of the study, the former Director of VA's Office of Quality Assurance and the research health science specialist in charge of developing the methodology explained to the Chief Medical Director that although VA could use the HCFA methodology as a guide, there were differences in the data bases and VA would use a different test of statistical significance. Although both HCFA and VA analyses compared hospital-specific mortality rates with systemwide rates, VA chose to modify the HCFA methodology, in part, because the VA patient population is significantly different from that of the HCFA study. The VA patient population was 98 percent male, of whom 60 percent were under the age of 65, while the HCFA Medicare patient population consisted of more equal numbers of men and women, most of whom were 65 or older. Further, the way in which the VA study defined patient diagnosis differed from the way it was done in the HCFA study. HCFA used the principal diagnosis, which is defined as the main reason for admission to the hospital, while VA's data files record the patient's primary diagnosis, which represents the condition accounting for most of the days spent in the hospital.

In addition to noting these differences in the data bases, VA's research specialist said that the HCFA statistical test was inappropriate because she believed that, to some extent, it predetermined study results by including a factor called interhospital variance.[3] According to the research specialist, adjusting for interhospital variance assured HCFA that only 2.5 percent of its hospitals would fall above and below the range of expected rates.[4]

VA's Office of Quality Assurance officials proposed a different statistical procedure that did not include the interhospital variance factor. They believed it was important to acknowledge differences in hospitals and that, for quality assurance purposes, VA's study should identify a higher proportion of hospitals than the HCFA study. The Office of Quality

[3]The interhospital variance factor allows for systematic differences among hospitals, such as quality of care provided, severity of illness, or administrative differences, that could not be accounted for in the statistical analysis. Inclusion of this factor has the effect of reducing the number of hospitals that fall above the range of expected rates, but not by any given percentage.

[4]As reported by HCFA, inclusion of the interhospital variance factor reduced the number of hospitals that would fall above the range of predicted rates, but to a level of 4 percent rather than 2.5 percent. Without the interhospital variance factor, the proportion of hospitals with significantly higher-than-expected overall mortality rises to 11 percent.

Assurance staff also explained that because of differences in the data bases and the statistical test used, no direct comparisons could be made between VA and HCFA mortality study results. We did not evaluate VA's rationale for not using HCFA's statistical methodology.[5]

The Chief Medical Director did not accept this position and continued to urge that VA adopt HCFA's methodology. Conversely, his staff continued to insist that use of the HCFA methodology was not appropriate, particularly for VA's quality assurance purposes. Ultimately the Chief Medical Director agreed to use the methodology proposed by his staff.

Preliminary Study Results Not Acceptable to Chief Medical Director

In a January 1988 meeting, the former Director of the Office of Quality Assurance told the Chief Medical Director that VA's preliminary data showed that 12.8 percent (or 22) of VA's hospitals had higher-than-expected hospitalwide mortality rates. (This figure is not to be confused with the 43 hospitals identified as having higher-than-expected mortality rates in one or more of the patient group/diagnosis categories as discussed on p. 3.) We could find no documentation for this 12.8-percent figure, nor could anyone in the VA tell us its origin. (The former Director of the Office of Quality Assurance died in April 1988.) The research specialist told us, however, that at that time she had not calculated a percentage of hospitals having overall higher-than-expected mortality rates.

The Chief Medical Director was disturbed with the 12.8-percent figure because he had expected results close to those HCFA had obtained. He could not understand how VA could have such different results if it were using HCFA's methodology as he had directed. He was concerned, he said, about negative public reaction to VA mortality study results that were much higher than HCFA's. He again stressed to the former Director of the Office of Quality Assurance and his staff that VA's methodology be as close to HCFA's as possible, and that he expected results similar to HCFA's results. Many staff at this meeting interpreted these statements as instructions to alter VA's mortality study results. However, the Chief Medical Director also requested that other researchers review the proposed methodology. The research specialist said that three VA researchers and one outside expert reviewed and concurred with the methodology VA was using. Their perspectives were shared with the Chief Medical Director, who then agreed to proceed.

[5]For additional information on VA's mortality study methodology, see the Office of Technology Assessment's April 1989 staff paper for the Senate Committee on Veterans' Affairs.

In February 1988, the research specialist said that the former Director of the Office of Quality Assurance asked her to prepare an overall observed to expected mortality ratio for each hospital using the VA methodology for a presentation to the Chief Medical Director.

Overall Mortality Data Calculated Using 99-Percent Confidence Level

According to VA's research specialist, summary mortality data were calculated on individual hospitals because such data would be easier to use in a discussion with the Chief Medical Director than all the individual group or diagnosis category data. She said she had produced no summary data before this time. She used a 99-percent confidence level to determine the statistical significance of the ratio of each hospital's overall actual observed mortality rate to an expected rate generated from the results of the analysis. (See footnote 2 on p. 3.)

She said she chose a 99-percent confidence level because the aggregated data for most hospitals represented very large numbers of cases; thus, she thought a statistical test at the 95-percent confidence level would have identified a large number of hospitals that had only very small differences between the observed and expected mortality rates. By contrast, she said, the 95-percent confidence level was appropriate for the analysis of mortality rates for the group/diagnosis categories because those categories encompassed many fewer cases. Moreover, VA wanted to identify as many hospitals as possible for the follow-up quality assurance reviews. For summary data, however, that were not intended for quality assurance purposes, using the 99-percent confidence level increased VA's confidence that the hospitals identified had differences between the observed and expected mortality rates that VA considered meaningful. At that confidence level six hospitals—3.5 percent of the total—had overall mortality rates higher than expected. When these figures were presented to the Chief Medical Director in February 1988, he was satisfied with the results, the methodology, and the statistical test used.

According to the research specialist, she was not requested by the Chief Medical Director or anyone else to produce a study result that would be closer to HCFA's or that showed fewer hospitals with high mortality rates than actually exist. She added that she had never calculated summary data using a 95-percent confidence level before our November 1988 request for such data. (At the 95-percent confidence level, 12 hospitals—7 percent of the total—had overall mortality rates that were

higher than expected.)[6] She also said she did not know the origin of the 12.8-percent figure presented in the January 1988 meeting by the former Director of the Office of Quality Assurance.

Status of VA's Mortality Study

In June 1988, the VA Administrator decided that no study results would be published until follow-up studies could be completed on the hospitals that had higher-than-expected mortality rates in one or more of the group/diagnosis categories using the 95-percent confidence level. According to the Chief Medical Director, the follow-up studies were to identify hospitals where quality of patient care was less than optimal or where practices deviated from commonly accepted standards of medical practice. VA's Medical District Initiated Peer Review Organizations have completed focused reviews in these hospitals. VA plans to present the results to the Congress by the middle of May 1989.

Conclusion

We cannot conclude that the Chief Medical Director or any other VA official acted inappropriately. The Chief Medical Director was convinced that the HCFA methodology was the "gold standard" and, if used by VA, would show results similar to HCFA's study. Further, the use of a 99-percent confidence level for determining overall study results was not used to lower a previously determined number of hospitals with higher-than-expected mortality rates as alleged in the Washington Post article. We believe, however, that the Chief Medical Director communicated his wishes regarding the methodology and the protection of VA's public image in a manner that gave the appearance to many VA staff that he was ordering that study results be altered.

We emphasize that the actions discussed in the October 1988 Washington Post article occurred while the mortality study was in progress and that the summary hospital mortality rates discussed within VA were not final results. As of May 1, 1989, no mortality data have been released to the public.

Agency Comments

By letter dated May 8, 1989 (see app. III), the Secretary of VA transmitted comments of the Chief Medical Director on a draft of this report. The

[6] The 6 hospitals identified at the 99-percent confidence level and all but 1 of the 12 hospitals identified at the 95-percent confidence level were among the 43 hospitals already being reviewed because they had higher-than-expected mortality rates in the group/diagnosis categories. The one other hospital was added to VA's review.

Chief Medical Director said he initially intended that VA hospital mortality be directly compared with the mortality experience of Medicare patients in community hospitals. He asked VA staff to use a study methodology identical or similar to that used by HCFA and assumed that when this same statistical analysis was applied to the Medicare-certified and VA hospitals, approximately the same proportion of hospitals would be identified as having higher-than-expected mortality rates. Because of differences between VA and Medicare records, the Chief Medical Director acknowledged that no direct comparisons of mortality data could be made. Thus, he said no conclusions can be drawn about the quality of VA care compared to that of community hospitals.

We are sending copies of this report to other congressional committees and subcommittees; the Director, Office of Management and Budget; the Secretary of Veterans Affairs; and other interested parties. Major contributors to this report are listed in appendix IV.

Sincerely yours,

David P. Baine
Director of Federal Health Care
Delivery Issues

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Abbreviations

HCFA	Health Care Financing Administration
VA	Veterans Administration

Request Letter

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United States Senate

COMMITTEE ON VETERANS' AFFAIRS
WASHINGTON, DC 20510-6375

October 12, 1988

Honorable Charles A. Bowsher
Comptroller General of
the United States
General Accounting Office
Washington, D.C. 20548

Dr. John Gibbons
Director
Office of Technology Assessment
600 Pennsylvania Avenue, SE
Washington, D.C. 20003

Dear Charles and Jack,

I am writing to request that both the General Accounting Office and the Office of Technology Assessment look into matters pertaining to the Veterans' Administration's (VA) FY 1986 Patient Treatment File Mortality Analysis.

Enclosed is an October 11, 1988, Washington Post article, entitled "VA Researchers Ordered to Report Fewer Problem Hospitals", in which it is alleged that the VA altered the design of its mortality study so that more favorable results would be obtained. According to the article, the confidence limits -- the range within which there is a probability of concluding that there is a true or real difference between the observed and predicted -- were expanded from 95 percent to 99 percent. It is my understanding that such a change might result in decreasing the number of VA medical centers erroneously identified as having a higher mortality rate than predicted, but would also have the potential for missing some centers with a higher than predicted mortality rate and in need of further study. According to the article, over the objection of the VA's then-Director of Health-Care Quality Assurance, the VA's Chief Medical Director (CMD) "ordered the researchers" to come up with a lower number of potential problem hospitals because the CMD reportedly was concerned that the "VA could not withstand the criticism that 'inevitably' would result from comparison between its survey" and the survey of mortality in private hospitals released by the Health Care Financing Administration (HCFA) in December 1987.

I believe that these allegations and the VA's methodology warrant a detailed study and investigation at this time. Thus, as Chairman of the Veterans' Affairs Committee, I am requesting that the Office of Technology Assessment carry out a study designed to address the following issues:

1. Was the methodology utilized by the VA when analyzing its hospital's mortality rates a scientifically valid and reliable methodology? In responding, please specifically address the

-2-

appropriateness of using either 95-percent or 99-percent confidence limits and of changing the confidence limits after the data have been gathered.

2. Is the methodology utilized by the VA comparable to that utilized by HCFA? If not, in what ways do they differ and is one methodology preferable to the other?

I am requesting that the General Accounting Office investigate the following matters:

1. At what point in the development and implementation of this study was the decision made to use higher confidence limits for measuring overall mortality rates between VA medical centers, why was that decision made, and who was responsible for making that decision?

2. Did the Chief Medical Director or any other VA official inappropriately attempt to give the appearance of fewer quality-assurance problems at VA medical centers than actually exist?

Because of the serious nature of the allegations and the need to keep the public informed of the degree to which high quality health care is being provided within all VA medical centers, I am requesting that these studies be expeditiously undertaken.

Thank you for your continuing assistance. I look forward to working with you in proceeding with these reviews. Should you have any questions, please have your staff contact Sandi Isaacson, Professional Staff Member (224-9126).

With warm regards,

Cordially,

Alan Cranston
Chairman

Enclosure

Patient Groups and Diagnostic Categories Used in VA's Patient Mortality Study

Patient Groups

1. Nonsurgical (patient did not have a procedure).

2. Surgical procedure (patient had a surgical procedure).

3. Operative diagnostic/palliative procedure (patient had a surgical procedure for diagnostic purposes alone, e.g., biopsy).

4. Nonoperative procedure (e.g., CAT scan).

Diagnostic Category

1. Cancer.

2. Cerebrovascular disease.

3. Severe heart disease.

4. Metabolic and electrolyte disorders.

5. Pulmonary disease.

6. Ophthalmologic disease.

7. Low-risk heart disease.

8. Gastrointestinal disease.

9. Renal and urologic disease.

10. Orthopedic conditions.

11. Infectious and parasitic disease.

12. Symptoms and ill-defined conditions.

13. Aftercare, rehabilitation, follow-up examinations.

14. All other conditions.

Comments From the Department of Veterans Affairs

Office of the Administrator of Veterans Affairs

Washington DC 20420

MAY 8 1989

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

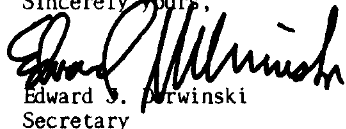
Dear Mr. Thompson:

This responds to your request that the Department of Veterans Affairs (VA) review and comment on the General Accounting Office (GAO) April 7, 1989, draft report VA HEALTH CARE: Allegations Concerning VA's Patient Mortality Study.

An October 1988 Washington Post article contained allegations that VA altered the design of its patient mortality study to obtain results more favorable to VA. GAO reviewed the allegations and found no evidence that the Chief Medical Director or any VA official acted inappropriately.

Enclosed are the comments of John A. Gronvall, M.D., Chief Medical Director, on the GAO report.

Sincerely yours,



Edward J. Derwinski
Secretary

Enclosure

Enclosure

COMMENTS OF THE CHIEF MEDICAL DIRECTOR,
DEPARTMENT OF VETERANS AFFAIRS, ON THE
APRIL 7, 1989, GENERAL ACCOUNTING OFFICE DRAFT REPORT
VA HEALTH CARE: ALLEGATIONS CONCERNING VA'S PATIENT MORTALITY STUDY

When the VA patient mortality study was initiated, the Chief Medical Director intended that VA hospital mortality be directly compared with the mortality experience of community hospitals. Because of differences between VA and Medicare records (as described in the GAO report), no such direct comparison could be made. Thus, the study does not allow any conclusion about quality of VA care compared to that of community hospitals.

Both the Health Care Financing Administration (HCFA) study and the VA study, therefore, compare individual hospital mortality data to aggregate data for the whole system of Medicare or VA hospitals respectively. The analysis then identifies individual hospitals with higher (or lower) than expected mortality. HCFA pointed out that no direct conclusion about quality of care can be drawn from such analyses. The VA study proceeded to actual case record reviews, as the GAO report describes, to see if there had been problems in the quality of care provided.

The Chief Medical Director had asked VA staff to use a study methodology identical to, or at least similar to, that of HCFA's. He thus assumed that when this statistical analysis was applied to these two large systems (all Medicare hospitals, or all VA hospitals), approximately the same proportion of hospitals would be identified as "high outliers," having higher than expected mortality rates. The GAO report documents that this was the Chief Medical Director's assumption, without giving his rationale for it.

In any event, as the GAO report points out, the Veterans Health Services and Research Administration had decided to do a followup medical record review in all hospitals where higher than expected mortality was found in any of the patient group/primary diagnosis categories (a total of 43 hospitals).

In the interest of technical accuracy, we request that GAO make the following changes in the report as well as the changes shown on the attached annotated extract of the report.

--Page 2, RESULTS IN BRIEF: A sentence should be added, stating that both the 95 and 99 percent confidence levels were used in calculating data. There is no mention of the 95 percent confidence level until later in the report. Since one of the allegations in the Washington Post was that the Chief Medical Director ordered a change in the confidence level used, it should be pointed out in the beginning of the report that both levels were in fact used, and that the analysis of the aggregate data at the 99 percent confidence level was conducted only

2.

to provide summary data. The analysis of data by patient groups and diagnosis categories, conducted at the 95 percent level, was always to have been the basis for the case reviews--the purpose of the study. Excluding this information early in the report makes it appear as though an analysis was conducted only at the 99 percent confidence level. Persons who may only read the RESULTS IN BRIEF, not the entire report, would not have an accurate understanding of the calculations.

Now on p. 4.

--Page 7, line 1: Delete "only." The VA's data files record more than the patient's primary diagnosis.

Now on p. 4.

--Page 7: Footnote 4 should specify that the HCFA mortality rate was for the hospital's overall mortality rate.

Now on p. 5.

--Page 8: Last sentence, first full paragraph: The meaning of the word "they" is unclear.

Now on p. 5.

--Page 9: The second-last sentence should read, "Three researchers within the VA ... using." Delete "The research specialist said that" because this is a factual statement.

Now on p. 7.

--Page 12, line 5: The followup studies were performed for a number of reasons, including identifying VA medical centers "where quality of patient care was less than optimal or where practices deviated from commonly accepted standards of medical practice...." The followup review was limited to an assessment by physicians of the quality of care provided in specific cases. Therefore, it would be inappropriate to state that the purpose of the followup was to "determine whether these hospitals have quality-of-care problems."

Major Contributors to This Report

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