VHA'S RISK MANAGEMENT POLICY AND PERFORMANCE

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

OCTOBER 8, 1997

Printed for the use of the Committee on Veterans' Affairs

Serial No. 105–23

U.S. GOVERNMENT PRINTING OFFICE

46–316 CC WASHINGTON : 1998

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-056429-8

AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

COMMITTEE ON VETERANS' AFFAIRS

BOB STUMP, Arizona, *Chairman*

CHRISTOPHER H. SMITH, New Jersey
MICHAEL BILIRAKIS, Florida
FLOYD SPENCE, South Carolina
TERRY EVERETT, Alabama
STEVE BUYER, Indiana
JACK QUINN, New York
SPENCER BACHUS, Alabama
CLIFF STEARNS, Florida
DAN SCHAEFER, Colorado
JERRY MORAN, Kansas
JOHN COOKSEY, Louisiana
ASA HUTCHINSON, Arkansas
J.D. HAYWORTH, Arizona
HELEN CHENOWETH, Idaho
RAY LAHOOD, ILLINOIS
BILL REDMOND, New Mexico

LANE EVANS, Illinois
JOSEPH P. KENNEDY II, Massachusetts
BOB FILNER, California
LUIS V. GUTIERREZ, Illinois
JAMES E. CLYBURN, South Carolina
CORRINE BROWN, Florida
MICHAEL F. DOYLE, Pennsylvania
FRANK MASCARA, Pennsylvania
COLLIN C. PETERSON, Minnesota
JULIA CARSON, Indiana
SILVESTRE REYES, Texas
VIC SNYDER, Arkansas
CIRO D. RODRIGUEZ, Texas

CARL D. COMMENATOR, *Chief Counsel and Staff Director*

SUBCOMMITTEE ON HEALTH

CLIFF STEARNS, Florida, *Chairman*

CHRISTOPHER H. SMITH, New Jersey
MICHAEL BILIRAKIS, Florida
SPENCER BACHUS, Alabama
JERRY MORAN, Kansas
JOHN COOKSEY, Louisiana
ASA HUTCHINSON, Arkansas
HELEN CHENOWETH, Idaho

LUIS V. GUTIERREZ, Illinois
JOSEPH P. KENNEDY II, Massachusetts
CORRINE BROWN, Florida
MICHAEL F. DOYLE, Pennsylvania
COLLIN C. PETERSON, Minnesota
JULIA CARSON, Indiana

CONTENTS

Page

OPENING STATEMENTS

Chairman Stearns 1
Hon. Luis V. Gutierrez 2
Prepared statement of Congressman Gutierrez 55
Hon. Michael Bilirakis 3
Prepared statement of Congressman Bilirakis 61
Hon. Lane Evans, Democratic Ranking Member, Committee on Veterans' Affairs 4
Prepared statement of Congressman Evans 63
Hon. Jerry Moran 5
Hon. John Cooksey 30
Hon. Joseph P. Kennedy, II 32
Prepared statement of Congressman Kennedy 58
Hon. Asa Hutchinson 15

WITNESSES

Doherty, T.C., Director, Miami VA Medical Center, accompanied by Douglas Bradshaw, Assistant General Counsel, Department of Veterans Affairs 37
Prepared statement of Mr. Doherty 141
Headley, Elwood, M.D., Director, Boston VA Medical Center 35
Prepared statement of Dr. Headley 135
Kizer, Kenneth W., M.D., M.P.H., Under Secretary for Health, Department of Veterans Affairs accompanied by Nancy Wilson, M.D., M.P.H., Director, Office of Performance and Quality, Department of Veterans Affairs; James McManus, M.D., Medical Inspector, Office of Medical Inspector, Department of Veterans Affairs 21
Prepared statement of Dr. Kizer 107
Leape, Lucian, M.D., Harvard School of Public Health 5
Prepared statement of Dr. Leape 93
Mather, John, M.D., Assistant Inspector General for Health Care Inspections, Office of the Inspector General, Department of Veterans Affairs 23
Prepared statement of Dr. Mather 117
Valentine, Billy, Director, Muskogee VA Medical Center, Department of Veterans Affairs 39
Prepared statement of Mr. Valentine 148

MATERIAL SUBMITTED FOR THE RECORD

Articles:
"Deaths rise at VA hospitals," *Times Herald-Record*, (Middletown, NY) May 13, 1997 72
"VA hospital deaths soar," *The Reporter Dispatch*, May 15, 1997 73
"Families describe deaths," *Times Herald-Record*, May 15, 1997 75
"Vet fades. A casualty of 'chaos'," *Times Herald-Record*, May 13, 1997 78
"Castle Point deaths under investigation,"*Poughkeepsie Journal*, May 21, 1997 80
"Veterans' suffering is more than numbers," *Times Herald-Record*, May 21, 1997 81
"Families tell of VA neglect," *Times Herald-Record*, May 26, 1997 82
"Dead in 38 days," *Times Herald-Record* July 1, 1997 84
"Deaths blamed on VA cutbacks," *Times Herald-Record*, August 6, 1997 87

Page

"Tales of neglect rise at VA hospitals," *Times Herald–Record* 88
"Vets battle bureaucrats," *Times Herald–Record* 89
"What they say," *Times Herald–Record*, Augst 5, 1997 90
"Anger and sorrow mark vets' plight,"*Poughkeepsie Journal*, August 5, 1997 92
Report—"Patient Deaths Under Unusual or Apparently Avoidable Circumstances at VAMCs," prepared by Dr. John Mather, September 26, 1997 130
Statements:
Hon. Maurice D. Hinchey, a Representative from the State of New York .. 66
Hon. Sue Kelly, a Representative from the State of New York, with attachments 69
Written committee questions and their responses:
Congressman Evans to Dr. Kenneth Kizer, Under Secretary for Health, Department of Veterans Affairs 156,174
Congressman Evans to Dr. Elwood Headley, Director, VA Medical Center, Boston, MA 163
Congressman Evans to T.C. Doherty, Director, VA Medical Center, Miami, FL 166
Congressman Evans to Billy Valentine, Director, VA Medical Center, Muskogee, OK 169
Congressman Evans to Dr. Lucian Leape, Harvard School for Public Health 178
Congressman Evans to Dr. John Mather, Office of the Inspector General, Department of Veterans Affairs 183

VHA'S RISK MANAGEMENT POLICY AND PERFORMANCE

WEDNESDAY, OCTOBER 8, 1997

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in room 334, Cannon House Office Building, Hon. Cliff Stearns (chairman of the subcommittee) presiding.

Present: Representatives Stearns, Bilirakis, Moran, Cooksey, Hutchinson, Gutierrez, Kennedy, and Peterson.

Also Present: Representative Evans.

OPENING STATEMENT OF CHAIRMAN STEARNS

Mr. STEARNS. Good morning, everybody. The subcommittee will come to order and I welcome my colleagues. Over the course of the last two years, the VA health care system has undergone dramatic change. In many respects, the change has been beneficial for veterans with establishment of systems for providing veterans' routine outpatient care, opening of community-based clinics and greater emphasis on improving customer service.

With an accompanying emphasis on the part of VA health care managers on cost-cutting and improved efficiency, however, VA employees have faced unsettling times with hospital downsizing reorganization and threats of reduction in force. These sweeping changes have made all the more important the need to ensure that the quality of VA care remains high.

This morning we examine one aspect of that obligation, VA's effort to prevent injury to its patients. Patient safety is by no means simply a VA issue. We are fortunate this morning to hear from a national expert on the prevention of error in health care delivery.

Dr. Leape's estimate that approximately one million Americans are injured by errors in hospital treatment each year and that 120,000 die as a result thereof is chilling. Our concern certainly is to be sure that VA is doing all it can to ensure veterans' well-being in its care delivery. VA has sadly experienced some tragic mishaps resulting in unexpected patient deaths.

One can only react with horror at the image of a Miami VA nurse interrupting the start-up of a patient's blood dialysis to take a personal phone call, returning to find the patient's blood flowing from the dialysis machine on to the floor and then attempting to cover up the incident, rather than seeking emergency help.

Cases like that lead me to wonder whether a new risk management policy is really the answer. I raise that question with the knowledge that VA has had risk management policies for some time. For years, a key element of VA policy has been to require both system-wide reporting of unexpected patient incidents and national review of that rolled up data to identify trends and institute remedial changes.

I was astounded to learn, however, that until the committee asked and recently received tabulated national data on adverse incidents, for years, no VA official had compiled the data, let alone analyzed it. If VA headquarters ignores its own policy directives, I have to wonder how much trust to place in, quote, "new policy pronouncements," however enlightened they might be.

It is clear that this hearing raises some uncomfortable questions for the department. It has also become apparent that since we began to take a close look at these issues, VA has given the subject far more attention and concern. I approach this hearing, therefore, with cautious optimism that patient safety has become a critical VA issue but, also, with the resolve that this committee will be vigorous in its continued oversight of this area. It goes without saying that this is a most important hearing and I very much appreciate the efforts of those who came such a distance to be with us this morning. I look forward to their testimony. But before calling on our first witnesses, I am pleased to recognize our Ranking Member, my colleague and friend, Congressman Gutierrez for his opening remarks.

OPENING STATEMENT OF HON. LUIS V. GUTIERREZ

Mr. GUTIERREZ. Thank you very much, Mr. Chairman. Allow me to reiterate the importance of the subject matter of this hearing today. Improved patient safety and the prevention of unplanned clinical occurrences is a goal we all wish to achieve. In this regard, the Department of Veterans Affairs, our Nation's largest health care provider, is no different than nongovernmental health care providers. However, the VA serves a unique patient base and thus carries a unique responsibility to address patient safety.

The VA as a Government provider is also under the budgetary constraints imposed upon it by the Congress and because this committee is responsible for oversight of veterans' health issues, we are also responsible for the health of veterans who use the VA for medical purposes.

I believe this hearing is particularly timely. Unanticipated deaths at a number of VA medical facilities have raised our awareness of patient safety issues and the adverse medical effects that occasionally result from medical treatments. The statistics do not point to a greater number of unanticipated deaths at VA hospitals nationally for this year, but cases in Ohio and in upstate New York demonstrate the need for new approaches to be developed and implemented to address this problem.

I am pleased to see the VA start this process. The VA has recently announced a partnership to address these important issues in conjunction with other national health care organizations, such as the American Hospital Association and the National Patient Safety Foundation of the American Medical Association is certainly

a positive step. The implementation of a comprehensive risk management strategy with concrete proposals for preventing injuries to patients, visitors and VA employees is also a useful endeavor that should help the VA synchronize its efforts throughout the system.

Ensuring the quality of care throughout the VA is vitally important. Dr. Kizer has admitted that health care quality varies from hospital to hospital; that some hospitals are better than others and that some facilities have more reports of adverse events than others. For me, this variance from place to place means we are letting some veterans down and I believe by failing to offer the best quality care to all veterans, regardless of their location or network, we in turn let all veterans down.

To address this problem, the recent actions of the VA must be followed up by more tangible steps. Access to information must be improved, the reporting of adverse events in VA hospitals is even more inconsistent than health care. A formal structure should be established to ensure that incidents of this nature are reported promptly throughout the system. In addition, the number of adverse events facility-by-facility, year-by-year, must be chronicled.

We cannot determine if the VA health care has improved unless we have reliable statistical evidence that VA must make this an urgent priority if it is to address the issue in a responsible manner. Allow me once again to express my support for what the VA is currently doing to improve patient safety. These are positive steps worth commendation and they should help us all understand the true nature of this problem and assist in the creation of innovative solutions. I thank you all for joining us here today on this important issue and I look forward to questioning the witnesses later this morning. Mr. Chairman, thank you so much.

Mr. STEARNS. Thank you. My colleague from Florida, Mr. Bilirakis.

OPENING STATEMENT OF HON. MICHAEL BILIRAKIS

Mr. BILIRAKIS. Thank you, Mr. Chairman. I ask unanimous consent my entire statement be made a part of the record. And Mr. Chairman, I would like to commend you for scheduling this hearing. I do want to thank you for postponing it from the prior date. As you know, I had FDA reform at that time and I wanted to be here. I also would like to join you and others in welcoming Dr. Doherty, the Director of the Miami VA Medical Center, here to Washington.

Earlier this year, Mr. Chairman, as we all know, one of my district newspapers printed a series of articles on VA health care. These articles chronicled the stories of a number of patients who died unexpectedly because of adverse events. That paper reported that at least 23 veterans have died under unusual or avoidable circumstances at 17 VA hospitals and nursing homes around the country since 1993. These articles also recounted a series of mistakes that resulted in the deaths of 23 veterans in Florida and I won't go into those specific adverse events, Mr. Chairman. I suppose in our hearing today, it will go into those, but it is tragic.

I think it is important we realize as tragic as these events are, the purpose of today's hearing is not to condemn the VA health care system. In fact, I have always believed that the VA health

care system is a national asset that provides high quality care to our Nation's veterans. I am concerned, obviously, that events such as this sort of lessen the credibility in veterans' minds of the VA health care system, and I think that is the biggest problem with it all.

Over the years, I visited, as have many others, VA health care centers. I have also heard from many veterans who have taken the time to share their positive experiences at VA medical facilities with me. Moreover, Mr. Chairman, it is important we realize adverse events are not unique to the VA.

A 1993 Harvard study estimated one million preventable injuries and 120,000 preventable deaths occurred at American hospitals in a single year. While we would obviously prefer that adverse events never occur at any hospital, it is unrealistic to think that such events can be completely eliminated. After all medical providers are human and mistakes will occur if only by human error. So rather than set an unachievable goal, it is the responsibility, I think, of this subcommittee to ensure that when an adverse event does happen, it is properly investigated by the VA in a timely manner. Moreover, it is important that the VA establish appropriate risk management policies, as you indicated, to prevent such events from occurring.

We must also conduct proper oversight to ensure the risk management policies are being followed by VA medical personnel. This is particularly important because of the significant changes that have taken place within the VA health care system over the last couple years. These changes were designed to reduce health care costs and increase the timeliness of care provided to veterans.

As the reorganization of the VA health care system continues, we must monitor the impact that these changes have on the quality of care veterans receive in VA medical facilities. Simply put, Mr. Chairman, veterans deserve to know they will receive the highest quality of care of VA medical facilities, and it is our job to make sure they do. I thank you, Mr. Chairman, for scheduling this hearing and, hopefully, we can get to the problems.

Mr. STEARNS. I thank my colleague. The Ranking Member of the full committee, Mr. Evans.

OPENING STATEMENT OF HON. LANE EVANS, DEMOCRATIC RANKING MEMBER, COMMITTEE ON VETERANS' AFFAIRS

Mr. EVANS. Thank you, Mr. Chairman. I guess I want to associate myself with the remarks just made by our colleague from Florida. You all know that this issue is a very important one. We congratulate you for holding this hearing. We know it goes to the heart of the basic issue of providing quality health care to our Nation's veterans, and when we have preventable mistakes occurring, it is often sensational and graphic in the media reports we receive, but I think as shocked as we all are, we need to keep these events in perspective as the gentleman from Florida indicated. Every system has its problems.

One of our committee staff members shared an experience about the potentially life-threatening mistakes in her father's health care under one of the Nation's most preeminent health care organizations, so we must not characterize the VA by the number of unfor-

tunate incidents that have occurred. We need to be practical and make sure they don't occur again and I completely associate myself with the remarks made by the gentleman from Florida.

Mr. STEARNS. Mr. Moran.

OPENING STATEMENT OF HON. JERRY MORAN

Mr. MORAN. Mr. Chairman, thank you. I appreciate the opportunity to hear the testimony today and I congratulate you on having this subcommittee hearing. I think all Americans have a right to expect quality health care when they are admitted to a health care system, and it is especially true for veterans who have served our country and who are receiving medical care provided by the United States Government, so I think this is a very important topic and I appreciate the opportunity to participate in today's subcommittee meeting.

Mr. STEARNS. Mr. Peterson.

Mr. PETERSON. Nothing.

Mr. STEARNS. Without objection, all Members' opening statements will be made a part of the record.

And now we will start with the first panel, Dr. Leape, from the Harvard School of Public Health. Welcome, this morning, and we will have your opening testimony.

STATEMENT OF LUCIAN LEAPE, M.D., HARVARD SCHOOL OF PUBLIC HEALTH

Dr. LEAPE. Mr. Chairman, members of the committee, thank you very much for the opportunity to come and testify before you. Although I am currently at the Harvard School of Public Health, I want to make sure you know that I am a real doctor; that for 25 years I was a practicing pediatric surgeon, so I think I have some understanding of these problems from the trenches as well as from academe. I also am a veteran so I have an interest in what is going on.

I have not, however, studied the Veterans' Administration hospitals, but I have no reason to think they are any different from the rest of the hospitals in the country in terms of the nature of the problems and the way they are approached. As the Chairman has pointed out, we have a serious problem. We have far too many injuries and deaths as a result of treatment that is designed to help people, and it is very important to try to understand why that occurs so we can do something about it.

Clearly, health care is a high hazard industry. It has not thought of itself that way. We think of ourselves as a highly effective industry and, indeed, in the last 10 or 20 years, the improvements in medical science have, indeed, been breathtaking. We are highly effective. We are now, of course, also highly technological and highly complicated and complexity breeds opportunities for error and that is how injuries happen.

But other industries are also high hazard, highly effective, high technology industries but have much lower injury rates. I think, first off, of aviation and nuclear power. Nobody questions the fact that these are very risky enterprises and yet they go wrong very seldom. What do they know that we don't know? Why is it that when you enter a hospital, your chances of dying from an accident

are one in 200, but when you climb on an airplane, your chances of dying in an accident are one in 2 million?

Clearly, we can learn a lot from what has been done in industry and it is time we apply these lessons to health care. Why haven't we done something before this? I would submit there are three basic reasons: The first is that the leaders in our hospitals have been unaware of the severity of the problem. It has only been in the last few years that these reports have come out that show the high incidence of injuries and accidents and errors, and the other reason is they don't receive the reports within the hospital.

The reason we don't get voluntary reporting is that we punish people when they make errors, and, therefore, no one is going to report an error they can hide. These egregious incidents you have heard of already increase the fear that is so present in our hospitals among personnel concerning errors, and until we change that, we are not going to get good reporting. We may be able to snoop around as policemen, but we won't be getting the voluntary reporting.

The second is that our method for dealing with errors is misguided and ineffective. Our focus, traditionally, since time immemorial, has been on the individual. We attempt to get perfection in care by training doctors and nurses and pharmacists to be perfect and then punish them when they fail. The "train and blame" approach has been shown to be ineffective and the results speak for themselves.

The high hazard industries that have low risks, such as aviation, do not get there that way. They have found, as we have learned from human factors experts over the years, that errors are not made on purpose, and that errors don't occur out of the blue, but that human beings make errors because of the situations, the processes, that they are functioning in; that is, defective systems make errors more likely and more difficult to pick up. Pilots aren't any better than doctors, but they make fewer errors because their systems make errors more difficult and when errors do occur, and they make errors also. They can identify them and correct them before an accident happens. So we have to think in terms of systems terms, rather than individual terms.

When something goes wrong, we always want a head to roll, we look for somebody to blame, we cry negligence and abuse and so forth. Very, very few of our errors, I would say less than 1 percent, are due to real negligence. Most are made by good conscientious people that make a dumb mistake, just like you and I do every day. Errors are part of human experience.

What we need to do is to have systems that keep them from hurting patients. For example, two medications that have similar looking labels are an accident waiting to happen. Two medications with similar sounding names are an accident waiting to happen. Nurses and doctors who work double shifts and have increased patient loads, who are tired and under stress, those are accidents waiting to happen. We all know that stress makes you more likely to make a mistake and yet doctors and nurses and pharmacists are often under great stress.

The recent tendency to substitute less trained people for highly skilled nurses in our care of patients is absolute idiocy at a time

when the intensity of illness in hospitals has gone up, as more and more patients are taken care of outside. At a time when care has become increasingly more complicated, we are reducing the level of expertise of people delivering the care. This is absolute madness. It is a setup for errors and it is not surprising they occur.

Illegible handwriting has long been a big joke. Doctors' handwriting has always been known to be something you can't read. It is not a joke when it leads to the wrong medication or wrong dose. This is something we should eliminate. And so it goes. So we have a lot of things in our system that, if you will, set up people to make mistakes.

In fact, I would say the nurses and the pharmacists and the doctors are our best defense against these defects. They don't make mistakes most of the time. They keep from doing the things they are being set up to do.

The third reason, in addition to the fact that our efforts have been misguided, is that hospitals and health care organizations have not made safety a number one priority. I think it is quite evident the time has come to do that. We have to stop reacting to crisis events and start being proactive in thinking about how to design our systems. It has already been mentioned there has been some recent progress. I think I should take one minute to mention that.

Last October, there was an exciting conference sponsored by the Annenberg Center in which we brought together members from the health professions as well as industry and academics to talk about error prevention. At that time, the AMA announced its formation of the National Patient Safety Foundation, specifically committed to improving information dissemination, education and sponsoring research in error prevention. I think this is a significant step forward by the AMA, and they ought to be commended for it.

At the same time, the Joint Commission on Accreditation of Health Care Organizations announced it was changing its reporting policy, to make it less punitive and more constructive. The American Society of Health-Systems Pharmacists published a list of eight or nine major features that hospitals should incorporate to prevent errors. If these were adopted by all hospitals in the country, errors in the medication process would be significantly reduced. And hospitals are beginning to do something about it.

We had a collaborative effort to reduce medication errors run by the Institute for Healthcare Improvement. We had 41 hospitals signed up and another 20 that we couldn't take, so there is an interest and demand; hospitals are trying to do something about it. We need to help them as much as we can. However, it is going to take a major culture change. It is going to take hospitals beginning to look upon errors as what they are, which is symptoms of a disease, not the disease itself. The disease is faulty systems. Until we concentrate on the system faults, we are not going to stop the errors. It is time to shift the target away from the people and on to the process.

There are several things we could do right up front. It is time to move ahead with the electronic medical record. It is madness that we have medical records that nobody can read. It is time to move to computerized physician order entry so when doctors make

an error, the computer picks it up and corrects it before it gets executed. It is time to implement bar coding of medications. We do it in our supermarkets, but we don't do it in our hospitals.

The pharmaceutical industry ought to be called upon to bar code every drug and to bar code all unit doses, and hospitals should have bar coding of medications and bar coding of patients to prevent error. I am optimistic. I think what the VA has done with its new risk management policy is a step in the right direction and I think hospitals throughout the country are making a lot of progress, but we have a long way to go. Thank you.

[The prepared statement of Dr. Leape appears on p. 93.]

Mr. STEARNS. Thank you, Dr. Leape. I have an article in front of me from the Washington Post, dated October 7, and, basically, Dr. Kizer, who is the VA Under Secretary for Health, indicated that despite all the incredible advances in medical science of the past several decades, the simple fact is too many adverse events happen as a result of medical treatment, which pretty much corroborates what you have just said.

Obviously, the statistics of 1 in 200 in a hospital, versus one in two million in an airline is something we have to work harder on and it is scary, frankly, to think about it. Further on in this article, near the end, you say that basically you hail the VA for taking, quote, "a giant step forward," end quote, by joining the effort to improve patient care.

My question is, while your testimony or your comment in the newspaper praises the VA's, quote, "new risk management policy" and the potential it holds, in terms of measurable outcomes or results, how could this committee best assess the effectiveness of that policy, particularly in the absence of baseline data?

Dr. LEAPE. It is going to be very difficult. They are no different from any other hospital. We don't have good baseline data anywhere because we have had very limited reporting in the past. We estimate that fewer than 5 percent of significant errors get reported and I have no reason to think the VA is any different from any other hospitals in that regard, so it is difficult to assess improvement.

What can be done, however, is to take some baseline measurements now. This can be done in the form of focused audits. One can identify certain specific kinds of errors that are known to occur. One can do a survey of one or two units, nursing units in a hospital, and get a fix, if you will, on what the baseline rate is, so it is possible with intensive review of records and discussion with personnel, to get a good idea of where you stand and then reassess it by the same method a year or two later. But you do not have baseline data, you are absolutely correct, and neither does anyone else.

Mr. STEARNS. So let me review. You know, it was disappointing for us in the committee to realize that this information was not regularly sent, and if it got there, it was just put into a room and it was not looked at on a periodic basis. So this baseline data is absent, and we don't have any way to evaluate it. Is there any difference between what is being done—what occurred in the VA and in the private sector.

Dr. LEAPE. Not to my knowledge and as a matter of fact, one of the disturbing things is most hospitals have incident reporting systems and we found, number one, they miss 95 percent of the events. Number two, usually nothing happens after a report goes in.

One of the frustrations of medical personnel, nurses and doctors is they file a report and never hear anything back and nothing happens and that is unfortunately all too typical now. I obviously can't speak for all hospitals, but in the ones we have looked at that has been characteristic and this has got to change. I think it is changing, and that is why I complimented the VA on trying to change it, but it is not surprising it wasn't there before.

Mr. STEARNS. So you are saying that what occurred in the VA system is typical of what occurs in the private sector.

Dr. LEAPE. I believe so.

Mr. STEARNS. So the nurses will offer the information, but low and behold, no one looks at it. There is no one who studies the baseline data and comes up with any conclusions.

Dr. LEAPE. Of course, that is not a blanket statement that applies to all hospitals in the country because some do, but in general it tends to be more that way than the reverse, unfortunately.

Mr. STEARNS. Well, how do we know that once we institute the new system that Dr. Kizer is talking about, and I commend him for it, that we are going to have any new results. That is really a question for Dr. Kizer. But my concern is, in your testimony you counsel against blame and punishment as tools to minimize clinical tools. In the private sector, if there is not performance, if there are continued adverse problems, they make change, they do something about it. This whole idea of blame and punishment in a medical center, should we use that as a means to implement new procedures, if we find, for example, one institution, one VA hospital, that has an enormous or adverse risk that is out of the norm, I mean, should there be some type of management reform, new safety measures done at that institution? I mean, we can collect all this information, but if you have an institution that is managed in such a way that safety is not preeminent, I mean, I guess what I am saying is what is the enforcement mechanism and is blame and punishment a motivator?

Dr. LEAPE. Well, I think what you are suggesting is what most regulators suggest. In other words, what is the rule and how do we enforce it? The evidence is that that is not the way you reduce errors. You have a fiduciary responsibility to monitor what they are doing and therefore you need to have data and you need to follow it, but that alone is not going to get you where you want to go.

We really have to have a climate where people feel free to talk about their errors and where people think of errors as systems problems, not people problems. You still think of them as people problems. I was that way. When I had residents, I would chew them out when they made a mistake. It never occurred to me when I made a mistake it was something in the system; I always thought it was me. But experts say that isn't the way it is and again I come back to aviation.

They have been fantastically successful and they have been successful because they have looked beyond the individual and said

let's try to figure out what is going wrong so we can prevent it from happening again. So if you want to improve safety in the VA, you have to change the climate. That won't be easy. It will take time and, number two, you can legitimately expect each hospital to have in place features that we know reduce errors.

For example, every hospital should have, I assume they do, but I don't know this, should have the unit dosing system, which reduces medication dose errors by 80 percent. Every hospital should have within 5 years computerized physician order entry. Every hospital should have within 5 years electronic medical records. Every hospital should have a full-time pharmacist and so forth and so on. So there are a number of things that we know make a difference and there is no excuse for them not being done and you can certainly monitor that. You certainly want to get a fix on what the incidence of adverse events is, but if you really want to have errors drop, it is going to require culture change and that isn't going to happen overnight.

I think this policy sounds as if that is what they are trying to do. They are trying to be proactive. They are trying to put an emphasis on involving people and getting every individual thinking safety. They don't think that way now, and if the VA could get its people in the trenches, the people in the units, thinking safety and realize when they have an idea, it is responded to and people make changes, then things will improve. I think you need to keep the heat on them to do that, but it seems to me they are trying to do that from what I read here. I have no, you know, firsthand knowledge.

Mr. STEARNS. I think that is a significant point and at this point I turn over to the Ranking Member, Mr. Gutierrez.

Mr. GUTIERREZ. Thank you. Doctor, could you share with us some specific examples that you might know of hospitals, medical institutions, things that have happened there and actions that particular institutions have taken?

Dr. LEAPE. You mean specific awful events? They have been in the newspapers.

Mr. GUTIERREZ. No.

Mr. LEAPE. You don't mean that.

Mr. GUTIERREZ. Specific actions that have been taken by the medical institutions, like a medical institution, things that have already been done. Here is what was going on; here is how they addressed it so that we can get a sense of what is happening.

Dr. LEAPE. Sure. We got very interested in the whole business of computerized physician order entry because if the doctor has to order the medication in a computer, the computer will remember that the patient is allergic, which the doctor might forget, the computer will remember the patient is on another medication which interacts badly with it, so you can prevent errors by computerized prescription entry. And of two major hospitals we studied, one was going to implement that, the other hospital was not all ready to do that yet. They weren't set up. They didn't have the money and so forth.

As an alternative, what they did was they got their pharmacist to come out of the basement and come up on the floors and make rounds with the doctors and nurses. Well, the pharmacist is a gold

mine of information about drugs, I mean, that is what he knows, and they found with the pharmacist there that the physicians would ask them for advice and so forth. The pharmacist would see something going wrong and he would make an offer, and in a 6-month period, we found that the pharmacists had made 394 recommendations of changes, and the doctors had accepted 390 of them.

I mean, there wasn't much question that this was well-accepted. The nurses thought it was wonderful because, of course, they didn't have to go get the orders changed and so on. So the simple device of having a pharmacist make rounds with the team is a great step forward. Others have worked on the handwriting problem. They have sent the orders back to the doctors and said, you know, we can't read this. That sounds pretty obvious, but it wasn't being done and they have standardized their procedures to make sure that orders are correctly written.

Chemotherapy is a hazardous form of treatment, as you know. People can die from their medications, and it is too easy to give an overdose because it's so complicated to compute these. Every drug has a different system and they give so much per day for how many days and so forth. Well, you can reduce errors greatly in that by merely having a pre- printed form in which the person is led through the calculations in which the weight and height and all those things are in, so they are less likely to make a mistake than if they just remember the dose and write it down. So some of the things are exceedingly simple. Bar coding is exceedingly simple.

Mr. GUTIERREZ. What does bar coding exactly do, Doctor? Tell me the benefits of bar coding.

Dr. LEAPE. Well, with bar coding, with a simple wand, you can identify that the medication you are about to give a patient is the right medication and that it is for that patient and then you can bar code the patient and make sure it is the right patient. You can link up the drug to the right patient, right drug, right patient, right dose, and this has been done in some institutions with significant reduction in errors.

Mr. GUTIERREZ. And what can the VA do to encourage its clinicians to report quickly adverse—what kinds of things have been done in other settings. You said it is a systems problem, and that it takes time to change, so what have people done, and what can you recommend they do, to encourage a change and more honesty in coming forward.

Dr. LEAPE. This is a leadership issue, isn't it, so the chairman of the department of medicine or surgery has to believe in this and he has to communicate it down. So if you want to change the culture, you have to change it from the top down, and this hearing today may help start it. But you have to have the heads of the hospitals understand and believe—it is not a religion, but it sounds like it. You really have to believe the way to make improvements is to take the focus off people and put it on the system.

Once you believe that, it gets transmitted readily. So if the chairman of surgery at the weekly morbidity and mortality conference, we always had weekly morbidity and mortality conferences, if it is quite clear to everybody there that the name of the game is to try to understand why it happened, not try to figure out who to blame,

the information will pour out. We had one nurse supervisor at our training sessions who went home and decided she was going to try this out because she really thought it made a lot of sense. She convinced the other nurses she was sincere that they were not going to be punished. She said "I really want to know what has been going on."

The number of reported errors in that unit were approximately eight per month for the preceding year. In the month after this happened, they had 160 reported, a 20-fold increase from merely the nurse saying we are going to change the way we do business here. We think errors are symptoms. We think you are good people. The errors are made by good people trying to do a good job, but we all make mistakes every day. If you really say let's get the focus off the individual and onto the systems, miracles happen.

Mr. GUTIERREZ. So unless you change the leadership, you are not going to get the information and until you get the information, you can't correct the situation.

Dr. LEAPE. Absolutely.

Mr. GUTIERREZ. Mr. Chairman, thank you very much. I agree with you. I go to the hospital, I relax, I get on an airplane, I tense up.

Dr. LEAPE. You've got it backwards.

Mr. GUTIERREZ. According to Dr. Leape, I got it kind of backwards. But that is the way I think most of us probably feel. You have a sense of confidence and here is your doctor—not that I don't confide in the airline pilots, but I just feel like I don't get on an airline and get help. I go to my doctor and hospital to get help and there are professionals there. And you are right, we do have to do some things, even in the private sector. And if you visit even a manufacturing site, there are signs that say so many days without an accident, and they do have recommendation boxes, at good plants, you know, where people put their recommendations for safety and there is a safety box and there are all kinds of incentives to give workers so they can tell and take pride and actually report what is going on so they can do that. Thank you very much, Doctor, I really appreciate your testimony this morning.

Mr. STEARNS. Thank you. Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Dr. Leape, you have been very helpful and all of us really appreciate you taking the time to be here. Let me go back, and I don't want to spend very much time on this, but that 1993 Harvard study that estimated, that one million preventable injuries and 120,000 preventable deaths occurred in American hospitals in a single year. When the study came up with that figure, and I realize the word "estimated" is in there, this is versus how many total preventable injuries and versus how many total injuries and how many total deaths occurred.

Dr. LEAPE. Those numbers were extrapolated from a study that was done in New York State in which 30,000 hospital records were looked at, random sample, all kinds of hospitals, and tried to get a population estimate. Most studies come out of one hospital, and they are often teaching hospitals and, you know, they are not representative. So we think it is reasonably representative. You may come from Idaho or Mississippi, you may not think what happens

in New York is representative, in which case you can adjust, but we extrapolated.

From that we found there were 1.3 million injuries and 69 percent were related to an error, so 69 percent times 1.3 comes out to be approximately 1 million. We estimate a total of 1,180,000 deaths. Two-thirds of that is 120,000. So two-thirds of all the injuries, 69 percent, we found, were due to errors.

Mr. BILIRAKIS. Preventable.

Dr. LEAPE. And therefore preventable, yes, right, by definition preventable, potentially preventable.

Mr. BILIRAKIS. Well, you know, Doctor, you are right. I know Mr. Gutierrez mentioned a change in leadership. I don't know about changing the leadership, but I think everybody meant and he meant changing the culture, changing the thinking, if you will. I know we have had many instances in our hearings over the years here where there is great concern expressed by veterans, and I think we have all seen it if we visit enough centers, that a lot of the personnel there—I don't necessarily mean the medical doctors and what not, but a lot of the personnel have a feeling of, oh, well, the people here are on welfare. In other words, they don't treat the veterans with the respect that they certainly deserve, so that is a culture, even though it may be a lower level of clerk or whatever the case may be, it is very important.

I know that a few years ago, maybe the 2 or 3 years before the series of articles on VA health centers appeared, there was an article in the local newspaper in Florida, of a particular local hospital, where a doctor was involved in deaths. I think it was during open heart surgery and the articles indicated that that doctor had been involved in other incidences prior to these immediate deaths that the article referred to. The reason why he wasn't let go by the hospital is because the doctor threatened to sue them, and they were concerned about a lawsuit. They would go bowing out of the culture and that is really a part of it, is it not?

Dr. LEAPE. The whole malpractice situation overlays this. You see, doctors are told by their lawyers not to tell the patient anything. You can't even say I'm sorry. All of that is designed to focus on a bad apple. All the best surgeons I know, and a lot of the best surgeons are my personal friends, every one of them has been sued. Now, they are not negligent, they are not bad apples, but the system does that and therefore doctors are inhibited and they are reluctant to participate in this. They don't want to report errors. Why should they incriminate themselves? That is a very major issue. It may be less of a problem in the VA, I don't know, but it is a very major issue we have to deal with.

Mr. BILIRAKIS. Reform is something you feel is a major issue and is required.

Dr. LEAPE. Absolutely, yes.

Mr. BILIRAKIS. You also mentioned, and I guess this goes maybe to cultural thinking, cultural changes, but my oldest son is now a physician and part of his residency was included at the VA hospital in Tampa. I think back 3 or 4 years ago. I think back to the hours the people worked. You talked about the stress. Is that changing, these fantastic hours that these residents work and certainly it has to result in some problems taking place.

Dr. LEAPE. You may remember that New York State passed regulations a few years back in reaction to the *Libby Zion* case to restrict the hours. There was a tremendous resistance to change, particularly in the surgical community, because, again, the culture, really what I grew up in, is that you have to be there and be with the patient day and night to really understand what is going on and to develop your sense of responsibility.

One of the most important things we want to develop in young doctors is a sense of responsibility and it certainly does that. It also makes you so tired that if you have an operation the next day, you may have trouble keeping your eyes open. That is a long way of saying there have been some efforts, but they haven't been very successful, and people who look at this from the outside are aghast.

Health care is the only industry in this country that doesn't seem to believe that fatigue degrades performance. If you are a pilot, you are forced to take hours off between flights at night and the idea that surgeons and anesthetists can be up all night doing an emergency operation and then at 8 o'clock the next morning start a new case, that is madness, yet it happens in every hospital.

Mr. BILIRAKIS. So the bottom line of what you are basically telling this committee is the problems at the VA are similar to the problems in health care throughout America and probably throughout the world.

Dr. LEAPE. Absolutely.

Mr. BILIRAKIS. And the way they are going to be correctable is not just at the VA, but throughout the entire—really, throughout the medical world.

Dr. LEAPE. But you, of course, can be part of this process and things like this new policy, I think, are a leadership move. If it can be implemented, if you can do the things there that is moving ahead and if the VA does some exemplary things, other hospitals will learn from that, so I think you have an opportunity for leadership here, I really do.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. STEARNS. Mr. Evans.

Mr. EVANS. Thank you, Mr. Chairman. Picking up on the gentleman from Florida again. Based on your knowledge of the VA and other health care systems, are VA patients more likely than patients of other systems to experience an adverse event that results in serious injury or death.

Dr. LEAPE. I have no idea. I don't have any data on that.

Mr. EVANS. All right. Well, VA has obviously been influenced by your work in developing their current risk management guidance. Do you have any views on the adequacy of their new policy and does it compare to policies used by other major health care systems? Are there good models that it might follow?

Dr. LEAPE. As I look at this policy, and I haven't looked at VA hospitals or their data, but I have looked at this policy; there are several features of it that strike me as really exemplary, and as I say, if they are implemented will be a real move in the right direction.

First of all, it is a proactive policy. Most error programs, error prevention programs, or what are often called risk management programs are reactive. Somebody does something awful and we

have a big shake-up and try to change the system. This policy is an attempt to get the frontline people: nurses, doctors, pharmacists, to identify accidents waiting to happen and redesign the system before that happens.

If you can do that, you are really on the right track. We have to do more than just react to disasters and this attempts to do that.

Secondly, it attempts to—it sets as a goal—to incorporate the concepts of continuous quality improvement into the everyday routine of the nurses and doctors in the hospitals. That is, thinking of themselves as part of a team to ensure safety, to be thinking about how to make the process better. That has to do with reporting and then getting some feedback and some response when you report.

If that can be done, that is going to be one of the most important things you can do to improve quality. Third, they are setting up an Intranet, not an Internet, an Intranet, a computerized Internet within the VA hospital system, which not only nurses or doctors or any personnel can report things they have learned about a way to prevent a certain kind of error, but the results from the review by the Office of Performance and Quality and by the Medical Inspector will be distributed through this.

Aviation has this and pilots read these things avidly. If we could learn from each other's mistakes, which is what this tries to do, clearly that would be helpful. You know, you have 173 hospitals. You have 173 potential laboratories for improving the way things are done and if that information is disseminated, clearly that will be a good thing. So I think these are very important and impressive features.

Also, the emphasis on promptly informing patients, that doesn't happen in most hospitals. That is one of the reasons lawsuits happen, but patients are often the last to know that there has been an error, so one of the policies listed here is that patients will be promptly informed of what is going on.

It has a lot of bureaucratism in it and it has a little too much regulation for my way of thinking. It reminds me of my days in the Navy, but on the other hand, the goals are good and what they are trying to do makes a lot of sense, and I think if you can implement it, it will be a giant step forward.

Mr. EVANS. Thank you.

Thank you, Mr. Chairman.

Mr. STEARNS. Mr. Hutchinson.

OPENING STATEMENT OF HON. ASA HUTCHINSON

Mr. HUTCHINSON. Thank you, Mr. Chairman, and I apologize for coming in late, but I want to assure you, doctor, that I have read your testimony and I very much appreciate your participation in this hearing, and I thank the Chair for conducting this very important hearing.

I was intrigued with some of your comments and the emphasis upon systems to help correct errors and a different approach to it. Even under a systems approach, though, errors will still occur, but the whole object is to provide more training, positive reinforcement, and systems to correct or define the errors and prevent them.

Dr. LEAPE. Right.

Mr. HUTCHINSON. Am I getting the gist of that?

Dr. LEAPE. That is right. It is not possible to make things perfect, but you approach perfection and part of your approach is two-pronged. One is to make it much more difficult for errors to occur and, secondly, to make it possible to intercept them before they cause harm. That is the goal, and you are right now say at a 50 percent level. Get to the 90 percent level in 5 years and 5 years later get it to the 95 percent level, and keep on closing in until we get to a 99.9 percent perfection.

Mr. HUTCHINSON. Which is exactly where we want to go, but there is always going to be some errors that sneak through and injuries as a result of that. I was intrigued by your comments on the tort system and in your written testimony, you talk about the tort system focus on the individual who made the error causing an injury, assuming that punishment will make the person less likely to err again.

The concept of a systems cause is really considered. Just a comment on the tort system, though. The tort system is not designed for punishment, but it is designed for compensation, and even if you have a good systems approach, there are still going to be some errors that happen, some injuries that occur and compensation is still going to be important, would you agree?

Dr. LEAPE. You are touching on a subject that is dear to my heart. I happen to think we should compensate everybody for their injuries. I think hospitals should be required to pay the cost of health care for everybody that is hurt by treatment because right now the health insurance mechanisms, among people outside the government hospitals, only pay about three-fourths of the cost, and the patient ends up picking up the rest of it, and those costs are sometimes substantial.

Insurance doesn't cover it, they can't get insurance for that and so the patient is left holding the bag. If hospitals had to pay the cost of injury, they would have a tremendous incentive to reduce injuries and that is probably the single thing we could do to make the most difference, and I don't think the chances of that happening are very great.

Mr. HUTCHINSON. Yes, I think you answered my last question, which you raised the question in your written testimony about should hospitals and health care organizations, instead of physicians, be held responsible for adverse events. I think your answer is that should be looked at very affirmatively.

Dr. LEAPE. Resoundingly, yes.

Mr. HUTCHINSON. Now, a follow-up question would pain and suffering be included in your compensation?

Dr. LEAPE. That is a sticky one. In Sweden and other countries where they have attempted to do things like this, they have not included that. Interestingly enough, if you talk with patients who have been injured, they want two things. They like to hear the doctor say I'm sorry and they like to see that the health care system is going to do something to keep that from happening again. Money is a distant third objective and I think the pain and suffering thing is all part of the anger that comes from a doctor that won't talk to them and a system that won't do anything. That may turn out

not to be very important if we really had a good system of dealing with errors.

Mr. HUTCHINSON. I think that is a good observation. I am not sure I agree 100 percent, but it is a good observation. And in regards to the admission of error, if the doctor says I'm sorry or whoever is responsible, and I am sure as part of your job you have reviewed medical records, is there hesitancy now for doctors to put in medical records all of the facts that might make them look bad.

Dr. LEAPE. Absolutely. I have never seen a record that said I made a mistake.

Mr. HUTCHINSON. I am not sure I have either.

Dr. LEAPE. I certainly never wrote that.

Mr. HUTCHINSON. Is there any system that can be developed that would help in that regard.

Dr. LEAPE. Sure. What we are talking about: If the physician is functioning in a hospital, in a department, where the understanding is that he or she is trying to do a good job and made a mistake, didn't make it on purpose. Let's see if we can figure out how to keep anybody from making the same mistake again. We are really sincere about it and the discussions are confidential and, of course, under the peer review statutes they are nondiscoverable in most States, so we don't need a law to do this. But if we had that kind of a system, then the physicians would be very interested in doing that, because all health workers want the same thing as patients want. They want to figure out a way to keep the mistake from happening again and the way you do that is to start talking about it. I don't think there is any question they would participate.

Mr. HUTCHINSON. Doctor, thank you very much.

Mr. BILIRAKIS. Will the gentleman yield for a minute?

Mr. HUTCHINSON. Certainly.

Mr. BILIRAKIS. Getting back to the immediate conversation, Doctor, you would have a strict liability type of a thing insofar as health care is concerned.

Dr. LEAPE. Yes, this is very controversial obviously. We have had a couple States that have had some interest in implementing this and whether it will come to pass, I don't know. We should try it out at a State level to see what the problems are. But if you think about it, if you really believe systems failures are the cause of errors, you need to put the responsibility on the party that can do something about the systems.

Doctors can't change the systems by themselves; the hospital has to do that. So if the hospital were responsible for the consequences of the injuries, the hospital would have a strong incentive to try to reduce that and would think about changing systems instead of just fingering the individual.

Mr. BILIRAKIS. You would have, then, a process where it would have to be determined whether this was a preventable injury versus a nonpreventable one; isn't that correct.

Dr. LEAPE. Well, I would make it for all injuries caused by treatment, as opposed to caused by the disease. I mean, not complications of the disease, but all complications of treatment, yes, because the nonpreventables hurt just as bad as the other.

Mr. BILIRAKIS. Give me an example of a nonpreventable, that is not the cause of disease.

Dr. LEAPE. Sure. You wouldn't have to compensate for this but a rash from a drug, a person is allergic to a drug, it was not known before, they got the drug for the first time, they had an allergic reaction. At the present time, we have no way of preventing that. It could be fatal, all the way from a simple thing like a rash to being fatal. It is not the doctor's fault that happened and we don't have any mechanism for compensating them, so I think that the hospital should pay that and then the hospital would work on it. They obviously couldn't do anything about those, but they would work on the ones that are preventable, which are two-thirds of them.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. STEARNS. Mr. Peterson.

Mr. PETERSON. Thank you, Mr. Chairman, and thank you, Doctor, for giving us some compelling testimony here. I just wonder, how realistic it is that we can get to some of the places you want. You talk about a change in leadership. It seems to me that maybe people sitting around this table might be a key component of that. Right now, we have a situation where everybody is beating the heck out of the IRS because they are doing what we told them to do. Listening to what you are saying, it makes a lot of sense to me, but it just seems that your solutions are going to cost a lot of money. And the VA system is under a lot of pressure. They don't have enough money to do what they are doing now. I think to some extent, you have the same thing happening in the regular health care system where it is driven by costs, it is not driven by safety.

Dr. LEAPE. Right.

Mr. PETERSON. And what you are suggesting is going to cost more money. If you are going to tell people they can't work 80 hours, they can only work 40 like an airline pilot—and I am totally persuaded computerizing records, bar coding would save a significant number of errors—that is going to cost money.

I assume Dr. Kizer is going to tell us that they don't have the money to do that, to the extent because they can't take care of the patients they have. I would imagine you have people in the regular health care system that are not doing it because of the same reasons, am I right or wrong on that? Have you studied that whole aspect of this?

Dr. LEAPE. Two answers, one theory and one reality. In theory, quality pays. That is, most studies done in the past show improving quality cuts cost.

Mr. PETERSON. It costs more money at the beginning——

Dr. LEAPE. It costs less money to make a perfect car than to make one with defects and have to redo it.

Mr. PETERSON. But how do you get there?

Dr. LEAPE. Yes, right, in general. Now, specifically, I will give you one example. The Brigham and Women's Hospital recently put in a computerized physician order entry system, all orders have to be put in the computer. By doing that, it looks as if we have reduced adverse drug events by a sizable percentage, probably as much as 40 percent.

Every preventable adverse drug event in that hospital costs $4,685 to the hospital. The hospital is spending $2.8 million a year by our estimate on preventable adverse drug events. If we cut that in half, they will save $1.4 million a year, that's every year. That

will pay for a lot of computers. That may be more dramatic than most. Putting bar coding in would certainly save money, because if you eliminated 100 adverse events a year because it was the wrong dose and so forth. The business about reducing hours is a little stickier.

People are getting paid by the hour, the nurses and pharmacists are. The house officers are not, but nurses working double shifts get double pay. In fact, they get more than double pay, so it isn't necessarily more expensive. I think it is up front going to be more expensive, but in the end it will save money.

Mr. PETERSON. Well, if it is saving all this money, why isn't everybody doing it?

Dr. LEAPE. Well, they haven't known about it. It hasn't been self-evident up until now. I mean, computerized entries are a new thing just coming down the line.

Mr. PETERSON. Are you kidding me?

Mr. LEAPE. No, I'm not kidding you.

Mr. PETERSON. I was in the hospital in my District 5 or 6 years ago and I think some of the people in the hospital understood if they could computerize, they would save a lot of money. They couldn't get their people running the hospital to do it.

Dr. LEAPE. Yes.

Mr. PETERSON. So it is hard for me to believe the whole industry didn't know about this, about bar coding. Bar coding has been around for 15 years.

Dr. LEAPE. It is hard to believe, isn't it? I am with you. I mean, seriously, why haven't they done it yet?

Mr. PETERSON. And I would guess, there is no money in the VA budget to bar code every VA hospital, to computerize every VA hospital so they can have an order entry system. I am totally convinced if we did that, it would save us money, probably a lot of money and a lot of problems.

Dr. LEAPE. Well, see, in the private sector, it is the patients who have been paying, you know.

Mr. PETERSON. Well, the patients have no idea what they are paying for. That is part of the problem, and the media is part of the problem with this, too. They don't put the right message out about what is going on with it.

Dr. LEAPE. The other answer to your question is if it costs more, so be it.

Mr. PETERSON. I agree.

Dr. LEAPE. I mean, we are talking about lives. If it is going to cost us a little more to do it safe, we have to pay a little more to do it safe. You wouldn't begrudge the airlines increasing the price of your ticket by 20 percent if it reduced your chances of having a crash. It is the same thing here. I really believe that in the long run it will save money. All the evidence from industry indicates that. But if it costs more up front, then we should pay that.

Mr. PETERSON. I totally agree with you, but the reaction out of Congress might be, because of the media, to put more regulation on, to punish people more, which would have the exact opposite effect.

Dr. LEAPE. We are starting to turn that around this morning. It is time to change and it starts in one room on one day and then it goes on.

Mr. PETERSON. Amen. You need to go to talk to the appropriators I think, too.

Dr. LEAPE. I appreciate your help.

Mr. STEARNS. Dr. Leape, before you go, the staff pointed out to me there is a provision in VA law that the VA hospitals, in fact, have to compensate when an event occurs not reasonably foreseeable. Disability or death caused by hospital care, including carelessness, negligence, and lack of proper skill and error.

Dr. LEAPE. Well, see, you are ahead of all the rest. You are already a leader.

Mr. STEARNS. Before you go, you cite one in 200. But then you go on to say that doctors don't want to report their errors. Nurses don't want to report it. No one ever tells the patient, but in the airline industry we get good reporting. In all candidness, is this one in 200, maybe it is 1 in 100 or 1 in 70. How do we have any confidence in this 1 in 200 when we have doctors not reporting, nurses not reporting, no one across the hospital industry looking at the baseline information? I mean, how do we have any confidence in this?

Dr. LEAPE. I am going to make it worse. That number came from our study which was a review of medical records. Every doctor knows—every doctor and nurse knows what is not in medical records.

Mr. STEARNS. So medical records have really already been diluted.

Dr. LEAPE. What I am saying is when we say it is one million and 120,000 deaths, that is based on data from medical records. The number is almost certainly higher than that, maybe two or three times as high. I don't think we need to get everybody all shook up, but I think it is clearly a lower bound. It is clearly worse than that.

Mr. STEARNS. But you are just saying for the record, you said two or three times so if I took three into 200, I am at 70, so 1 in 70 is probably a limit you are indicating for the record.

Dr. LEAPE. It might be. I mean, we don't have that kind of data, but it certainly might be.

Mr. STEARNS. Okay. Well, I thank you for your time.

Mr. GUTIERREZ. Mr. Chairman, I ask unanimous consent that the Members be allowed to submit follow-up questions and responses for the hearing record.

Mr. STEARNS. Without objection. We thank you for your time and we will now hear from the second panel. We have Dr. Kizer, Under Secretary for Health, Department of Veterans Affairs, accompanied by Dr. Wilson, Director, Office of Performance and Quality Department of Veterans Affairs, Dr. McManus, Medical Inspector, Office of Medical Inspector, Department of Veterans Affairs; Dr. Mather, Assistant Inspector General for Health Care Inspections, Office of the Inspector General, Department of Veterans Affairs.

Let me again welcome our panelists and particularly Dr. Kizer for his valuable time and for coming here this morning and we await your opening statements.

STATEMENTS OF KENNETH W. KIZER, M.D., M.P.H., UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS ACCOMPANIED BY NANCY WILSON, M.D., M.P.H., DIRECTOR, OFFICE OF PERFORMANCE AND QUALITY, DEPARTMENT OF VETERANS AFFAIRS; JAMES MCMANUS, M.D., MEDICAL INSPECTOR, OFFICE OF MEDICAL INSPECTOR, DEPARTMENT OF VETERANS AFFAIRS; JOHN MATHER, M.D., ASSISTANT INSPECTOR GENERAL FOR HEALTH CARE INSPECTIONS, OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT KENNETH W. KIZER., M.D., M.P.H.

Dr. KIZER. Good morning, Mr. Chairman, members of the subcommittee. You have my written statement. I am not going to repeat that now. Instead, in the interest of time, I would like to take these few minutes to make just five points. First, I hope that Dr. Leape's comments made clear that the problem of adverse events resulting from medical treatment is a problem affecting health care everywhere, public and private hospitals, nursing homes, clinics, doctors' offices throughout the country.

The size and dimensions of the problem are far greater than commonly realized. Indeed, investigators in this area have repeatedly stated that the statistics arising out of studies probably indicate only the lower bounds of the problem; that is, it is a problem much larger than the chilling numbers cited by the Chairman and Mr. Bilirakis earlier and those which Dr. Leape noted.

The second point I would make is that as a former regulator of over 5,000 health care facilities in the State of California for quite a few years; as a physician who has practiced in a number of settings, ranging the gamut from university teaching hospitals to small rural hospitals; and as a consultant on quality of care issues, I can tell you, without any question, that the type of medical treatment problems seen in the VA are the same types of problems that occur every day in non-VA facilities throughout the Nation.

The major difference is that these problems elsewhere rarely receive the public scrutiny that events in the VA do.

Third, while the quality of care provided by the veterans health care system overall is as good, and often better, than that provided in the private sector, as attested to by various objective indices, the system is far from perfect, and the quality of care is not as uniform throughout the system as it should be.

We truly regret that treatment mistakes and some tragic errors have occurred. I personally consider even one death or injury resulting from medical treatment to be too many, and I concur with the Chairman, or at least with the statement that is attributed to the Chairman in the media, that the VA is and should be held to a higher standard than the private sector.

The fourth point is that as part of the veterans health care system reengineering effort that we have discussed before this committee and other committees on a number of occasions, we have implemented a very comprehensive quality care framework, one element of which is a new risk management policy that will routinely identify and analyze adverse events that may be related to medical care.

Our approach to this has been reviewed by a variety of entities, and we have gone to other health care systems to seek their critique and input on this policy, and I can tell you they have been uniformly very complimentary. In fact, to date, we have not been able to identify any other health care system in the country that is taking as rigorous approach to ferreting out this information as the VA is in its new policy.

I should note, though, that as we actively seek out these problems in the months and years ahead, I would not be surprised to see the number of identified untoward incidents grow; in fact, that is something we should expect to see.

The last point I would make, and as will be discussed by the third panel in more detail, I believe VA hospitals have generally done a good job of analyzing and correcting facility specific circumstances that may have contributed to untoward treatment-related outcomes. However, VA has done less well in taking those individual lessons learned and generalizing the findings to the system overall; that is, in fact, a focus of much of our efforts at present and underlies much of the thinking behind the new risk management policy. I can cite perhaps a couple of examples of how we are trying to approach this.

In the last 3 years, we have had three deaths due to errors in blood transfusions. We are now moving forward with a bar coding system that will be used when any blood transfusion or blood product is to be given. I think Mr. Peterson asked about the cost of that. Part of any of these things we talk about doing is what it costs for one facility, and then we have to look at the entire system. We think this particular intervention will cost about a half a million dollars, of which, I believe, we can readily absorb. We have to write some software programs and other things to incorporate it into the system, but that is moving forward.

As another example in a similar vein, we have had an institution who has been looking at bar coding for pharmaceuticals or the administration of drugs. We are now looking at this for the implications, fiscal and otherwise, for system-wide implementation. When we flush that out we will be either moving forward with it or coming back and seeking funds to implement it. We are hopeful we can do it with the savings that we are generating by doing other things within the system. Let me stop here.

I would just conclude by saying that I think we have set the stage for changing the way that we do business, and I think this will have a salutary effect on the way health care is provided throughout the entire Nation. I would say, though, that, frankly, we need your help.

We need a change in the atmosphere and the environment in which these things are approached, as Dr. Leape spoke so eloquently about. We welcome your oversight, and we enlist your assistance in trying to solve this very major national problem. That is by no means solely a VA problem. It is a problem affecting health care everywhere in this country.

[The prepared statement of Dr. Kizer appears on p. 107.]

Mr. STEARNS. Dr. Mather.

STATEMENT OF JOHN MATHER, M.D.

Dr. MATHER. Good morning, Mr. Chairman. I appreciate this opportunity to appear before you today and discuss VA's policy and performance in the area of risk management and also the role of the Office of Medical Inspector. With your permission, Mr. Chairman, I request my written prepared statement be entered into the record and I will use this opportunity to summarize key issues.

Mr. STEARNS. Without objection.

Dr. MATHER. Veterans receiving their medical care through the VA can expect the health care professionals who treat them to do it well without inflicting serious harm. Even so, over the past 5 years, there have been instances where this has not been so and there have been a dozen or so widely publicized and apparently avoidable deaths.

The Veterans Health Administration, with its system of medical centers, has long had policies which were intended to minimize risks to their patients of inadvertent error in medical care. Actions have been taken which, if consistently and properly applied, would have prevented serious disability and deaths under unusual or apparently avoidable circumstances.

The risk management policy focused on achieving effective VA medical center programs, with appropriate oversight by regional networks offices (the VISNs), and headquarters offices including the Inspector General. Over the past several years, whenever there have been incidents of serious disability and avoidable deaths under unusual adverse circumstances, VA medical centers have taken the situations very seriously. Their staffs have conducted in-depth investigations, determined the nature of the error, assigned individual culpability, devised mechanisms to prevent similar incidents and filed reports with senior management.

Over the past 5 years, the VA has issued a series of policy directives on risk management. It has recently published a strong and comprehensive risk management policy. This latest directive fully addresses the criticisms we have previously raised concerning omissions and weaknesses. The present policy has the potential for significantly strengthening the VA's present procedures and mechanisms for coordinating an effective risk management program.

VA's risk management policies have always had reporting requirements for the VA medical centers with defined procedures for oversight by regional components (the VISNs), and headquarters. Over the past couple of years, it seems that issues related to resource allocation, strategic planning and the implementation of a performance measurement system have been dominant on their agendas. Consequently, components in Central Office have not given careful attention to reviewing aggregate information on adverse events. This new risk management policy seeks to remedy this deficiency by assigning more definitive roles to VISNs and Central Offices.

Eventually, throughout the VA's health care system, the information on adverse events can be appropriately standardized to insure that comparable data and information are collected and available for review. In this regard, the risk management directive gives broad guidance and each VISN is required to appoint a statistical consultant who can provide some consistency. Once data and infor-

mation on risk management are collected, it is essential that it be tracked and regularly examined for trends. This requires assignment of clear roles and responsibility in the VISNs and for Central Office components.

Here, the new policy provides the specific guidance for the organization of an Adverse Events Registry and the establishment of a Central Office Risk Management Oversight committee. The VA's Medical Inspector is a member of the committee, but his participation is likely to be compromised as long as questions persist about the role and staffing of the Office of the Medical Inspector.

The Risk Management Oversight Committee needs to regularly review the Adverse Events Registry and identify relevant information for prompt dissemination to VA medical centers. This communication is an essential feature of a risk management policy for a health care system as large and complex as the Veterans Health Administration.

My Office of Health Care Inspections is the primary office in the Inspector General's office, with direct clinical and quality assurance oversight responsibilities. In fulfilling this role, we have generally reviewed as paramount the VA's need to revise its risk management policies and significant progress has been made in correcting several previously deficient areas.

My office will continue to actively monitor the implementation and effectiveness of these risk management policies. Mr. Chairman, this completes my oral testimony. I will be pleased to answer any questions or provide written commentary in the future.

[The prepared statement of Dr. Mather appears on p. 117.]

Mr. STEARNS. Thank you, Dr. Mather. As I understand, Dr. Kizer, those are the two only opening statements, or are there additional?

Mr. KIZER. No sir.

Mr. STEARNS. Okay. I think the big question I have is, how big a problem is safety with the veterans' hospitals? You are quoted, again, in the Washington Post saying, quote, "we really do not know the complete dimensions of what we are dealing with." You know, that is a very candid statement, and I commend you for what you are doing here in issuing a new directive and, as you pointed out in the press, your joint effort to improve hospital care and get an understanding of the safety.

But, Dr. Kizer, until we made a request to see the systemwide patient incident reports, that data had not been systematically reviewed for several years, and as I understand, this is contrary to your own policy directive of April of 1995, chapter 35, of VA manual M-2. I guess the first question is how do you explain that, and how do we know it is going to occur after your new directive?

Dr. KIZER. I think there are probably a lot of things that can be said on why it was not occurring. I would just sum it up by saying some things that I had thought were being done were not being done. I think the focus and the attention has significantly changed, and I know that one of the reasons why you can have confidence that things will change is because you are going to ensure that they do, in addition to our efforts.

But I think within the organization there is now a commitment to our risk management progress. As Dr. Leape alluded to, much

of the problem here is a cultural problem in medicine, and medicine everywhere, as far as a willingness to identify and openly talk about and thoughtfully analyze errors and mistakes that occur—some of which are preventable, some of which may not be. VA health care practitioners are like what you would find elsewhere in that there is often a reluctance to do that, either because of fear of litigation or other concerns, because of the way things typically get sensationalized in the media with anecdotes getting blown out of proportion, and a whole host of other things. The bottom line is there have been changes put in place, and they are going to be carried through on.

Mr. STEARNS. You know, when I heard Dr. Leape talk about underreporting, it comes to my mind the staff has shown me statistics that the number of reported incidents in 1994 were 5,063; and in 1996, it was 3,622; and this year the number of incidents is shrinking further. I mean, I don't know, but just looking at that report makes you concerned.

Then when you go to look at the patient incident reports at particular networks, through 1997, mid-September, there are some very low numbers here. Some are reporting 13 incidents, 15, 21. So, I mean, this would sort of corroborate what you have been saying and what Dr. Leape has been saying. I mean, I would suspect, there seems to be underreporting from the data we have here.

Do you want to comment on the fact that there appears, from the data here, that things are going down, and that the different networks are reporting very, very small incidents, and based upon what we have heard from Dr. Leape, it gives you a question of underreporting?

Dr. KIZER. I think you are absolutely correct; that is a very legitimate question. It is one that we are looking at as well. The nonuniformity of this across the system is certainly one that we are looking at to see if we can better explain it.

The nature of the drop in reported incidents may well be due to underreporting. It may well be due to other things as well, including shorter hospital stays and the shift in care to outpatient settings. We have other data, for example, that shows significant improvements in care. For example, 3 years ago, we began tracking specific types of patients—i.e., specific vulnerable cohorts of patients—and looking at their longevity and clinical outcomes; we now see that over that period of time, there have been statistically significant increases and improvements in their 1-year survival rates.

There are some other indicators that also would suggest that the quality of care is improving. For example, in surgery the numbers show fewer deaths and complications related to surgery. So at this point, I think underreporting is certainly a potential problem and may well account for some or indeed much of lower counts. But we also have data that suggests that quality of care is improving, and the actual numbers of complications are dropping.

I am not going to stand before you and say that it is one or the other. I think we need to continue to look at this. I also would note that no matter how much we look at what has happened historically, we will probably never be able to ferret it out completely. What we are trying to focus on is where we go from here and how

we move forward and get the sort of baseline data and ongoing mechanisms in place that can answer the questions you have, and also provide our patients with the sorts of assurances they need, and how we can demonstrate leadership to the rest of the health care community.

Mr. STEARNS. I think that is good. And you are pointing out, as Mr. Bilirakis pointed out, about setting the culture.

Let me just suggest or comment that your new policy, as I understand it, calls for a headquarters committee meeting once monthly to review all adverse events and all Board of Investigation reports. Now, considering there are thousands of cases, and you have this backlog of information, doesn't the headquarters committee have a responsibility to meet daily to look at this, rather than monthly, to carry out this responsibility, particularly in light of the fact that what appears here, we have all the information collecting, we are not doing anything with it, it seems to me you should jump on this and do it daily. Am I wrong?

Dr. KIZER. The frequency of review is certainly not set in stone, and if it turns out we need to meet weekly, biweekly, daily, then will do so. These are all things that as we move forward with implementing this policy, are subject to change, according to what the data and our results show.

Mr. STEARNS. My last question is for Dr. Mather. Would you elaborate on the concern you have expressed in your testimony, and we sent out the letters to all the administrators of the hospital, as a result of the articles that were in Congressman Bilirakis' congressional district. We read these articles, and we were concerned, just as he was. And then we sent these letters to all the administrators, and they came back, and you, as I understand it, looked at these letters.

The VA's new risk management efforts—let me just read it to be very clear. Would you elaborate on the concern expressed in your testimony that VA's new risk management efforts may be compromised to the extent that its Medical Inspector's Office is understaffed; that is the key, is it understaffed.

Dr. MATHER. Mr. Chairman, in the Under Secretary's written statement, and also in mine, there is an elaboration there of some of the roles that have been performed by the Office of the Medical Inspector over the past few years. I know Dr. Kizer has a contract to review that role and function, which he anticipates will be completed later this year.

If you look at this risk management policy, there is clearly a very key role for the Medical Inspector, Dr. McManus, to perform. Not only is it the receipt and review of those Boards of Investigation and the focus reviews, but to be very much of an active participant in that particular oversight committee, the Risk Management Committee. I think it is a dilemma he has, and that is while all the scopes of responsibilities he has, his staff over the last 3 years is down under half what it was. He did have a staff of some 20, and with what I see as the scope of what Dr. Kizer has in mind for that office, I do not see how Dr. McManus, with his small staff, and also with, generally speaking, a nonclinical staff, has really the wherewithal to be a complete and active participant in that oversight committee, the Risk Management Oversight Committee.

Mr. STEARNS. Thank you. Mr. Gutierrez.

Mr. GUTIERREZ. Thank you very much, Mr. Chairman.

Welcome to the panel. Welcome, Dr. Kizer. I guess we have a great opportunity for the VA to set a standard for the rest of the Nation, and I guess—I don't guess, I know that apart from your comment, Dr. Kizer, that this committee won't allow it to happen, I think we also have a responsibility to deal with everybody at the VA to ensure that you have the resources.

So we would also like to hear, if you are going to issue a report back to us and you are going to be communicating to us, I think that is just as important as everything you are doing is everything you need to get it done so that the Members can be fully aware so that in the future, I think it is very fair for someone to be able to say, well—for me to be able to add, well, Dr. Kizer, you know, this is what you did; and for you to be able to say, yes, this is what I asked you in order to get there. And I think if we are going to do that, I certainly would like to have a complete list of the things you need to get it done.

Having said that, if you could just share, Dr. Kizer, with us some specifics and reiterate just exactly what you intend to do, but not in general terms, but in specific terms. What can we expect to happen at VA hospitals that they are going to make the system better?

Dr. KIZER. I think what you can expect is that as we analyze these incidents, we will be looking at all of them for systemwide improvements, and what you will see is a succession of systemwide implementations of interventions that are identified at the local level as being successful. Patient identification by bar coding, in the case of blood transfusions, is one example. Bar coding for pharmaceuticals is another.

But as these are identified, the focus here is how can we implement those from a systemwide perspective. I wouldn't be surprised if there were resource needs associated with these interventions as we move forward. And as the committee knows, because of budgetary reductions, our headquarters operation has been reduced by about 30 percent of its staff in the last 3 years. As we have tried to look at the staffing needs for the Office of the Medical Inspector, that has to be done within the context of overall, very substantial reductions that we are forced to live with, in addition to some particular issues regarding the overlap in law, as well as in policy and operations, of the Office of the Medical Inspector and the Office of Health Care Inspections within the Inspector General's Office. As was commented on, or has been identified in other sources, there is overlap there, and that results in some confusion as far as exactly who is responsible for what.

We have also—as Dr. Mather noted—hired a consultant to review the functions of this office because this is unique; there is no such entity as the Office of Medical Inspections elsewhere in the health care system. That function simply doesn't exist anywhere in the private sector, and there are notable differences between how that office has operated in the past in the VA, as opposed to the Department of Defense, where there is an analogous office. To help with that, we have contracted with a consulting group to try to help ferret out some of those things. We have some preliminary information, and we expect to have their final report within the next

couple months. Based on that, we will be looking at what the staffing needs may be for that department.

But I would also add, as I have reiterated to Dr. McManus on a number of occasions, that while his office may have only a certain number of people, there are approximately 15,000 physicians in the system that are at his disposal should he need them; there are tens of thousands of nurses and other personnel. All he has to do is tell me what type of person he needs, and we will make those available to his office to conduct reviews or inspections, as needed.

Mr. GUTIERREZ. Thank you very much, Dr. Kizer.

Thank you, Mr. Chairman.

Mr. STEARNS. Mr. Bilirakis.

Mr. BILIRAKIS. Thank you very much, Mr. Chairman.

A lot has been made of the underreported adverse incidents, and we can't belittle that. Because if we don't know what the problems are and we don't know what the occurrences are. How in the world are we even going to possibly try to address them and to solve them?

One of you, it might have been Dr. Mather, I am not sure, said something about we need your help. Exact three words: We need your help. I guess Dr. Kizer said it. And I think that is good. Although, unless you tell us what you want us to do, I mean, other than more money, I am not sure that we can help, and I would hope that more would come from you all here today in that regard.

But let me go to a couple specifics here, because this cultural thing is very important, and we talked a lot about it, if you recall, when we had the sexual harassment hearings surface. There is a culture there. There is an accusation of good old boys culture and culture at the VA, and it is just very important.

I am going to refer to a June 15 article in the *St. Petersburg Times* and ask two questions regarding that article. The *Times* reported the VA was forced to rehire a doctor that an assistant U.S. attorney called, "a menace to his patients' well-being." This doctor, who worked at the Beckley, WV, VA Medical Center had four malpractice complaints against him and eventually had his license suspended by the West Virginia Board of Medicine. His license was formally revoked in January of 1997. And the article also went on to report that one VA physician had to take the medical examination 10 times, 10 times before passing.

So the questions are, first, how big of an impairment is this for you as you try to effectively manage the VA health care system?

Dr. KIZER. Let me say two things. First, you cited a couple of instances, and just should the people sitting immediately behind me generalize that to the rest of the physicians in the VA, I would note that 70 percent of physicians in the VA are university faculty, and you won't find that at any other health care system in the country. These are what we generally consider the best physicians in the country.

Mr. BILIRAKIS. But we want as close to 100 percent as we can get, don't we, Dr. Kizer? I don't think we should be sitting on 70 percent. I mean, it is a good statistic, and I appreciate that.

Dr. KIZER. Seventy percent are university faculty, and you are mixing two things there. The point, or specifically the point you raise, and I will respond to it the way I responded at a number of

other hearings and settings as well, whether it is sexual harassment or whether it is some of the issues related to how we deal with physicians who we would like to—or other professionals we feel aren't serving the system well, the civil service laws and rules are a major impediment. I understand they are well-intended and that they are certainly derived by good motivations, but the personnel system has become so complex and so difficult and unworkable that it is creating many of the problems that you are now focusing on.

Mr. BILIRAKIS. You are attributing some of the problems to the fact that you can't fire, let go, or maybe in another way reprimand a Federal employee because he or she is a Federal employee.

Dr. KIZER. There are so many levels of appeal and other mechanisms to circumvent disciplinary action that the system is exceedingly difficult to work with. The case you cited is one particularly egregious example of that where we tried to terminate the person, but the system forced us to rehire the individual.

Mr. BILIRAKIS. All right. But have you come to the Congress, or has anyone at the VA come to the Congress and said to the Congress, look, you know, the laws mean well, we don't want to hurt innocent people, et cetera, but these are some changes that we recommend to allow us to be able to serve the veterans better?

Dr. KIZER. We have discussed this, I would say, informally. But if I could take that as an invitation, we will come back with some more specifics.

Mr. BILIRAKIS. Sure, you can take it as an invitation. I can't really speak for the committee, although the chairman is shaking his head yes.

Mr. STEARNS. I agree completely.

Mr. BILIRAKIS. Then it goes on to what type of standards does VA have for hiring of physicians and other medical personnel. Now, why would this physician who had to take the medical examination 10 times before passing have been hired by the VA?

Dr. KIZER. If he is a licensed physician, the law doesn't allow us to discriminate against him because he had to take it 10 times. Once he passed and was licensed, by statute we cannot discriminate.

Mr. BILIRAKIS. But you don't have to take everybody who applies, do you, just because they happen to be a licensed physician, and there happens to be an opening? I mean, isn't there some criteria there, whether it be subjective or otherwise, which allows you to not hire this one individual because the person might have something wrong with him or whatever the case might be?

Dr. KIZER. Well, I think it is not that simple.

Mr. BILIRAKIS. It isn't?

Dr. KIZER. No, it is not. We would certainly be willing to engage in further discussions on specifics.

Mr. BILIRAKIS. I know this is a public hearing, and there might be sensitivity to some things that might be said and all that, but darn it, we are talking here about veterans. You know how I feel about the veterans health care system, but problems are there, and we can say that those problems are no worse there than they are in the regular health care system in America or maybe in the world. That doesn't make any of us feel any better because we are

talking about treating veterans, who are special people. And so it seems like we ought to be confronting some of these things head on, because when we are talking about culture and cultural changes, I think these things are part of all that.

Dr. KIZER. And I agree.

Mr. BILIRAKIS. And there is something in the law that precludes you from being able to make a decision when more than one person applies for a job that you take this person versus the other person or whatever; is that right?

Dr. KIZER. Without being able to focus on the specific circumstances, it is pretty hard to talk about that in the abstract. All I can—I would go back that the prohibitions against discriminating against somebody are very strong and very explicit in the law.

Mr. BILIRAKIS. But, sir, excuse me, forgive me, Doctor—Mr. Chairman, with your indulgence—but you use the word "discriminating." I am talking about making a decision. I mean, you know, we are human beings, and when we hire people, I don't think we should be discriminating. Are we saying that this particular individual had to take the examination 10 times, it would have been considered discrimination if we hadn't hired that person?

Dr. KIZER. It might well have been, yes. That is the nature of the law and how it is being interpreted.

Mr. BILIRAKIS. So if I am not hired, the law will protect me in terms of they can say, hey, they don't like Greeks, or something of that nature; is that right?

Ms. WILSON. Or someone with an anxiety disorder, and the reason they took the test 10 times was because of that, we would be discriminating against someone with a psychiatric illness.

Mr. BILIRAKIS. I am sure the veterans love to hear that.

Dr. KIZER. Well, we don't write the laws, but the way they are interpreted in the real world, in interpreting these things, they are not always used to the advantage of the employer or in the way they were intended; they do not work to the advantage of the system all too often.

Mr. BILIRAKIS. Thanks, Mr. Chairman.

Dr. KIZER. I would, if I might, mention one of the new policies that we put in effect a few months ago was the requirement that any new physician that is hired into the VA system must be board certified in the specialty that he or she will be practicing in. While this requirement is present in some other health care systems, that is not the norm in the community at large.

Mr. STEARNS. Dr. Cooksey.

OPENING STATEMENT OF HON. JOHN COOKSEY

Mr. COOKSEY. Thank you, Mr. Chairman. Well, this, no doubt, is a problem, and it is a problem that needs to be addressed. And in defense of the VA, the veterans' hospitals have received some cuts, I think oftentimes too many cuts will ultimately lead to the reduction in quality of care, because when you cut and cut personnel, it is going to create a problem. I happen to personally believe that when you have the best physicians, the best health personnel, nurses and so forth, you are going to get the best quality of care. But too often we make decisions based on the cost of care instead of quality of care, and as long as we are making decisions, health

care decisions, based on cost of care and not quality of care, we are not going to get good quality care.

But in this current climate, these decisions are dictated by politicians, and now that I have changed from being a physician to being a politician, I assume I am part of the problem. They are made by bureaucrats, they are made by numbers crunchers, and they are influenced by the media and the tort system, which is greatly distorted, and it is a shame.

And I agree with my colleague, Congressman Bilirakis, that it is a shame that physicians who have failed an exam 10 times can be brought in, because there are physicians out there. I happen to serve on the ethics committee of our State medical board for about 8 years, and it is the worst job ever—I realize there are people out there that probably should not be working, and too often they can end up in a State hospital because they have had their license jerked, and the only thing they can get is an institutional license, which means they can work at a State hospital or a veterans' hospital. I think the veterans deserve better than that. So it is a problem.

Dr. KIZER. Let me just interject, just to clarify one point. They may well be able to work at the State hospital, I can't comment on that, since there are 50 different sets of laws dealing with the States; but if they have had their license revoked, they cannot work in a VA hospital. They have to be licensed to work for the VA.

The other thing I would comment on is your comment about the malpractice and tort system in this country being a major barrier to addressing this problem of adverse events related to medical treatment. It is an absolute major contributing factor to why these things aren't talked about openly and why they aren't dealt with in health care overall.

Mr. COOKSEY. Sure, no question about it. But, unfortunately, the trial lawyers carry the day. In case you didn't know, Dr. Kizer, I am sure you know this, there are 172 lawyers in Congress, and I think 52 or 53 in the Senate, and that is part of the problem, and there are too many in State legislatures. But anyway, I am obviously biased, and I do discriminate against trial lawyers and relish it.

But, you know, I think we are all here to make sure we get the right health care for veterans because there are good veterans out there. I had a retired physician, a veteran, World War II, good guy, tell me about some concerns at a local veterans' hospital in my District, and we checked it out, and there really was some misinformation there. There is still a lot of misinformation and this particular veterans' hospital is doing top quality work with good physicians, and I am pleased to be affiliated with it. There is another veterans' hospital in the general area that perhaps does not—has not addressed all these problems, but it does get back to quality of care, and that is what I think we are all about. And I applaud your efforts in moving in the right direction.

And this is the type of flowchart that you need to find these problems, and it is one we deal with in the private sector as well, but we can do it—these problems will best be solved by properly motivated health personnel making the decisions, instead of politi-

cians, lawyers, and the media trying to make these decisions or influence these decisions to their own advantage.

Thank you, Mr. Chairman.

Dr. KIZER. If I can make one final comment, please. One of the ways you can help is exactly what Dr. Leape mentioned as far as the climate and how these issues are perceived. There was an excellent article in the *New York Times* a few months ago about the need to change the mindset around this problem; it specifically dealt with medical treatment errors in private institutions. Insofar as starting at the top, the culture can change to facilitate open and thoughtful discussion of these things, and anything Congress can do in that regard certainly would be beneficial and would translate probably very tangibly into ultimately better care for our veterans.

Mr. STEARNS. Let me just thank you for your candidness, and towards this idea of the culture that we want to improve the system, may I suggest, and we would welcome, if you would follow up, perhaps, with suggestions for us to improve the selection, the management of these facilities, because in the end, if we could together work to do that, we would provide immeasurable benefit to the veterans in this country.

The last sort of question I have is when it is all said and done, what will this committee get from your Department in the way of records showing that you have increased effectiveness, you have determined that these records are not underreported, and so forth and so on? So I am just asking you as a management policy, what will this committee see from your Department?

Dr. KIZER. Obviously, in general terms, you will see whatever you want, whatever we can provide, and if the information that we do provide you as far as the statistics and numbers and the specific examples of things that have changed is not adequate, then we will increase that to give you, the committee and the Congress a level of comfort that it needs to be confident that the problem is being addressed and that improvements are being made.

Mr. STEARNS. Again, I want to thank all of you.

Mr. KENNEDY. Mr. Chairman, can I just make one point?

Mr. STEARNS. Absolutely, Mr. Kennedy.

OPENING STATEMENT OF HON. JOSEPH P. KENNEDY, II

Mr. KENNEDY. I apologize, Dr. Kizer, and other members of the panel for being late. I had, as you know, another conflict up here at the same time.

But I just wondered if you might comment generally, Dr. Kizer. I think that the fear that people have, generally speaking, after a movie a couple years ago, I think it was called Article 99, that sort of demonstrated, you know, kind of a cannibalistic health care system within the VA, where parts of the VA health delivery system had to be robbing from other parts in order to be able to provide any kind of reasonable amount of care. And the real concern, I think, goes back to hearings that we have had in this committee room over the course of the last several years, where we have had, for instance, VA directors come before us, tell us everything was in fine shape within their own regions, and then I have walked out the door and had a VA director grab me and say, listen, I can't, in fact, tell you the truth within that committee because it will

mean my job, but the truth of the matter is that underneath we are really in trouble in terms of having enough money to be able to actually create the kind of health care system that will provide the basic protections.

I apologize for missing your testimony, but do you have concerns that you just don't have enough resources to actually get the job done to be able to provide the kinds of assurances that you would actually see within the private health care system?

Dr. KIZER. Let me just say, on the movie, that I have heard of it, but I have never seen it.

Mr. KENNEDY. You got to catch it. It is worth the rental.

Dr. KIZER. I have heard contrary views.

Mr. KENNEDY. I am sure where you work you have.

Dr. KIZER. Resources are always an issue. I think that many of the changes we are putting in place, as we have discussed at other hearings, are showing that we can take the limited and constrained resources that we do have and make them go a lot further. We really are able to do this; this year we have treated more veterans than have ever been treated in the VA before, and we are able to show very tangibly that the quality is better.

Are there issues? Yes. And we are going to have to continue to focus on those.

Mr. KENNEDY. All right. But I guess what I am really trying to deal with is—I understand that, and I think everybody gives you great high marks for revamping the VA health care system and kind of bringing it into the 21st century. But I am asking a slightly different question, and I am making a different point.

There have been a number of instances where there—and these are always pointed out to be individual circumstances—where bodies have been found in hallways, where they were—where body parts, I believe, were found at a VA health facility in the Midwest, out buried in different parts of the facility. In my own district I am certainly aware of VA health facilities that were in very, very bad condition with plaster falling down into the mouths of dental patients and the like. I mean, these are the kinds of—where an individual had died in a hallway and had been left for a couple of days, you know.

I mean, these are circumstances that could, in fact, be isolated incidents. On the other hand, they could be circumstances that portray a pattern that I don't think, you know—the last thing we want to do is have you feel defensive about the system and feel that it is an automatic response to come in and just say, oh, we are getting better, if, in fact, there is a major problem below that is just not getting the kinds of resources that are necessary to deal with creating an adequate health care delivery system.

So I just want to make—I want to make it very clear that nobody, I think, is interested in seeing any kind of whitewash of serious problems that exist because of a lack of resources. If that is an issue, I think, you know, we should just know it and understand it, rather than just be told that, and have you or anybody else feel that this is going to be a reflection on the kinds of changes that you have brought about, which I think, as I said earlier, people I think are generally very supportive and complimentary to the leadership that you have shown. But I am and have always been con-

cerned that below the surface there is a great deal of need within all sorts of the VA health facilities that maybe we just aren't even, you know, coming close to the kinds of adequate resources that are necessary to deal with the problem.

Dr. KIZER. Well, you know, I think you cite some specific anecdotal things that hopefully wouldn't be generalized in the system, because I don't think they accurately characterize the nature of the care, the physical plant or other aspects of the system.

But I would go back, again, to note that resources certainly are and will continue to be an issue. The VA budget over the past 15 years has gone up each year, generally, 2 or 3 percent. Medicare and Medicaid are going up 8, 9, 10 or 12 percent each year. I mean, unquestionably the funding support for the veterans health care system is not on par and has not kept up with other government health care programs as far as the funding they are receiving.

Mr. KENNEDY. And it is your opinion, then, that that has created serious shortfalls in terms of the kind of quality care that is necessary to provide—you know, just the adequate health care to the veterans?

Dr. KIZER. I don't think the funding is at the root of this. I think there are other things we have talked about at some length this morning that really will help, but I don't think that resources are the root cause of the problems that have been cited.

Mr. KENNEDY. Thank you, Doctor.

Mr. Chairman, I appreciate your indulgence.

Mr. STEARNS. Sure. We are going to take a recess now before the third panel, which is very important, that is the directors from three major hospitals who have answered our request. So the committee is in adjournment until we have two votes, and we should be back perhaps in about 15 minutes, or I should be back after the two votes in about 15 minutes.

Dr. KIZER. Mr. Chairman, it was my intent to sit through the third panel, but I do have a speaking engagement that I need to go to.

Mr. STEARNS. I understand. Is there anything you would like to add before we conclude?

Dr. KIZER. No, that is fine.

Mr. STEARNS. Okay. Thank you all for your time.

[Recess.]

Mr. STEARNS. The committee will come to order, and we will resume with the third panel: Dr. Elwood Headley, Director of Boston VA Medical Center, Department of Veterans Affairs; T.C. Doherty, Director, Miami VA Medical Center, Department of Veterans Affairs; and Billy Valentine is Director, Muskogee VA Medical Center.

Gentlemen, I want to thank you for coming, and I know, having been in business myself, you have to take time in your busy schedule to come here; so we appreciate your taking your time and sharing with us your opening statements.

So at this point you can begin.

STATEMENTS OF ELWOOD HEADLEY, M.D., DIRECTOR, BOSTON VA MEDICAL CENTER; T.C. DOHERTY, DIRECTOR, MIAMI VA MEDICAL CENTER, ACCOMPANIED BY DOUGLAS BRADSHAW, ASSISTANT GENERAL COUNSEL; AND BILLY VALENTINE, DIRECTOR, MUSKOGEE VA MEDICAL CENTER, DEPARTMENT OF VETERANS AFFAIRS

STATEMENT OF ELWOOD HEADLEY, M.D.

Dr. HEADLEY. Thank you very much, Mr. Chairman, members of the committee, thank you for the opportunity to present the details regarding this incident. Written testimony has already been submitted and this will be a brief summary of that testimony. I will present the circumstances of the case, the nature and findings of the investigations which occurred, and remedial steps which were taken.

The patient was a 60-year-old man with cancer of the esophagus. He had previously undergone surgery for this and was taken back to the operating room for reexploration of the surgical site and drainage of fluid accumulation from the right side of his chest. He was seriously ill prior to the surgery and judged to be a high-risk surgical candidate.

During the surgical procedure, he suffered a cardiac arrest and attempts at resuscitation were unsuccessful. In the process of reviewing the events surrounding his death, it was discovered that he had received two units of packed red cells, typed and cross-matched for another patient.

Needless to say, the staff was devastated. Fact-finding was begun immediately, the patient's family was promptly notified of the incident, and of their rights, appropriate internal VA and external notifications were immediately accomplished. An administrative board of investigation was charged to review the incident. And if I might just add, a typographical error in the submitted testimony states that the administrative board of investigation was begun March 8, 1997, it was 1996; I apologize for that. It was an immediate board of investigations.

Mr. STEARNS. Unanimous consent, so corrected.

Dr. HEADLEY. Thank you.

Findings of the board. The identification of the patient prior to and during the surgical procedure was an area that was looked at. Each discipline in the operating room independently identified the patient, but there was no interdisciplinary process in place to verify this identification. Another finding was that blood was stored in a refrigerator in the operating room by room number, this is a relatively standard practice in operating rooms. This patient was in operating room number 7. He received the blood prepared for the patient who preceded him in operating room number 7.

The arm band identification of the patient was not verified against the blood product prior to administration. This was clearly in violation of policy and procedure.

The conclusion of the administrative board of investigation was that the transfusion error had both a human error and a system component. Had the verification process included the confirmation of patient identification, as reflected on the wrist ID band, the incident could have been avoided. While the transfusion error was the

result of human error, there were also opportunities to improve systems and existing policies and procedures.

The remedial steps that were taken: In addition to the administrative board of investigations summarized above, a root-cause analysis was undertaken of our entire blood administration process. This is a method of reviewing processes as an aid to restructuring them. Based on the findings of the administrative board and the root-cause analysis, it was decided to reengineer our blood and blood products policies and procedures totally, in order to prevent this from ever happening again.

The following were implemented: Letters of reprimand were issued to the anesthesiologist, the certified nurse anesthetist and the nurse involved. There was a total redesign of the process of blood administration to assure interdisciplinary verification of patient identification prior to the initiation of anesthesia or procedures, and prior to the administration of blood or blood products. There was a redesign of the process to a uniform system of dispensing blood to the operating room by individual patient, rather than in bulk, and eliminating storage of blood in the operating room and outside of the blood bank, minimizing risk to patients. Blood is now individually dispensed to the patient in the operating room, directly from the blood bank.

There was a change in policy to require documented, informed consent for blood transfusion, medical center-wide to facilitate active involvement of patients in the treatment decisionmaking process.

Educational programs addressing all of the above were instituted hospital-wide with special emphasis on the operating room. Educational programs on risk management were presented hospital-wide with emphasis on the operating room.

Ongoing monitoring of all the steps in the blood administration process were instituted and are being followed by the transfusion committee of the Boston VA. An annual review of blood and blood product administration was instituted in the hospital's ongoing clinical staff education program.

The Joint Commission on the Accreditation of Health Care Organizations paid us an unannounced visit for cause to review our blood administration program. While we were in compliance with their standards at the time of the visit, we were placed on accreditation watch, pending implementation of the recommendations from the administrative board and the root-cause analysis.

We were revisited several months after this initial visit and the watch was lifted. We were re-reviewed as a part of the triennial survey 3 weeks ago and were found to be in total compliance with Joint Commission standards.

Thank you very much.

[The prepared statement of Dr. Headley appears on p. 135.]

Mr. STEARNS. Dr. Headley—I guess we got the name tags mixed up.

Mr. BILIRAKIS. Change around the name plates in front of you. Which one is Dr. Headley?

Mr. STEARNS. Okay. So, Mr. Doherty.

Mr. DOHERTY. Sorry about that.

Mr. STEARNS. No problem.

STATEMENT OF T.C. DOHERTY

Mr. DOHERTY. Mr. Chairman, members of the subcommittee, you have my statement, and if acceptable, I would just like to enter the statement into the record and give you a brief statement regarding the untimely death of Mr. Martin.

I would like to say in the beginning, Mr. John Martin was more than a patient of ours, he was a personal friend. John came out of the military after a very brief stint and became a patient of the VA. We cared for him for more than 25 years before his untimely death. John was noncompliant, he was in the end stages of renal disease, and we did everything humanly possible to encourage him to change his dietary and other habits. Prior to John's death, there have been no—there had been no adverse effects related to staff performance in our dialysis program.

The Miami VA Medical Center instituted the first dialysis treatment program in 1966. There were more than 135,000 treatments provided our veterans and, absolutely, this was the first untoward incident that had occurred. Mr. Martin's death was because the dialysis nurse, who had cared for him for a number of years and who was an experienced nurse, 16 years service, connected Mr. Martin to the dialysis machine, and she failed to connect the venous dialysis line to the return port. Instead, the line was left and his blood went into a container. This resulted in a loss of more than 1,800 cc's of blood.

A brief overview of the events is as follows: As the dialysis nurse began the dialysis connection process for Mr. Martin, she encountered a problem with the venous transducer, which is a center unit that indicates blood pressure; she was unable to correct the problem and she called the nurse, a dialysis technician. While they were working, the dialysis nurse, his principal nurse, was called to the telephone. The dialysis technician continued to troubleshoot the transducer and the machine and determined the transducer needed to be replaced.

After she replaced the transducer, the technician proceeded to leave the patient's bedside. At this point, she heard the hissing of blood going out of his body.

The dialysis nurse returned—she was on the phone for approximately 2 minutes—she and the technician immediately began to replace the blood that had been lost by Mr. Martin with large amounts of saline solution. The technician also began to clean up the blood spill. In the process of cleaning up, the technician showed a second dialysis nurse the amount of blood that had been spilled. The second nurse then began to assist with Mr. Martin's care.

He appeared to stabilize, he spoke to the nurse, he spoke to the dialysis technician, but shortly after, his stability began to deteriorate, and an emergency code was called. The code team responded promptly. The team, however, was not informed of the blood loss; instead they were told the patient had developed abdominal pain followed by low blood pressure.

Resuscitation measures were attempted, but not successful. Mr. Martin was pronounced dead at 8:25, June 22, 1996.

Upon learning of this event, I immediately convened a three-person board of investigation to thoroughly investigate all the circumstances surrounding Mr. Martin's death; and I would like to

say at this point that I am a former Staff Investigator for the House Veterans Affairs Committee, and when we conduct an investigation, my medical center, I usually assist in all investigations to make sure that they are thorough and complete.

I then contacted his family. Mr. Martin had been separated from his wife for more than 23 years. His sister was identified as his next of kin. I nevertheless contacted the widow and the sister, and invited them to come to the medical center. They came to the medical center, and I informed them that an investigation was under way, because I was not satisfied with the events leading up—the circumstances leading up to Mr. Martin's death.

At the same time I had directed the investigation be conducted, I also ordered that the two dialysis nurses, the dialysis technician, the dialysis unit nurse manager be removed from the dialysis unit pending the outcome of the investigation.

After the board of investigation was completed, the following actions were taken. The employment of the primary nurse assigned to Mr. Martin was terminated, and the nurse was reported to the State licensing board. She immediately left the country and I believe is somewhere in either Puerto Rico or Guam.

The second dialysis nurse was suspended for 30 days and reassigned. She resigned from the VA.

The nurse manager of the dialysis unit was suspended for 14 days, and was permanently reassigned. The dialysis treatments were moved to newly constructed dialysis units, which had been planned prior to the incident.

The nursing staff of the dialysis unit was redesigned to ensure a more uniform approach among all staff members and with all patients. All the nursing leaders within the dialysis unit were given formal leadership training. All dialysis staff members have been engaged in ongoing training procedures relating to administrative and clinical problems and procedures. Plans are under way for all members of the interdisciplinary dialysis team to participate in a team-building program in order to advance a positive, cohesive team spirit that has been developed since this tragic accident.

In conclusion, let me say—and I am a retired Marine Corps paratrooper, and I saw a lot of combat and I had multiple gunshot wounds; believe me, I have empathy for my patients, my veterans, and I relate to them. And as I indicated earlier, this was a tragedy that affected me very personally.

We pride ourselves on providing the best possible care to our patients, and to have something of this nature occur has required us to humbly sit back and take a look at ourselves, asking how we can ensure that something like this never happens again. We have learned many lessons from this tragedy and have emerged from the incident with a renewed sense of mission to do everything we can to provide the very best for our veterans, which they deserve.

And we thank you very much for being able to come before you today.

[The prepared statement of Mr. Doherty appears on p. 141.]

Mr. STEARNS. Thank you. Mr. Valentine.

STATEMENT OF BILLY VALENTINE

Mr. VALENTINE. Yes, sir. Mr. Chairman, members of the subcommittee, I have submitted written testimony that explains in detail the events that occurred at Muskogee VA Hospital. I will briefly take a minute to recap the events of May 24 and 25.

I am pleased to be here this morning; it is just unfortunate it is under such tragic circumstances, that in 30 years in the VA I have but one opportunity to appear before a subcommittee, and it is under these tragic circumstances.

Mr. STEARNS. That is a good point.

Mr. VALENTINE. Our staff at Muskogee was saddened by the untimely death and also disappointed that this isolated accident so overshadowed the compassionate care that has been provided day to day at Muskogee VA Medical Center for over 60 years. The patient in question was a 65-year-old veteran admitted on May 22 with a diagnosis of gastrointestinal bleeding with other complications. From the time of his admission, he had progressively improved medically. He exhibited appropriate interaction with staff, was judged to be oriented and competent to make his own decisions. He was receiving no sedatives, relaxants or psychoactive medications.

On May 24, at approximately 10:30 p.m., the patient left the ward without telling the staff or signing out. We can only assume he left the ward to go for a smoke, as he had done that several times that day. The staff noted that he was missing about 15 to 20 minutes after he departed the ward, and immediately began our search policy.

At approximately 8 a.m. the next morning, May 25, the VA policemen found the body of the missing patient in the construction site adjacent to the medical center. Investigations were conducted by the Muskogee Police Department, the Board of Investigation and the Office of the Medical Inspector. The death was ruled an accident which was precipitated by the actions taken by the patient. We will never know why the patient went to such a seldom used, isolated smoking area, nor will we know why he disassembled a chain-link fence to enter the construction site, why he walked 40 or 50 feet, over piles of bricks and construction debris, to the point that he fell to his death.

What we have learned from this is that we have a commitment to continually analyze and redesign our systems to assure that our patients, employees and visitors are provided a safe environment.

[The prepared statement of Mr. Valentine appears on p. 148.]

Mr. STEARNS. Thank you, Mr. Valentine.

Let me just echo your point about it is unfortunate that perhaps the one time you are coming in front of the committee, the subcommittee here, would be under these circumstances. But I think the larger issue is, how can we develop this culture that we have talked about, that we have a system-wide program to stop these and help out. So if all of us can work towards that, I think the larger goal will be immensely helpful to the VA hospital, and that is sort of the imprint we are trying to do here.

So you are here obviously to try and improve the system and that is why—so towards that end, I understand that something happened in Muskogee, and then a year later, the same thing hap-

pened in the Miami hospital; and if there had been actual reporting of this incident, perhaps the procedures could have been placed so that in the Miami hospital, it would not have occurred.

To your knowledge, Mr. Valentine, did the Central Office prominently notify other VA medical centers of the lessons learned as a result of the incident to which you just testified?

Mr. VALENTINE. No, not to my knowledge.

Mr. STEARNS. Now, there is a good example, where if that was put on a bulletin board and notified, then Mr. Doherty and Dr. Headley could all look at it and say, by golly, here is something we should do to prevent something happening.

Mr. Doherty, when the press reported that particular example, the kidney dialysis—and I used that in my opening statement—you went into the system-wide problems, the clinical problems. But the press has identified other patient deaths at the Miami hospital; I understand there have been four more cases involving failure to treat a veteran's bladder cancer, for example.

So my question is, have all of these cases prompted a broader review of the systems of care delivery at your hospital, and is this a change in philosophy that is just starting now, or what can you say?

Dr. DOHERTY. I think, number one, we regret—as Dr. Kizer indicated, one death is one too many, and we regret that any deaths occurred—untimely and unwarranted deaths—and I think that each case has to be viewed separately.

And I think that, yes, we have instituted a system whereby—and Dr. Kizer, I think, alluded to that in his statement—the VA is going to have a database system whereby all of this stuff will be funneled in to headquarters. When anything occurs at our medical centers, we immediately notify our VISN director, and he in turn notifies our headquarters, Central Office, of the incident; and immediate steps are always taken at the medical center level to determine what happened, how did it happen, why did it happen, and what steps can be taken to prevent it from happening again.

And not all of these things that happened can be blamed on the medical center or the failure of medical center personnel to act properly. For example, you mentioned the case of the missing patient.

Mr. STEARNS. Right, which you talked about.

Dr. DOHERTY. The patient was brought to our hospital, he had a fire in his home, his wife brought him to the hospital and asked if we would hospitalize him because he could not get along with his mother-in-law and we agreed to take him in. He had been a patient previously in our nursing home and we had had the gentleman on the locked ward, secured unit, of the nursing home. His wife was determined that he was not going to be placed on the secured unit, locked ward of the nursing home; she felt this would be counterproductive and that he would lose all the confidence that he had, and that he was able to take care of himself.

A conference was held at the nursing home, and it was determined they would go along with the wife of the veteran, and they placed the veteran in an unlocked ward. Four days later, he wandered away from the ward.

Mr. STEARNS. And we looked at the Dillmore case in November of 1996, where wheelchair brakes failed and the individual toppled from the bus and was killed.

Dr. DOHERTY. Yes.

Mr. STEARNS. The Ribler case in 1995, the patient died after VA failed to—well, what I am saying is, all these things should have prompted a system-wide——

Dr. DOHERTY. Well, I think we are continually in a system-wide investigative posture to make sure that there are no accidents or untoward events that are occurring in our medical center. I think this is a daily occurrence, and I think that we take great pride in our medical center, in ensuring that our veterans not only receive quality care, but we take every measure to ensure their safety.

In the case of Mr. Dillmore, sir, I can assure you, we took Mr. Dillmore out for an outing to buy some stuff at a local shopping center. Upon his return, he was loaded onto the elevated wheelchair lift. Mr. Dillmore was a quadriplegic and he operated his wheelchair by his chin. When he was loaded onto the wheelchair, he put his wheelchair into motion, and it was a very heavy wheelchair, electric-powered wheelchair, and the attendant was unable to stop the wheelchair from moving forward. Mr. Dillmore had full control of that wheelchair, and he toppled over and fell 4 feet to the pavement.

He indicated he was all right, and we immediately rushed him to the Parkway Medical Center; and unfortunately, he did expire, but I don't think it was a system failure. As—again, as in Mr. Martin's case, it was not a system failure; it was a case of failure of one individual to properly perform their duty.

But in answer to your question, sir, yes, we are daily evaluating and measuring what steps can be taken to prevent any untoward incident from happening in our hospital. We are constantly putting systems into effect.

Mr. STEARNS. I would submit, though, Mr. Doherty, if a person is controlling the wheelchair with his mouth, he should not be in control of the wheelchair when he is on that kind of structure.

Mr. DOHERTY. You are absolutely right, sir.

Mr. STEARNS. But be that as it may, here is something that I have no feel for and this is a general question for all of you.

There were some $53 million paid in malpractice cases in 1996, fiscal year. And I read earlier that the hospitals have an obligation—as opposed to the private sector, they have an obligation to pay for negligence and errors and so forth. How has that impacted your hospital, the fact you have malpractice—and I might ask Mr. Headley, and I will move from my left to my right—because, you know, we have records of malpractice insurance claims and, obviously, in which hospital it occurred.

For example, in Mr. Doherty's hospital, it is my understanding, more than 4.4 million was attributable to cases involving your facility, and so I think just my question is not specific to any individual. And I don't even have a feel if 53 million is a lot. But just tell me, from your standpoint, this malpractice, is this a concern of yours at all; and is there something that the committee should know in reference to these claims?

Dr. HEADLEY. Well, I think malpractice is always a concern because it indicates that there has been a failure of the system. It indicates that something has been done wrong. It indicates that there is something that we can improve.

And indeed we use tort claims as part of our performance improvement activities. At the Boston VA, we do have a very mature performance improvement system, which has been in place probably for 20 years now which tracks and indeed does trend all of the various components of our quality management program. We look at tort claims, we look at patient incidents, we look at minor patient incidents, we look at medication errors, we look at all of the errors in our hospital. We trend these quarterly, we put them together annually, we share them with clinical staff, we take lessons from these; we use the tort claim data in order to improve performance. Financially, this is an impact; I don't know exactly how to compare this $53 million versus the private sector.

Mr. STEARNS. I don't either.

Dr. HEADLEY. And the amounts that go on there.

Mr. STEARNS. Yes, sir, Mr. Doherty.

Mr. DOHERTY. I would piggyback on Dr. Headley's statement. We are doing all of the same things that he indicated. To me, today it is very—you know, we get many frivolous claims that we have to entertain, and some of our—when you look at the malpractice suits that are filed, you wonder why there are so many. As I indicated, many of them are frivolous in nature, and the majority of the suits, claims that are filed against VA Medical Center of Miami, are denied.

I personally encouraged the widow and the sister of Mr. Martin to file a claim, and that was the only claim that was filed in the five deaths, and I assisted them in filing that claim because I felt in this case that they were deserving of something.

Mr. STEARNS. Mr. Valentine.

Mr. VALENTINE. I share in the concerns, any time you have a tort claim filed, there is a perception by the patient or his family, that the care that they have received was inappropriate, and that is the last message any health care facility would want to send. We do trend and track the filing of tort claims regardless of whether they are accepted or whatever action happens on them just so that we can get some tracking process into what may be hot spots in the facility; and I would certainly feel that $53 million is a significant amount of money. That is enough money to actually fund one small hospital for a year's operation. So we do have a concern.

Mr. STEARNS. Okay. Mr. Kennedy.

Mr. KENNEDY. Thank you very much, Mr. Chairman.

First of all, I was struck by the testimony that the three of you gave in terms of just how it seemed as though you all cared very deeply about the loss of life that took place in your facilities, and I think that is an important demonstration for not only the people here, but for your staff, as well, to understand, you know, just how important these lives are that you are taking care of.

I think, you know, it is also important to point out, as I understand, that there are about a million cases each year of patients that are injured by mistakes in treatment and that over 120,000 of them across the United States die, so I don't think that we are

here to just try the three of you based on the fact that there are incidents in each one of your facilities where people have been killed as a result of inadequate or wrong medical treatment.

I do think what we are trying to do is determine whether or not appropriate steps are being taken by your facilities, and whether or not there is a systemic problem that needs to be fixed, and I think there are enough incidents that have taken place around the country over the course of just in the last 10 years or more, since I have been serving on this committee, that would lead one to believe that there is, in fact, some kind of underlying problem that needs to be dealt with. And I think that I would like to just pursue that and get your thoughts on whether or not there is in fact, you know, a deeper issue that needs to be examined by this committee and dealt with either legislatively or administratively.

First and foremost, I mentioned in my opening statement, when I was talking to Dr. Kizer, I remember—and I don't have a listing in front of me, but I remember, I believe it was in Columbia, Missouri, there was an incident in the last couple of years where there was sort of a rogue individual running around killing a whole rash of different patients.

I remember there was another incident where there were patients' bodies that were found buried on VA grounds. There were all these kinds of cases, you know, in terms of bodies being lost in various exits and horror story after horror story after horror story.

We are told that these are sort of different, isolated incidents that have no reasonable relationship to one another. On the other hand, we have heard, I think, enough of them to, for instance, have the chairman of the subcommittee call all three of you here to ask you what is going in your facilities; and the real question is whether or not there is a systemic problem that either requires additional resources—I mean, Dr. Headley, I noticed you brought up the JCOA. Now, as you may recall, we had to bring in the Joint Commission to inspect the Court Street Clinic, going back several years ago. When they came in and looked at Court Street, they condemned the place. Subsequent to that we got a very nice new temporary facility where the veterans are very, very happy in terms of the quality of care they received. But it did take bringing JCOA in to condemn an older clinic in order for us to move on and get the kind of funding that was required, and I am wondering whether or not—you know, what brought JCOA into your situation.

You indicated, I thought, according to your testimony, that they had come in and given you some sort of status that was not exactly adequate, and you then made some improvements to get yourself into the adequate category. So can you just explain what happened there, please?

Dr. HEADLEY. Yes, certainly. The Joint Commission is routinely—let me back up one step. When there is an incident involving blood administration, it automatically gets reported to the FDA as a part of the external reporting mechanism. The FDA notifies the Joint Commission and the Joint Commission does go in and investigate each case of this nationally. So this was a routine visit of the Joint Commission for an incident. It is called a visit for cause, and it is for death involving blood administration.

The surveyor who came to us said that they investigate three to five of these nationally a year—not in VA hospitals, but nationally. At the time that the investigator came in, we had already done our administrative Board of Investigation, and I believe had already done our root-cause analysis.

The Joint Commission surveyor who came in said that, indeed, you have basically done all of the things, you are basically in compliance, but we will put you on what is called "accreditation watch" until you implement all of the recommendations that you came up with.

Mr. KENNEDY. Does that indicate that, in fact, you were below their standards prior to their arrival?

Dr. HEADLEY. It means we had an incident.

Mr. KENNEDY. If it is on some sort of temporary status, after they arrived, doing the investigation, it would imply that you were not operating at the status that JCOA requires.

Dr. HEADLEY. I am not sure what accreditation watch exactly means. It is something that they implemented about a year and a half ago. They made organizations conditional; they rendered them conditional accreditation if they came in and investigated an incident, until they took some remedial steps.

Mr. KENNEDY. Well, it bothers me a little bit to hear you say you don't know what that means. I mean, I am not trying to be unnecessarily hard on you there, Doc, but you know, you are the administrator of the hospital, and if the accreditation board is coming in and you are saying that they are not giving you an adequate—you are saying to us before the committee they didn't give you an adequate appraisal, they put you on temporary status, and you are saying to me you don't understand what they really meant by--

Dr. HEADLEY. I understood exactly what they meant for us. What I am saying is, I am not quite sure what "accreditation watch" means in terms of Joint Commission accreditation, it doesn't have an official sort of—it means that they detected in our blood administration program some areas that could be improved.

For instance, we had said that we felt that having the refrigerator in the operating room and blood delivered to that refrigerator was a potential cause of error in the administration of blood in the operating room; and we had determined that we were going to remove that refrigerator, we were going to replace it with blood being delivered directly to the operating rooms from the blood bank. We instituted that as part of our systems process. We changed—the Joint Commission surveyor said and felt that an interdisciplinary identification of patients in the operating room was better than having each discipline identify the patient separately, having physician identify, having nurse identify, and we changed that procedure in our operating room.

Mr. KENNEDY. And I appreciate the Chairman to just give me a minute to wrap up here.

But I heard in your testimony these changes you made, and I think the question before the committee is whether or not these are changes that should have been imposed as a result of normal oversight by an administrator of a situation involving a life-threatening procedure.

Dr. HEADLEY. Yes, they are.

Mr. KENNEDY. And whether or not these are, you know, where people aren't looking to, you know, just come in and sort of gratuitously whack you around here Dr. Headley.

What I think it is our responsibility is to make certain that, in fact, proper oversight of administrative procedures is going on within the VA; and I am still, to be honest with you, Mr. Chairman, somewhat unclear as to how that has occurred here.

Mr. STEARNS. I will tell my colleague, we can go another round if you like. Let me call on my colleague, Mr. Bilirakis, who, I might point out, is the Chairman of the Commerce Health Subcommittee, which deals with Medicaid and part of Medicare, so he has large jurisdiction. My colleague.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

I want to welcome the gentlemen, and particularly Mr. Doherty, who comes from our State, even though it is not our congressional district. And really, Mr. Kennedy hit upon it, and before you came in, Joe, we talked about the need for cultural change. I mean, there is an atmosphere there that really many of us think results in a lot of these problems and you hit upon it.

Let me ask you, Mr. Doherty, in the case of Mr. Martin, who bled to death while receiving the dialysis, the *St. Petersburg Times* reported it took ten-and-a-half months to report the nurse responsible for the incident to the State licensing authorities and the national data bank that collects the names of medical professionals who err; is this correct?

Mr. DOHERTY. Yes, sir, but I think it needs explanation.

It wasn't a delay; we had to conclude the investigation and the other processes that are necessary before reporting to the national data bank.

Mr. BILIRAKIS. Is this a process?

Mr. DOHERTY. This is a process, Mr. Bilirakis, that we have no control over; it is something that is imposed upon us.

Mr. BILIRAKIS. By whom?

Mr. DOHERTY. By the data bank and by the system, the system being the——

Mr. BILIRAKIS. By the data bank, in other words, the national data bank?

Mr. DOHERTY. We have to furnish certain documentation, including a report of investigation and other matters, meaning that this case is finished by the VA and has been investigated by our peers and everything else.

Mr. BILIRAKIS. But in the meantime, during this almost 11-month period of time—this nurse is no longer in the VA system?

Mr. DOHERTY. She immediately left the VA. We suspended her immediately and then terminated her. Upon completion of the investigation, she returned to her home in Puerto Rico. As I understand, now she is in Guam, but her license was pulled.

Mr. BILIRAKIS. Well, you know, there is a period of time there; in other words, during this approximately 11 months, she could have gone out, and maybe she did go out and get a job as a nurse someplace.

Mr. DOHERTY. You are absolutely right, sir, and this happened with the young lady we suspended for 30 days, she resigned and

went to work immediately for the Cedars of Lebanon Hospital, directly across the street from us—at higher pay, I might add.

Mr. BILIRAKIS. Well, and then what happened, did you plug her into the national data bank ultimately?

Mr. DOHERTY. Her offense was not reportable to the national data bank.

Mr. BILIRAKIS. It was not reportable?

Mr. DOHERTY. No, sir. There are certain parameters that we have to follow and requirements for reporting to the national data bank.

Mr. BILIRAKIS. By "the national data bank," they are not VA requirements, they don't come from headquarters in Washington?

Mr. DOHERTY. Right.

Mr. BRADSHAW. Excuse me.

Mr. BILIRAKIS. Yes, sir.

Mr. BRADSHAW. Mr. Bilirakis, I am Doug Bradshaw, Assistant General Counsel in the VA, and just to clarify the reporting to the data bank, for adverse personnel actions, the data bank takes reports on licensed physicians and dentists, but not nurses. For malpractice payments, we can report any licensed provider.

Mr. BILIRAKIS. For malpractice payments?

Mr. BRADSHAW. Yes, and in this case there was a malpractice claim filed, it was settled and upon settlement and payment of the claim, the data bank procedures went into effect at that stage and the nurse was reported for the malpractice payment. That is what the time lag was.

Mr. BILIRAKIS. Due process is very important and we don't want to watch a person, just because of a particular event which maybe has not been proven yet, that is a result of his or her negligence, to suffer. On the other hand——

Mr. DOHERTY. I think the unusual delay in this case, sir, was because of the tort suit claim that had been filed.

Mr. BILIRAKIS. And you felt—in other words, you didn't want to interfere with the legal process is what you are basically saying, I guess.

Mr. DOHERTY. Not exactly, not with the VA.

Mr. BILIRAKIS. Well, you know, Mr. Doherty—let me ask, do you hire your physicians? Who hires physicians, who hires nurses; do you have the kind of authority to hire people?

Mr. DOHERTY. Are you asking me?

Mr. BILIRAKIS. Yes, I am asking all three of you.

Mr. DOHERTY. Yes, sir. But our physicians—we have—naturally they go through a clearance, and the chief of staff and his staff and the credentialing of people, I mean, to make sure——

Mr. BILIRAKIS. The "chief of staff," meaning up here in Washington?

Mr. DOHERTY. No. The Chief of Staff at the Medical Center have the final say in the matter.

Mr. BILIRAKIS. Mr. Doherty, you indicated you were a paratrooper, you were wounded in action, et cetera, so you care about the veterans; and Mr. Kennedy talked about the strong feeling all three of you showed as far as caring is concerned.

If a person who is a medical doctor applies, and you find out that this person failed the test 10 times in succession, would you still hire them, him or her?

Mr. DOHERTY. I would probably stand to run the risk of losing my job, but I don't think I would, no, sir.

Mr. BILIRAKIS. Well, there has to be some courage, some guts here somewhere, for crying out loud.

Mr. DOHERTY. I would be very suspect of anybody that failed because, like with the bar exam, if you failed the bar exam seven or eight times——

Mr. BILIRAKIS. The bar exam is probably not life and death either, but here we are talking about life and death and we are talking about veterans besides.

Mr. DOHERTY. Yes, sir, I understand.

Mr. BILIRAKIS. And it kind of blows my mind to see these things happening. You know, perception, as we find out up here, sometimes is more significant than facts.

Let me get back to some of the cases. George Dillmore, the metro Dade police say unfortunately they have been uncooperative, we have not gotten anywhere with them. I don't understand what the big deal is; all we want to do is talk to the people who were there. Accidents do happen. Apparently they were stonewalled, right?

Mr. DOHERTY. Mr. Bilirakis, the metro Dade police know they have access to my office, to our security and police office. They did not contact us. They contacted a clerk in our Medical Release Bureau, and the young lady——

Mr. BILIRAKIS. She was unauthorized probably to talk to them.

Mr. DOHERTY. Yes. After reading about the article in the *St. Petersburg Times*, we contacted the officer. It took us 7 days to make contact with him.

Mr. BILIRAKIS. You tried to contact him?

Mr. DOHERTY. Then he finally contacted us and we are cooperating with him, we told him, you know, all the years we have been in business, the police department comes to us, police and security, we cooperate fully, but we have to be very careful of the Privacy Act.

Mr. BILIRAKIS. And I can understand, things happen and there is some sensitivity to them, and just anybody doesn't have the authority to talk to—whether it be law enforcement or whatever. But these things take place.

You know, the case of the American Legion commander, Mr. Fincham, I believe it was.

Mr. DOHERTY. Yes, sir, Fincham.

Mr. BILIRAKIS. Well, Mr. Fincham. The names off the top of other x rays were cut, the x rays involving Mr. Fincham's situation disappeared. No one owned up to altering the missing and defaced x rays. The hospital's associate director said Friday the x rays later turned up.

You know, it doesn't sound right.

Mr. DOHERTY. I can understand, Mr. Bilirakis, and I fully appreciate what you are saying. In the teaching setting that we—we are an affiliated medical school—the identity of the patient is removed from the x ray when it is used for teaching purposes. This probably

happened. I am not saying it did, but this probably happened in the case of Mr. Fincham.

And in the case of Mr. Fincham's death, I would like to say this. Mr. Fincham, God bless him, was a very, very heavy man, it took four or five nurses to get him back in bed when he fell out. He kept putting his side rail down, and he was always pulling his IVs out and pulling his tubes out; and we had a sitter with him, and there was no clear-cut evidence, but it is highly believed that he removed the tracheal tube himself and it was put back in by the sitter. We have no evidence to indicate otherwise, but we have no evidence to indicate that this actually happened. But I think it should be known.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

Mr. STEARNS. I just have two questions, I guess.

One, Mr. Doherty, I mentioned earlier, there is $53 million in malpractice insurance in fiscal year 1996; $4.4 million was attributed to your facility. No other facility had more than $3 million.

Can this be explained? Is this just an aberration?

Mr. DOHERTY. We are one of the most active medical centers in the State of Florida, and one of the busiest; and many of our patients come to us, believe me—I mean, we take care of very, very sick patients. I am not saying these cases were not legitimate, but I can cite one case that I have very strong, serious doubts about. I don't think anyone wants me to go into that, but I deeply regret that this kind of money has been paid out in the settlement cases, Mr. Stearns.

Mr. STEARNS. I understand.

Let me just conclude my questions, and Mr. Kennedy and Mr. Bilirakis can ask another series of questions afterwards.

Dr. Kizer has instituted new policy procedures. The Washington Post had an article yesterday where he says, basically, the simple fact is that too many adverse events happened as a result of medical treatment, and he says he is going to do all this new system—new policy.

What specific steps have been or will be taken at your facility to carry out that policy, and how will it be different if we come back here in 1998 and we are talking. And this is for each one of you.

Mr. DOHERTY. I would think the system—we are in a tracking mode now; we track everything that happens in hospital medication—errors and untoward incidents, everything else that occurs, this is tracked and documented, this is reported, and the database is set up so that we will know instantly, and all the care-givers will be given access to know, so that we can identify areas that have—that are suspect and that people can look into and find out just what is happening here, that we have so many errors, medication errors and other things.

So I think that Dr. Kizer is on—I think he is taking a very aggressive role in this thing. And he indicated to us in our meeting yesterday that he intends to set up a database where all of this stuff will be funneled into headquarters, and the medical centers, everyone will have access to know where things are occurring, why they are occurring, how can we prevent them, how can we stop them, what is necessary to change the system.

I think it is a wonderful step that he is taking.

Mr. STEARNS. Mr. Valentine.

Mr. VALENTINE. Well, I agree with Mr. Doherty. I think the VA handbook, 1051, is probably the most cutting-edge document that I have seen on risk management in health care for some time. Many of the issues covered in the handbook are activities that are going on within facilities at this time. I think the most significant area that must be put into place, if we are really going to reap any benefits from the changes, is that we need to be able at the facility level to learn very rapidly what has occurred at other facilities, what caused sentinel event to occur and what actions were taken to prevent a reoccurrence of it.

I think the failure in the system in the past has been that we don't find out about these things in a timely manner, like was said earlier in the panels, that information may sit in a room for 2 years with no follow-up action; and if the steps that are outlined in the VA handbook in fact are implemented, and that that processing house and headquarters in fact do disseminate the information to the facility, I think the facility will benefit from this.

Dr. HEADLEY. I would like to agree with the previous two speakers. I think that the VA has an opportunity to lead the way in the improvement of errors in medical care and the damages that occur, because we do have an integrated national system that is capable of pulling the information together and sharing it throughout the system.

I think that many of us have had very active quality improvement, performance improvement, risk management programs at our facilities, but we have not necessarily had the benefit of findings at other facilities. There have been times in the past when this information has been shared, but it has not been continuous. I think that the plan that is currently in place makes this a very real possibility, and makes us have the potential to really make some significant contributions to the national effort, not just the VA, but to the national effort of reducing errors in health care and deaths secondary to those errors.

Mr. STEARNS. When you mention the responsibility, we probably have a moral responsibility, even more so, than the private sector because these are veterans. Mr. Kennedy.

Mr. KENNEDY. Thank you, Mr. Chairman.

I want to come back to the issue we were discussing, Dr. Headley. I mean, I think that if you look at any profession where there are life-threatening situations, whether you are talking about a military situation, which has reasonably well-defined rules of engagement, if you look at the rules that police officers and fire departments or other people that are involved in the setting of health and safety of the American people, there are fairly strict rules and regulations which folks have to follow.

Now, as I understand, in the Boston situation where this fellow received the wrong blood, the two nurses that were involved in the transfusion still work at the VA facility. The anesthesiologist quit, so they took this on themselves to deal with what their future was, and the situation where the VA fired the anesthesiologist; no one going up the management scale in any way was penalized that I am aware of.

Is it your opinion that this was simply a situation where a procedure was in place that was inadequate, that had no—where there was no demonstrable responsibility by any health care provider to anticipate the risk that the patient was being put in?

Or, in fact, is this the kind of situation where, when the monitoring body of the government came in and looked at it and said, hey, wait a minute, this thing is not—you know, you guys aren't following the procedures that you ought to be here, and therefore we are putting you on hold and not giving you, you know, the sort of gold star or the green light on your current procedures, and you have got to bring your procedures up to a certain standard, and then you were going to then give them the kind of—the checkoff saying, you are in good shape? And if, in fact, it is the latter, is it your opinion that no one should have been fired, no one should have been in any way held accountable for this loss of life?

Dr. HEADLEY. Mr. Kennedy, we did a thorough Board of Investigation; at the time that this incident happened, reprimands were issued to the physician and to the two nurses involved in this.

Mr. KENNEDY. What does that entail, Doc?

Dr. HEADLEY. A reprimand is a letter and a counseling to an individual that there has been a problem with their performance, it is expected that this performance will improve, that they are being monitored for performance in this area, and that this letter goes into their personnel file.

Mr. KENNEDY. Permanently?

Dr. HEADLEY. It goes in for I believe a period of a year and it goes—it can be removed after a year.

Mr. KENNEDY. Were these removed?

Dr. HEADLEY. I don't believe they have been at this point in time.

Mr. KENNEDY. But you don't know?

Dr. HEADLEY. I don't know if they have been removed yet.

Mr. KENNEDY. Do you think that is appropriate? Do you think it is appropriate?

Dr. HEADLEY. That they be removed?

Mr. KENNEDY. I am trying to understand. You know, somebody died in this case.

Dr. HEADLEY. Yes.

Mr. KENNEDY. I am not an expert on what hospital emergency room or operating room procedures are, so I feel somewhat uncomfortable in trying to understand exactly whether or not there was greater risk and responsibility than is being owned up to here. And as I said before, it sounds like there is the possibility that that is the case, and I am trying to get a better understanding of whether or not this was simply a situation where, you know, year in and year out, we followed these certain procedures. It has always worked before and, gosh, nobody ever anticipated that this particular situation would occur; and therefore, somebody accidentally died, and now we have to go fix up what had been accepted, reasonable procedures.

This is a very different circumstance than, look, you know, there was a procedure set up over in this particular operating room that was half-baked, harebrained, and people were putting patients at undue risk, and as a result, an individual died.

You know, we have got two letters of reprimand that go into a file for a year; they are then withdrawn. And the anesthesiologist quits, and I don't know if he went off and got a better job, like the nurse did, but you are leaving open the possibility that accountability was not placed in order here, right, and that is what I am trying to get at.

Dr. HEADLEY. Yes, I think that we do take this very seriously. I think that we have policies and procedures in place in the operating room, in the administration of blood, that we expect people to follow.

We have a transfusion committee——

Mr. KENNEDY. I understand all that. I don't want to hear about all of the—I am just trying to understand whether or not the procedures that were in place were, in your opinion, adequate, given the historical record; or whether or not they were, in fact, inadequate.

Dr. HEADLEY. Yes, I believe that the procedures that were in place were adequate, given the historical record. The procedures of checking an arm band before you administer blood and checking it against the blood, for some reason, this procedure was not followed.

There was another procedure——

Mr. KENNEDY. So the procedure that was acceptable was not followed?

Dr. HEADLEY. It was not followed.

Mr. KENNEDY. And even though the procedure that was acceptable was not followed, the only thing that occurs in terms of disciplinary action is a letter of reprimand.

Dr. HEADLEY. That is correct.

Mr. KENNEDY. Do you think that is adequate?

Dr. HEADLEY. I don't know; I have thought a great deal about that.

We heard this morning from Dr. Leape about the need to change the way we approach errors of this sort to become less punitive, so that people will be forthcoming in discussing errors when they are made and trying to improve systems so that these will not occur; and Dr. Leape made some very compelling arguments about this this morning.

When we approached this, we approached it in a twofold manner; we approached it in looking at individual performance and we approached it in looking at systems problems.

Mr. KENNEDY. Well, if we have gotten to a point where we are now saying we are going to forgive, you know, just blatantly, sort of inadequate procedures and the performance of those procedures in order to have a greater amount of openness, you know, we are entering the realm of the bizarre.

I am all for having procedures where people aren't going to be hurt by coming forward with problems that exist in a system, but that should never get in the way of creating adequate responsibility on behalf of individuals to do their jobs properly, and—I mean, you know, if somebody isn't following procedures, and it ends up that a patient is killed—I mean, it is up—that is your job, to determine what is the proper way of handling it.

You can get a bunch of Congressmen to come up here and try to tell you that, but ultimately you are the VA administrator.

Dr. HEADLEY. That is correct.

Mr. KENNEDY. All right.

Mr. STEARNS. The gentleman's time has expired.

We have a vote, but I think we have enough time for Mr. Bilirakis.

Mr. BILIRAKIS. I will just hustle through this, Mr. Chairman.

Gentlemen, some Members of Congress claim that the VERA, the new resource allocation method, of course, which has not been in place all that long—and a lot of these problems occurred long before VERA—is the cause of poor patient care in areas of the country which receive under VERA less funding.

Do you, Dr. Headley, believe that VERA is having an adverse impact on those areas of the country, such as yours, for instance?

Dr. HEADLEY. I can't really say at this point in time. I don't believe that, as yet, we have experienced the full impact of VERA.

Mr. BILIRAKIS. There is one particular delegation that is very vocal here who are maintaining that and your delegation is not in that category, but I appreciate your honesty.

Mr. Doherty and Mr. Valentine, I don't know if you have any quick comments regarding that.

Mr. DOHERTY. I think VERA has enabled us to provide quicker access and faster delivery of service by opening up community-based outpatient clinics; and we have opened up two of them, and our veterans, I think, are now being better served. We get a lot of snowbirds down in Miami, so we are very grateful for the extra money we get.

Mr. BILIRAKIS. I am going to go on here, Mr. Valentine; if you will forgive me, I am going to finish it up. We have heard about new procedures put into place, and if you all were in the room, you heard my opening statement.

I think that VA health care is pretty darn good in general, but we have heard about some of the things that have taken place, we have heard that cultural changes need to take place, we have heard about how existing civil service laws make it very difficult, sometimes almost impossible, to fire Federal employees and how that is a problem—and, boy, I would like to spend a little more time on that with you, but time doesn't permit because of the vote. And we have heard that on October the 6th, a couple of days ago, VA announced a national effort designed to improve the safety of patients at its hospitals.

I guess some of you all, in responding to the Chairman and to Mr. Kennedy, you talked about certain ideas put into place. It seems to me practically every one of those ideas are common sense, and I sit here and I sometimes wonder, well, hell, why haven't they been in place all along anyhow? Does it take a newspaper article to kick this thing off? Does it take then Mr. Kizer—Dr. Kizer to basically maintain these things are put into place? It seems like good gentlemen, caring as much as you do, would have probably put some of these things into place all along.

We have heard during sexual harassment about, as I said before, a good old boys network and protecting one another and things of that nature. I tell you, the image is not as good as I think it deserves to be, because I don't think that health care in general is a bad system of health care or a bad quality of health care—maybe

that is the best way to put it—through my experience with the VA; and I have had some experience.

But we have got to do something about these things, and we invited Dr. Kizer—and I know the Chairman was going to reiterate the invitation, Dr. Kizer, to kind of tell us how Congress can help in terms of the changes that maybe can be made in the laws to be of some help. And I would strongly urge you—and we don't have the time now because of the vote—I would strongly urge you to submit your inputs to Dr. Kizer, and if Dr. Kizer ignores some of them, if you want to get them to some of us around the bend, so to speak, we certainly would welcome that.

But if we are going to help out here, we have to change, I think, our mental outlook, starting at the top and going all the way down to that clerk in the lobby when the VA member or when the family first comes in; and some of them are just not as courteous as they should be.

Having said all that, Mr. Chairman, thanks very much.

Mr. STEARNS. I want to thank my colleagues for their second round of questions, and I want to thank our panelists for their patience and waiting between votes and everything.

We now call the subcommittee of health adjourned.

[Whereupon, at 1:32 p.m., the subcommittee was adjourned.]

APPENDIX

Statement by Rep. Luis V. Gutierrez
Subcommittee on Health
Committee on Veterans' Affairs
U.S. House of Representatives
October 8, 1997

Thank you Chairman Stearns.

Allow me to reiterate the importance of the subject matter of this hearing today.

Improved patient safety and the prevention of unplanned clinical occurrences is a goal we all wish to achieve.

In this regard, the Department of Veterans Affairs, our nation's largest health care provider, is no different than non-governmental health care providers.

However, the VA serves a unique patient base and thus carries a unique responsibility to address patient safety.

The VA, as a government provider, is also under the budgetary constraints imposed upon it by Congress.

And because this committee is responsible for oversight of veterans health issues we are also responsible for the health of veterans who use the VA for medical purposes.

I believe this hearing is particularly timely.

Unanticipated deaths at a number of VA medical facilities have raised our awareness of patient safety issues and the adverse medical effects that occassionally result from medical treatments.

The statistics do not point to a greater number of unanticipated deaths at VA hospitals nationally for this year, but cases in Ohio and in upstate New York demonstrate the need for new approaches to be developed and implemented to address this problem.

I am pleased to see the VA start this process. The VA's recently announced partnership to address these important issues in conjunction with other national health care organizations, such as the American Hospital Association (AHA) and the National Patient Safety Foundation of the American Medical Association (AMA), is certainly a positive step.

The implementation of a comprehensive risk management strategy with concrete proposals for preventing injuries to patients, visitors and VA employees is also a useful endeavor that should help the VA synchronize its efforts throughout the system.

Ensuring the quality of care throughout the VA is vitally important.

Dr. Kizer you have admitted that health care quality varies from hospital to hospital, that some hospitals are better than others, and that some facilities have more reports of adverse events than others.

For me, this variance from place to place means we are letting some veterans down and I believe that by failing to offer the best quality health care to all veterans, regardless of location or network, we in turn let all veterans down.

To address this problem, the recent actions of the VA must be followed by more tangible steps.

Access to information must be improved. The reporting of adverse events in VA hospitals is even more inconsistent than the health care.

A formal structure should be established to ensure that incidents of this nature are reported promptly throughout the system.

In addition, the numbers of adverse events, facility by facility, year after year, must be chronicled.

We cannot determine if VA health care has improved unless we have reliable statistical evidence. The VA must make this an urgent priority.

Allow me once again to express my support for what the VA is currently doing to improve patient safety. These are positive steps worth commendation and they should help us all understand the true nature of this problem and assist in the creation of innovative solutions.

I thank you all for joining us here today to discuss this important issue and I look forward to questioning the witnesses later this morning.

Mr. Chairman, thank you again.

THE HONORABLE JOSEPH P. KENNEDY, II
Opening Statement
before the
Committee on Veterans Affairs
Hearing on Improving Patient Safety

October 8, 1997

Thank you, Mr. Chairman, for holding this hearing today to decide what we can do to reduce errors and improve patient health care at VA Medical Centers. I want to welcome everyone who is here to testify, especially Dr. Elwood Headley of Boston's Veterans Affairs Medical Center, and Dr. Lucian Leape of the Harvard School of Public Health.

We must acknowledge that accidental injury and death does occur in our VA hospitals, and in public and private hospitals across the nation.

Dr. Leape made very good points in his testimony that human beings are not perfect, and that health care professionals do make mistakes. And he also pointed out that health care professionals are blamed for being careless when they make mistakes. But in fact, these mistakes are accidents waiting to happen due to the system - such as working double shifts and having twice as many patients to take care of. This causes fatigue in our doctors, nurses

and pharmacists. Inevitably, mistakes happen. And tragically, sometimes they happen at the expense of the lives of our patients.

A tragic human error happened at the Boston VA Medical Center on March 5th of 1996, when Peter Anderson, an Army veteran who served in the Korean War, died after he was given a transfusion of the wrong blood type during surgery. The Boston VA Medical Center acknowledges this tragic human error and has taken corrective steps to try to minimize the chance this will ever happen again.

Three days after the tragedy, the Boston VA began an investigation and improved their process of verifying patient IDs and their process of dispensing blood for transfusions. In addition, all hospital personnel are required to participate in programs on risk management, especially in the operating room.

I am pleased to announce today that the Boston VA Medical Center was just surveyed last month by the Joint Commission on Accreditation of Healthcare Organizations, which gave Boston a rating of 96. This is an "A." It shows Boston is achieving safe, quality health care for its patients and is doing its best to minimize mistakes. I want to congratulate Dr. Headley for the high rating.

In general, we need to take corrective steps throughout our VA hospitals and our healthcare system across this country.

We must put a stop to the statistics that indicate a million patients are injured by mistakes in treatment each year, and that 120,000 of them die. We must develop a national system to track mistakes and implement effective corrections. We owe this to the families of patients we have lost through tragic mistakes, and we owe it to incoming patients who put their trust in health care professionals.

Thank You, Mr. Chairman.

The Honorable Michael Bilirakis
Subcommittee on Health
October 8, 1997

Hearing on the Prevention of Adverse Events in
the Provision of VA Medical Care

Thank you, Mr. Chairman.

First, let me take this opportunity to commend you for scheduling this hearing. I also want to thank you for postponing this hearing from an earlier date so that I would be able to participate today. Unfortunately, a scheduling conflict would have made it impossible for me to attend the hearing on September 25th so I appreciate your cooperation on this matter. I would also like to welcome T.C. Doherty, the Director of the Miami VA Medical Center, to Washington.

Today, we are going to be examining the issue of "adverse events" in the provision of VA health care and what is being done to prevent such incidences from occurring. An adverse event is generally described as "an unintended injury that was caused by medical mismanagement and that resulted in measurable disability."

Earlier this year, one of my district newspapers printed a series of articles on VA health care. These articles chronicled the stories of a number of patients who died unexpectedly because of "adverse events." The paper reported that at least 23 veterans have died under unusual or avoidable circumstances at 17 VA hospitals and nursing homes around the country since 1993. These articles also recounted a series of mistakes that resulted in the deaths of 23 veterans in Florida.

The accounts of the "adverse events" that led to the deaths or injury of veterans in VA medical facilities were disturbing. According to the news articles, two veterans suffered fatal burns in scalding bath water. Three more died after nurses gave them the wrong blood type. Another veteran receiving dialysis lost nearly two quarts of blood while his nurse talked on the telephone. Insulin overdoses, poisoned oxygen and malfunctioning equipment resulted in the deaths of other veterans. In some instances, misdiagnosis, delay or fragmentation in care led to the deaths of VA patients.

Even more disturbing were the actions of some VA employees after the certain incidents occurred. In the case of the dialysis patient, the nurse and other employees attempted to cover up the incident by cleaning the area and hiding the information from the team that came to revive the patient. The nurse was eventually fired and the other employees were disciplined.

After reading these articles, I requested that our Subcommittee hold a hearing on these incidents. As members of the Subcommittee with jurisdiction over VA health care, it is incumbent upon us to investigate these incidents and whether or not adequate steps have been taken to prevent the same thing from happening again.

As tragic as these incidents are, the purpose of today's hearing is not to condemn the VA health care system. In fact, I have always believed that the VA health care system is a national asset that provides high quality care to our nation's veterans.

Throughout my congressional career, I have visited many VA medical facilities and met hundreds of VA employees who are dedicated to providing veterans with high quality care. Over the years, I have also heard from many veterans who have taken the time to share their positive experiences at VA medical facilities with me.

Moreover, adverse events are not unique to the VA. A 1993 Harvard study estimated that one million preventable injuries and 120,000 preventable deaths occurred in American hospitals in a single year. While we would obviously prefer that adverse events never occur at any hospital, it is unrealistic to think that such incidents can be completely eliminated. After all, medical care providers are human and mistakes will occur if only by human error.

Rather than set an unachievable goal, it is the responsibility of this Subcommittee to ensure that when an adverse event does happen, it is properly investigated by the VA in a timely manner. Moreover, it is important that the VA establish appropriate risk management policies to prevent such events from reoccurring. We must also conduct proper oversight to ensure that these risk management policies are being followed by VA medical personnel.

This is particularly important because of the significant changes that have taken place within the VA health care system over the last two years. These changes were designed to reduce health care costs and increase the timeliness of care provided to veterans. As the reorganization of the VA health care system continues, we must monitor the impact that these changes have on the quality of care that veterans receive in VA medical facilities.

Simply put, veterans deserve to know that they will receive the highest quality of care at our VA medical facilities. It is our job to make sure that they do.

Once again, Mr. Chairman, I thank you for scheduling this hearing. I look forward to working with you and the other members of the Health Subcommittee on this important matter.

STATEMENT OF LANE EVANS
RANKING DEMOCRATIC MEMBER
HOUSE VETERANS' AFFAIRS COMMITTEE
TO SUBCOMMITTEE ON HEALTH
HEARING ON VA'S PREVENTION OF ADVERSE EVENTS
OCTOBER 8, 1997 at 10:00 AM

Thank you, Mr. Chairman. Today, your subcommittee will examine an issue that is of the gravest concern to veterans—an issue that goes right to the heart of the quality of their health care—the processes and systems the VA system uses to prevent avoidable patient deaths and injuries. The cases the media presents to us on medical practice gone awry are often sensational and graphic. They cast indelible images for all of us—I am touched by these tragic events and join others in being outraged over mistakes or clinical negligence that cause them. Some indicators tell us that VA has no more of these unexpected deaths or injuries than other providers. And yet the stories we hear about VA providers going through major changes that appear to result in lower quality care for veterans lead us to believe it is our duty to assess the systems VA uses to ensure patient safety.

While it is both necessary and appropriate for us to investigate the systems and procedures VA uses to manage risk and also for us to understand whether VA has more of these events than other providers, it

would be unfortunate for us to view sensational events as representative of the health care VA generally provides. As shocked as we are, we need to keep these events in perspective. Every system has its warts—one of our Committee staff members shared an experience with us about potentially life-threatening mistakes in her father's care under one of the nation's pre-eminent health management organizations. *WE MUST NOT CHARACTERIZE THE VA SYSTEM BY THESE UNFORTUNATE OCCURENCES,* but rather explore how they happened and ensure that VA *NEVER ALLOWS SIMILAR EVENTS TO HAPPEN AGAIN.*

The testimony we will hear today indicates that the Veterans' Health Administration is trying to deal constructively with these distressing isolated incidents. We also have objective criteria to help us assess quality and performance. For example, all VA medical centers voluntarily comply with the Joint Commission on Accreditation of Healthcare Organizations criteria—a mark of quality sought be many health care providers. Many facilities have been awarded accreditation with commendation. Numbers of reported incidences of adverse events have decreased since fiscal year 1994. I also commend VHA for the initiative it has undertaken along with the American Nurses Association, the American Hospital Association, the National Patient Safety Foundation, the American Medical Association, and others to improve

patient safety. VHA has a long history with risk management and recently put in place a revised protocol for dealing with adverse events. It appears to address some very complex issues involved in the reporting, tracking, and response to so called "sentinel events". External parties have reviewed their procedures and will tell us that VA appears, both in policy and practice, to take these events very seriously indeed.

Some of the events we will hear about today could color our opinion of VA forever. We could indict VA for its health care quality (whether or not it is different from other providers) based on our feelings about these events. Or we could move forward to address the systems that ensure the prevention of these events are sound and that VA is taking concrete steps to correct systematic deficiencies. I believe this is the more constructive of the two approaches and I will look forward to hearing more from our expert witnesses today to learn how we can improve VA's systems.

Thank you, Mr. Chairman that concludes my testimony.

Statement of Rep. Maurice D. Hinchey
House Veterans' Affairs Committee
Subcommittee on Health
October 8, 1997

I believe we would all agree that the purpose of the Veterans' health care system is to assure our veterans that they will always have access to quality health care. It has changed and evolved over the years, as it should, but that commitment remains its core purpose.

Today most veterans do not come to the VA for health care, often because they do not need to and sometimes because it is inconvenient. They use non-VA facilities; the cost is often covered by Medicare or by employer-paid insurance. The VA now recognizes that it is not always convenient or appropriate to provide care at its hospitals, and has begun developing outpatient clinics and other means of providing services to veterans closer to home. I think the VA deserves to be commended for this effort. However, that should not mean that the commitment to provide quality health care at its own hospitals will be relaxed or abandoned. The VA hospitals should continue to provide quality services to those veterans who continue to need them.

Unfortunately, that has not always been the case. I would like to call to the subcommittee's attention the problems at a VA hospital that serves many of my constituents, the hospital at Castle Point, New York. I am concerned that--for whatever reason--the quality of care at Castle Point has deteriorated. Many of our veterans have lost their confidence in Castle Point, and to a considerable degree, in the VA itself.

All of us who represent veterans in the Hudson Valley have lodged numerous complaints with the VA about the situation at Castle Point. We have had numerous meetings about it with VA administrators, up to and including former Secretary Brown and Acting Secretary Gober. I think it is fair to say that we know our complaints have been heard, we know that the VA is paying attention, but we don't yet know if the problems will be resolved in a way that addresses the needs and concerns of the veterans that Castle Point is supposed to serve.

I would like to submit a written statement for the record which includes several detailed case histories of serious problems that some of my constituents have encountered at Castle Point. I want to emphasize that the cases in my statement represent only a small sampling of the many complaints I have received. I have been disturbed not only by the number of complaints, but also by the wide range of problems that have been reported to me. They include allegations about misdiagnosis, errors in treatment, and surgical mistakes that suggest serious incompetence. They include complaints about poor relations between doctors and patients, and the inability of doctors to

communicate with patients--a problem that Undersecretary Kizer confirmed in our most recent meeting with him. They include complaints about shortages of professional nursing staff and allegations that patients have been neglected as a result of these shortages. I have heard allegations as well about unsanitary conditions, poor maintenance of the facility, and misapplication of funds.

Many of our veterans have expressed concern that the VA may be ignoring these problems because it is concentrating too much effort on more abstract management issues--most importantly, the shift of funding known as VERA. The VA has told us repeatedly that VERA would not reduce services or compromise quality of care at Castle Point--but that is what seems to be happening. Undersecretary Kizer recently told us that there were "notable problems" at only four VA facilities that were being consolidated--but he did not include Castle Point on that list. I want to make it clear that I believe that the problems at Castle Point are indeed "notable."

At my request, as the Committee knows, the VA's Inspector General is conducting a thorough investigation of the problems at Castle Point, including reports of an increased mortality rate, declining quality of care, quality and adequacy of the staff, and the effects of resource allocation on Castle Point. We will be eager to see that study when it is complete. In the meantime, I hope the committee will consider some of the broader questions about government management and VA management that this situation has raised.

Specifically, these are some of the issues that concern me. Is management of VA health care being driven by computer analyses and allocation formulas, while actual day-to-day conditions and the concerns of individual patients and their families are ignored? If so, how can this be remedied?

Does the problem lie with applying uniform rules and standards and salary schedules across the country? Is it harder, for instance, to find good physicians and nurses in New York than in some other places?

Would the problems be alleviated if there were better communication between VA administrators and veterans? Is it possible to require clearer communications, as in the regulatory process, for instance? We have heard constant complaints that veterans' concerns are ignored, that they are not notified about changes in services provided, that they are not consulted.

Finally, and perhaps most importantly, are the problems attributable to a shortage of funds? VA administrators have suggested this to us on several occasions, and I have asked several times if they need more money to provide the services veterans expect and deserve. I haven't had an answer. Congress may be at fault here by imposing arbitrary budget ceilings; the

Administration may be at fault in its budgeting process. I don't know. But if cold, hard budget decisions made in an analyst's office in Washington mean that a diabetic veteran in New York is left unmonitored and ignored, then the public needs to know that. The VA has suggested to us that this may be the case. We should try to find out.

SUE W. KELLY

Congress of the United States
House of Representatives
Washington, DC 20515–3219

Statement of Congresswoman Sue Kelly (*NY-19*)
Hearing on the prevention of adverse events in the provision of VA medical care
House Committee on Veterans' Affairs, Health Subcommittee

Wednesday, October 8, 1997 -- 10:00 AM; 334 Cannon House Office Building

---

Chairman Stearns, Ranking Member Gutierrez, I want to thank you for allowing me to present testimony before the House Veterans Affairs Subcommittee on Health. I cannot think of a more important issue for veterans nationwide than the proper oversight of veterans medical care facilities to ensure that our veterans receive only the best medical care possible. Today's hearing, examining "unusual or avoidable" deaths at VA hospitals must take a strong look at the two VA medical centers -- Castle Point VAMC and FDR Montrose VAMC-- in my district.

For the past 15 months, we have seen an appreciable drop in the quality of care at these two facilities. Keep in mind, this occurred during the preparation for, and implementation of, the VA's Veterans Equitable Resource Allocation (*VERA*) program, which has resulted in a shift of $180 million from our New York area VA facilities to those elsewhere in the nation. While we are not absolutely certain of a concrete connection between these reports and the VERA plan, we have certainly seen volumes of anecdotal evidence that suggests otherwise. Plus, Mr. Chairman, it was only ***AFTER*** reports of aberrant deaths and highly suspect quality care surfaced from local veterans service organizations (*VSOs*), as well as area media outlets, that positive changes have been instituted at these two facilities.

In early August, Congressman Gilman and I prevailed upon Congressman Shays, Chairman of the Human Resources Subcommittee of the House Government Reform & Oversight Committee, to convene a field hearing in Middletown, New York, examining these reports of diminished quality care. At this event, we heard from more than 100 veterans and family members who shared their personal experiences with those of us on the panel.

The stories they related were heart wrenching. One man was admitted to the hospital by his wife for treatment of a broken hip, and ended up being transferred three times between the Castle Point, FDR Montrose and Brooklyn VAMCs, before he then developed an infection and died. Another man tearfully described how he had admitted his wife for a seemingly minor medical treatment, only to have her die nine days before their 52nd wedding anniversary.

Similarly, a young woman related how her father was released from Castle Point with

only a so-called "virus". Yet, two weeks later, she had to rush him to a non-VA hospital where her father was diagnosed with a perforated ulcer within hours after he was admitted. However, due to his advanced condition, he passed away that same evening, for no other reason than poor quality care at our VA hospitals. I would like to ask unanimous consent that articles that detail these and other such cases be made part of the record.

My greatest concern is the reduction in the quality and accessibility to health care that veterans deserve, and depend on, through our nation's VA medical facilities. While VERA is a three-year plan that officially went into effect on April 1, 1997 the changes to the VA facilities in my VISN began as early as late September 1996. In that time, my office has been inundated by reports of reductions in the quality of care that veterans receive.

As we speak, the VA's Medical Inspector is undertaking what it describes as a rigorous and in-depth examination of the conditions at the Castle Point and FDR Montrose VA Medical Centers. Unfortunately, the results of this probe will not be available for at least two months. Meanwhile many of my colleagues and I worked to secure language in the *FY 98' VA-HUD Appropriations bill* requesting an additional GAO study that examines the impact of VERA in the most adversely impacted regions and reports of reductions in quality care.

Hopefully, the GAO report and the result of the VA medical inspectors investigation will shed some much-needed light on some of the unintended consequences of VERA's implementation. So while I have no idea what may or may not be in these reports, I have faith that the GAO will conduct a fair and honest accounting of the situation, just as they have in their past review of the VA and the VERA program.

On September 17, 1997 the GAO released a report that outlined the current problems with VA oversight of VA Medical Facilities. As background, in my area of the country we have the highest number of specialty care veterans nationwide. As you know, speciality care veterans are the most expensive to treat, the national price for speciality care is $35,707 per veteran per year. In it's September Report, the GAO concludes:

> "Moreover, VA lacks measures for monitoring changes in special patient category services, which include the most expensive services VA delivers. Monitoring these changes is important because of [the VA's new spending plan] incentives to reduce the cost of patient care and because of [the VA's new spending plan] incentives to reduce the cost of patient care and because the special care population is particularly vulnerable. ...some [veterans service areas] are increasing the number of patients served in VA-operated nursing homes without increasing the number of beds or staff available by reducing patients' average length of stay."

Because of this conclusion, GAO made the recommendation for the VA to:

> "...improve oversight of [veterans service areas'] allocations of resources to their facilities by (1) developing criteria for use in designing [veterans service areas] resource allocation methodologies; (2) reviewing and approving the resulting methodologies, and (3) and monitoring the impact of these methodologies on veteran's equitable access to care."

In response to that recommendation Secretary-designee Gober replied:

> "I believe that the oversight now provided to the [veterans service areas] is appropriate and that managements's focus should be on performance outcomes rather than on dictating inputs."

By overlooking this warning by the GAO the VA is putting the most vulnerable veterans, the speciality care veterans, of which I have the highest number, at risk. I ask that you get a full commitment from the VA to truly make the VA monitor the implementation of this new spending plan as closely as possible.

Also, in GAO's May 1, 1997 report on *VA Health Care -- Assessment of VA's Fiscal Year 1998 Budget Proposal*, the GAO notes several warnings about the implementation of VERA: **1)** potential risks and vulnerabilities that these changes pose to low-income uninsured veterans; **2)** that VERA many shift some resources inappropriately because it may not fully account for justifiable differences in regional cost variations; **3)** that the VA may not have taken into account, for example, that veterans are sicker and need more health care services in different parts of the country, so that additional case mix adjustments may be necessary to fully explain regional cost differences; and **4)** that VERA's incentives for lower per veterans costs and higher workload numbers could lead to unintended consequences.

Finally, the GAO report concludes that "Delaying a decision on VA's legislative proposals until such critical information is available -- including a plan describing how the system will look and operate in 2002 -- may result in a better legislative decision on VA's budget proposal. It will also afford VA and the Congress time to better assess how VA's future resource needs may be affected by the new decentralized management and resource allocation initiatives."

It is this very "delay" that I have been pressing for over these past nine months, and will continue working for until we get all the answers from the VA. I ask the Committee to take into account the conclusions of these two GAO reports. The attached articles are only a sampling of what I believe are the noticeable effects of VERA on only two VA Medical Centers in VISN 3 over the past ten months.

I thank the Committee for affording me this opportunity, and taking these accounts into your consideration.

Deaths rise at VA hospitals

Families say blame rests on staff cuts

By BETH MULLALLY
Staff Writer

CASTLE POINT — The death rate has doubled at two local veterans hospitals since October, when deep staffing cuts and a major reshuffling of resources began.

At Castle Point VA Medical Center in Dutchess County, the monthly death rate has steadily trucked upward, from seven to 14 deaths per 100 patients.

Between Jan. 1 and April 29, 71 men died at Castle Point. In previous years for that same four-month period, there was an average of 36 deaths.

The death rate is rising even as the hospital's patient capacity has dropped from 278 beds to 198 beds. The hospital has an 82 percent occupancy rate.

At the FDR Veterans Hospital in Montrose in Westchester County, which formally merged with Castle Point last month, the death rate steadily increased by 80 percent between October and March.

Penny Koustoubakis, director of public affairs at Castle Point, said about 200 jobs have been eliminated at both hospitals since last fall when the Department of Veterans Affairs began to streamline and restructure services.

The staffing cutbacks are part of a plan to shift millions of dollars worth of veterans' medical care out of New York to the South and West, where high numbers of retired veterans live. New York will lose about $180 million annually in the shift.

MaryAnn Musumeci, acting director of both hospitals, said the steady increase in the death rate is "not significant."

"You have ups and downs," she said. "Part of the increased death rate at Castle Point is due to the fact that the medical ward at Montrose has closed down, so sicker patients are transferred to Castle Point."

The medical ward at Montrose closed in December. The transfer of sicker patients does not explain why the death rate at Montrose has also gone up in the same period.

"We're in a period of transition right now," said Ms. Koustoubakis. "It's hard to look at that data (death rates) and draw conclusions. We're still in the process of improving our services and being more efficient."

She said she's heard no reports of patient neglect as a result of the increased workload shared by fewer workers.

But two staff members inside the hospital system, as well as two patients' families, said patients suffer because the staff has no time to feed those who can't feed themselves. In many cases, the solution has been to hook the patients onto feeding tubes.

These sources also say staff members don't have time to get patients up and out of bed, so many patients can spend all their time lying in the same position.

Rep. Sue Kelly's office is investigating conditions at the hospitals, including an incident in which doctors attending a staff meeting at Castle Point left their beepers outside the room so they wouldn't be disturbed. According to Kelly's office, the intercom system was supposed to serve as back-up. When an emergency occurred on the medical ward during the meeting, the nurse tried to summon a doctor for help over the intercom system. The intercom failed, and the nurse was unable to go get the doctor because she was alone on the floor. The patient died.

Kelly, R-Katonah, whose district includes both hospitals, said she and other local congressmen voted in favor of the bill that shifted resources to the South and West because the potential impact on New York was unclear at the time of the vote. She has since introduced a bill to block the cost-shifting, but the bill stands little chance of passing.

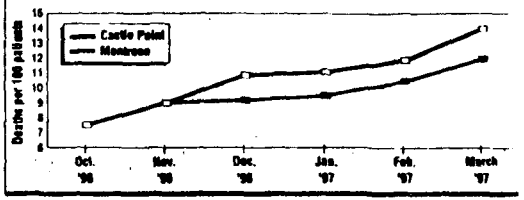
"With a mortality rate that's doubled, we're already seeing a very real impact," said Dan Boston, spokesman for Kelly. "We don't want to point fingers, but we want to make sure the federal government understands there are very real human consequences going on here."

Gerry Cullifton, a spokesman for the VA hospital network in southeastern New York, said the hospital administration is "looking top to bottom at both hospitals to make sure adequate patient care is being provided.

"If there are people out there with information about poor patient care, we want to know about it right away. It's our job to make sure veterans get good care."

Times Herald Record
(*Middletown, NY*)
May 13, 1997

VA hospital deaths rise sharply



INSIDE TODAY:

Yanks win in 12th
O'Neill's homer beats Minnesota 6-5, **1D**

New deal on NATO
Russia gets voice, little else on expansion, **1B, 3B**

Getting outside
Music, outdoor events abound, in **Weekend**

ocal
pdate

man won't run

...ana Mayor Sy
...on yesterday announced
...down-to-the-wire of the
...town, citing family
...illness. Behind him
...councilman William
..., a Democratic
...e to replace Schulman.
...spoke to supporters on
... of City Hall. Story, 11A

THE REPORTER DISPATCH

Wednesday, May 15, 1997 ©Gannett Suburban Newspapers http://www.rynews.com 50 cents

VA hospital deaths soar

Lawmakers demand probe as numbers climb at Montrose, Castle Point amid budget cuts

By [illegible]
Staff Writer

John Mayon was supposed to get regular exercise when he entered the FDR Veterans Affairs Hospital Center in Montrose in September 1995. Instead, his family says, he's spent so much time in bed that his legs are now permanently contracted.

But that's not the worst of it. In March, a worker at the hospital gave his family an even greater shock.

"Somebody at the hospital told me that they had had a lot of deaths," his daughter, Anne Nelson, said yesterday. "And they told me that out of remorse for my father."

Records show patient deaths at the Montrose facility, and at Veterans Affairs Medical Center at Castle Point in Dutchess County, have roughly doubled in the past four to six months. Federal lawmakers, citing recent funding and staffing cuts at both hospitals, are clamoring for an investigation.

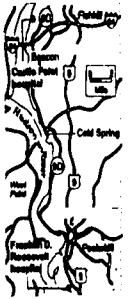
"It looks as though there is a steadily increasing death rate since about January," Rep. Sue Kelly, R-Katonah, said yesterday. "If that is so, then we really need to do something."

Kelly and 17 other New York representatives have called for an investigation and want a public briefing from Veterans Affairs Secretary Jesse Brown by Tuesday. Figures provided by the Department of Veterans Affairs to Kelly's office show an 80 percent increase in patient deaths at Montrose since October.

At Castle Point, patient deaths nearly doubled — from 34 to 73 — during the first four months of this year, compared with the same period in the previous three years.

At the same time, the two hospitals, which merged last month, have cut a combined 300 positions as part

Please see HOSPITALS, 3A



Urban renewal:

House staff pay can top

Hospitals: Number of deaths soars

Continued from page 1A

of a nationwide confiscation of Veterans Affairs medical funds.

The agency, which allocates $17 billion annually among 22 regional hubs nationally, began shifting funds quickly out of the New York area in the fourth and final half.

It formally announced the shift in January by saying more veterans were moving to these areas.

The changes, Kelly said, mean that Veterans Affairs facilities in the New York metropolitan region, which includes the lower Hudson Valley, stand to lose $200 million in the next five years.

Kelly and other lawmakers protested the cuts last winter and now want the money restored in light of the mortality-rate increase.

Gerry Cullinan, a regional Veterans Affairs spokesman, disputed the mortality-rate figures. He said the staff cutbacks at the hospitals did not involve patient care.

"We feel very strongly that our data indicate that there are no significant changes in the deaths at either facility, and the quality of care has not been compromised in any way," Cullinan said.

The spokesman said the department told Kelly and other lawmakers that the information they received was inaccurate. The department was cooperating with them fully, he said.

Nelson, whose father is being treated for Alzheimer's disease, prostate cancer and diabetes, said she didn't know about the shift in funding.

"But when I went back through my records, all of them problems really began for us in November-December and have gotten worse," said Nelson, a registered nurse from Montgomery in Orange County.

She had her father transferred to Castle Point last month.

"I wanted him out of Montrose," she said. "I didn't know at that point that Castle Point had the same problem."

Cullinan said the veterans department had been working with members of Rieyere family for months to address their concerns.

The Montrose facility, opened in 1950, treated 10,200 vets in 1996, a 28 percent rise from 1995. Castle Point, which opened in 1974, treated 8,700 veterans last year, an increase of 7 percent from 1995.

Urban: Redevelopment mixes success with loss

Continued from page 1A

[redacted]

urban renewal say they were shocked by the sudden demolition. "I didn't think it would affect me," said Pauline Enos, who lived on Fisher Avenue across the street from the renewal zone. "All of a sudden, my whole world went down in front of me. There was nothing left."

The McBrien family has watched the changes from their front porch on Barker Avenue, now surrounded by parking lots and condominiums.

"Everything looks like a cardboard box," said Frank McBrien.

White Plains, transformed

A Looking east on early model for the urban renewal area. The plan called for an elevated highway, a new city hall and a cultural center.

Before

Briefing

New York City

Effects of rent control

A city-sponsored report claims ending rent controls on vacated apartments would have limited impact in the first two years, but a top city official says policymakers should beware of unforeseen, long-term effects. 19A

Nation

Cancer study

Women with certain genes that strongly increase their risk of breast cancer could live an average of three to five years longer by having their breasts removed at age 30 while they are still healthy, a study finds. 4B

World

Post cold-war relations

NATO and Russia agree on a landmark accord outlining post-Cold War security. 1B

Business

Get spinning

Health clubs are forgetting the Stairmaster, step aerobics and the other trends in fitness. Today, to get the customers they need to spin. 1E

Lifestyles

Families describe de

TH Record 5/15

Heat on local VA hospitals mounts under calls for probe

By BETH MULLALLY
Staff Writer

CASTLE POINT — As officials in Washington continued to demand answers about rising mortality rates at Hudson Valley VA hospitals yesterday, several local families came forward to tell their own stories about poor care and unsanitary conditions at Castle Point Medical Center.

In Washington, Rep. Benjamin A. Gilman, R-Middletown, introduced legislation Tuesday night that would stop the transfer of funds from VA hospitals in the Northeast to those in the South and West.

A bill passed by Congress last fall — the Veterans Equity Resource Allocation, or VERA, will cost New York VA hospitals $180 million in funding. All of the New York delegation voted for the shift in funds, but the amount of money involved and the effect of the shift was not clear at the time of the vote.

"While no definitive link has been established between VERA and the increase in deaths at Castle Point and Montrose," said Gilman, "this possibility cannot be discounted."

Since October, when 200 positions were eliminated at the two hospitals, the mortality rate at Castle Point has doubled. At Montrose, it has gone up by 80 percent. Families and hospital sources said patients are being neglected because they are short-staffed.

Rep. Sue Kelly, R-Katonah, drafted a letter Monday to Veterans Affairs Secretary Jesse Brown asking for an immediate investigation into the rising death rates and the allegations of neglect at both hospitals.

Members of New York's delegation are working as a bloc on the matter.

"I absolutely want to know what's going on in these hospitals," said Rep. Maurice Hinchey, D-Saugerties. "This needs public attention immediately."

Gerry Cullinton, a spokesman for the VA hospital network in Southeastern New York, said Monday that The Times Herald-Record report on the rising death rate was "totally inaccurate" despite the fact the numbers were based on Castle Point's own data. He said officials were "putting together a response." The response was not available yesterday, however.

At same time, dozens of veterans or their families have contacted The Times Herald-Record and congressional offices to make public their own stories of neglect and poor conditions at Castle Point.

Among them are the following stories as told by the families. Hospital officials are unable to comment due to patient confidentiality:

● Harold Niver, 78, of Cold Spring, was admitted to Castle Point on March 24 with severe abdominal pain. For two weeks, doctors there told his family it was "probably just a virus," according to Niver's granddaughter, Cindy Trimble of Beacon.

"During the time he was there, the man in the bed next to him, Charlie, called us on at least six occasions," said Ms. Trimble. "You better get up here,' he'd say. 'Harold needs help, and no one's coming.'"

On several occasions, Niver needed a bed pan because he'd developed diarrhea.

"When we got there, Charlie told us he'd been asking for a bed pan for five hours and never got one," Ms. Trimble said. He soiled himself and his bed as a result.

On another occasion, he developed severe chest pains. The nurse gave him nitroglycerin and told the family it was probably angina or a panic attack.

Because his condition had worsened, the family demanded he be transferred to Hudson Valley Hospital Center in Peekskill on April 8. Within an hour of their arrival, the doctor there found bacteria in his blood, indicating widespread infection, and determined that Niver had a perforated ulcer. It was also determined that his chest pain had been a heart attack.

Emergency surgery was performed at 11:30 p.m. but the infection was too widespread to save him. He died April 10.

● Thomas Cragan, 65, of Walden, was admitted to Castle Point on Feb. 7 for surgery to remove his esophagus. Doctors there had found a stage 3 pre-cancerous dysplasia and recommended the surgery, according to his son, Michael Cragan of Walden.

A specialist, who the family never met, was called in to do the surgery.

"Afterward, we were told the surgery was a success but that they'd accidentally nicked his spleen and had to remove it," Cragan said. "They said it was no problem because a man of his age doesn't need a spleen."

Cragan was sent to the hospital's intensive care unit for four to five days, where he was tube-fed and received oxygen through a tube.

"They put him into restraints because the tubes were uncomfortable, and whenever the morphine wore off, he was trying to pull them out," Cragan said. "But on the third day, they failed to restrain him, and he pulled both tubes out."

The tubes were not replaced. A day and a half later, Cragan vomited. Because the vomit was trapped, he inhaled it into his lungs. He developed chemical pneumonia as a result, and his organs began to fail.

"Everything just shut down," Cragan said. "He gradually lapsed into unconsciousness and stopped responding."

Thomas Cragan died March 18.

"I'm convinced that it was the poor post-operative care he received that caused his death," said his son.

● Allen Tvrdik, 66, of Walden was admitted to Castle Point with congestive heart failure in mid-February.

"It was the only place he was willing to go because, in the past, he'd had wonderful experiences there," said his daughter, Linda Platt, of Gardiner.

This experience would prove different.

Michael Cragan and his sister Patricia St
their father, Thomas Cragan, who served

es describe deaths

'A hospitals calls for probe

confidentiality:

● Harold Niver, 70, of Cold Spring, was admitted to Castle Point on March 24 with severe abdominal pain. For two weeks, doctors there told his family it was "probably just a virus," according to Niver's granddaughter, Cindy Trimble of Beacon.

"During the time he was there, the man in the bed next to him, Charlie, called us on at least six occasions," said Ms. Trimble. "You better get up here,' he'd say. 'Harold needs help, and no one's coming.' "

On several occasions, Niver needed a bed pan because he'd developed diarrhea.

"When we got there, Charlie told us he'd been asking for a bed pan for five hours and never got one," Ms. Trimble said. He soiled himself and his bed as a result.

On another occasion, he developed severe chest pains. The nurse gave him nitroglycerin and told the family it was probably angina or a panic attack.

Because his condition had worsened, the family demanded he be transferred to Hudson Valley Hospital Center in Peekskill on April 8. Within an hour of their arrival, the doctor there found bacteria in his blood, indicating widespread infection, and determined that Niver had a perforated ulcer. It was also determined that his chest pain had been a heart attack.

Emergency surgery was performed at 1:30 p.m. but the infection was too widespread to save him. He died April 10.

● Thomas Cragan, 65, of Walden, was admitted to Castle Point on Feb. 7 for surgery to remove his esophagus. Doctors there had found a stage 3 pre-cancerous dysplasia and recommended the surgery, according to his son, Michael Cragan of Walden.

A specialist, who the family never met, was called in to do the surgery.

"Afterward, we were told the surgery was a success but that they'd accidentally nicked his spleen and had to remove it," Cragan said. "They said it was no problem because a man of his age doesn't need a spleen."

Cragan was sent to the hospital's intensive care unit for four to five days, where he was tube-fed and received oxygen through a tube.

"They put him into restraints because the tubes were uncomfortable, and whenever the morphine wore off, he was trying to pull them out," Cragan said. "But on the third day, they failed to restrain him, and he pulled both tubes out."

The tubes were not replaced. A day and a half later, Cragan vomited. Because the vomit was trapped, he inhaled it into his lungs. He developed chemical pneumonia as a result, and his organs began to fail.

"Everything just shut down," Cragan said. "He gradually lapsed into unconsciousness and stopped responding."

Thomas Cragan died March 18.

"I'm convinced that it was the poor post-operative care he received that caused his death," said his son.

● Allen Tyrdik, 66, of Walden was admitted to Castle Point with congestive heart failure in mid-February.

"It was the only place he was willing to go because, in the past, he'd had wonderful experiences there," said his daughter, Linda Platt, of Gardiner.

This experience would prove different, however. Conditions had deteriorated and almost immediately, he wanted out.

"For the first three days there, he was next to an empty bed that someone else had apparently been using before he arrived," she said. "For the entire three days, a full urine bag was left attached to the side of the empty bed."

There was also dried urine on the floor in the hallway. Her father's pajamas were always dirty when she visited, she said. And during one visit, another patient in the ward lost control of his bowels and soiled himself and the bed.

"I went for the nurse but couldn't find anyone around," she said. "I finally found everyone in the break room." It was an hour, she said, before the man was

See VETS page 10

JEFF GOULDING/The Record

Michael Cragan and his sister Patricia Stoltz, both of Walden, hold a picture of their father, Thomas Cragan, who served in the Korean conflict.

Vets

From page 3

cleaned up.

After three weeks in the hospital, her father's doctor ordered a second CAT scan before releasing him because she (the doctor) suspected there was fluid in his lungs.

"But someone in radiology — the doctor said it was a technician — overruled her decision and refused to do it," Mrs. Platt said. "The doctor was in a fury that her own decisions were being overruled by a technician and she resigned. She said she couldn't practice medicine any longer under these conditions. It was the last straw for her."

Tvrdik was sent home without the CAT scan. Seven days later he was rushed by ambulance to St. Luke's Hospital in Newburgh with double pneumonia. He had grown sick and become disoriented in his Walden apartment, and his family had found him naked and unconscious.

He was sent back to Castle Point after his condition was stabilized at St. Luke's. But he has continued to deteriorate ever since. His diabetes medication was not monitored, and his toes are now blue. Doctors have told the family that his feet will likely have to be amputated.

"My father never should have been sent home without that second CAT scan," Mrs. Platt said. She said members of her family have filed a formal written complaint with hospital officials but have not received a response.

● Carl Irwin, 74, of Port Jervis, was sent to Castle Point on Feb. 5 after breaking his hip while living at the Montgomery Nursing Home. He was immediately transferred to the Bronx VA hospital, where he was scheduled to have a partial hip replacement.

"At first, we couldn't find him," said his daughter, Jayne Kowal, of Port Jervis. "We called Castle Point and they said call the Bronx. We called the Bronx, and they said they never heard of him."

He was "found" by the end of the day. "It felt immediately like the right hand didn't know what the left was doing," Mrs. Kowal said.

The surgery was a success, and her father was returned to Castle Point for aftercare on Feb. 10. "He was really himself when they sent him back — cranky because he felt terrible — and we considered that a good sign," his daughter said.

But once he was returned to Castle Point, no one was getting Irwin out of bed. Getting up is extremely important during recuperation to prevent the development of pneumonia.

"He was lying in the same position all the time, and a terrible bedsore developed right next to his spine," Mrs. Kowal said.

Within three days, her father had been transferred to intensive care. He had pneumonia, she was told. "The next thing we know, he's got a feeding tube down his throat," she said. "I kept asking, 'Why? He can eat. There's no reason for a feeding tube.' I never got a satisfactory answer."

On March 5, she requested her father's medical records be sent to her. As of yesterday, the hospital still had not responded to the request.

Vet fades, a casualty of 'chaos'

By BETH MULLALLY
Staff Writer

CASTLE POINT — John Meyers has been lying in a hospital bed behind a curtain for so long that his legs have contracted. They're now at a permanent 90-degree angle, and there's little chance he'll ever get up again.

The 70-year-old Middletown man has also lost 50 pounds in the past four months. At 115 pounds, his bony shoulders and collar bones protrude from his hospital gown.

His daughter, registered nurse Anne Nelson of Montgomery, is convinced that her father's condition deteriorated because the Veterans Administration did not take care of him.

Meyers is a nursing home patient who has been shuttled between VA hospitals in Montrose, the Bronx and Castle Point for the past year and a half. His family has seen first-hand the results of a system in transition.

John Meyers

"It's chaos, but who do you complain to?" said Mrs. Nelson, who has advocated for her father since his admission to the nursing home at Montrose.

"What I've seen is a lot of doctors and nurses who, individually, seem to care," she said. "But collectively, no one seems to have the responsibility or the power to change anything."

Veterans Administration officials did not comment on Meyers' case. Patient confidentiality covers individual cases.

But according to his family, John Meyers got sicker from the time he entered the care of the VA.

Meyers, who had been a radio operator in the Army Air Corps during World War II, entered the Montrose nursing home in September 1985 because he'd begun to exhibit symptoms of Alzheimer's disease. He also had a slow-growing prostate cancer — a condition common in a man in his age — and diabetes that was controlled with oral medication and diet. He also had a surgically implanted tube in his urethra (called a stent) to keep the urine flowing properly from his kidneys to his bladder.

"But he was strong and relatively healthy when he went in," said Mrs. Nelson. "He could play baseball in the hall with the kids when we visited him."

She first came to realize that there was confusion in the system a couple of months after he was admitted. Her father's false teeth had gotten lost.

"It took me 15 phone calls just to find the person I was supposed to talk to about replacing them," she said. "And if they ever were replaced, I've never seen them."

Because the stent in his urethra needed to be changed every four months, Meyers was scheduled to be sent to the VA hospital in the Bronx to have the procedure done in early 1996. But one problem after another occurred, said his daughter.

"First they sent him down, but the doctors in the Bronx said he wasn't scheduled to be there, so they sent him back," she said. "Then they sent him down without his X-rays. That happened more than once."

It wasn't until July that the stent was changed. But because it was an ordeal, the decision was made in October to remove it and leave it out. His kidneys

See HOSPITAL page 11

5/13
THR

THR 5/13

Hospital

From page 3

were functioning well at that point.

Four months ago, the pressure in his kidneys started to rise dangerously. Something was wrong, and his daughter feared he would go into kidney failure.

He needed a sonogram to determine the cause of the problem, "but he made the mistake of going into kidney failure over Martin Luther King weekend" when the hospital is thinly staffed, she said.

By then, the medical unit at Montrose had been closed down. At that point, all nursing home patients had to go to the Bronx when they developed a medical problem. But a fight over her father ensued between Montrose and the Bronx, said Mrs. Nelson.

"I'd call the Bronx and they'd tell me Montrose should handle it by giving him some (intravenous) fluid and antibiotics," she said. "I'd call Montrose and they said he definitely had to go the Bronx to find out what was causing the kidney failure."

At Mrs. Nelson's insistence, her father was sent to the Bronx on Friday of Martin Luther King weekend. But nothing was done to treat his condition, so she went down on Sunday.

Doctors there said they didn't have the radiology staff to do the needed testing because it was a holiday weekend. A sonogram would have to wait until Tuesday.

"I knew enough that if they waited until Tuesday his kidney would blow," she said. "His pressure was unbelievably high, and there was absolutely no urine output."

She said she badgered the resident on duty until the right medical staff was called in to treat her father. A sonogram was done and a tube was inserted through his back into his kidney to lower the pressure and ensure drainage.

He was sent back to Montrose several days later. But within two days, he had blood in tube. He was sent back to the Bronx.

But the Bronx didn't want him. "They told me that all that was needed to be done was to irrigate (flush out) the tube," said Mrs. Nelson. They sent him back to Montrose.

He went back and forth several times during February and March because of simple problems related to flushing the tube, said Mrs. Nelson.

On March 31, he was sent back to the Bronx once again. "Montrose told me his tube fell out of his back," said Mrs. Nelson. "But when I called the Bronx, they said the tube was sutured in place and couldn't have fallen out."

On that visit, he was kept at the Bronx for the weekend because there was no transportation back to Montrose.

By April, a decision was made to transfer him to Castle Point, so he could be treated in the medical unit there.

He arrived without a discharge summary detailing the medications he was supposed to be on. Among them would have been listed his hormone medication, which controls his prostate cancer.

"His Castle Point doctor told me she wanted to do surgery to remove his testicles to control his prostate cancer," said Mrs. Nelson. "I said, 'didn't you read his chart? He's on medication for that.' She told me she didn't have time to read his chart."

Two weeks later, Castle Point mistakenly sent him back to Montrose. A hospital social worker intercepted the transfer and he was returned to Castle Point.

He has been in a bed there ever since.

"What should have been a simple medical procedure that could have been resolved quickly was drawn out for so long that he's been in bed for several months," said Mrs. Nelson. "He can't [illegible] his legs. He can't feed himself. This kind of deterioration should never have happened."

Two days ago, when Mrs. Nelson visited her father, she found him staring at empty space from his bed. He didn't recognize his wife, Kathleen Meyers, or his two daughters, Mrs. Nelson and Maura Meyers.

The water pitcher at his bedside was empty. There was mold growing in the suction tube behind his bed. There was no soap in the dispenser at the sink in the ward he shared with four other men. There was a dirt-encrusted spoon in the drawer next to his bed. And John Meyers seemed hungry.

Mrs. Nelson went down the hall to a refrigerator and brought back a container of Ensure, a high-protein drink. He drank greedily through the straw that his wife held to his lips. He asked for more. And he drank a second container in a matter of minutes.

"He's not eating," said Mrs. Nelson. "I know he's a difficult man, and he probably tells the nurses to go away, that he's not hungry. But it's their job to make him eat. He's just wasting away, and someone needs to take the time to help him."

eaport
l fragile

$168,000 a year in rent. It also calls for $51,000 in annual payments in lieu of taxes.

But members of the Common Council said that contract needs more detail to protect the city's interests. They want a percentage of the project's profits, better guarantees of public access and more specifics on what would be built.

Bonura has expressed frustration with the negotiations, saying he wants the matter resolved now.

Survey: No paybacks given

Last week, the EDC surveyed five cities similar in size to Poughkeepsie with public-private development agreements for their waterfronts.

The EDC surveyed the projects because members of the business community were "concerned the deal might fall apart," Conroy said.

Each of the five projects — Newport, Kentucky; Middletown, Connecticut; Wilmington, Delaware; Norfolk, Virginia; and Chattanooga, Tennessee — called for an investment of public money. None required the developer to pay a percentage of profits.

That's what makes Poughkeepsie's deal with Bondib significant, Lafuente said. There is no public investment, Lafuente said. "I don't see where the city will have th oney to do this kind of infrastructure investment," she said.

Obituaries 2
Our Towns 3
Business 5
B

WEDNESDAY, MAY 21, 1997

Castle Point deaths under investigation

VA Office team examines records

By Thomas N. Tobin
Poughkeepsie Journal

An inspection team from Department of Veterans Affairs headquarters in Washington spent Tuesday at the Medical Center at Castle Point looking into charges of inadequate care.

Four employees of the VA's Office of Medical Inspectors reviewed records and policies at the Town of Fishkill hospital, according to Castle Point spokeswoman Penny Koustoubelis.

Details about the inspection were not released and no one from the review team would speak publicly.

"They are not going to engage in talking to the media during the investigative process, as it is too preliminary to comment at this time," Koustoubelis said.

Today, the inspectors are scheduled to visit another VA hospital, the FDR Medical Center in Montrose, Westchester County.

The VA hospitals have come under scrutiny following reports that mortality rates have skyrocketed since budget cuts took effect in October 1996. The hospitals have disputed the reports, saying they distorted hospital statistics.

U.S. Reps. Sue Kelly, Benjamin Gilman and Maurice Hinchey have urged independent investigations of the allegations. The New York congressional delegation met Tuesday with Veterans Affairs Secretary Jesse Brown regarding problems at Castle Point and Montrose.

On Tuesday, Brown defended the hospitals, insisting there were no problems with their health care.

"As far as we know there have been no problems with the quality of care at Castle Point," Brown said.

Brown blasted what he called "misinformation" in newspapers and accused local newspapers of scaring veterans unnecessarily.

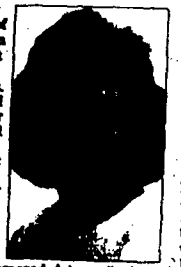
On Monday, two Ulster County families complained of substandard care at Castle Point. One man, Clifford Maddison of Ellenville, was misdiagnosed at the Castle Point emergency room in 1996, contributing to his death, his family said.

Another, Frank Bove of Marlborough, was not nourished properly and his condition worsened, his family said.

Employees at FDR Montrose sued the hospital last year, claiming they were punished, and in some cases fired, for complaining about patient abuse and other problems, including malnutrition, inaccurate diagnosis and unsanitary conditions.

The suit currently is before the Equal Employment Opportunity Commission in Washington.

Veterans' suffering is more than numbers



This is in response to the "my view" by Maryann Musumeci of May 20 and the recent articles in the Times Herald-Record about the VA medical centers.

It is unfortunate that Ms. Musumeci seems to have missed the point of this entire uproar regarding the VA. However, I must say I am not at all surprised by this. The public response of the VA administration has paralleled my experience with them over the past year and a half.

What they do not seem to understand is that this is not about "new data" versus VA processed data or "not significant" trends versus significant trends. This is about the people the system is supposed to serve. In many cases, this is about people who cannot speak up for themselves. The ONLY concern the VA should have is that people in these hospitals are complaining and something hostly about some very serious problems.

The only public response should be that the VA is also concerned and will look immediately into it. But, instead, the administration has continued to persevere on the subject of statistical significance. Even the reference to sick people and deaths as "numbers" continues to run rife.

You say in one hollow sentence in the second to last paragraph that you are "just as concerned" when you

Anne Nelson's father, John Shepere of Middletown, has been a patient in the VA hospital system for the past two years. She is a registered nurse who lives in Montgomery.

"my view"
Anne Nelson

hear stories of poor care. Well, Ms. Musumeci, let me tell you more about my experience with your "caring."

During my father's stay at Montrose and Castle Point I was in touch with your office. I could not get an appointment with you. Over two months ago, I called your office with my horrific story and spoke with your assistant administrator. He immediately feigned ignorance of clinical issues and said he would put me in touch with the chief of staff instead. I left a message with your assistant that I wanted to speak with you and he assured me you would call — you never did.

I then spoke at length with your chief of staff. He agreed to review the chart and meet with me. But, before I ever had a chance to have that meeting, I had a conversation with my father's new doctor at Castle Point. This was the doctor who "didn't have time to read the chart." And when I asked her to write an order to feed him she said, "I'll write it, but I don't know if they'll do it."

There were many more quotable quotes but suffice it to say I was horrified and so alarmed that I called the chief of Staff and told him I needed to meet with him immediately — I had an urgent matter. We met the next day at Montrose and I again reviewed the history of my father's experience and this new problem with the doctor. He stopped the meeting at one point to go find you. He said you "needed to hear this," but you were gone for the day.

I left feeling perhaps something would happen now to help right this situation, after all I was at the top. But once again, I heard nothing.

I do remember as I left the administration building at Montrose that day, I stopped outside the building and marveled at the beautiful spring flowers and manicured gardens and lawn. I remember thinking how the care of the grounds was in such stark contrast to the care of the patients.

I also remember thinking this was pretty much the end of the line. I had been to the top administrator's office and if nothing happened now I would have to do something drastic. After all, what would Americans think if they knew the VA system was in collapse? What would they think of the care of their veterans?

This last encounter with administration was not my only encounter. I have worked my way through the system in these past months speaking to supervisors, social workers, doctors, patient advocates and other administrators. And as I have stated previously, many of these individuals seemed to genuinely care but none were able to make the right things happen. Many of the staff, in their frustration, told me of their own struggles with the VA system. With every trip to the Bronx VA in the past four months a doctor would pull me aside and say "get him out of Montrose ... their patients come in terrible condition."

A doctor commenting on the lack of diagnostic services on the holiday weekend in January told me "you think you're in a hospital (the Bronx VA) but you're in a glorified clinic. I am limited to what I can do for your father by what they (the VA) allow me to do."

I am and continue to be a reasonable, patient person. Perhaps I have been too patient but this system has pushed me and my family beyond all limits. I feel certain I speak for all veterans' families when I ask the VA system for technological care that is coordinated and meets the standards of medical care and custodial care that is humane so that patients are allowed to die with dignity and comfort.

THR 5/26/97

remembering our heroes

Families tell of VA neglect

JOE GOULDING/The Record

Lowell T. Hulse and his wife, Patricia, in their home in Rio. She is very grateful that he is [illegible] days after nearly losing him in the VA hospital.

Amputation, death blamed on hospital's medical care

By BETH MULLALLY
Staff Writer

The families of veterans continued to step forward during the past several days to tell tales of medical neglect at Castle Point and FDR Montrose VA hospitals.

They say the care at Castle Point has declined since October, when more than 200 positions at the two facilities were eliminated in anticipation of budget cuts. At Montrose, employees say the cutbacks have worsened what was already a bad environment for the patients.

The following are among the several dozen accounts people have come forward to tell:

Lowell Hulse, Sparrowbush

It was in 1994 that Lowell Hulse, a 68-year-old Korean war veteran, began to experience severe pain in his stomach. The pain, said his wife Patricia, grew so unbearable that he had to sit in a recliner day and night and was unable to sleep well. He doubled over whenever he walked.

Her doctor at Castle Point repeatedly diagnosed the pain as "just nerves," said Mrs. Hulse. He was given pain killers, and when they failed to work, the prescription was switched.

"I really had to push to get any tests taken," said Mrs. Hulse. "I was told that tests cost a lot of money for the hospital."

Over the course of more than two years, Hulse's stomach grew distended and hard. The couple's appeal for testing was ignored, she said. "Finally, on Dec. 15, 1996, I brought my husband to the emergency room at Castle Point. That way, I thought, we could have another doctor other than the doctor who was assigned to his case."

The emergency room doctor ordered tests and called in a surgeon. In emergency surgery, Hulse's gall bladder was removed. "The surgeon told me it was the size of a newborn baby," said Mrs. Hulse. Her husband had an acute infection, as well. Gangrene and peritonitis were present.

He recovered from the surgery. Two months later, though — in February — Hulse fell and broke his left arm. A doctor at the Castle Point emergency room said the couple would have to go to the Bronx VA hospital to have it casted.

"This happened during an ice storm," said Mrs. Hulse. "He wanted me to drive to New York in an ice storm."

The emergency room doctor sent the couple away. "They claimed they didn't even have a sling to put on his arm," said Mrs. Hulse. "He was sent away with a broken arm and no treatment."

She said the hospital has recently cut back on her husband's medication and testing. "How dare they?" she asks. "Our soldiers were promised certain things for fighting for our country. How dare they now tell us it costs too much."

Casimir Otlowski, Newburgh

When Casimir Otlowski developed back pain in early March this year, he went to the outpatient clinic at Castle Point for help.

The 72-year-old veteran was having trouble doing normal things as a result of the pain, said his son, Steve Otlowski.

"They told him he had a pinched nerve in his back and prescribed physical therapy," said Otlowski. "The pain was so severe, they put him on a narcotics patch. The patch is so strong, the nurse has to use gloves to touch it, but it didn't come close to helping the pain."

During that first visit, Otlowski also pointed out a swollen, bruised-looking area on his ankle. The doctor dismissed it, said his son.

Three weeks later, on the Saturday before Easter, Otlowski bent down to touch his ankle. "It erupted with blood," said his son. "He was rushed to Castle Point. It turned out to be gas gangrene. They amputated the foot."

Ten days later, while he was recovering from the amputation, he began to hemorrhage from the bowel. He was sent

See NEGLECT, page 12

Neglect

From page 5

to intensive care for transfusions then to the VA hospital in the Bronx for surgery.

It turned out that he had a huge abscess in the large bowel," said Odowski. "That's what had been causing his back pain. Not a pinched nerve."

And it was caused by the same bacteria that had caused his gangrenous ankle. He'd had a system-wide infection. Odowski has only recently learned that his doctor had determined he had diabetes during an outpatient visit last October. He had never been told. He had never been treated for it.

Odowski now wears a colostomy bag and has only one foot. He is still in Castle Point.

H. Robert Patterson, Newburgh

For two months last summer, H. Robert Patterson, 69, underwent outpatient testing at Castle Point to determine what was wrong with him.

Patterson, a Vietnam veteran, appeared to have liver disease. He was very jaundiced, his belly was swollen and he was losing weight.

"But they kept changing their minds about it," said his daughter, Stacia Patterson. "First, they said it was his liver. Then, it wasn't. They never seemed to be able to give us a straight answer."

By early September, the doctors landed on gall bladder as a diagnosis. Over Labor Day weekend, doctors removed it and told the family he'd had a few stones.

That night, he went into kidney and liver failure," said Ms. Patterson. He was transferred to intensive care. It was a nurse there who told the family that he had advanced liver disease.

"The nurses in intensive care kept whispering to us, 'Get him out of here. Get him out of here,'" said Ms. Patterson. "We didn't know what was going on. Everything was very hush hush."

Her father's condition steadily worsened. By the end of September, the family told doctors at Castle Point that they wanted him transferred to St. Luke's Hospital in Newburgh.

"The doctors gave us a hard time," said Ms. Patterson. "They didn't want him pulled out. I don't think they wanted anyone reviewing the charts."

The family finally enlisted the help of a physician family friend to arrange a transfer to St. Luke's. He was immediately put on kidney dialysis. But it was too late. He developed pneumonia and lapsed into a coma. Patterson died Nov. 9.

"My father was a wonderful, wonderful man," said Ms. Patterson. "This shouldn't have happened to him. At St. Luke's we were told that treating his liver should have been the priority, not the gall bladder."

Good stories predate cutbacks

A handful of veterans or their families have also come forward to say they have had good care at the hospitals, particularly at Castle Point. Most, however, date their good experiences to before October, when the cutbacks began.

MaryAnn Musumeci, the acting director of both hospitals, said the good outweighs the bad.

"For every patient who complains, I can produce a

Hospitals

From page 5

been put into an ambulance at least 16 times in the past few months to be ferried back and forth between Montrose, the Bronx and Castle Point.

"It's crazy," said his daughter, Anne Nelson of Montgomery. "He's an elderly man in fragile health, and they're shipping him all over the place for simple medical procedures."

Both Ms. Alston and Ms. Barnack are part of a class-action lawsuit brought by employees against the hospital. They are among several employees who say they were harassed and demoted for trying to draw attention to poor medical standards and practices.

They and other employees say consolidation and staff cutbacks aren't the entire problem, though. Poor patient care should have had congressional attention years ago, they say.

"It's been going on for so long, where do you start?" said Ms. Alston. "It's an old, deep-rooted problem."

Mary Ellen Gennetti, who was fired in November 1995 after 30 days as risk manager at Montrose, said she lost her job because she refused to whitewash instances of patient neglect or abuse.

Among the several documented cases she has now decided to make public are:

- A patient who suffered brain damage because he had been given toxic doses of lithium, a drug that must be monitored by regular blood tests. He was unconscious for 17 days and needed hemodialysis three times a day.
- A second case of lithium toxicity that resulted in death.
- An elderly patient who fell on a Monday and broke his back. A consult with a "rehab specialist" was needed. The doctor did not see the patient until Thursday.
- A "decubitus bedsore room" existed in which elderly, unconscious, contracted patients who usually have DNR (do not resuscitate) orders are kept alive with gastric tube feedings and antibiotics.

In those cases, she said, the hospital is keeping patients alive against their wishes.

"It's a terribly administered place," said Ms. Gennetti, who is part of the class-action lawsuit and has filed a separate whistle-blower complaint. "The regime there is death giving, and the patients are persecuted."

Photo provided

H. Robert Patterson is shown during his service in the Vietnam War.

each of patients who are happy," she said.

Two local congressional representatives are trying to discover just how widespread the problems are.

Rep. Benjamin A. Gilman, R-Middletown, is requesting that veterans, their families and employees who have information about patient care at either of the hospitals attend a "town hall meeting" Wednesday at 8 p.m. at Port Jervis City Hall.

In addition, he has arranged for a congressional hearing to be held in the Castle Point area in July, conducted by a subcommittee of the Government Reform and Oversight Committee. All those interested in testifying, either in writing or verbally, should notify his office by writing to him at 3449 Rayburn Building, Washington D.C. 20515-3220 or by faxing to (202) 225-2541.

Rep. Sue Kelly, R-Katonah, has scheduled four meetings to gather anecdotal evidence of problems at the two hospitals. The meetings will be held in Westchester, Putnam, Dutchess and Orange counties in June. The sites have not yet been determined.

Interest finds in their congressional offices can be made by calling up the on-line edition of The Times Herald-Record at th record.com

The Record

lead in 38 days

Thirteen U.S. veterans died at the Montrose V.A. Medical Center in a five-week period in the fall when a plan to streamline nursing-home services there went awry, say nurses who work at the hospital.

And that number — borne out by Health Department records — could actually be as high as 26, nurses charge, if patients who died after being transferred to other facilities are included.

Nurses charge that the deaths occurred when nursing-home patients were transferred to new wards without identification or medical charts.

story, page 3

Multiple deaths at Montrose

Nurses: 13 vets died last fall at VA hospital

By BETH MULLALLY
Staff Writer

MONTROSE - Thirteen U.S. veterans died at the Montrose VA Medical Center in a five-week period last fall when a plan to streamline nursing home services there went awry, say nurses who work at the hospital.

In addition, nurses charge another 13 patients died during the same period after they were transferred to Castle Point or Bronx VA hospitals in critical condition. The patients died either en route or shortly after arriving at those facilities.

Normally, the 200-bed nursing home unit at the hospital sees an average of one to three deaths per month, said MaryAnne Musumeci, acting director of the hospital.

Musumeci maintains that the number of deaths during that time period, Oct. 8 to Nov. 17 last year, was "no different than any other month."

But state Health Department records indicate otherwise. Death certificates for the 13 patients who died at Montrose have been filed with the Health Department's Bureau of Vital Records, the department confirmed yesterday.

Nursing union officials and other staff members at Montrose said a chaotic reshuffling of patients and downsizing of staff last October resulted in the unusually high mortality rate.

One of those deaths included an elderly patient with senile dementia, who died after inhaling small bits of tissue.

Speaking on condition of anonymity, several nurses and representatives of the nurses' union Local 1119 said a reorganization plan, which was put into effect in early October, involved clustering elderly nursing home patients in new areas of the hospital. One of the six 40-bed wards was closed in the process.

"They were sent to new wards, to strangers, without ID bracelets or medical charts," said one union official. "For the patients, it was like being sent to China. They were terribly confused and disoriented. For the nurses, we had no idea which patient had what medical problem."

As a result, she said, "Patients were getting the wrong medications or going without medication for heart conditions, seizures, diabetes, and so on."

In addition, the staff had no way of knowing what was normal behavior for the patients and what might indicate a potential problem. Nor did they know which patients needed to be watched. For example, she said, some patients tended to choke on their food and needed to be watched. Newly assigned staff had no way of knowing who to monitor during meals.

"We had one man in there who had a habit of tearing small bits of paper and tissue and putting them up his nose," said one RN. "The staff on his new ward had no idea they needed to keep tissues away from him."

The patient sat in the hallway unmonitored for several hours putting bits of tissue up his nose. He inhaled a paper and died.

Montgomery resident Anne Nelson, whose 78-year father, John Meyers, was a nursing home patient at Montrose at that time, said her father was among those who was shifted to a new ward last fall. As a result, she said, he grew critically ill after suffering kidney failure and was transferred to the VA hospital in the Bronx.

Doctors there told her the kidney failure had resulted from dehydration.

During one visit to her father before his transfer to the Bronx, she said she searched for one particular nurse.

See MONTROSE, page

Montrose

from page 3

ude who had taken care of him for about a year, but who was now located in a different ward.

"The aide told me the patients and staff were all upset," said Mrs. Nelson. "She said she went to visit my father after her shift ended and found him so agitated that she stayed with him. She told me, 'Nobody knows him here in this ward. They don't know what he needs. They don't know they have to watch his food and water intake.' And she told me about all the deaths that had occurred."

Chief Nurse Marjorie O'Connor, who spearheaded the development and implementation of the plan to move patients and cut staff, was removed from her position shortly after the nurses' union threatened to file an Unfair Labor Practice lawsuit against the hospital in November, nurses said. She remained employed at the hospital in another job until today, when she will retire with full benefits.

The reorganization plan also called for a reduction in the number of registered nurses in the nursing home unit by more than 50 percent, from 49 to 22.8. That meant one RN would cover a 40-bed ward during the day shift. No RNs were to be scheduled to cover evening and night shifts.

But nurses said the plan failed almost immediately because the transfer of the elderly, mostly senile, patients to new wards took place so chaotically.

Musumeci said she was unaware of any movement of patients and staff reductions during that period because she did not take over at Montrose until March of this year.

Hospital administrator Jack Grady, who was there in October, did not return phone calls.

Union officials said they protested the plan, which was called the NHCU Re-engineering Plan, before it was implemented Oct. 1. The plan was developed in response to expected cuts in the VA budget, which were approved by Congress at the end of September.

In memos to O'Connor in July and September, the nurses expressed fears that moving the patients and cutting staff would affect patient care.

In a July 3 memo to O'Connor, a union chief steward wrote, "The drastic cut in professional care and supervision will impact on quality patient care and the working conditions of the employees."

The union asked the administration not to implement the plan without input from nurses on patient-care issues.

In a Sept. 6 memo to the union, O'Connor wrote, "Your concerns are appreciated, however, as noted there were opportunities available for union input."

The plan was finalized Aug. 30 and went into effect Oct. 1.

As patients died, union officials began collecting data on the deaths.

"We went down to the morgue and pulled the records," said one union official. Nurses provided The Times Herald-Record with the documentation that supports their claims. They also kept an informal record of patient transfers.

The union officials said they, along with Irwin Gerard, commissioner of the Federal Mediation and Conciliation Service, met with hospital officials in October and again in November to protest the staff cuts and ward reassignments.

"The mediator recommended that the staffing arrangements be returned to normal," said one union official.

Gerard said the dispute was resolved amicably. As a result, nurses said they were offered the option of returning to their own patients. The planned staff cuts on the night shift did not go into effect. The death rate has since dropped to normal, the nurses said.

Nurses said O'Connor was removed from her position shortly after the mediated agreement and took a job as coordinator of women veterans affairs at the hospital for a few months until her retirement.

O'Connor declined to comment on the circumstances of her job change and retirement, and she referred all questions to hospital officials.

Musumeci said that "as far as I know, it was her choice to leave her position."

Musumeci also disputes the nurses' claims that 13 veterans died after transfer during that period. "Our records show five transfers," she said. "Their numbers are all wrong. No patients died unnecessarily."

The October and November deaths at Montrose are part of mounting allegations of medical neglect and poor patient care resulting from budget and staffing cuts at VA hospitals in the region. About 350 employees, or roughly 15 percent of the staff, at both Montrose and Castle Point hospitals have been let go in recent months, and more cuts are expected.

The VA's own medical investigators are looking into the allegations. In addition, a surprise, on-site evaluation of both Montrose and Castle Point facilities was conducted last week by the Joint Commission on Accreditation for Hospitals, which sets hospital standards.

The results of that evaluation will be considered by the group's accreditation committee on Sept. 4.

At the same time, a Congressional field hearing is planned for some time within the next month. A date for that hearing will be set within the next few days. Employees who wish to testify are protected by whistleblower legislation.

"We need to hear from people with information about these deaths at that hearing," said Rep. Sue Kelly, R-Katonah, whose district includes the two hospitals. "These numbers are very disturbing, and they give further evidence that cutbacks have been extremely detrimental to the veterans of New York."

Deaths blamed on VA cutbacks

By BETH MULLALLY
Staff Writer

Hospital employees as well as families of several U.S. veterans who died at the Montrose VA hospital last fall came forward yesterday to describe the chaotic conditions there that they say led to many of the deaths.

Nurses said that as many as 36 veterans in the 200-bed nursing home unit died during October and November last year when a reorganization plan went awry. Due to cutbacks in the VA budget, the RN staff was cut by more than 30 percent. At the same time, elderly, often senile patients were moved to different wards, in some cases without identification or medical charts.

An LPN who worked in the nursing home at that time said two of the dead had Huntington's disease, a condition that makes it difficult to swallow.

"When you have Huntington's, you have to eat very slowly so you don't choke," said the LPN, who asked not to be identified. "But we just didn't have time to feed them. They basically died of malnutrition."

She said the staffing cuts meant three staffers — one LPN and two aides — had 20 minutes to feed 20 patients. "That's about 2½ minutes per patient," she said. "We were literally shoveling the food in."

But for the Huntington's patients, food couldn't be shoveled in, she said. They ate only a mouthful or two at each meal, whatever they could manage at a slow pace.

The first of the two patients — a woman in her early 70s — died Oct. 8. She weighed 80 pounds when she died. The other patient — a 6' 1" man — weighed less than 90 pounds when he died Nov. 5, the nurse said.

She said many of the patients on her ward had open bed sores. "This was the skin care unit, and most of the patients had Alzheimer's disease and were bedridden," she said. "A lot of them had bed sores the size of your fist on their hips, their tailbones, their heels, backs and shoulders."

Doctors generally left orders that the sores were to be cleaned and irrigated every shift — three times a day. "But it got to the point where we just didn't have the time," she said. "We had one patient with a huge bed sore on his tailbone. It went untended for so long that mosquitoes had laid larvae in the sore."

MaryAnne Musumeci, acting director of the hospital, has denied that any unusual deaths occurred at Montrose during that period. She said the stories of poor patient care, understaffing and unusually high death rates were the fabrication of disgruntled employees.

However, the state Health Department has confirmed 13 of the deaths. The other 13, said nurses, occurred after critically ill patients were transferred out of Montrose to other VA hospitals.

Family members with relatives in the Montrose nursing home said they noticed enormous pressure on the nurses and aides after the cutbacks and shift changes went into effect Oct. 1.

Middletown resident Anthony Kelvasa, whose 77-year-old brother died at Montrose after inhaling small bits of paper tissue that he'd put up his nose, said he begged the administration not to move him from a ward he'd grown comfortable on.

"But it was like talking to the enemy when I appealed for help," he said. "Nobody was on the veterans' side. The nurses tried their best, but the administration mismanaged that whole thing."

His brother was moved twice, from Building 6 to 9 to 10. "The last move just killed him," said Kelvasa. "He was like a lost puppy. He didn't know any of the staff, he was in a room all by himself."

Left alone, he engaged in the habit that his long-term nurses knew about and had prevented before he'd been transferred to a new ward.

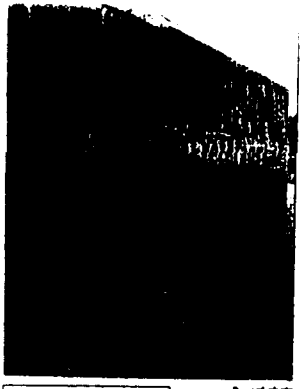
But Kelvasa was not told that's how his brother died. "The death certificate says 'cardiac arrest, possible myocardial infarction,'" he said. He realized only yesterday, after reading The Times Herald-Record, that his brother's death could have been prevented had someone been watching him.

"I knew it had to be him in the paper even though he wasn't named because it was a long-term habit," he said. "The nurses in Building 6 knew enough to protect him."

Marie Grazioso of Marlboro said her 73-year-old husband, Carman, who suffered from Alzheimer's disease, died April 29. "But he was a victim of last fall's mess over there," said Mrs. Grazioso. "After six years on the same unit, they sent him out to a private nursing home last Oct. 22."

Hospital administrators told her they had to make room for new veterans to come in. "But they lied to me," she said. "They didn't take in new people. They were closing a ward."

The move to the private nursing home was wrenching for him, she said. "He'd been on Ward 6CD for 5½ years," she said. "His nurses were like family to him. The care and love they gave him was a beautiful thing.



Record photo

Above, a sign at the Montrose VA hospital salutes America's veterans. At left, Carman Grazioso of Marlboro, who served in World War II, died after being transferred out of the VA hospital into a private nursing home. He had Alzheimer's disease.

They took their time with him. 'Carman,' they'd say 'Would you like some water?' After the cuts, no one had time to ask the men if they were thirsty. And they couldn't speak up for themselves."

She said her husband had to be fed slowly because he tended to choke on his saliva. At the new nursing home the staff didn't have time to feed him. They wanted to put a feeding tube in his stomach.

"I said 'no,'" said Mrs. Grazioso. "He's in good health. There's nothing wrong with him. He just needs to be fed slowly, that's all."

Her husband's condition deteriorated rapidly after the transfer. He stopped recognizing his wife. He grew increasingly confused. His weight dropped from 145 to 117. And then he died.

"My husband should be counted among those death statistics," she said. "He died needlessly. This is a man whose feet were frozen at Anzio during the war. It hurt him to walk the rest of his life. And they didn't have time to feed him."

John Lamont, a 78-year-old veteran of Highland Falls, said he lowered his flag to half mast yesterday after reading the account of last fall's deaths at Montrose. "I want to honor my buddies who died in that VA hospital," said Lamont.

He is calling on all area residents to fly their flags at half-mast on July 4. "It's time for everyone to rally together on this," he said. "It's time to stir up the politicians. It's time to let the commander-in-chief know that this is enough."

Anyone with information about patient care at the VA hospitals in Montrose or Castle Point is invited to testify at a congressional hearing on Aug. 4 at 1 p.m. at the Town of Wallkill Community Center, 8 Wes Warren Drive, Middletown.

The hearing, to be co-chaired by Rep. Benjamin Gilman, R-Middletown, and Sue Kelly, R-Katonah, is sponsored by the Human Resources Subcommittee of the House Committee on Government Reform and Oversight.

Veterans, family members and employees are asked to testify, either in person at the hearing or in writing, or both. Employees are protected from reprisal by whistleblower legislation.

Those who want to testify should contact Gilman's office at (202) 225-3776 or Kelly's office at (202) 225-5441.

— BETH MULLALLY

Tales of neglect rise at VA hospitals

by BETH MULLALLY
Staff Writer

While debate over changes in the VA hospital system has raged in Congress, families of veterans have continued to step forward to tell stories of poor patient care at both Castle Point and Montrose VA hospitals.

Warwick resident Alan Lesando said this week that his 77 year-old father, Rosario Lesando, was sent away from the Castle Point out patient clinic twice last week with what turned out to be a cerebral hemorrhage.

"My father had begun to grow confused early last week," said Lesando. "He couldn't remember our names, and he felt dizzy, like he was going to fall."

Up to that point, family members said he'd always been very sharp and independent. He did his own driving, shopping, cooking and laundry.

Alan Lesando took his father to the emergency room at Castle Point on July 9. He said he described his father's sudden memory loss to a nurse practitioner there.

"She gave him some medicine and sent us home," Lesando said. "His blood sugar was high because, it has turned out, he stopped taking his diabetes shots."

His father was worse the next day. His memory seemed to have faded completely. Father and son returned to Castle Point. This time, a family practitioner in the out-patient clinic saw them.

Rosario Lesando
turned away

"I begged the doctor to admit him," Lesando said. "Look at him," I said. 'Something's not right.'"

His father did not know the day, the time, the year, or his own name. He sat slumped in a chair, largely unresponsive.

"But she told me she didn't have the authority to admit a patient," he said.

The family practitioner could not be reached for comment.

The next day, on July 11, he called his own family doctor, Dr. Nicholas Pennings, in Warwick. Pennings immediately sent them to the emergency room at St. Anthony Community Hospital and ordered a CAT scan.

The testing showed a cerebral hemorrhage. "It's possible he was bleeding for about a week," Pennings said. "I doubt if it was any longer than that."

Lesando was admitted to St. Anthony, where he was in stable condition yesterday.

"It's hard to say what occurred at Castle Point when you're not standing in the other doctor's shoes," Pennings said. "But at St. Anthony's, when a patient exhibits a dramatic change in mental status, we do a CAT scan immediately. There's no hesitation. It's just a given."

Sources at Castle Point have said limitations have been placed on hospital admissions. One source said doctors need the approval of the medical director before admitting.

But hospital spokeswoman Penny Koustoubelis said doctors can continue to admit patients based on their own clinical judgment.

However, the hospital is now operating primarily as an out-patient clinic and a nursing home.

Surgeries came to an end there July 1, and only medical patients are now hospitalized there.

Koustoubelis said patient confidentiality precludes the hospital from commenting on patient-care issues.

Acting director MaryAnn Mustacchi continues to "personally investigate each claim" of poor treatment, she said. Michael Sabo, director at the Brooklyn VA, will also over at Castle Point and Montrose on Monday.

Montrose, Ulster Park resident Malina Melville said her father died as a result of neglect when a plan to streamline nursing home services at Montrose VA hospital went awry.

"Within a week, they lost his teeth and glasses. His condition went from bad to worse. Without his teeth, he couldn't eat solids. His ankles swelled to the point where I could barely put socks on him."

– Malina Melville,
speaking of her father,
William "Cappy" Prendergast

Nurses at that hospital have said as many as 28 veterans died during a period of acute understaffing and confusion in the fall.

William "Cappy" Prendergast, 74, was among those 28, his daughter said.

He was admitted in early October because he was suffering from Alzheimer's disease.

"But physically, he was in perfect health when we brought him there," she said.

Her plan had been to move him to a nursing home in Ulster County as soon as an opening came up.

"But he didn't live long enough," she said. "When he arrived at Montrose, the one thing he had going for him — his physical health — was taken away."

In written testimony, she has prepared for a congressional hearing Aug. 4 on patient care at the local VA hospitals, she writes. "Upon admission, all of his clothes were lost. So the first time I visited him, he sat strapped in a chair on a cold day with a sleeveless shirt and polyester pants. He had not been shaved.

"Within a week, they lost his teeth and glasses. His condition went from bad to worse. Without his teeth, he couldn't eat solids. His ankles swelled to the point where I could barely put socks on him."

Each time she asked for help, the staff spoke of understaffing and cutbacks.

"As time passed, on every visit, I found my father in the same position — strapped in a chair with no teeth, no glasses and someone else's clothes on, and with no one walking, talking or caring for him.

"During one visit, my father's companion found him lying on the floor in a pool of blood. He had cut his head open falling out of bed. The nurse told her to wash him up and put him back to bed.

"He developed a cough and was hot to the touch. His temperature went on for several days before the staff agreed to send him to the medical ward."

ENERGY EVENTS / Page 3

Photo provided

The family of William "Cappy" Prendergast, 74, of Kingston, shown in this undated photograph, said he was strapped into a chair and ignored after being admitted to the VA hospital in Montrose. He died soon afterwards.

Cappy Prendergast had pneumonia. He was eventually transferred to Castle Point. Within 48 hours of transfer, he was dead.

"My father died Dec. 23, 1994, just two months after we entrusted his care to the country he had served so proudly," Melville said.

She has not yet received a copy of his death certificate, so she doesn't know what is listed as the official cause of death.

Veterans to rally against cuts

MIDDLETOWN — Veterans from the mid-Hudson region will be holding a rally against the cuts in services and threatened closing of Castle Point VA Hospital at 1 p.m. Aug. 4 at the Town of Wallkill Community Center, 8 Wes Warren Drive, Middletown.

The rally will be in conjunction with a congressional field hearing about patient care at both Castle Point and Montrose VA hospitals.

Chapter 144 of the Disabled Veterans of America has arranged to charter buses to provide veterans with free transportation to and from the rally. The buses will leave Castle Point at 11 a.m.

People are advised to bring a lunch and plenty of water. For further information, call Bob Duncan at 562-3971.

Vets battle bureaucrats

Hundreds take aim at hearing

By LISA M. JOHNSON
Staff Writer

SCOTCHTOWN — They were a formidable battalion, and they had come to fight.

Each branch of the military was represented, the ranks filled by experts at land, sea and air combat. They'd fought in trenches, deserts and jungles. And they were angry.

"Our guys are dying here," said John Leonhardt of Middletown. He stood among the hundreds of veterans gathered at the Wallkill Community Center for yesterday's congressional hearing on conditions at Castle Point and Montrose VA hospitals.

There have been staff cuts, budget cuts and unexplained increases in mortality rates. And for the soldiers who filled the center and entrance, that is a call to arms.

"The Congress let everything slip away," said Leonhardt, who gave the Army four and a half years during World War II. "Men died because of this."

As politicians and suit-wearing officials from the Department of Veterans Affairs filed into the Community Center, veterans and their allies rallied at the front door, under the flag.

And before the hearing had even begun, this group out front had dubbed themselves The Rally Vets.

"The government sees us as nothing but tools," said Anthony Falanga of Poughkeepsie, a Vietnam combat vet. "Now because some of the tools are broken, they want to just throw them away."

They demanded a full investigation into recent deaths and reports of deplorable conditions at the hospitals. They demanded quality and accessible health care. They demanded that their country keep promises made to them.

"I do not believe in their slogan, that veterans come first," called an impassioned Anne Samoyle, a Vietnam veteran and former VA employee. Cheers from the crowd punctuated her words.

"I believe that within the VA system, the number one priority is to protect and promote the highly paid, nonveteran bureaucrats. I believe that the second priority is to save money off the backs of our veterans," Samoyle said.

Darlene Riley, wife of a disabled Vietnam veteran, made her way through the crowd, circulating a petition calling for a national investigation. She wants every state, every hospital, probed.

"We must never forget who found the courage in their hearts to serve," Riley said.

It was that same courage that brought men like Henry Hertberg of Montgomery to Wallkill yesterday. He was a machine gunner in the 71st Infantry, enlisted in the Army in 1940, and he still boasts that he dug a better trench than any other man in his division. He stood for the rally, alongside vets of the Gulf, Korea, and world wars as well as peacetime. But he headed home not long after the hearing began.

"I can stand just so much talk from them congressmen. They're the rottenest bunch of stinkers you're ever gonna see," Hertberg said. "I came out here today because these veterans here fought for something. We can still fight."

CHRIS RASMUSSEN/The Record

Veterans gather outside the Town of Wallkill Community Center to listen and speak their minds before the start of a congressional hearing on the state of New York's VA hospitals.

TIMES HERALD RECORD 8/5/97

what they say

"There is one thing I can't understand. How come we can investigate things up to the sky, investigate things that spoil peoples' lives, investigate everything. So how could we make a decision to cut funds before we really knew what could happen to our veterans?"

– Gerry Blumenthal,
Middletown veteran

"I have been disturbed not only by the number of complaints my office has received about the VA, but also by the wide range of problems. They include allegations about misdiagnosis, error in treatment, and surgical mistakes that suggest serious incompetence. They include complaints about poor relations between doctors and patients, and the inability of doctors to communicate with patients. They include complaints about shortages of professional nursing staff and allegations that patients have been neglected as a result of these changes. I have heard allegations as well about unsanitary conditions, poor maintenance of the facility, and misappropriation of the funds."

– Rep. Maurice Hinchey,
D-Saugerties

"We have carefully reviewed each case that has been brought to our attention during these past few months, either by the media, our elected representatives or veterans. It breaks my heart to hear any stories of poor care. I want you to know that I offer my personal apologies to any veteran, and their family, who has not received the best care this nation has to offer. We can all understand the pain of a family member whose sole purpose is the compassionate care and treatment of their loved one. Our veterans have earned the best because they gave us their best in service to the country."

– James Perserta,
director of NY/NJ VA Network

"My grandfather died as a result of a lack of treatment at Castle Point VA Hospital. The short of the story is he was admitted on March 24 with a so-called virus. Two weeks later, when his condition had deteriorated, we had him transferred to Hudson Valley Hospital Center in Peekskill.

Within one hour of his arrival, the diagnosis was a perforated ulcer. They took him in for immediate surgery, but he died two days later, as a result of the infection that had set in during the delay."

– Cindy Trimble,
Beacon,
granddaughter of a veteran

"I believe that the VA's initial response to the situation poisoned the atmosphere and eliminated any hope for a workable solution with veterans in the local community. Their concerns were obviously not being addressed adequately, and I felt that congressional intervention was warranted."

– Rep. Benjamin A. Gilman,
R-Middletown

"As we speak, the VA's Medical Inspector's office is finalizing its in-depth examination of the conditions at the Castle Point and Montrose VA Medical Centers, but the results will not be available for at least two to three months.

Meanwhile, we have the network leadership making blanket statements about their ability to deliver care, without waiting on the Medical Inspector's report.

The VA has a credibility gap to say the very least."

– Rep. Sue Kelly,
R-Katonah

"The implementation of VERA has now pitted veteran against veteran and state against state for medical funds which have been inadequately appropriated.

The tales of patient neglect and rising deaths at VA hospitals at Castle Point and Montrose are not unique to the Hudson Valley. We at the Division of Veterans' Affairs have heard similar allegations from veterans and families from other areas of the state, including western and upstate New York, and the metropolitan area.

Veterans, and their loved ones, are dismayed and fearful. VA hospitals were once a beacon of hope. Now, however, veterans are being turned away for care they once took for granted."

– Lawrence Del Santos,
deputy director of the New York State
Division of Veterans' Affairs

"The concept that 'we want to take care of you' coming from the VA is for many veterans hard to swallow. Veterans and their families believe that there is an unseen dagger. They believe that the Veterans Affairs, at least when it comes to medical care, will cease to exist.

If the government abandons that veteran today, may we abandon our duties as citizens tomorrow?"

– James Whisle,
deputy director of Dutchess County
Office of Veterans Affairs

"My personal experience with most physicians at Castle Point reflects the complete disregard for patient welfare.

After years of experiencing problems as a result of exposure to Agent Orange, I made a visit to Castle Point requesting an examination with a physician. After explaining my circumstances to the doctor, he made his diagnosis right from his chair without so much as a question. I quote: "You look fine to me. I don't see anything." My government not only tried to kill me once by exposing me to carcinogenic herbicides, but with the lack of proper medical care and attention almost succeeded a second time."

– Ralph Karabec,
Monroe veteran

Activist petitions for probe

Darlcar Riley, a veteran's rights activist and wife of a disabled Vietnam veteran, is calling for a national investigation into the Department of Veterans Affairs. At yesterday's congressional hearing, she circulated a petition and gathered hundreds of signatures. The petitioners' demands include:

- That the Inspector General and an appointed independent council impose a moratorium on all funding shifts and cuts for veterans' health care until all medical facilities have been investigated.
- That the investigation include all regional offices and compensation doctors in the United States to determine which obstruct or delay health claims.

And that a report on claims be compiled, and the report include how many vets died while waiting for claims to be processed and how much money the government saved by delaying claims and how much interest was earned while claim money is held.

- Hospital services and budget cuts be determined by quality and need, not size or location.
- That mortality rates and quality of patient care at VA hospitals be compared to civilian hospitals and that that information be made public.

what they say

"We ask for a complete investigation by the inspector general and an appointed independent council into all veterans regional offices and compensation doctors in the United States to determine which offices and doctors are in the business of obstructing veterans legitimate claims! The prevailing philosophy behind the protections in our Constitution is the abuses of power occur when there is no system of checks and balances! The veterans administration should be required to respond correctly to veterans claims within 90 days or an interest penalty should be imposed! Unless there are penalties for inefficiency and obstruction of claims, veterans will continue to be treated unjustly!

Hospital services and budget cuts should be determined by the quality of services rendered, veteran need, and accessibility of services, not by size or political location! Veterans should not sleep while our smaller hospitals are being eliminated in favor of huge monolithic institutions where our chances of receiving quality care are greatly diminished.

It is past time for veterans to unite and fight for the justice, respect, and dignity which they deserve. If we do not raise our voices and exercise our rights, pretty soon we will wake up to find we do not have any! Let us show the world that we will not "go quietly into the night" while the Veterans Administration continues to perpetuate injustice in the lives of even one of our combat veterans!

Let us stand up and be counted in this cause! Let us demand an investigation by the Inspector General and an independent council today.

Let our cry for justice ring out over this land until our voices are heard, and the justice and respect which was promised to our veterans is finally rendered onto them!

The call to action is now!"

– Bob Duncan,
Vietnam Vet and patient advocate at Castle Point and rally leader

"With Castle Point, over the last year, I feel everything has gone downhill. In April, after having a series of tests, the doctor told me he'd be in touch with me when he got the results back. It's now August and I haven't heard one single word.

Tomorrow, I will wander my way over again to the VA and ask them, "Have you come up with my test results?" And I can guarantee what the answer is gonna be: "We can't find the files" because they already did that twice this year."

– Richard Johannes,
Pleasant Valley veteran

"I was selected as Montrose VA Hospital Risk Manager (a registered nurse position) in October 1995. A hospital risk manager's responsibility is to make sure that the patient gets the best care possible, that safety prevails, that no accidents occur, etc.

While serving there, it became obvious that Montrose routinely and consistently departed from acceptable medical practice. I was terminated after only 38 days there for bringing the administration's shortcomings to their attention. I was told by the director of HR that I had no rights.

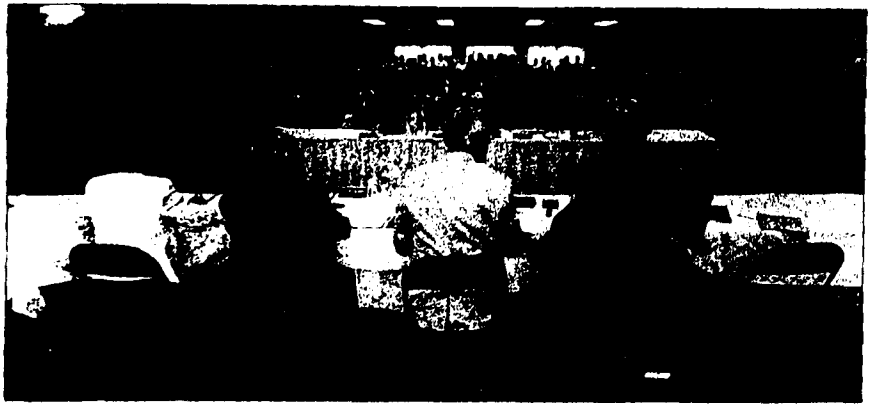
Some of the most egregious examples of malpractice at that time were:

- A hospital employee drove one of the patients to the Bronx to obtain street drugs. The patient was found dead three days later from a drug overdose. There had been previous allegations of this same nature made against the same employee.
- A patient had a hand imprint on the front of his neck. This patient cannot speak. My investigation concluded that we could not rule out forceful grabbing of his neck. My boss would not let my report go through. He wanted me to say that no one could prove that his neck had been grabbed.

These are just highlights of how things were at Montrose before the budget cuts were made.

Please know that Montrose is a gem of a facility on a magnificent piece of the Hudson just 60 miles north of New York City. The population is mostly long term either as elderly nursing home patients or a long-term psychiatric, substance abuse or as homeless. Many of these patients cannot speak, are confused, do not know their name, the date, etc. Many have no family to monitor and to act as advocates. They are innocents. Innocents who in their youth were willing to die for our country. Now our country is letting them be neglected to death."

– Mary Ellen Gionetti,
risk management assessor at FDR Montrose



Ken Blodgett/Poughkeepsie Journal

Veterans crowded the Town of Wallkill Community Center near Middletown Monday for a hearing of the Human Resources subcommittee of the House Government Reform and Oversight Committee. The committee is investigating reports of inadequate care at Veterans Affairs hospitals. While some veterans praised the hospitals, there were more veterans and relatives upset with how care has changed at the centers in the face of downsizing. "It is becoming a referral service and pharmacy under the name of a medical center," said Sandra Schwartz, a member of the Disabled American Veterans auxiliary

Anger and sorrow mark vets' plight

By Thomas N. Tobin
Poughkeepsie Journal

The doors to the Wallkill Community Center flung open Monday and the veterans, grievance and sorrow written into unsmiling faces, moved into action.

They formed platoons and companies once again. Some pushed others in wheelchairs. Some were in shorts, others in ties and jackets. They carried looseleaf papers on which were written stories of pain and indignity.

They set their sights on the head tables. At one, sat local members of Congress, Reps Sue Kelly, Benjamin Gilman and Maurice Hinchey. At another sat administrators of the federal Department of Veterans Affairs.

For most of the day, the veterans listened and seethed. They yelled angrily when they heard what they thought was a lie. They clapped when they heard what they thought was support.

They had things to say -- about care not received at Castle Point Medical Center, about inattentive doctors and insensitive staffers. Some praised the operation and the employees, but there were more stories of grief.

Daughters spoke of fathers dying too soon. One man told the committee that he had asked his suffering wife in go to a VA hospital. She did and she died, he said. He'll always regret what he did, he said, as his voice broke.

Families in grief with questions

"On March 24 of this year, my grandfather went to Castle Point and was sent home with a so-called virus," Cindy Trimble of Glenham said. "We had him transferred to another hospital. He had a perforated ulcer.

"By that time, there was nothing that could be done. He died two days later. In figuring mortality rates, does the VA count those patients who, like my grandfather, died at home or at another hospital? And by the way, three days after my grandfather died, he received a patient-care survey from Castle Point."

Another woman, Jayne Kowal, of Port Jervis, spoke about her father. "He was admitted to Castle Point with a broken hip. I kept trying to get information, to have a doctor call me back, but no one would.

"When I asked one how my father was, he said, 'Well, his heart is beating.' On March 3, he died. My father died of a broken hip. My misguided trust in the VA system made this happen."

Sandra Schwartz, a member of the Disabled American Veterans auxiliary, said that Castle Point was changing for the worse.

"It is becoming a referral service and pharmacy under the name of a medical center," she said. "Fairness to veterans requires that they be held differently at budget time."

Craig Shera, a Vietnam War veteran, sat in his wheelchair as he made his statement. He had nothing written down, but the words came.

"Don't let them close it down," he said. "I have no insurance. I have nowhere else to go."

Poughkeepsie Journal

92

HARVARD SCHOOL OF PUBLIC HEALTH

Department of Health Policy and Management

Lucian L. Leape, M.D.

October 3, 1997

Cliff Stearns
Chairman, Subcommittee on Health
Committee on Veterans' Affairs
U.S. House of Representatives
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Stearns:

Enclosed are the materials for my testimony scheduled for October 8, 1997:

- A camera ready copy of my testimony
- My disclosure statement
- My CV
- 150 copies of my testimony
- A diskette with copies of my testimony in ASCII and WordPerfect formats

I look forward to the opportunity to discuss these issues with members of your committee.

Yours sincerely,

Lucian L. Leape, MD

677 Huntington Avenue Boston, Massachusetts 02115 617 432-2008 Fax: 617 432-4494

TESTIMONY OF LUCIAN L. LEAPE, MD

Members of the Subcommittee on Health of the Committee on Veterans Affairs:

I am Lucian L. Leape, MD, a professor at the Harvard School of Public Health with a primary professional interest in improving patient safety in health care through reduction of errors. I come before you to discuss the problem of accidental injury to patients in our health care system, particularly among hospitalized patients.

First, it must be said that the rates of errors and injuries in hospitalized patients are far too high. In 1991 the Harvard Medical Practice Study reported that 4% of hospitalized patients suffered an injury due to treatment and that two-thirds of these were caused by errors. Extrapolating to the nation as a whole, we estimated that approximately 1 million Americans are injured by errors in treatment in hospitals each year, and that 120,000 people die as a result of these injuries. This is 3 times the number who die on the highways, and 1000 times the annual airline fatality rate. The cost of these injuries in 1984 was estimated at $33 billion. Because that study was based solely on a retrospective review of medical records we thought our findings represented a lower bound. Indeed, recent studies by others suggest the rate of injury caused by errors might be two or three times what we found.

Barriers to error reduction

It is evident that hospitals and other health care organizations have major deficiencies in their ability to insure the safety of patients. Why? The reasons are complex:

1) Lack of information. Studies have shown that only 2-3% of major errors are reported in hospital "incident report" systems. As a result, most hospitals are unaware of the extent of their errors and injuries. The reason for low reporting is that personnel are typically punished when they report errors. Because of this punitive environment workers tend to report only those events that cannot be concealed.

2) Health care organizations accept low levels of performance. For example, a recent report of screening rates for breast cancer in HMOs found mammography rates for women at risk varied from 30% to 90%, rates of performance that would be unacceptable in other industries, particularly high-hazard, "high-reliability" industries, such as aviation and nuclear power.

   But, despite the evidence to the contrary, health care does not think of itself as a high-hazard industry, much less a high-reliability industry. In part, this reflects the preoccupation of doctors and nurses with diagnosis and treatment, but also the traditional view of many providers that health care is so extraordinary and so socially useful that some slippage or inefficiency is an acceptable by-product. As a result, hospitals are incredibly inefficient, and tend to accept inefficiency as a normal component of health care delivery.

3) Hospital personnel (as well as most of the public) tend to regard errors as evidence of personal carelessness, the failure of the individual to meet the standard of perfect performance. Human factors specialists and high-reliability industries reject that view, recognizing that errors almost always result instead from defects in the systems in which people work. These students of error have taught us that errors are not accidents occurring out of the blue. Errors have reasons - and those reasons are very rarely carelessness or malice. Human beings make mistakes because the systems, tasks, and processes they work

in are poorly designed. Two medications with similar names or with similar labels are an accident waiting to happen. Working double shifts or having twice as many patients to take care of is an accident waiting to happen. We all know that fatigue causes errors, yet we work our doctors, nurses, and pharmacists long hours and give them extra patients to take care of. These are the kinds of systems failures that underlie the apparently simple errors that people make. These are the kinds of systems failures that must be corrected if errors are to be prevented. Hospitals don't think of errors as systems problems.

4) Our methods for eliminating errors are ineffective and misdirected. Because of the focus on individuals and on carelessness as the cause of errors, hospitals and health care organizations rely almost exclusively on training, rules, and punishment to prevent errors. We insist on perfect performance and punish people when they (inevitably) fall short.

   Unfortunately, human beings, even careful, conscientious, caring doctors and nurses, are incapable of perfection. Everyone, even the most careful, makes errors - every day. Punishment for errors merely acts as an incentive to conceal. Ironically, rather than reduce errors, punishment increases them because it makes it difficult to uncover the underlying causes of errors and remedy them. The paradox is that the single greatest impediment to error prevention is that we punish people for making them.

   High reliability industries, such as aviation, air traffic control, and nuclear power, learned long ago the fallacy in this perfectibility approach. They also believe in training, rules, and high standards, but they don't rely on them. They look to their systems.

5) Hospitals and health care organizations also lack clear incentives to do something about errors because patients, doctors, and insurance companies bear most of the costs of medical injuries. In truth, of course, errors, like any process inefficiency are costly for hospitals in terms of rework and prolonged hospitals stays by injured victims. But these have been largely unrecognized costs.

As a result of these factors, hospitals and health care organizations have not made error prevention a corporate objective, or, in most cases, even put it on the agenda. We have not made safety "job one" in health care. But, even if our health care organizations were to do so, our society imposes some formidable barriers in the regulatory and legal systems that make changing our approach to error prevention difficult.

Public approaches to error prevention

The public approaches to medical error, which are often mirrored within hospitals, are based on inspection, incentive, punishment of offenders, and controlling outbreaks. These approaches are neither modern, scientifically grounded, nor powerful forces for improvement. Worse, they add cost, reduce information exchange, produce fear, and cause their own hazards.

- Both state agencies, such as departments of health and boards of registration in medicine, and private regulators reinforce the "blame the individual" approach to error prevention. They call for identification and punishment of the responsible person.

- The media reinforce this focus on finding the person responsible - heads must roll.

- The tort system focuses on the individual who made the error causing an injury, assuming that punishment will make that person less likely to err again. The concept of a systems cause is rarely considered.

What needs to be done?

The problem of errors in health care is now becoming recognized as a major health quality issue. It will not disappear from public concern. Sentinel events reported in the media focus the attention of oversight agencies, consumer groups, organized medicine, managed care organizations, and health care executives. A body of research on the prevalence and etiology of medical error has emerged, informed in part by the experience of the aviation and nuclear power industries, and by students of human factors engineering. Health care organizations are beginning to respond. Managers within health care organizations are developing tools and techniques for the identification and prevention of errors, including sophisticated information systems, pharmacy tracking systems, practice guidelines, and quality improvement methods. These initial efforts are impressive - and reassuring that the private sector is taking up its responsibility. Some noteworthy initiatives:

- In October, 1996, under the auspices of the American Association for the Advancement of Science, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Medical Association (AMA), and the Annenberg Center, and with sponsorship by a host of health-related organizations, and others, a major conference was held that brought together people from diverse backgrounds, industrial and theoretical as well as health-related, to exchange information and ideas on how to prevent errors in health care.

- The AMA has launched a major initiative, the National Patient Safety Foundation (NPSF), dedicated to error prevention through research, education, and the dissemination of information. It can serve as a clearing house for information and a stimulus for the development of new knowledge. The NPSF has a national board of directors and has already supported some innovative approaches to error reduction while developing information resources about what is being done throughout the nation.

- The JCAHO has revised its reporting and examination procedures to reflect an emphasis on systems repair rather than punishment as a means of preventing errors.

- The American Society of Health-System Pharmacists has long led the efforts to reduce medication errors. Together with representatives from the major health care organizations and the United States Pharmacopeia they have published a guide to important systems changes that all hospitals should incorporate to reduce medication errors.

- The Institute for Health Care Improvement recently carried out a collaborative effort to reduce adverse drug events due to errors. Forty-one hospitals and health care organizations participated in this year long effort; a second collaborative is about to begin.

In the public sector, state Departments of Health and Boards of Medicine are re-evaluating their procedures to focus the attention of hospitals and health care organizations on systems problems, while still maintaining vigilance to identify and remediate individuals whose performance is dangerously below the acceptable level.

At the federal level, the Veterans Health Administration has developed a Handbook for Risk Management that incorporates some of the new insights into error prevention through systems change. This new system for identification, reporting, and analysis of adverse events has the potential to greatly expand our understanding of the scope and causes of injuries and errors in health care. It also represents an enhanced level of accountability from which all will benefit. This proactive approach can serve as a model for all health care organizations, public and private, as they seek ways to more adequately take responsibility for patient safety.

Future directions

Much remains to be done, however. We have just begun what may (and should) turn out to be a major overhaul of how we deliver health care. Some of the questions that have to be addressed include:

1. What is the best way to create incentives for hospitals and health care organizations to make error prevention a major strategic objective?

2. In the short-term, prior to implementing the needed major systems reforms, how can hospitals be motivated to implement lesser changes that are effective in reducing errors?

   These measures, which are not in place in most hospitals, include such things as bar-coding of drugs and patients, use of computerized order entry, the use of protocols for emergency treatment and for complex drug therapy, such as chemotherapy, 24-hour presence of a pharmacist, and limited work hours.

3. How can hospitals and health care organizations be motivated to eliminate punitive reporting systems? How do we make reporting of errors "safe"?

4. What measurement and monitoring systems should be developed for tracking errors and effectiveness of corrective measures?

   We lack good measures for error detection, analysis, and tracking. To be effective for improvement, measurement systems must be designed to gain knowledge, not to administer punishment.

5. How can the necessary report gathering function of regulators be modified to become a force for error reduction rather than an incentive for error concealment?

6. How do we educate health care professionals, both students and established practitioners, to help them understand, accept and act upon modern concepts for error prevention? (Including such things as teamwork, effective communication, and application of human factors principles)

7. How can we facilitate the exchange of information between health care organizations and other industries that are more expert in error prevention and system re-design?

8. Should hospitals and health care organizations instead of physicians be held responsible for adverse events (including compensating patients)? If so, what type of legislation is needed?

9. How can the perceptions of the media and the public be changed from the idea that errors are best controlled by blame and punishment to an understanding of the central roles of systems redesign and corporate responsibility?

A tall order. But we are off to a good start. And, with typical American initiative, many innovative approaches will be developed in the next few years. Making health care safe is finally on the national agenda.

HARVARD SCHOOL OF PUBLIC HEALTH

Department of Health Policy and Management

Lucian L. Leape, M.D.

To: Subcommittee on Health, Committee on Veterans' Affairs
Date: October 3, 1997
From: Lucian L. Leape
Subject: Federal support and conflicts of interest

I hereby declare that I have not received any funding or support from any Federal grant or contract related to the subject matter of my testimony within the past two fiscal years. Nor am in the employ of any commercial enterprise that makes or distributes health related equipment or supplies.

Lucian L. Leape, MD

677 Huntington Avenue Boston, Massachusetts 02115 617 432-2008 Fax: 617 432-4494

Lucian L. Leape, MD

Lucian L. Leape is a health policy analyst whose research has focused on quality of health care, particularly unnecessary surgery, the development of practice guidelines, and error prevention. He is currently Adjunct Professor of Health Policy at the Harvard School of Public Health and a member of the Health Sciences Division at RAND. Prior to joining the faculties at Harvard and RAND, he was an academic surgeon, most recently as Professor of Surgery and Chief of Pediatric Surgery at Tufts and the New England Medical Center from 1973 to 1986.

At RAND, Dr. Leape has directed several studies of overuse and underuse of cardiovascular procedures. At Harvard, he participated in the Medical Practice Study of malpractice and the Resource Based Relative Value Study. His experience in the Medical Practice Study led him to investigate the causes of error in health care practice and to carry out studies of adverse drug events and their underlying systems failures. He is currently leading the Institute for Healthcare Improvement initiative in error prevention. He has served on the AHCPR Health Services Research Review Committee, the Institute of Medicine Committee on Technological Innovation in Medicine, and the PPRC Access Advisory Committee. Dr. Leape is a graduate of Cornell University and Harvard Medical School and trained in surgery at the Massachusetts General Hospital and at the Boston Children's Hospital.

CURRICULUM VITAE

LUCIAN L. LEAPE, MD

ADDRESSES:

Office: Dept. of Health Policy and Management
Harvard School of Public Health
677 Huntington Ave.
Boston, MA 02115
(617) 432-2008

Home: 12 Laurel Drive
Lincoln, MA 01773
(617) 259-9620

PRESENT POSITION: Adjunct Professor of Health Policy, Harvard School of Public Health
Consultant, The RAND Corporation

PERSONAL INFORMATION:

Born: November 7, 1930, Pittsburgh, PA
Social Security No. 183-24-3308

MILITARY SERVICE: Lieutenant (j.g.), U. S. Navy (1952-55)

EDUCATION: A.B. Cornell University, 1952
M.D. Harvard Medical School, cum laude, 1959

POSTDOCTORAL TRAINING:

Internship and Residency in Surgery
Massachusetts General Hospital
1959-62; 1964-65

Resident in Pediatric Surgery
Boston Children's Hospital, 1962-64

Registrar in Pediatric Surgery
Alder Hey Hospital
Liverpool, England, 1965-66

Health Policy Fellow
The RAND Corporation, 1986-87

CERTIFICATION AND LICENSURE:

Licensed in Massachusetts (# 26580) (1959)
National Board of Medical Examiners (1960)
American Board of Surgery (1967)
American Board of Thoracic Surgery (1967)
Certificate of Special Competence in Pediatric Surgery, American Board of Surgery (1975), Recertified, 1984

PREVIOUS ACADEMIC AND HOSPITAL APPOINTMENTS:

Instructor to Associate Professor of Surgery, Senior Surgeon
University of Kansas School of Medicine, 1966-73

Professor of Surgery
Tufts University School of Medicine
Chief of Pediatric Surgery
New England Medical Center Hospital, 1973-87

AWARDS AND HONORS:

Society of the Sigma Xi, Harvard University (1957)
Alpha Omega Alpha, Harvard Medical School (1958)
John and Mary R. Markle Scholar in Academic Medicine, Kansas University (1968)

EDITORIAL BOARDS: Associate editor, Journal of Pediatric Surgery (1971-1987)

NATIONAL COMMITTEES:

AHCPR Study Section, 1990-92
IOM Committee on Technological Innovation in Medicine, 1991-
PPRC Access Advisory Committee, 1992-

PROFESSIONAL SOCIETIES:

American Academy of Pediatrics
American College of Surgeons
American Pediatric Surgical Association
American Public Health Association
Association for Academic Surgery
Association of American Medical Colleges
Association for Health Services Research
Boston Surgical Society
British Association of Pediatric Surgeons
Lilliputian Surgical Society
National Wilms Tumor Study
New England Pediatric Society
New England Surgical Society
Roxbury Clinical Record Club
The Society of University Surgeons

Lucian L. Leape

Recent Publications

1. Leape, L L, Unnecessary Surgery. A Pew Memorial Trust Policy Synthesis: 7. HSR: Health Services Research, 1989, 24 (3):351-407.

2. Leape, L. L., Park, R. E., Solomon, D. H., Chassin, M. R., Kosecoff, J., and Brook, R. H.: Relation between surgeons' practice volumes and geographic variation in the rate of carotid endarterectomy. New Engl J. Med, 1989, 321:653-657.

3. Hiatt, H. H., Barnes, B. A., Brennan, T. A., Laird, N. M., Lawthers, A. G., Leape, L. L., Localio, A. R., Newhouse, J. P., Peterson, L. M., and Thorpe, K. E.: A study of medical injury and medical malpractice. An overview. New Engl J. Med, 1989, 321:480-484.

4. Leape, L. L., Park, R. E., Solomon, D. H., Chassin, M. R., Kosecoff, J., and Brook, R. H.: Does inappropriate use explain small area variations in the use of health care services? JAMA, 1990, 263:669-672.

5. Leape, L L, Practice guidelines - an overview. QRB, 1990; 16:42-9.

6. Brennan, T. A., Localio, A. R., Leape, L. L., Laird, N. M., Peterson, L., Hiatt, H. H., and Barnes, B.: Identification of adverse events occurring during hospitalization. Ann Int Med, 1990, 112:221-226.

7. Brennan, T. A., Leape, L. L., Laird, N. M., Hebert, L., Localio, A. R., Lawthers, A. G., Newhouse, J. P., Weiler, P. C., and Hiatt, H. H.. Incidence of adverse events and negligence in hospitalized patients: Results from the Harvard Medical Practice Study I. New Engl J. Med, 1991, 324:370-376.

8. Leape, L. L., Brennan, T. A., Laird, N. M., Lawthers, A. G., Localio, A. R., Barnes, B. A., Hebert, L., Newhouse, J. P., Weiler, P. C., and Hiatt, H. H.. The nature of adverse events in hospitalized patients: Results from the Harvard Medical Practice Study II. New Engl J. Med, 1991, 324:377-384.

9. Leape, L. L., Brennan, T. A., Laird, N. M., Lawthers, A. G., and Hiatt, H. H.. Adverse events and negligence in hospitalized patients. Iatrogenics, 1991, 1:1-5.

10. Brennan, T.A., and Leape, L. L.. Adverse events, negligence in hospitalized patients: Results from the Harvard Medical Practice Study. Perspectives in Healthcare Risk Management, 1991, 11:2-7.

11. Brennan, T. A., Hebert, L. E., Laird, N. M., Lawthers, A., Thorpe, K. E., Leape, L. L., Localio, A. R., Lipsitz, S. R. Newhouse, J. P., Weiler, P. C., and Hiatt, H. H.. Hospital characteristics associated with adverse events and substandard care. JAMA, 1991, 265:3265-3269.

12. Leape, L. L., Hilborne, L. H., Kahan, J., Stason, W. B., Park, R. E., Kamberg, C. J., and Brook, R. H., Coronary Artery Bypass Graft. A literature review and ratings of appropriateness and necessity. Publ JRA02. Santa Monica, 1991, the RAND Corporation.

13. Hilborne, L. H., Leape, L. L., Kahan, J. P., Park, R. E., Kamberg, C. J., and Brook, R. H., Percutaneous Transluminal Coronary Angioplasty. A literature review and ratings of appropriateness and necessity. Publ. JRA01. Santa Monica, 1991, the RAND Corporation.

14. Leape, L. L.. Unnecessary surgery. Ann Rev of Public Health, 1992, 13:363-383.

15. Johnson, W.G., Brennan, T.A., Newhouse, J.P., Leape, L. L., Lawthers, A.G., Hiatt, H.H., and Weiler, P.C.. The economic consequences of medical injuries: Implications for a no-fault insurance plan. JAMA, 1992, 267:2487-2492.

16. Leape, L. L., Park, R. E., Kahan, J. P., and Brook, R. H.. Group judgments of appropriateness: The effect of panel composition. Qual Assur in Health Care, 1992, 4:151-159

17. Ballard, D. J., Etchason, J. A., Hilborne, L. H., Campion, M. E., Kamberg, C. J., Solomon, D. H., Leape, L. L. , Kahan, J. P., P ark, R. E., and Brook, R. H., Abdominal Aortic Aneurysm Surgery. A literature review and ratings of appropriateness and necessity. Publ JRA04. Santa Monica, 1992, the RAND Corporation.

18. Bernstein, S. J., Laouri, M., Hilborne, L. H., Leape, L. L., Kahan, J. P., Park, R. E., Kamberg, C. J., and Brook, R. H., Coronary Angiography. A literature review and ratings of appropriateness and necessity. Publ. JRA03 Santa Monica, 1992, the RAND Corporation.

19. Leape, L. L., Freshour, M. A., Yntema, D. B., and Hsiao, W., Small-group judgment methods for determining resource-based relative values. Medical Care, 1992, 30:NS28-39.

20. Leape, L. L., The Future of Surgery. In: Blendon, R. J. and Hyams, T. S., eds. Reforming the system: Containing costs in an era of universal access. Washington, DC, 1992, Faulkner and Gray.

21. Bates, D. W., Leape, L. L. and Petrycki, S., Incidence and preventability of adverse drug events in hospitalized adults. J. General Internal Medicine 1993, 8:289-294.

22. Weiler, P. C., Hiatt, H. H., Newhouse, J. P., Brennan, T. A., Johnson, W. G., and Leape, L. L., Patients, doctors and lawyers: A study of medical injury, malpractice litigation, and patient compensation. Cambridge, Harvard University Press. 1993

23. Leape, L. L., Hilborne, L. H., Park, R. E., Bernstein, S. J., Kamberg, C. J., Sherwood, M., and Brook, R. H., The appropriateness of use of coronary artery bypass graft surgery in New York state. JAMA, 1993, 269:753-760.

24. Hilborne, L. H., Leape, L. L., Bernstein, S. J., Park, R. E., Fiske, M. E., Kamberg, C. J., Roth, C. P., and Brook, R. H., The appropriateness of use of percutaneous transluminal coronary angioplasty in New York state. JAMA, 1993, 269:761-765

25. Bernstein, S. J., Hilborne, L. H., Leape, L. L., Fiske, M. E., Park, R. E., Kamberg, C. J., and Brook, R. H., The appropriateness of use of coronary angiography in New York state. JAMA, 1993, 269:766-769

26. Leape, L. L., Practice Guidelines. In: Goldstone, J, et al, eds., Perspectives in Vascular Surgery 6:117-127, 1993, St Louis, Quality Medical Publishing.

27. Leape, L. L., Lawthers, A. G., Brennan, T. A., and Johnson, W.G., The preventability of medical injury. Qual Rev Bull 1993, 19:144-149.

28. Leape, L. L., McGlynn, E. A., Naylor, C. D., Bernstein, S. J., The Canadian Coronary Angiography Panel, Park, R. E., Kahan, J. P., and Brook, R. H., Coronary Angiography: Ratings of Appropriateness and Necessity by a Canadian Panel. Publ. MR-129-CWF/PCT Santa Monica, 1993, the RAND Corporation.

29. Naylor, C. D., McGlynn, E. A., Leape, L. L., Hilborne, L. H., The Canadian Revascularization Panel, Park, R. E., Kahan, J. P., and Brook, R. H., Coronary Artery Bypass Graft Surgery and Percutaneous Transluminal Coronary Angioplasty: Ratings of Appropriateness and Necessity by a Canadian Panel. Publ. MR-128-CWF/PCT Santa Monica, 1993, the RAND Corporation.

30. Shiffman, R.N., Leape, L. L., and Greenes, R. A., Translation of appropriateness criteria into practice guidelines: Application of decision table techniques to the RAND criteria for coronary artery bypass graft. Proc. 17th SCAMC (1993) 243-252.

31. Leape, L. L., Strengthening the connection between evaluative research and coverage adoption decisions. In: Gelijns et al, eds, Adoption decisions in Health Care. Washington, D.C., 1994, National Academy Press.

32. Leape, L. L., The Preventability of Medical Injury. In: Bogner, M. S., ed., Human Error in Medicine, 1994, Lawrence Erlbaum Associates.

33. McGlynn, E. A., Naylor, C. D., Anderson, G. M., Leape, L. L., Park, R. E., Hilborne, L. H., Bernstein, S. J., Goldman, B. S., Armstrong, P. W., Keesey, J. W., McDonald, L., Pinfold, S. P., Damberg, C., Sherwood, M. J., Brook, R. H., Comparison of the appropriateness of coronary angiography and coronary artery bypass graft surgery between Canada and New York State. JAMA, 1994, 272:934-940.

34. Kahan, J. P., Bernstein, S. J., Leape, L. L., Hilborne, L. H., Park, R. E., Parker, L., Kamberg, C.J., and Brook, R. H. Measuring the necessity of medical procedures. Medical Care, 1994, 4:357-365.

35. Leape, L. L., Error in Medicine. JAMA, 1994, 272:1851-1857.

36. Bernstein, S. J., Hilborne, L. H., Leape, L. L., Park, R. E., and Brook, R. H., The appropriateness of use of cardiovascular procedures in men and women. Arch Int Med, 1994, 154:2759-2765.

37. Bates, D. W., Boyle, D., Vander Vliet, M., Schneider, J., and Leape, L. L., Relationship between medication errors and adverse drug events. J. Gen Int Med, 1995, 10:199-205.

38. Leape, L. L., Preventing adverse drug events. Am J Health-Syst Pharm, 1995, 52:379-382.

39. Leape, L. L., Translating medical science into medical practice. Do we need a National Medical Standards Board? JAMA, 1995, 273:1534-1537.

40. Leape, L. L., Bates, D. W., Cullen, D. J., Cooper, J., Demonaco, H. J., Gallivan, T., Hallisey, R., Ives, J., Laird, N., Laffel, G., Nemeskal, N., Petersen, L. A., Porter, K., Servi, D., Shea, B. F., Small, S., Sweitzer, B., Thompson, B. T., and Vander Vliet, M., Systems analysis of adverse drug events. JAMA, 1995, 274:35-43.

41. Bates, D. W., Cullen, D. J., Laird, N., Petersen, L. A., Small, S., Servi, D., Laffel, G., Sweitzer, B., Shea, B. F., Hallisey, R., Vander Vliet, M., Nemeskal, R., and Leape, L. L.. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. JAMA, 1995, 274:29-34

42. Cullen, D. J., Bates, D. W., Small, S. D., Cooper, J. B., Nemeskal, A. R., and Leape, L. L.. The incident reporting system does not detect adverse drug events: A problem in quality assurance. Jt Com J Qual Improv, 1995, 21:541-548.

43. Leape, L. L., A brief account of the founding of the American Pediatric Surgical Association. J. Ped Surg, 1996, 31:12-18.

44. Kahan, J. P., Park, R. E., Leape, L. L., Bernstein, S. J., Hilborne, L. H., Parker, L., Kamberg, C.J., Ballard, D. J., and Brook, R. H. Variations by specialty in physician ratings of the appropriateness and necessity of indications for procedures. Med Care, 1996, 34:512-523

45. Leape, L. L., Hilborne L. H., Schwartz, J. S., Bates, D.W., Rubin, H. R., MD, PhD; Slavin, P. L., Park, R. E., Witter, D. M., Panzer, R. J., Brook, R. H., and the Working Group of the Appropriateness Project of the AMCC, The appropriateness of coronary artery bypass graft surgery in academic medical centers. Ann Int Med, 1996, 125:8-18.

46. Leape, L. L., An overview of adverse drug events. U.S. Pharm, 1996, October Supplement: 2-8.

47. Leape, L.L., Out of the darkness. Hlth Sys Rev, 1996, Nov/Dec:21-24

48. Bates, D.W., Miller, E., Bernstein, S.J., Hauptman, P.J., and Leape, L. L., Coronary angiography after acute myocardial infarction: A literature review. Ann Int Med, 1997, 126:351-359.
press.

49. Bates, D.W., Spell, N., Cullen, D.J., Burdick, E., Laired, N., Petersen, L.A., Small, S.D., Sweitzer, B.J., and Leape, L.L., The costs of adverse drug events in hospitalized patients. JAMA, 1997; 277:307-311.

50. Matchar, D.B., Oddone, E.Z., McCrory, D.C., Goldstein, L.B., Landsman, P.B., Samsa, G., Brook, R.H., Kamberg, C., Hilborne, L.H., Leape, L.L., and Horner, R., Influence of projected complication rates on estimated appropriate use rates for carotid endarterectomy. Hlth Serv Res. In press.

51. Leape, L.L., A systems analysis approach to medical error. In: M.R. Cohen and N.M. Davis, Medication Errors: Causes and Prevention, Washington, DC., Am Pharm Assoc, In Press.

STATEMENT OF

KENNETH W. KIZER, M.D., M.P.H.

UNDER SECRETARY FOR HEALTH

DEPARTMENT OF VETERANS AFFAIRS

ON VA'S RISK MANAGEMENT POLICIES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 8, 1997

Mr. Chairman, I am here to discuss VHA's risk management program and changes that have been made to facilitate system learning to reduce untoward outcomes related to medical treatment. Before addressing specifics of our risk management policy, however, I want to briefly describe VHA's overall approach to quality management.

VHA's Approach to Quality Management

As you know, during the last 2-3 years, great progress has been made in reengineering the veterans healthcare system. Many of the changes that have occurred were thought to be impossible not long ago.

As part of this reengineering effort we have implemented a very comprehensive quality care framework. This framework consists of 12 dimensions. In brief, these dimensions are as follows:

1. Credentialing and privileging of personnel.
2. Accreditation of programs, facilities, and networks by such groups as the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the American College of Surgeons, and the College of American Pathologists, to name a few.

3. Ins itution of clinical care strategies such as practice guidelines and clinical pathways, case management, provider profiling, shared decision-making, and improved palliative care.
4. Use of performance indicators such as the new Chronic Disease and Prevention Indexes, surgical morbidity and mortality rates, and standardized functional outcome instruments.
5. Internal review through mechanisms such as clinical pathology conferences and ad hoc review teams.
6. External and independent review from contracted external peer review organizations and from such entities as the General Accounting Office, the Inspector General, and congressional oversight committees.
7. Customer feedback from such activities as patient satisfaction surveys, patient focus groups, and patient complaint tracking.
8. Continuous quality improvement activities such as the National Quality Council, 360-degree personnel evaluations and employee satisfaction surveys.
9. A risk management program that encourages open reporting of untoward outcomes and includes an adverse events registry and root cause analysis, among other specific methods.
10. Use of VA's education apparatus for training healthcare professionals as well as the new VA Learning University that focuses on workforce development.
11. Research in areas such as quality of care, clinical care studies, health services delivery, and technology assessment.
12. Change management and organizational learning through activities such as executive performance agreements, a new resource allocation strategy (VERA), and integrated collaborative planning.

It is important to understand the various dimensions of the framework, and what they target, when considering the specific function of the risk management policy and role of the Office of the Medical Inspector (OMI).

Risk Management in VHA

I would like to turn now to our risk management program, the major focus of today's hearing. This is a program that focuses primarily on patient safety -- i.e., on adverse events that are related directly or indirectly to medical treatment.

A number of well publicized and tragic events during the last few years have made it clear that increasing patient safety should be a national priority for healthcare systems everywhere. Research findings certainly support this conclusion. In particular, the widely respected Harvard Medical Practice Study indicated that 180,000 Americans die each year and 1.1 million are injured or disabled because of adverse events, two-thirds of which are thought to be preventable. Other studies have found that about 5 per 1,000 in-patients experience an adverse event that results in their death. Investigators also report that they believe these data represent the lower limits of the occurrence of these events and that the actual occurrence is much higher.

VHA has recently implemented an improved risk management program that I believe will place it at the forefront of efforts everywhere to provide safer medical care. Indeed, on sharing drafts of this policy with various private sector organizations they have all been highly complimentary.

VHA's program is based on a new paradigm for risk management – one which has emerged from a number of significant research findings during the last few years. First, studies of private sector care, such as the Harvard Medical Practice Study, have shown that serious injuries resulting from medical care are common – in fact, much more common than generally believed. Second, most of these patient injuries result from preventable errors. Third, errors usually result from poorly designed systems or processes that either induce errors or make them difficult to detect and intercept (as opposed to negligent or ill intentioned people). Fourth, and most important, analysis of the underlying systems can often lead to process or system redesigns that will

significantly reduce the likelihood of errors. The latter requires an atmosphere that encourages complete reporting and thoughtful analysis of such problems.

Based on these compelling findings, VHA is focused on designing patient care systems that will prevent errors. Implicit in this design is the need to break down currently prevalent disincentives for addressing medical errors. These disincentives include the traditional medical care culture that finds it difficult to acknowledge errors and mistakes, as well as the fear of litigation and sensationalistic anecdotal media coverage. In its place, we need to create a culture that permits medical care personnel to acknowledge the occurrence of errors and encourages open and complete reporting of adverse events. Of course, the system also has to ensure that when appropriate, personnel actions should be taken against employees whose negligence led to a patient injury. However, we are convinced that the real payoff in improving patient safety will come from changing the way medical care is provided in the VA and in the healthcare system overall.

We are using several different strategies to identify and make needed changes. First, our facilities routinely analyze all service delivery systems to identify redesigns of those systems that will increase patient safety. These analyses involve: (1) identifying those medical care processes most in need of redesign, and (2) introducing checks and balances for each of these processes so that the likelihood of errors is zero. The well-established procedure of having two staff independently check a patient's identity before administering a transfusion is a simple example of checks and balances. Another is the use of bar coding to prevent medication errors by electronically verifying the patient, drug, route, and time against the original order before a drug is given to a patient.

A second procedure to increase safety is to intensively review all adverse events from a care-site specific and systemwide focus. These reviews identify the root causes of each incident, the changes in design of systems needed to prevent recurrence, and any appropriate personnel actions.

Under VHA's new protocol, all reviews of adverse events are sent to the network office and to VHA headquarters where they are reviewed to identify:

1. The adequacy of the facility review and the appropriateness of the actions taken,
2. The frequency with which particular care delivery systems have been problematic so managers know where the best opportunities for improvement exist,
3. System redesigns that should be adopted throughout the network or nationally,
4. Needed changes in network and national policies and procedures, and
5. Lessons learned that can be shared throughout VHA on an Intranet database.

Within Headquarters, a Risk Management Oversight Committee accomplishes this review with representatives from the Offices of the Chief Network Officer, Performance and Quality, Medical Inspector, and Patient Care Services. As needed, the committee obtains the input of subject matter experts from throughout VHA. At a recent meeting, the committee reviewed a case involving the pharmacy mailout program and requested that VHA's Chief Information Officer and Chief Pharmacy Consultant also review this adverse event. As a result of their review, the committee decided that this incident contained important lessons. VHA software designers are now modifying the software for entering prescriptions to prevent such errors systemwide.

The sharing of risk management information between our facilities, particularly innovative system redesigns, is another key aspect of our improved program. All current VHA communication media, such as weekly VISN director conference calls and regularly scheduled nation-wide risk management conference calls, are being used for this purpose. In addition, a Lessons Learned Database on VA's Intranet is being developed as an interactive medium for the sharing of risk management information throughout our system. Information will be routinely entered by facility staff as well as the Risk Management Oversight Committee and the Offices of the Medical Inspector and Performance and Quality.

The improved policy also requires medical facilities to review morbidity and mortality data generated by national monitoring programs to identify problems in quality of care. The new policy also provides specific guidance regarding the notification of law enforcement authorities and other appropriate actions when review of morbidity and mortality data indicate an association between a specific practitioner and increased morbidity or mortality rates.

Finally, VHA's new Risk Management policy continues VHA's emphasis on minimizing the negative consequences of injuries to patients. It requires facility staff to promptly inform patients and their families about the clinical facts associated with injuries resulting from medical care, assuring them that measures have been taken to maintain life and minimize disability and discomfort. In addition, facility staff are required to advise patients and their families of any remedial options including clinical care and possible compensation.

To encourage rapid and effective implementation of its improved risk management program, VHA will include a risk management measure in its network director performance measures for FY 1998. To be fully successful in achieving this measure, a network must redesign a number of major service delivery systems to improve patient safety at all applicable network facilities. Site visits to validate the supporting documentation provided by the network will be performed. An exceptional rating requires also having at least one system redesign from the network assessed by other networks as one of the 10 system redesigns presented on the Lessons Learned Intranet Database that were most useful to them in redesigning their own care delivery systems.

Role of Medical Inspector

Mr. Chairman, you also requested that I discuss the role, function and organizational structure of the Office of the Medical Inspector (OMI) as it relates to Risk Management, and its other responsibilities.

The Office of the Medical Inspector is organizationally an adjunct of the Office of the Under Secretary for Health, and the Medical Inspector reports directly to me. The office is directed by a highly qualified physician with a unique background of many years assessing quality of care for the Joint Commission on Accreditation of Healthcare Organizations. His staff includes an experienced nurse with a Ph.D. in Epidemiology, an experienced health systems specialist with a Masters in Public Health and a Doctor of Science in Operations Research, two master level Health Systems Specialists, one with extensive knowledge and experience in planning and fiscal matters and the other with extensive clinical and quality assurance knowledge as an allied health professional and three office assistants. One of the health systems specialists is detailed to another agency for one year. Some time ago, I recognized the need for more personnel and authorized the OMI to hire two additional staff, a nurse and a physician. A nurse who served as a chief nurse at one of our facilities recently joined the OMI staff. She brings to the staff additional field perspective. A physician is being recruited.

The Medical Inspector is authorized to use specialists and consultants from the field, as needed, to carry out site visits and to conduct reviews. Depending on the issues, a specific interdisciplinary team is assembled for each site visit. OMI staff advise and direct the team and coordinate the site visit. Over 75 physicians, nurses, social workers, patient representatives, quality improvement managers, and others have participated in the past year. On occasion, the OMI joins forces with staff from the Office of Healthcare Inspections (OHI), Office of the Inspector General, on investigations when expertise from both offices is needed. The OHI also oversees the work of the OMI.

The OMI conducts case-specific/incident-specific and some program quality of care reviews through investigations, site visits, and other analyses. These are performed at the request of the Secretary of Veterans Affairs, the Under Secretary for Health, individual veterans, and a number of other stakeholders. These reviews range from the care provided to an individual patient to the quality of care provided by a medical center or

Veterans Integrated Service Network (VISN). A formal report of each investigation and review is developed and sent in draft form for comments to me and to other appropriate program offices, including the Office of the Inspector General. The final report contains findings, conclusions and, if applicable, recommendations. The involved medical center, VISN, or program office submits an action plan that addresses the recommendations. The action plan is monitored over time. When actions are completed, and supported by documentation, the report is closed. In the preceding 12-month period, the OMI conducted 21 reviews and investigations.

I have directed that VHA staff give all information requested and their full cooperation to the OMI in its reviews and investigations. By the same token, I have insisted that the OMI conduct objective and independent reviews and investigations, and that they submit thorough and fair reports.

Within the context of the new Risk Management Directive, the OMI assumes both reactive and proactive roles. The OMI has timely access to reports of adverse events, such as unexpected deaths and serious injuries to veterans, as well as to the reports of all Boards of Investigation and focused reviews. The new Risk Management policy provides for this access by requiring facilities and networks to report particularly significant adverse events to the Chief Network Officer within 48 hours who, in turn, provides the information to the office of the OMI and others. The circumstances surrounding these events are evaluated and actions are taken at the local facility and network levels. In the majority of instances, no further action is required at VHA Headquarters. I rely on the OMI and others to assess this information on a regular basis and to take appropriate action. The OMI is also involved in the development of a registry of adverse events that will serve as a resource for all relevant offices in VHA Headquarters and field facilities and the OMI will be a regular contributor to our 'Lessons Learned' homepage.

In addition to focused reviews and involvement with other risk management functions, I have asked the OMI to conduct other reviews or studies. This can best be illustrated by two recent examples. In January 1997, to become better informed as to whether Gulf War veterans were listened to about their possible exposure to various chemical and environmental agents, I asked the OMI to conduct a review of medical records to see what was documented regarding potential exposure to environmental agents. In the space of three weeks, the staff visited nine hospitals and reviewed a sample of 1200 medical records and reported their findings to me. In brief, the OMI concluded that VA Registry staffs at the selected VA facilities had been listening to Persian Gulf War veterans about possible exposure to environmental contaminants, particularly in the last two years. The second example was an analysis by OMI staff of all Boards of Investigation of Patient Abuse cases in inpatient settings over a period of three years, 1992 through 1994. The analysis showed an upward trend in the number of both alleged and substantiated patient abuse incidents in our VA facilities for the period. It was on this basis that my office authorized the formation and funding of a highly specialized task force to study the issue in depth and to render a report with recommendations for corrective actions to be taken.

In reviewing the role and functions of the OMI, I recognized the need for an outside review. As with other offices in VHA Headquarters, such evaluations are helpful in informing decision-making as it relates to the size and mix of the staff, and to changes in functions and organizational placement. This review is in progress and should be completed within 2-3 months.

To summarize, the OMI has a distinct and important place in VHA Headquarters. Its role in Risk Management events, its evaluation of quality of care issues, its ability to recommend changes and corrective actions, and its monitoring of the implementation of the changes and actions, serves to enhance the quality of VA healthcare.

Overall, Mr. Chairman, while I believe VA's record on patient safety is a good one compared to other healthcare systems, there is room for improvement. I believe VA's present framework for assuring quality of care, which includes the new risk management policy and a clarified role for the OMI, will translate into more rapid and more complete system learning about improving patient safety and far fewer adverse events related to medical care.

This concludes my statement. I will be pleased to respond to your questions.

STATEMENT OF DR. JOHN H. MATHER
ASSISTANT INSPECTOR GENERAL
DEPARTMENT OF VETERANS AFFAIRS

BEFORE THE SUBCOMMITTEE ON HEALTH,
COMMITTEE ON VETERANS' AFFAIRS,
UNITED STATES HOUSE OF REPRESENTATIVES

OVERSIGHT HEARING ON

THE VETERANS HEALTH ADMINISTRATION'S
RISK MANAGEMENT PROGRAM AND
ITS OFFICE OF MEDICAL INSPECTOR

OCTOBER 8, 1997

Mr. Chairman and Members of the Subcommittee, I appreciate the opportunity to appear today to discuss the Veterans Health Administration's policy and performance in the area of risk management, and the mission, role, and organizational structure of its Office of Medical Inspector (OMI), as it relates to both risk management and the OMI's other responsibilities.

1. Office of Inspector General (OIG) Role

The Office of Inspector General (OIG) has a mandate to provide independent oversight of the Department of Veterans Affairs. The OIG is accountable to both Congress and the Department in carrying out its mission to promote economy, efficiency, and effectiveness in VA operations; to detect and prevent fraud, waste, and abuse in VA programs; and to monitor VA's medical quality-assurance programs. In carrying out its mission, one of the OIG's primary goals is to help management succeed in its effort to reinvent government; that is, to build a government that works better and costs less for the benefit of today's and tomorrow's veterans and taxpayers. This goal speaks to the very essence of the OIG mission--and unites us with Department management and Congress as we strive together to ensure that quality services are delivered to veterans in a cost effective, efficient, and timely manner.

2. OIG Monitoring of Quality Assurance

In the mid-1980s, a perception developed that, at least in the area of having proficiency in the formal implementation of the healthcare quality assurance (QA) process, VA was lagging. The General Accounting Office (GAO) reported, "VA Has Not Fully Implemented Its Health Care Quality Assurance Systems[1], " in June 1985, followed immediately by a U.S. House of Representatives report entitled "Patients At Risk: A Study Of Deficiencies In the Veterans Administration Medical Quality Assurance Program"[2] Both reports were very critical of VA's formal QA programs and processes.

The GAO similarly criticized the VA Central Office's Office of the Medical Inspector (OMI) established to oversee quasi-legal and quasi-medical aspects of VA, mainly VA's patient injury control program, patient abuse, and practitioner licensing sanctions. VA's Medical Inspector office, which had been established within the

[1] VA Has Not Fully Implemented Its Health Care Quality Assurance Systems, U.S. General Accounting Office, GAO/HRD-85-57, June 27, 1985

[2] Patients At Risk: A Study of Deficiencies in the Veterans Administration Medical Quality Assurance Program, Seventh /Report By the Committee on Government Operations Together With Separate Views, April 30, 1987, U.S. Government Printing Office, Washington: 1987

Veterans Health Administration (VHA) in response to an apparent lack of effective central oversight and medical investigator capacity, was felt to require substantial revision in the GAO report, "VA's Patient Injury Control Program Not Effective."[3]

It is consistent with the broad charter of VA's IG--mainly the obligation to monitor the economy, efficiency, and effectiveness of the Department's programs and activities--to oversee VA healthcare and QA activities. Nonetheless, after substantial debate, Congress decided to provide emphasis in this area for VA's IG.

The first specific attempt at such a focus through the OIG was in Public Law 99-166, "The Veterans' Administration Health-Care Amendments of 1985,"[4] which mandated that "The Inspector General of the Veterans' Administration shall allocate sufficient resources including sufficient personnel with the necessary skills and qualifications to enable the Inspector General to monitor the [healthcare] quality assurance program." Eventually the Congress was to extend this legislation and, in the "Veterans Benefits and Services Act of 1988"[5], Public Law 100-322. It was more fully elaborated that VA should "upgrade and expand the activities of the Veterans' Administration's Office of Inspector General in overseeing, monitoring, and evaluating the operations of the Department of Medicine and Surgery's [VHA's] quality-assurance programs and activities and its Medical Inspector office so as to provide the Chief Medical Director [Under Secretary for Health], the Administrator [Secretary], and the Congress with clear and objective assessments of the effectiveness of those programs and operations, including ensuring such numbers of, and such skills and training on the part of, employees assigned to the Office of Inspector General as are necessary to carry out such oversight, monitoring, and evaluation effectively."

3. OIG Organizational Focus: Office of Healthcare Inspections

In 1988, VA's IG established a support Division within its Policy, Planning, and Resources Office known as the Quality Assurance Review Division (QARD). This Division was staffed in 1989. In 1991, coincident with the continuing and, indeed, increasing prominence of QA and oversight of health care systems, the QARD was upgraded to a full VA OIG "office," co-equal organizationally with its Office of Audit and Office of Investigations. This Office is named the Office of Healthcare Inspections (OHI).

The OHI fulfills for the IG the primary focus for general oversight and monitoring of VHA's quality-assurance activities and programs, and oversight of the VHA's OMI. These broad responsibilities are ongoing and become most specific as regards program evaluations, Hotline inspections, and the development of a new Quality Program Assistance (QPA) review.

a. General Oversight

i. Oversight of VA's QA Programs

Oversight of VA's QA programs at all levels, particularly its VACO/VHA Quality Assurance Office (now named, Office of Performance and Quality) was specifically mandated by Congress. OHI attempts to meet this mandate in two general ways. In individual case reviews, a facility's QA programs are routinely assessed, and

---

[3] VA Health Care, VA's Patient Injury Control Program Not Effective, U.S. General Accounting Office, GAO/HRD-87-49, May, 1987

[4] Public Law 99-166, "The Veterans' Administration Health-Care Amendments of 15," 99 STAT. 941, Title II--Health Care Administration Sec. 201 - 204, December 3, 1985

[5] "Veterans' Benefits and Services Act of 1978," May 20, 1988, Public Law 100-322, Section 201, 102 Stat. 508-509

generally commented upon in conjunction with OHI hotline inspections. Second, OHI understands that VACO/VHA coordinates several nationwide QA programs. These include its "Occurrence Screening Program," "The Patient Incident Reporting System," "Tort Claims Analysis," "Patient Satisfaction Survey Program, " "Utilization Management Program," "Cardiac Surgery Review Program," and the "External Peer Review Program."

OHI, in its oversight capacity has reviewed the strengths and weaknesses of many of these programs, such as the "Evaluation of the Veterans Health Administration's Patient Satisfaction Survey Program." This was followed by an "Evaluation of the Veterans Health Administration's Quality Improvement Checklist (QUIC) Program," and "Evaluation Of The Patient Representative Program." Its most recent report of a VACO/VHA directed QA program is a review of the "External Peer Review Program."

Earlier this year, OHI initiated an evaluation of VHA's quality assurance program at the request of the Senate Veterans' Affairs Committee (SVAC). This review will encompass and conduct:

1. A comprehensive evaluation of the VHA's current QA activities, including those at the VACO level the VISN level, and the local VA medical center (VAMC) level.

2. Identifying specific guidance provided to field facilities about QA matters,

3. Identifying the number of personnel who are assigned QA responsibilities on a full or part-time basis, and determine if they have the resources, authority, and access to ensure veterans receive quality care.

OHI is in the midst of this review which will include a review of VHA's risk management program. It is anticipated that this will be completed early in 1998.

ii. Oversight of the Office of Medical Inspector

VHA's Office of Medical Inspector (OMI) was established in 1980[6]. This office serves as an internal medicolegal oversight office for VHA, and in some sense might be considered a precursor to OHI. However, it is distinguished from the OIG's OHI, in that OMI is internal to VHA. OHI, being an OIG component, is external to the VHA. This distinction, which, unfortunately, has been a repeated cause of confusion, even to those familiar with VA, might be further explained by the analogy that the OMI serves as an internal overseer and "troubleshooter" for VHA and reports to the Under Secretary for Health (USH): while OHI is an external overseer of health care activities, reporting, through the Inspector General, to the Department's Secretary and Congress. These different reporting relationships provide the OHI with the assurance of an independence of its investigations that the OMI cannot always have. VHA's current operating philosophy is that the USH should have the opportunity to have available internal oversight mechanisms as a "troubleshooter" including an office configured as OMI, for a health care system the size of VHA.

The above notwithstanding, Public Law 100-322 provides OIG with a specific directive to oversee the OMI. This task has been approached in several ways. Initially, case reviews conducted by OMI are reviewed by OHI prior to final closure. In so reviewing the OMI's work, and having the imprimatur of final closure, both the quality and rigor of that Office's case reviews could be assessed, and hence the OMI overseen. Likewise, this means of oversight provided OHI with a sense of the issues and controversies current within VHA. Second, as OHI evolved, the

[6] "Oversight Activities of the VA's Inspector General," *Hearing Before the Committee on Veterans' Affairs, United States Senate, Ninety-Sixth Congress*, Second Session, June 11, 1980

approach of publishing a detailed summary report on the activities, needs, strengths, and weaknesses of OMI was added to OHI's oversight efforts of OMI, and this is discussed later.

b. Specific Oversight

i. Program Evaluations

More under the auspices of the IG Act than under Public Law 100-322 which focuses specifically on VA's quality assurance programs, review of VHA clinical programs other than strictly its QA programs, has been a continuing OHI activity. At the forefront of such program reviews are current critical issues in veterans health care. These include the Department's response to veterans who become ill after service in the Persian Gulf[7], provision of health care to an ever increasing number of female veterans[8] in a healthcare system largely designed to serve male veterans, and a review of VA's handling of the new, but extremely expensive and, toxic, high surveillance anti-schizophrenic drug clozapine[9]. In addition to the topics receiving medical and public attention, there are ongoing issues in veterans health care for which VA has developed programs, and which OHI inspected. These include VA's programs addressing such issues as homelessness, domiciliary care[10], ambulatory care[11], Advance Directives[12] and the impact of downsizing substance abuse rehabilitation programs[13]. It is anticipated that such programmatic reviews will continue, these being perennial health care issues which require oversight, and which are integral to a large health care system.

ii. Hotline Inspections

To fulfill the OIG organizational charge of identifying waste, fraud, and abuse in the agency, VA's OIG, like most Federal OIGs, maintains a "hotline." This "hotline" is an "800 number," and an address which is prominently displayed in VA facilities (medical and non-medical), and listed in local telephone directories and more recently can be accessed on the OIG Internet. On the order of 20,000 hotline contacts yearly are made to VA's OIG. A large portion of these contacts are clinical or QA related and hence OHI has found itself involved in numerous hotline cases. Additionally, Congressional constituent referrals, White House case referrals, and cases prominently highlighted in the media are often assigned hotline status. While the majority of these cases must be referred to VHA for primary review, many are referred to OMI--thus reinforcing the need for OHI oversight of VHA. However, as a means of independent verification of VHA's work, and due to its status as a clinical oversight body independent of VHA, OHI also independently inspects approximately 100 hotline cases yearly. Most of OHI's hotline cases have very high profiles. Through OHI's performance of hotline reviews, oversight data is

---

[7] "An Oversight Evaluation Of The Department of Veterans Affairs' Response To Health Care Issues Relating To Military Service In the Persian Gulf War," VA OIG Report No.: 5HI-A28-011, December 29, 1994

[8] "Evaluation of Papanicolaou Test Procedures for Veterans Health Administration Women Patients," VA OIG Report No.: 6HI-A28-032, March 26, 1996

[9] " Review of VHA's National Clozapine Coordinating Center," VA OIG Report.: 3HI-A28-153, August 27, 1993

[10] "Program Evaluation Of The Veterans Health Administration's Domiciliary Care Program," VA OIG Report No.: 5HI-A28-020, January 4, 1995

[11] "Evaluation OF VHA's Ambulatory Care Program," VA OIG Report No.: 5HI-A28-021, January 4, 1995

[12] "Evaluation of the Veterans Health Administration's Advance Directive Program," VA OIG Report No.: 7HI-A28-037, January 24, 1997

[13] The Impact of Downsizing Inpatient Substance Abuse Rehabilitation Programs on Homeless Veterans and Other Frequent Users," VA OIG Report No.: 7HI-A28-108, July 8, 1997

obtained in the form of independent verification of the quality and rigor of VHA's review of such cases. These inspections often give some insight into the effectiveness of a VAMC's risk management program. OHI is currently conducting a review of all hotline cases for Fiscal Years 1993 through 1995 from which it is expected that some profiles and patterns will emerge.

Also, OHI provides technical assistance to OIG's audit and criminal investigative branches. OHI provides technical assistance in clinical fields such as medicine, nursing, social work, respiratory therapy, nutrition, and clinical pharmacy to auditors and investigators not trained in those areas. OHI technical assistance has led, on occasion, to identification of clinical, i.e., non-audit and non-criminal, quality assurance issues, which may then be reported under OHI cover.

iii. Quality Program Assistance (QPA) Review

It has become apparent that OHI should "inspect" VHA's hospital facilities and inspect individual VAMC's QA programs, on-site, without the crisis atmosphere or adversarial nature that may accompany a hotline inspection. To meet this need, OHI is pioneering a system of proactive review.

OHI hopes to develop and implement a program of comprehensive medical center reviews which includes an assessment of the medical care and provides VHA managers with independent, objective findings which will assist them in improving the efficiency and effectiveness of their operations. The principles guiding the QPA program development are: healthcare remains, at its core, the interaction of professionals (providers) with clients (patients); the program should focus on broad general indicators of healthcare quality; inspections should be direct and consider historic data only secondarily; the process should not be duplicative of other internal or external review programs; the inspections should be undertaken by generalist healthcare inspectors; the process should use standard instruments, which might eventually allow results to be compared from center-to-center; and the process should be cost effective.

The program of QPA reviews was begun in early 1995 and after an initial pilot, six facilities were visited to further refine the process through late 1996. After a careful review of the experience gained from those early endeavors, a final prototype was devised with the advice of some VISN clinical managers, and was tested at six VAMCs at the end of fiscal year 1997. If, after a final thorough evaluation, it is concluded that this is a "value added" process, then it is projected that the QPA reviews will become fully operational in 1998.

4. OHI/OIG Oversight of VHA's Risk Management Policy

The general purpose of a risk management policy in healthcare facilities and healthcare systems is to have program and operational requirements, which have a fundamental orientation towards prevention of errors in the provision of personal medical services. Hence it is expected that an effective risk management program will:

- Minimize the likelihood of adverse events (risk) to patients, personnel and visitors;

- Protect resources and prevent loss by accurately identifying, reporting, trending, reviewing, and correcting problems leading to incidents, through risk identification and analysis, and systems improvements;

- Encourage healthcare facilities to view risk management as an overall activity which includes both clinical and administrative services; and

- Ensure that healthcare facilities, within a healthcare system, share information on adverse events which contributes to the systematic identification and assessment of their potentially harmful impacts.

Both the VHA and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) identify risk management as an integral part of quality improvement activities. VHA has been active in risk management for many years. Two of VHA's many risk management programs are the Occurrence Screening Program (OS) and Patient Incident Reporting (PIR) Program.

In May 1987, the GAO recommended that VAMCs be required to implement occurrence screening (see footnote 3). This interest resulted in legislation enacted in May 1988, Public Law 100-322, Section 201. Along with expanding and assigning higher priority and greater resources to quality-assurance programs and activities at each medical center, this law required the implementation of the review known as "occurrence screening" throughout all VAMCs. Patients' medical records are reviewed, with the maximum use of the facility's computerized management information system, for adverse events, which may not be the natural or expected consequence of the patient's disease, injury, or treatment.

The OS Program was based on a 1977 California Medical Insurance Feasibility Study, which reported that almost 5 percent of hospital admissions were associated with an adverse event that was potentially compensable. In the OS Program, cases are screened against a predetermined list of criteria. Those cases, which involve one or more of the occurrences, are reviewed to identify possible problems in patient care. The PIR Program has long existed in all VA medical centers and in 1974 it became one of the initial programs included under the QA umbrella. The goal of the PIR Program is to identify opportunities for improvement in patient care by monitoring, reporting, analyzing, reviewing, and investigating (if necessary) any unusual, unexpected or unfavorable incident involving a patient during the course of the patient's medical management.

Section 204(a) of Public Law 99-166, passed in 1985, and codified in Title 38 United States Code (U.S.C.) 7311, required VA to establish a comprehensive Quality Assurance Program, of which PIR was a part. In early 1980, VA transferred the program to the Office of Medical Inspector. Then in 1991, the program was transferred to the Office of the Associate Chief Medical Director for Quality Management, now the Office of Performance and Quality.

Both the OS and PIR Programs are automated and operate in the VA's Decentralized Hospital Computer Programs (DHCP). This allows VA to identify opportunities for improvements through local data analysis and the potential national roll-up of information relevant to the VHA healthcare system as a whole.

The VHA guidance on its Risk Management program has, during the last 5 years, changed four times, with the issuance most recently of the Risk Management Directive VHA Directive 105, September 25, 1997, and its accompanying Handbook. Prior to the issuance of this Directive, the most specific general guidance had been contained in VA Manual M-2, Part I, Chapter 35, "Integrated Risk Management Program" (IRMP), issued April 7, 1995. This was replaced with the VHA Directive 97-029, "Risk Management," June 6, 1997. The IRMP, April 7, 1995, had replaced the previous Chapter 35, August 7, 1992, with rescission of several other Directives. VHA guidance in each of these policy revisions has varied considerably in the scope, specificity and assignment of responsibilities at each managerial level in VHA: the VAMC, VISN and VACO.

5. <u>VHA's Risk Management Directives</u>

The present Risk Management Directive, VHA Directive 105, September 25, 1997, and its accompanying Handbook (hereafter referred to as the RM Directive) contains

guidance which satisfactorily addresses several issues that have been of great concern to the OIG. Further this RM Directive encompasses features that make it a much more definitive and comprehensive document than has been heretofore available in VHA. If fully and consistently implemented it has the potential for becoming an effective risk management policy

The issues, until the publication of this RM Directive, that have been outstanding for OHI/OIG are:

a. Recommendations made in OHI program reviews agreed to by VHA, which had not been incorporated into the prior risk management guidance.

b. Understandings reached with VHA concerning the tracking and trending of mortality data to identify unusual and unanticipated deaths.

c. Ensuring that the guidance to VAMCs, VISNs, and VACO will result in continuing improvements in quality.

The following discussion expands on these three areas:

a. **Incorporation of OHI/OIG recommendations.**

Three OHI program reviews had made specific recommendations related to VHA's Risk Management Directive:

i. "Oversight Inspection of the Veterans Health Administration's Office of Medical Inspector, Fiscal Year 1994" (Report No. 5HI-A28-039). - **Recommendation 1b - Delete the paragraph in the M-2, Part I, Chapter 35 revision draft that deletes OMI's review of VAMC's Boards of Investigation.**

This recommendation was implemented through the VHA Directive 97-029 "Risk Management," June 6, 1997. The role for the OMI has been further extended and clarified in the most recent RM Directive.

ii. "Evaluation of VHA's Policies and Practices for Managing Violent or Potentially Violent Psychiatric Patients" (Report no. 6HI-A28-038). - Recommendation 1a. The Under Secretary for Health should ensure that:

1a. All patient-on-patient and patient-on-staff assaults are properly and uniformly entered into the automated PIR program at all VAMCs to ensure accurate counting of assaults, but more important, to ensure that all assaulters are identified and the circumstances of the incidents are trended for use in both local and national VHA planning and monitoring purposes.

The issue of patients assaulting other patients or employees is a serious one. VHA health care facility right-sizing could exacerbate the problem and increase the risk of both types of assaults. When the subject report was issued in March 1996, the USH stated that one of the goals of a Risk Management Program would be to implement a uniform facility-level automated database that could also be accessed in VACO by the individual VISNs. The USH also stated that tracking, trending, and problem solution information could then be shared throughout the VHA. Implementation of such a system would necessitate a change in current regulations or PIR reporting as well as possible technical enhancements to the existing automated system. VHA Directive 97-029, Risk Management, dated June 6, 1997, did not implement these commitments. The most recent RM Directive has now incorporated this important procedure.

iii. Alleged Cover-up of an Unexplained Increase in Deaths, Harry S. Truman VA Medical Center, Columbia, Missouri" (Report No. 5PR-A19-115) -

Recommendation 4 - Revise M-2, Part I, Chapter 35 on reporting serious incidents at medical centers to provide clarifying guidance that facility Directors could use to determine if and when to report an incident such as the Columbia Medical Center's unexplained deaths to law enforcement authorities. The guidance in those cases where there is strong suspicion that a serious crime may have been committed, should emphasize both aggressive internal investigations to determine the possible clinical causes as well as simultaneous reporting to law enforcement officials.

This recommendation was implemented through the VHA Directive 97-029, "Risk Management," June 6, 1997, as an improvement upon the previous Manual reference. Even so, OHI did not consider that the guidance was sufficiently specific or strong for a VAMC Director. The latest RM Directive has further clarified the procedures to be followed by VAMCs under these circumstances.

b. Tracking and Trending of Mortality Data

In Title 38 U.S.C. § 7311, "Quality Assurance", it is required that mechanisms for monitoring mortality and morbidity rates for surgical procedures be established. The National Surgical Quality Improvement Program (NSQIP) analyzes data on surgical mortality (within 30 days) and morbidity (presence of 1 or more postoperative morbidities within 30 days). NSQIP allows VHA to monitor surgical outcomes system-wide as well as locally. Data are shared with VAMC directors and surgeons to advise them of the quality of care they are providing and of opportunities for improvement. This system has the potential for monitoring significant fluctuations in mortality.

In a broader context, stemming from situations at VAMC Columbia and other VAMCs in recent years related to unusual mortality occurrences, it has been considered essential that VHA develop more robust mechanisms of monitoring data on mortality. The expectation has been that a RM Directive would delineate tracking, trending, and analysis of specific risk management/quality indicators such as mortality and certain morbidity rates in order to achieve early identification of possibly serious, unacceptable health care practices.

The rates for individual VAMCs, VISNs, and VACO in regard to the data or information to be monitored, collected, reported, analyzed, organized, and "rolled-up" would be specifically defined. Provisions would also be made for VHA's healthcare system to be alerted to unusual or unexpected mortality rates.

The present RM Directive clearly provides an overall strategy to suitably track and trend information and data concerning unexpected deaths at the individual VA facility. The RM Directive's Appendix C clearly defines roles and responsibilities for the VAMC, VISN and VACO. In this same Appendix C, VISN directors are requested to designate from within the VISN a statistical consultant to assist in data analyses for risk management and other quality assurance functions. We consider these actions to fulfill VHA's commitment and should, when fully implemented, provide a vital mechanism for identifying unusual patient deaths from mortality data.

c. Ensuring Continuing Improvements in Quality

The present RM Directive has several features, which can potentially result in improvements to the quality of care for veterans across the VHA healthcare system.

Mr. Chairman, recently you asked me to review VHA's response to the Committee's concerning 18 incidents in which there were patient deaths under

allegedly unusual or apparently avoidable circumstances at VAMCs. There were 15 incidents in which there was a confirmed specific misadventure, including deaths from burns, administration of incorrect medications or blood, and so forth.

My personal impressions, as reported to you, were:

- Almost without exception each VAMC seriously engaged with the issues related to the incidents.
- All VAMCs indicated immediate extensive investigation of the incidents, with possibly two exceptions.
- The oversight by the Region/VISNs, OMI and/or OHI have ensured that these untoward incidents are definitively and completely reviewed, with few exceptions.
- Most of the 15 VAMCs with specific incidents have responded by careful in-depth inquiries which have resulted in several local policy changes.
- VAMCs which have reported incidents to external agencies, such as JCAHO and FDA, seem to be most highly motivated to complete more extensive facility-wide performance improvements such as root cause analyses.
- VHA Regions/VISNs and VACO did monitor these incidents, but it is unclear as to whether they have been accurately and consistently recorded on the DHCP data base.
- The OMI and OHI, when inspections have been completed, have generally validated that the incidents were adequately managed, and in several instances confirmed an excellent response by the VAMC.

The present RM Directive has the potential for ensuring greater accuracy and consistency in resolving these observations. Yet, there is an important question which goes beyond these 15 specific incidents, which is, "What has the corporate" VHA learned and what systematic changes in practices and policies have been promulgated throughout the VA's health care system, especially to all VAMCs, to assist them in preventing and avoiding similar occurrences?

This RM Directive has specific roles for the VISNs and VACO, including a mechanism for monitoring untoward events, with possible standardization of VISN risk management programs. Even so, the assistance role of the VISNs and VACO, capitalizing on the diligence at VAMCs to have effective Risk Management programs, will need to be evident and robust. The "lessons learned" from analyzing the specific incidents should be codified and disseminated in a timely fashion throughout VHA's health care system.

6. <u>Oversight of VHA's Office of the Medical Inspector</u>

Almost 2½ years ago, OHI filed a report on its oversight of the OMI[14]. The recommendations to the USH were:

A. Either provide additional staffing to the Office of Medical Inspector such that clinical staffing is increased sufficiently to perform its legislatively mandated function. This should result in an increase of at least four registered nurses and at least one senior physician; or

[14] "Oversight of the VHA's Office of Medical Inspector, Fiscal Year 1994," OIG Report No.: 5HI-A28-039, February 16, 1995

1. Submit a legislative proposal through the Office of the Secretary of Veterans Affairs to amend Public Law 100-322 to recognize the reduction in OMI's capability to conduct proper clinical evaluations; or

2. Since the capability for independent oversight overall within VHA is seriously limited, initiate action to transfer the OMI's resources to OIG.

B. Delete the paragraph in the M-2, Part I, Chapter 35 revision draft that deletes OMI's review of VAMCs' Boards of Investigation; and

C. Authorize the OMI to continue development of the self-assessment instruments in order to assist VAMCs to strengthen known program weaknesses.

Since then, only Recommendation B has been implemented through the recent RM Directive.

In response to the report on the OMI, the USH concurred with Recommendation C, but indicated that he wanted to defer decisions on Recommendations A and B, until a new VACO organization has been completed. This was agreed to as an interim measure by the OIG. Now, Recommendation A remains unimplemented and Recommendation C has recently moved into a non-concur status.

In May 1996, Dr. James McManus joined VHA as the new Director of OMI, i.e. the Medical Inspector, which brought the staffing level up to eight. Since then, the OMI lost its Deputy and one of its clinicians while adding a senior nurse located in Iowa City and, recently, another nurse in VACO. The OMI is currently recruiting for a physician Deputy. The staffing level will then be 9, which is far short of the OMI's initial more adequate 20 FTE staffing level.

The OHI and OMI offices have always coordinated their hotline inspection activities. The OHI has generally assumed responsibility for inquiries originating in Congress and complex issues that may or may not involve the OIG's Investigation office. The cooperation between all these offices continues. However, one of the impacts on OHI, from limited OMI staffing has been that OHI has had to assume more of this workload, leaving OHI with constraints on its resources to perform its other healthcare oversight activities, described earlier.

Just prior to Dr. McManus assuming the directorate of OMI, a VHA Directive 96-021, March 20, 1996, "Cooperation with the Medical Inspector" was issued. The role of the OMI was stated to be:

"The Medical Inspector serves as an investigative arm of the Office of the Under Secretary for Health (USH). When issues arise requiring further investigation, the USH, or designee, may ask the Medical Inspector to develop a factual analysis. In addition, the Medical Inspector may undertake investigation on behalf of the USH when requested to do so by veterans, VHA employees, the Inspector General, member of Congress or other stakeholders."

Late last year the USH responded to OIG follow-up inquiries as to the staffing and any modifications to the role of OMI. While the USH indicated additional FTE would be provided he also indicated that a contract would be awarded to an independent entity to study the structure and functioning of the OMI. This contract was awarded to Abt Associates, Inc., on May 6, 1997, with a broadly defined scope of work involving its assessment of the role, functions, and staffing of the OMI. The contractor's report is likely to be available in early November, according to VHA.

Until this past month, we had understood the implementation of Recommendation C was only dependent on OMI having sufficient staff to develop self-assessment instruments. We were informed by VHA that it now will discontinue the development of self-assessment instruments. Rather, VHA will replace the original commitment through the activities of VHA's Office of Special Projects' "Lessons Learned" initiative. The "Lessons Learned" initiative is a reactive process that is instigated after a serious or catastrophic event has occurred. The self-assessment instruments are designed and intended to help prevent incidents from occurring in the first place. Presently, OIG is seeking from VHA a substantive explanation for its apparent change of direction, and an indication as to its vision regarding how its revised approach will be effectively assist in preventing serious adverse incidents in the future

Hence, the OIG considers the issues raised in its report on the OMI to be mostly unresolved.

7. <u>An Analysis and Present Status</u>

VHA, along with most of the healthcare professionals it employs, has long had policies that are directed towards ensuring veterans receive safe, effective personal healthcare in VAMCs with an assurance that their risk of incurring inadvertent actions that threaten disability and cause avoidable deaths is minimal. VAMCs have long had in place and have applied policies to use appropriate screening mechanisms, confidential reporting mechanisms and investigative processes to accurately monitor, identify, evaluate and correct harmful and potentially harmful healthcare circumstances. These procedures, when consistently and properly applied, help to prevent injury and avoid harm.

VHA has a broad approach to quality assurance, including a risk management program, focused on achieving effective operations in the VAMCs, augmented by various oversight and investigative procedures. Over the past several years, it appears that when there are critical inadvertent and unusual adverse consequences to veterans in the course of receiving their healthcare through the VA, whether disability or death, VAMCs have for the most part taken the situations very seriously. In dealing with their own situations, VAMCs employees have conducted in-depth investigations, determined the nature of the error, assigned culpability, if needed, devised mechanisms to prevent similar incidents and filed reports with senior management. Unlike private sector healthcare providers, VAMC managers inform patients and families if they make serious errors, and explain their prerogatives for redress

In providing VAMCs with policies and guidance for its Risk Management program, VHA has, over the past five years, provided a series of four Directives. The most recent RM Directive was published this past September 25th and constitutes a strong and comprehensive policy, which fully addresses criticisms the OIG/OHI had previously raised concerning omissions and weaknesses in prior RM Directives, particularly the one published this past June. The current RM Directive has the potential to strengthen and enhance VHA's present mechanisms for conducting an effective risk management program.

In all previous RM guidance there have been VAMC reporting requirements and defined procedures for oversight by the Regions, (now replaced with 22 VISNs), and VACO. Within the past two years the VISNs have steadily been staffed, and the VACO offices have gained new leadership. During this time period it is evident that issues related to resource allocation, strategic planning and the implementation of a performance measurement system have been dominant on VHA's agenda. As a consequence, little or no attention has been given to reviewing information on the Patient Incident Reporting (PIR) program either in the VISNs or in VACO. The recently published RM Directive seeks to remedy this deficiency by assigning more definitive roles to the VISNs and VACO. It is essential that VISN programs be

appropriately standardized to ensure that comparable data and information is collected and available for review. The RM Directive has given some broad guidance in this regard although appointment of a statistician in each VISN can assist in ensuring some consistency in this regard.

Once data and information on risk management is collected it is essential that it be tracked and routinely examined for trends. This requires assignment of clear roles and responsibilities in the VISNs and for VACO components. The RM Directive provides the clearest guidance so far in this area with the establishment of an Adverse Event Registry and the establishment in VACO of a Risk Management Oversight committee. The OMI is included on this committee but its participation is likely to be compromised as long as questions persist about its role, responsibilities and functions, and the staffing level in the office remains restrained. Without resolving these issues very soon, it is difficult to envisage how the OMI can significantly and effectively contribute to this activity. A regular and systematic review of the Adverse Event Registry, with the identification of relevant information that must be prompt in its dissemination to all VAMCs, is necessary. This communication is an essential feature of a Risk Management program for a healthcare system as large and complex as VHA. It provides the critical step in the sequence of an effective risk management program which, uses the broad dissemination of what has been learned from inadvertent event(s), to assist in the prevention of a similar occurrence at the same or other VAMCs.

8. Conclusion

The OHI is a QA oversight office, unlike any other in government, including the rest of the OIG community. It has direct clinical and QA oversight responsibilities under law. The task of monitoring a health system's effectiveness and overseeing its QA activities has proved to be most challenging in an era of shrinking government yet continuing increases in health care expenditures for veterans in VHA.

In fulfilling its mandate to oversee VHA's quality assurance activities and the OMI, the OHI/OIG has generally viewed VHA's need to address its risk management policies as paramount. VHA has made significant progress in this area with the possible notable exception of clarifying the OMI's role, function, and staffing. OIG will continue to monitor the implementation and effectiveness of VHA's recently published Risk Management Directive.

DEPARTMENT OF VETERANS AFFAIRS
INSPECTOR GENERAL
WASHINGTON DC 20420

September 26, 1997

The Honorable Cliff Stearns
Chairman, Subcommittee on Health
Committee on Veterans' Affairs,
House of Representatives
335 Cannon House Office Building
Washington, DC, 20515

Dear Congressman Stearns:

I have now had an opportunity to more carefully review the report to you that I appended to my letter, September 17 th, 1997.

I found some areas that were worthy of clarification and I have revised the part that discusses the JCAHO. Would you kindly replace the previous copy with this version? Thank you.

Sincerely,

JOHN H. MATHER, M.D.
Assistant Inspector General for
Healthcare Inspections

Enclosure

cc: Under Secretary for Health (10/105E)

REPORT TO THE HOUSE VETERANS' AFFAIRS COMMITTEE

"Patient Deaths under Unusual or Apparently Avoidable Circumstances at VAMCs"

Introduction:

The Subcommittee on Health House Veterans' Affairs Committee solicited in two separate mailings in June and July, 1997, information from 18 VA medical centers related to the Committee's oversight of quality of care and risk management programs. The information requested concerned news reports of "patient deaths under unusual or apparently avoidable circumstances at Department of Veterans Affairs Medical Centers" (VAMCs) Each letter focused on a specific incident or situation at the VAMC, seeking a full account of the circumstances which included information as to whether a Board of Investigation or other mode of inquiry was initiated. Also, specific questions on the involvement of the Veterans Health Administration's (VHA) Office of the Medical Inspector (OMI) and/or the Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) were asked.

Background:

The general guidance for handling of unusual incidents for the time period for 12 of the 18 incidents is contained in M-2, Part I, Chapter 35, "Integrated Risk Management Program" (IRMP) that was issued April 7, 1995. This was replaced with the VHA Directive 97-029, "Risk Management," June 6, 1997. The IRMP, April 7, 1995, had replaced the previous Chapter 35, August 7, 1992, with rescission of several other Directives which reduced the VAMC reporting requirements. The earlier IRMP applies in 6 of the 18 incidents.

The VAMCs requested to provide information and the approximate time frame of the incidents are:

	VA Medical Centers	Time Frame
1.	Atlanta, GA	January 1997
2.	Baltimore, MD (Ft. Howard)	March 1995
3.	Bay Pines, FL	August 1994
4.	Beckley, WV	February 1994
5.	Boston, MA	March 1996
6.	Huntington, WV	December 1995
7.	Lake City, FL	August 1996
8.	Miami, FL	June 1996
9.	Muskogee, OK	May 1996
10.	Northampton, MA	[N/A] 1996
11.	Oklahoma City, OK	January 1993
12.	Omaha, NE	July 1993
13.	Poplar Bluff, MO (St. Louis)	August 1996
14.	Providence, RI	March 1997
15.	Richmond, VA	[N/A] 1996
16.	San Antonio, TX	November 1996
17.	Temple, TX	[N/A] March 1996
18.	West Los Angeles, CA	February 1995

Note: N/A: Not Applicable to a specific incident.

2.

Initial Analysis:
Amongst these 18 incidents there are two situations in which patient deaths are not specifically identified with a confirmed specific misadventure (VAMCs Northampton and Richmond). While the OHI is and has been very closely involved with the issues involved, specific recommendations in the draft and final reports have been made and accepted by VHA for improvements. Another incident (VAMC Temple) involved deaths related to a contaminated oxygen supply that may have. been a contributing factor in four or six deaths. The OMI was involved in an exhaustive review of the situation.

The other 15 incidents might be classified as follows, within the framework of inadvertent deaths:

Type	VAMC(s) = 15
Scalding and/or Burns	Atlanta, Lake City, West Los Angeles
Drug Administration "Error"	Baltimore, Omaha, Providence
Misdiagnosed/Delayed/Fragmented Care	Bay Pines, Beckley, Oklahoma City, Poplar Bluff
Incorrect Blood Transfusion	Boston, Huntington, San Antonio
Exsanguination during Dialysis	Miami
Wandering and Accident	Muskogee

Establishment of Boards of Investigation: (See: IRMP Manual Chapter 35)
The focus, in these 15 incidents, is related to deaths involving Mandatory Reportable Risk Events of Severity Level 3 and requires documentation on a VA Form 10-2633 with the information entered on the decentralized hospital computer program (DHCP) data base. Further, a Board of Investigation is convened in all cases where patient abuse is suspected and in certain other instances of reportable risk events.

This review of the documentation provided by the VAMCs indicates that most of them completed VA Form 10-2633, and probably entered the information onto the DHCP data base. The accuracy and consistency of this requirement in the 18 incidents could be independently validated through a separate query of the DHCP data base.

Boards of Investigation were completed in 12 of the 15 instances. One was merged in an OIG/OHI inspection (VAMC Baltimore). One was conducted as a focus review with essentially the same level of effort as a Board of Investigation (VAMC Huntington). One was considered unnecessary (VAMC Oklahoma City) because the patient died at home, although the OHI did conduct and file an inspection report.

3.

Reporting of Incidents: (See: IRMP Manual Chapter 35)
In general, these types of incidents, because of their severity, would be reported to various other levels in VHA. Until October 1995, with the abolishing of the four Regions and the establishment of the 22 Veterans Integrated Service Networks (VISN), the VHA reporting requirements were very clear. The Regions were vitally and closely involved as they received an immediate notification and reviewed the results of the VAMCs management of the incident. Eventually a judgment would be rendered by the Region as to whether everything was done that was needed. VA Central Office (VACO) would often be less intimately involved, and sometimes after the Region had completed its oversight role.

The documentation provided by the 15 VAMCs demonstrate that the Region or VISN was notified, but the degree of oversight by them is variable. In certain instances the Region's/VISN's role is superseded by the intervention of the OMI or OIG/OHI. The guidance is relatively flexible in law as to what extent an incident is reviewed by other levels in VHA when the VAMC has completed its inquiry.

Guidance does exist for when incidents need to be reported to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). When an incident is considered as a "sentinel event," although not a requirement, it is often reported to JCAHO and the VAMCs with more recent incidents have closely fulfilled this guidance. It appears that some VAMCs could well have reported the incident to JCAHO, but according to the documents provided, did not. The reporting of a "sentinel event" will involve the JCAHO in a special visit, and the VAMCs are generally expected to complete a root cause analysis. The specific definition of a sentinel event and when the option of reporting was established as a JCAHO guidance, is not immediately apparent and could be verified with JCAHO.

Five of these 15 VAMCs stated that they had made a report to the JCAHO (Boston, Miami, Muskogee, Providence, and San Antonio) with the JCAHO conducting special site visits to assess the accreditation status. It is evident that four of these five VAMCs conducted careful and in-depth root cause analyses according to the documents provided. The JCAHO also visited Northampton, Temple, and Richmond to review their situations which may have been reported as sentinel events.

In certain instances where there are blood transfusion errors, reports are made to the Food and Drug Administration (FDA). In the two instances where the mismatched blood transfusion was the obvious and proximate cause of death (VAMCs Boston and San Antonio), reports were made to the FDA. The other incident (VAMC Huntington) is less evident as to the need for a report to the FDA, and a report was not apparently filed.

4.

Involvement of OMI and/or OHI:

The stimuli for the OMI and/or OHI involvement in such incidents are variable. The Region/VISN may seek their involvement or other VHA officials, including the Under Secretary for Health. An OIG hotline or a congressional inquiry may also stimulate an OMI and/or OHI involvement.

The OMI was involved with VAMC Temple, while OHI has been involved with VAMCs Richmond and Northampton. Respectively, the stimuli were a referral from a VHA/VACO official, the OIG Hotline, and from OIG Investigations.

In the other 15 incidents, the OMI was, or is, involved in 7 while OHI was involved in 3, while an addition 1 was handled by OIG Investigations due to a potential homicide investigation. In four VAMCs (Bay Pines, Boston, Huntington, and West Los Angeles), neither the OHI nor OMI have been involved in an inspection.

It should be noted that the OHI has an oversight role with respect to inspections conducted by the OMI. It is a routine practice for OHI to review and comment on all OMI draft reports before the OMI issues them as final reports.

Notification of "Family" and Next of Kin:

It is generally required that the "family" and next of kin be notified of these possible misadventures in medical care. The understanding is that "communication" in of itself, is part of the treatment process, including admission of error, where appropriate. Review of the documents provided proved to be very difficult in determining the effectiveness of this process. Clearly a *post hoc* hotline or congressional inquiry complaint would tend to vindicate some breakdown in "communication." Also, the actual evidence for settling tort claims is not really found in the documents provided.

General Impressions:

The following are offered as general observations:

- Almost without exception, each VAMC seriously engaged with the issues related to the incidents.

- All VAMCs indicated immediate extensive investigation of the incidents, with possibly two exceptions.

- The oversight by the Regions/VISNs, OMI and/or OHI have ensured that these untoward incidents are definitively and completely reviewed, with few exceptions.

5.

- Most of the 15 VAMCs with specific incidents have responded by careful in-depth inquiries which have resulted in several local policy changes.

- VAMCs which have reported incidents to external agencies, such as JCAHO and FDA, seem to be most highly motivated to complete more extensive facility-wide performance improvements such as root cause analysis.

- VHA Regions/VISNs and VACO did monitor these incidents, but it is unclear as to whether they have been accurately and consistently recorded on the DHCP data base.

- The OMI and OHI, when inspections have been completed. have generally validated that the incidents were adequately managed, and in several instances confirmed an excellent response by the VAMC.

Other Observations:

It was the focus of the collection of information to not go beyond the incidents themselves to any great extent. The roll-up and trending of this and other data on risk management to be filed in DHCP is a very important function for a health care system such as VHA. It is unclear as to whether, from these untoward incidents, lessons have to be learned which would be useful to all VAMCs in the care of veteran patients. What corporate processes in the VISNs and at VACO can be clarified which will more likely ensure that systematic errors are not repeated? The assistive role of the VISNs and VACO, building the diligence at VAMCs to have robust risk management programs, needs to be evident and maximally effective.

Prepared by:

JOHN H. MATHER, M.D.
Assistant Inspector General for
for Healthcare Inspections

September 17, 1997

As amended September 26, 1997

STATEMENT OF

ELWOOD HEADLEY, M.D.

MEDICAL CENTER DIRECTOR FOR THE

BOSTON VETERANS AFFAIRS MEDICAL CENTER

ON PATIENT INCIDENTS

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 8, 1997

Mr. Chairman, members of the subcommittee, thank you for the opportunity to present details regarding this incident. As requested this testimony will discuss in detail the circumstances of the case, the nature and findings of the investigations which occurred and the remedial steps taken.

CIRCUMSTANCES OF THE CASE:

The patient was a 60 year old man with a history of esophageal cancer, who underwent an esophagogastrectomy (an operation to remove the cancerous esophagus and attach the lower esophagus to the stomach) February 13, 1996. This was complicated by a leak of the anastomosis (site of reattachment) and renal and respiratory failure. On March 5, 1996 he was taken to surgery to have a re-exploration of the right chest and drainage, repair of the anastamosis and a tracheostomy to improve ventilation. He was severely ill and the highest risk category patient. The procedure was only undertaken because of the life threatening nature of his problem. During the procedure he suffered a cardiac arrest and attempts at resuscitation were unsuccessful and the patient expired. In the process of reviewing the circumstances surrounding Mr. Anderson's death it was discovered that he had received two units of packed red blood cells typed and cross matched for another patient. The Medical Examiner was notified and declined the case, however the family consented for the autopsy to be performed by the Medical Center. Acute hemolytic

reaction secondary to incompatible ABO transfusion was identified as the immediate cause of death.

NATURE AND FINDINGS OF INVESTIGATIONS:

Fact finding was instituted immediately and an Administrative Board of Investigation was requested immediately and convened on March 8, 1997. It was chaired by the Director of Quality Management and consisted of the Associate Chief for Clinical Pathology and the Operating Room Nurse Coordinator.

The Board was charged with the following responsibilities:

a. to investigate the transfusion error of March 5, 1996;
b. to review the circumstances surrounding, and factors contributing to the error; and,
c. to make recommendations to minimize recurrence.

In order to comprehensively review the incident the board tracked and evaluated what were felt to be essential aspects of care for this patient with regard to the blood transfusion including the:

- identification of the patient prior to and during the surgical procedure;
- effectiveness by which information was communicated between the interdisciplinary team;
- storage and handling of blood and blood products in the operating room;
- adherence to policy and procedure associated with the verification and administration of blood and blood products;
- timeliness by which the error was identified, reported and appropriate follow up initiated.

The following individuals were called as witnesses:

- The Attending Thoracic surgeon
- The Attending Anesthesiologist
- Three Operating Room Nurses involved with the case.
- Blood Bank Supervisor

- Chief Anesthesia Section
- CRNA involved with the case
- One SICU Nurse

In addition, policies and procedures related to Transfusions of Blood and Blood Products, Standard Texts relating to Blood use, the Patient Incident Review Program and the Integrated Risk Management Program were reviewed. In addition, the patient's medical record was reviewed and the operating room refrigerator for the storage of blood and blood products was inspected.

FINDINGS:

Identification of the patient prior to and during the surgical procedure:

Each discipline (surgeon, anesthesia and nursing) identified comprehensive procedures for the identification of the patient prior to the procedure. Of note, however, this is not an integrated process. Each utilizes procedures that are specific to their discipline and conducts identification procedures as an intra-disciplinary, versus an inter-disciplinary process.

Effectiveness by which information was communicated among the interdisciplinary surgical team:

Each discipline as appropriate, described comprehensive procedures for the communication of essential patient information that was shared among the members of the team at various points during the procedure, such as at the time of transfer of responsibility for breaks. According to testimony, the extent to which information specific to patient identification is integrated into this process may vary. Of note, in this case a nurse assigned to assist in the room did not participate in patient identification procedures; however, he subsequently participated in the verification of blood prior to administration. Consequently, the omission of checking the patient's ID (wrist) band, by those participating in the verification became critical. Members of anesthesia who participated in the verification of the blood also participated in the care of the patient who preceded this patient in OR #7 and had, by then, begun to confuse the two patients. This

was further precipitated by the storage of the previous patient's blood in the refrigerator marked for OR#7 following completion of the case and his transfer to the recovery room. Because patient identification procedures are conducted by individuals rather than by the "team" without any subsequent interdisciplinary verification, this aspect of communication was felt to be less than optimal.

Storage and handling of blood and blood products in the operating room:

Blood and blood products are stored in the operating room refrigerator by room number, based on the operating room schedule and case assignment for a given day. Of note, as stated above, another patient's blood was located in the section of the refrigerator compartment marked as OR#7. Both the patient and the previous patients procedures were performed in OR#7 with blood ordered for both cases. The patient's blood was later found to be stored and marked for OR#6. The exact process by which the blood was inaccurately stored in this instance could not be ascertained in spite of comprehensive review.

The board feels that the storage of blood products and the identification of blood in the OR by room number rather than by patient increases the risk of errors. This aspect of care is not currently addressed in any existing policy or procedure.

Adherence to policy and procedure associated with the verification and administration of blood and blood products:

Policy and procedure clearly state that the verification process requires the confirmation of patient identification as reflected on the ID (wrist) band. This step was omitted during the verification process used for both units of blood.

Timeliness by which the error was identified, reported and appropriate follow-up initiated:

The timeliness by which appropriate follow-up, according to established protocol, was initiated was less than optimal. This included notification of the blood bank, notification

of the Chief of Staff or Risk Management and the initiation of the protocol for suspected blood transfusion reaction.

Based on testimony, notification and follow-up was delayed because of a lack of knowledge on the part of the medical staff. Both consultants (surgeon and anesthesia) reported the incident to their Section and Service Chiefs in a timely manner, however, there was a significant delay in the information reaching either the Blood Bank or Quality Management Office in accordance with established policy.

CONCLUSIONS:

The transfusion error was directly attributable to human error. If the verification process included the confirmation of patient identification as reflected on the ID (wrist) band, the incident could have been avoided.

While the transfusion error was clearly the result of human error there are opportunities to improve existing policy and procedure and minimize the risk of recurrence.

The Surgical Service was less than timely in reporting this incident in accordance with established policy.

REMEDIAL STEPS TAKEN:

In addition to the Administrative Board of Investigation summarized above, a Root Cause Analysis was performed which is a method of reviewing processes as an aid to restructuring them. No new information was introduced as a result of the Root Cause Analysis, it merely assisted in planning the remedial actions. Based on the results of the Administrative Board and the Root Cause Analysis it was decided to re-engineer our blood and blood products policies and procedures and the following steps were implemented.

Letters of reprimand were issued to the Anesthesiologist, the Certified Nurse Anesthetist and the Nurse involved.

There was a redesign of the process to assure interdisciplinary verification of patient identification prior to the initiation of anesthesia or procedure and prior to the administration of Blood or Blood Products.

There was a redesign of the process to a uniform system of dispensing blood to the operating room by individual patient rather than in bulk and eliminating storage of blood outside of the Blood Bank, minimizing risks to patients.

There was a change in policy to require documented informed consent for blood transfusion medical center-wide to facilitate active involvement of patients in treatment decision-making processes.

Educational programs addressing all of the above were instituted hospital-wide with special emphasis on the operating room.

Educational programs on Risk Management were presented hospital-wide with emphasis on the operating room.

An annual review of blood and blood product administration was instituted in the hospital's ongoing clinical staff education program.

STATEMENT OF

T. C. DOHERTY

MEDICAL CENTER DIRECTOR FOR THE

MIAMI VETERANS AFFAIRS MEDICAL CENTER

ON THE VETERANS HEALTH ADMINISTRATION'S

POLICY AND PERFORMANCE

RELATING TO SPECIFIC PATIENT INCIDENTS

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON VETERANS' AFFAIRS

U. S. HOUSE OF REPRESENTATIVES

OCTOBER 8, 1997

Mr. Chairman and Members of the Subcommittee:

I appreciate the Subcommittee's consideration of the serious case before it today.

In June 1996, Mr. John Floyd Martin, a hemodialysis patient being treated by the VA for more than 25 years, died during one of his dialysis treatments at the Miami VA Medical Center as a result of a massive blood loss. When informed of Martin's death, I immediately convened a Board of Investigation. Later, a Root Cause Analysis was completed. A brief summary of the nature of the circumstances of the case; the findings and conclusions related to the case; and the remedial steps taken follow.

It should be noted that prior to the tragic death of Mr. Martin, the outcome statistics for the Miami VAMC Dialysis Unit were above the national average, and our mortality rates are below the national average. In addition, there had been no adverse events related to staff performance in the estimated 135,000 dialysis treatments that have been performed since the unit opened in 1966.

I. Nature of the Circumstances of the Case.

On Saturday June 22, 1996, the dialysis nurse who was scheduled to give Mr. Martin his dialysis treatment arrived a few minutes late for duty. She immediately proceeded to connect Mr. Martin to the dialysis machine. She observed a problem with the venous pressure transducer. Unable to resolve the transducer problem, the nurse requested assistance from a dialysis technician. They worked together to correct the problem. During this process, the dialysis nurse was notified that she had a telephone call. She left the bedside to answer the telephone in the nurses' station. The dialysis technician remained at the bedside, troubleshooting the machine. The nurse completed her call and returned to the bedside. The technician replaced the transducer and was leaving the area, when she heard a hissing sound. She returned to the patient's bedside and observed blood overflowing from the 2-liter collection container located on the side of the dialysis machine. The nurse and the technician investigated and discovered that the venous dialysis line was not connected to the return port in the patient's vascular access. The primary nurse had failed to connect the venous line to the patient. This resulted in the loss of more than 1800cc of blood. The nurse and the dialysis technician then attempted to replace the blood loss with large amounts of physiologic saline.

The dialysis technician proceeded to clean up the blood spill. The blood-filled container was removed from the dialysis machine for disposal by the dialysis technician who called a second nurse to show her the blood-filled container and informed her that the blood was Mr. Martin's. The second nurse immediately rushed to Mr. Martin's bedside to assist. The technician emptied the container of blood and returned to the bedside to complete cleaning the area.

The patient appeared to stabilize briefly after the administration of saline. During the course of these events, one of the above-mentioned three staff members obtained a blood sample and sent it to the laboratory for determination of hematocrit.

An employee of the Environmental Management Service arrived on the Dialysis Unit at approximately 7:15 a.m. and proceeded to clean the area. He stated that he spoke to Mr. Martin when he first approached the bedside and that the patient responded to his greeting. He stated however, that when he left the area, "the patient didn't look good."

The patient's condition began to rapidly deteriorate. A third dialysis nurse was called to the scene from a separate room to assist with the care of the patient. She was not informed of the blood loss. Shortly thereafter, at approximately 7:30 a.m., a dialysis nurse called a code.

The code team physician reported that when he arrived on the scene, the other team members had already started the appropriate life saving measures. He stated that he questioned the staff at the bedside as to what had happened. He was told that the patient had developed abdominal pain followed by hypotension (low blood pressure). All three individuals (Mr. Martin's nurse, the second dialysis nurse, and the dialysis technician) knowingly withheld information concerning the blood loss from the code team. Knowledge of the loss would have been of great importance to the team in the proper assessment and management of the patient. At no time during the code did any one of the three caregivers inform the code team that the patient had lost a large quantity of blood or that it was replaced with physiologic saline. The patient was pronounced dead at 8:25 a.m. June 22, 1996 by the code team physician.

At approximately 9:30 a.m., the nephrology fellow questioned the nursing staff involved in this incident. They failed to advise him that the patient had lost blood, or to provide him with the flow sheet documentation of the dialysis treatment. The staff also failed to notify the Chief of the Nephrology Section of the blood loss when he questioned them at approximately 11:30 a.m.

On the morning of the incident, Mr. Martin's primary nurse called her supervisor (the Nurse Manager of the Dialysis Unit) at home and informed her about the incident. There is conflicting testimony as to what was actually relayed during the conversation.

The second dialysis nurse called the Nurse Manager of the Dialysis Unit at home the following day to inform her of the extent of the patient's blood loss. The Nurse Manager of the Dialysis Unit instructed the second dialysis nurse to report to work on Monday, June 24, 1996 (her scheduled day off) to further discuss this incident.

The Nurse Manager of the Dialysis Unit failed to inform her supervisor of the incident until the afternoon of Tuesday, June 25, 1996.

II. Findings and Conclusions Related to the Case.

Proximate factors contributing to Mr. Martin's death were massive blood loss and the cover-up of the blood loss. In addition, there were other factors that are believed to be related to this tragic event.

A. The Massive Blood Loss.

1. The patient lost in excess of 1800cc of blood during his dialysis treatment over a period of approximately 10 minutes between 6:45 a.m. and 7:00 a.m. This blood loss occurred because Mr. Martin's nurse failed to close the dialysis blood circuit.

2. In addition, Mr. Martin's nurse left the patient's bedside during the critical set-up phase of the dialysis treatment, without assuring appropriate care of the patient.

B. The Cover-Up of the Blood Loss.

Mr. Martin's nurse, the second dialysis nurse, and the dialysis technician were negligent when they attempted to handle the emergency upon discovery of the blood loss, without immediate notification of a physician, and when they did not inform the Code Team about the massive blood loss.

C. Other Related Factors.

1. The Nurse Manager of the Dialysis Unit failed to notify proper authorities in a timely manner.

2. The Dialysis Unit that was operational at the time of the incident was separated into two main areas that were divided by a corridor. The geographical division did not permit optimal observation of all patients by all staff members.

III. Remedial Steps Taken.

A. Personnel Actions.

1. Mr. Martin's nurse, the second dialysis nurse, the Nurse Manager, and the dialysis technician were immediately removed from the Dialysis Unit, pending the outcome of the Investigation.

2. Mr. Martin's nurse was terminated and the State Licensing Board was notified.

3. The second dialysis nurse was suspended for 30 days and permanently reassigned. She resigned.

4. The Nurse Manager of the Dialysis Unit was suspended for 14 days, and was reassigned.

5. The dialysis technician was suspended for 14 days.

B. Other Remedial Actions.

1. Dialysis treatments were moved to a newly constructed Dialysis Unit, which had been planned prior to the incident. This provides increased accessibility and visibility of staff to patients. The open design of the new unit permits staff to assist each other in the event of an emergency while ensuring patient privacy.

2. A total reorganization of nursing staff within the Dialysis Unit, including a new nurse manager and four new staff members, has taken place following the death of Mr. Martin.

3. The critical set-up process for dialysis has been redesigned to ensure a more uniform approach among all staff members and with all patients. A flow sheet was developed during the Root Cause Analysis to graphically represent the critical elements in the set-up process, particularly those involving the clamping of venous and arterial lines. The flow sheet clarified the need for nurses to stay with the patient throughout the critical phase of the treatment and it is displayed at each patient's dialysis treatment location. Ongoing monitoring of the revised critical dialysis set-up process has been initiated. Since the onset of the tracking, there has been 100% compliance with the set-up process.
4. Leadership issues on the Dialysis Unit have been addressed. Specifically, leadership training for the recently hired Nurse Manager and for designated charge nurses has been instituted. One-on-one mentoring for both the Nurse Manager and the charge nurse by the Associate Chief Nurse (ACN), Special Care has been ongoing. The nurse manager has received a formal supervisory training course from Human Resources specialists. The charge nurse and of all of the current RNs are participating in a nationally developed basic leadership development program which is being held over a six-month period.
5. Meticulous attention to all aspects of conformance to policies and procedures has been in effect since this tragic incident even though prior to Mr. Martin's death, monitoring activities did not reveal evidence of inappropriate patient care. Dialysis staff members have received on-going staff training in administrative policies and procedures, emergency procedures, dialysis procedures, incident reporting, and accepting personal telephone calls. Subsequent to the incident, all dialysis nurses have achieved certification in

Advanced Cardiac Life Support (ACLS). Fifty percent of the current dialysis staff nurses have received national certification in Nephrology Nursing. Ethics classes for dialysis staff and others have been provided by The National Center for Clinical Ethics.

6. The Chief, Dialysis Unit; the ACN, Special Care; and the Nurse Manager of the Dialysis Unit meet regularly with all staff members to ensure accurate communication.

7. Modifications in the culture of the Dialysis Unit have been made. The new dialysis team is functioning effectively to provide safe, competent care to veterans. The entire interdisciplinary dialysis team collaborated to revise and improve the dialysis order forms and documentation forms and to update 100% of the dialysis policies and procedures utilizing the most recent dialysis science data. All registered nurses on the Dialysis Unit are reviewing patient charts as part of the peer review process to ensure continued quality. Patients, when questioned, express satisfaction with their care. A plan for all members of the interdisciplinary dialysis team to participate in a team-building program presented by Project Challenge is underway to advance the positive, cohesive team spirit that has been developed.

IV. Conclusion.

From Mr. Martin's death, we at the Miami VAMC have learned many lessons. We have taken remedial personnel actions, have improved the Dialysis Unit's operating procedures, and have conducted intensive education and training of staff members.

Again, thank you for allowing me to explain the circumstances surrounding this tragic deviation from the high quality care that has been the hallmark of the care provided to our veterans in the thirty-one years since the Dialysis Unit opened.

STATEMENT OF

BILLY M. VALENTINE

MEDICAL CENTER DIRECTOR FOR THE

MUSKOGEE VETERANS AFFAIRS MEDICAL CENTER

ON THE DEATH OF A PATIENT AT A CONSTRUCTION SITE

ON MAY 24,1996 AT

THE VAMCMUSKOGEE, OKLAHOMA

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

OCTOBER 8,1997

Mr. Chairman and Members of the Subcommittee:

I appreciate the Subcommittee's weighty responsibility for oversight of the VA healthcare system and fully understand concerns regarding uncommon, isolated events resulting in a patient's death.

The staff of the medical center were deeply saddened by the untimely death of the patient. This tragedy was highlighted in various news medias and provoked anxiety among the staff for many months. Although an unfortunate event, it was the only such accident that has occurred of its nature having to do with patient safety. The coverage of this isolated incident far outshadowed the compassionate care delivered by our staff each and every day to hundreds of veterans. In keeping with our mission, our staff continue to "provide personalized, high quality care with dignity and compassion."

The patient was a 65 year old male with an admitting diagnosis of gastrointestinal bleeding and chronic alcohol abuse. He was brought to the Emergency Care and Treatment area at the Muskogee VAMC at 7:15 p.m. on May 22, 1996, complaining of abdominal pain, nausea, vomiting and diarrhea for two to three days. He had a history of chronic alcohol abuse and had alcohol on his breath. Vital signs were taken. A naso-gastric tube was inserted, intravenous fluids were begun with intravenous famotidine (Pepcid) and he was transfused with two units of red blood cells. He received one injection of 50 mg of chlordiazepoxide (Librium) for restlessness. On May 23, 1996 the naso-gastric tube was removed. He was able to take clear liquids by mouth and was allowed out of bed in a wheel chair. On May 24, 1996, he was further improved and stated he was hungry. He was started on oral feedings with supplementary potassium and phosphate and begun on oral famotidine (Pepcid).

The patient's medical condition had improved significantly since his admission. He had interacted appropriately with staff. He was judged to be appropriately oriented as to place, time and person. He was receiving no sedation, relaxants, or psychoactive medications. He was growing increasingly independent from his wheel chair, using it only for short rest and usually

walked behind it. Staff were sure that the patient was oriented and competent to make his own decisions.

Prior to the time of the incident, his hospital stay was uneventful, with all activities of care well coordinated and timely. On May 24, 1996, around 10:30 p.m., the patient left the ward without informing the nurses, possibly to smoke. This patient was a smoker and left the ward on several occasions to smoke. When he did not return within approximately 15 minutes, a search was conducted but the patient was not located. On May 25,1996, at around 8 a.m., the patient was found dead in the construction site.

The local Muskogee police and the VA police both investigated the incident immediately. The Medical Center convened a Board of Investigation June 3-7, 1996, and the Office of the Medical Inspector conducted a site visit on June 26-27, 1996.

The local police department investigated the death and ruled it accidental. The Board of Investigation and the VAMC police also found the death as accidental.

Findings of the Administrative Board of Investigation resulted in the following recommendations and subsequent actions by management.

a) All patients are to be assessed for risk of wandering or falls at the time of admission and reevaluated routinely. This is to be documented in the medical record. *(Managerial response - Policy was revised to ensure all patients were assessed for wandering*

and/or falls and that medical records indicate the assessment. There is ongoing monitoring for compliance.)

b) The instructions provided to patients upon admission should be documented in the medical record, including instructions regarding appropriate smoking areas. *(Managerial response - Documentation of orienting the patient to this requirement is reflected on the Nursing Admission Assessment Form and on the Multidisciplinary Patient/Family Education Safety Tracking Flow Sheet.)*

c) All patients should be cautioned to avoid all areas adjacent to the construction site. *(Managerial response- A letter was developed stating the dangers. This letter continues to be distributed to every patient entering the medical center and is posted throughout the medical center.)*

d) All staff with the potential to serve as a coordinator in a missing patient search should receive annual training on VA and medical center search policies and procedures. *(Managerial response - This has been addressed in the new policy. All staff have received formal education and will receive annual updates.)*

e) In addition to the interim recommendations made by the Safety Committee on 5/28/96, a formal assessment of the environment of care should be made in the areas of security, life safety and construction management. *(Managerial response - Formal assessments were completed and are contained as Tabs 13, 14, and 15 in the documents submitted to Mr. Cliff Sterns.)*

f) Signage indicating "This door locks automatically behind you" should be placed on all applicable exit doors. *(Managerial response - Appropriate signage was developed and installed.)*

g) Policies (i.e., MCMs and service-level) pertaining to search procedures should be reviewed and modified as needed to minimize any potential areas of ambiguity or weaknesses. *(Managerial response – New policies were developed and continue to be revised as necessary. An inservice for all staff on the new policy was conducted by the Safety and*

Occupational Health Manager and incorporated in the annual training program. See Tabs 21 - 26.)

Following the Administrative Board of Investigation, the Office of Medical Inspector (OMI) conducted an investigation. This was in response to the family's request for an investigation from OMI. In response to this request the Deputy Under Secretary for Health asked the Medical Inspector to determine if the VAMC's actions prior to and subsequent to the death were in compliance with VA policy and to review the Board of Investigation's report and other evidence to determine if a full site team visit and investigation by the OMI were needed.

The OMI reported the following findings in their final report dated February 12, 1997, which is contained in the reference book sent earlier to the Subcommittee.

The OMI determined that prior to the event of May 24, 1996,the patient had been allowed appropriate independence in movement. It was on that date the patient found himself locked out of the hospital when he went outside to smoke. While other options for reentry were available, such as calling for help from a telephone in a well-lit smoking shelter or waiting in the smoking shelter until someone came looking for him, he apparently tried to find a path back to the front door. "After squeezing through the seam between two sheets of construction fencing," (it was later determined he had unfastened metal ties connecting the fence), he walked around part of the perimeter of a construction hole. He fell 35 feet into the construction hole where he was impaled on an uncapped steel rebar imbedded in concrete. His decision to force his way into a construction site, which was clearly marked as dangerous, exposed him to the

hazards that resulted in his death. Maintenance of the construction site by the independent contractor was brought into question by the Board of Investigation; however, some of the citations and findings of that Board were corrected or questioned by the VHA Chief of Facilities Maintenance Officer and found to be unsubstantiated.

The patient's absence was almost immediately noted by the ward staff, and search procedures were implemented. The patient, however, was not found until the next morning.

The Office of Medical Inspector found that the Medical Center and local police conducted complete and thorough investigations.

Based on the review by the Medical Center and OMI's concurrence with the Medical Center's findings, the following recommendations were made:

1) All doors, which lock behind those exiting should be clearly marked as such. In the event that a patient, staff, or visitor is inadvertently locked out, instructions on how to regain entry should be posted on the outside of the door. *(Managerial response - All exit doors, which lock behind those exiting, have been clearly marked.)*

2) Search procedures should be expanded to include any closed-off construction areas to determine if the perimeter is intact. *(Managerial response - The Medical Center Search Policy was revised to include a search of the perimeter of any construction area.)*

3) All hazardous areas, such as construction sites must be fully lighted at night. *(Managerial response - The construction area is illuminated by a flood light The Medical Center Search Policy includes a search of all construction sites. Corrective action was taken immediately following the incident.)*

4) Consideration should be given to requiring patients to sign out when leaving the ward, at night and on weekends. *(Managerial response - Patients are required to sign out when leaving the ward. Monitors are in place to ensure compliance. Corrective action was taken immediately following the incident.)*

5) Medical Centers should develop a mechanism to limit acute care patients, who wish to smoke, to designated smoking areas outside the building. *(Managerial response - Orientation for patients pertaining to the Medical Center Smoking Policy, location of patient smoking shelters and uses of sign-out sheets was implemented as a result of the Medical Center Administrative Investigation. Appropriate nursing staff received education and training for this orientation.)*

Recommendations were made to VHA to incorporate much of what was recommended to the VAMC into VA policy. All VAMCs should be directed to review the foregoing recommendations as an alert to prevent a similar tragic accident.

The Medical Center took immediate action to comply with all recommendations set forth in the administrative investigation and the Medical Inspectors Report. As indicated in the reference material sent to the Subcommittee earlier, and in my testimony today, search policies were

followed appropriately. Policies have been modified to delete any areas which may have been ambiguous and training for the entire staff of the Medical Center has taken place and will continue to be a part of the annual training each Medical Center employees goes through.

Our Risk Management Program is aimed at improving the quality of care through identification of system design flaws and other problems and redesign of patient care systems to decrease the likelihood of deviations that can harm patients. Our Medical Center, like all medical centers and VISNs throughout the country is in the process of revising our Risk Management Program to comply with the new National Risk Management Directive and the VISN 16 Risk Management Policy. We have a designated Quality Management Specialist who serves as our facility's Clinical Risk Manager and a full time Safety Officer. We participate in an exchange process whereby we have the benefit of review from other VA facilities and also perform reviews for them when requested. We have a formal process, which follows the guidelines set forth in the National Risk Management Directive for reporting any events that are, or may become, high profile to our VISN within 24 hours. In addition, the Quality Managers from VISN 16 had a meeting in Dallas where our Quality Manager gave a presentation on Risk Management related to these events. So as you see we have an elaborate and extensive network for reviewing, improving, and evaluating our potential for risk. As directives are finalized, staff will be educated on the changes.

It is unfortunate that this accident occurred, and we have taken steps to minimize the possibility of any reoccurrence.

POST-HEARING QUESTIONS
CONCERNING THE OCTOBER 8, 1997
HEARING ON VHA'S RISK MANAGEMENT
POLICY AND PERFORMANCE

FOR KENNETH W. KIZER, M.D., M.P.H.
UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS

FROM THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Question 1: How does VA track and trend malpractice suits and 1151 claims taken against VA or its agents? Please provide a profile of the number of each type of action brought against VA and their dispositions. Also, please provide an estimate of the costs of malpractice and 1151 benefits to VA each year.

Answer: The Office of General Counsel maintains a system-wide database that is designed to track all claims filed with the Department of Veterans Affairs pursuant to the Federal Tort Claims Act (FTCA). The system is called the Tort Claims Information System (TCIS) and follows the progress of both malpractice and non-malpractice claims from the date they are received until final disposition administratively or by litigation. VA's medical malpractice experience for the past decade is detailed in the attachment.

According to the Compensation and Pension Service of the Veterans Benefits Administration, claims filed with VA pursuant to 38 U.S.C. § 1151 are entered into the Target system with the special law code of 07, and VBA is able to retrieve the number of 1151 claims for any month or period of months. With the Supreme Court decision in *Brown v. Gardner,* 130 L.Ed.2d 462 (1994), the number of living section 1151 recipients increased dramatically from 479 in September 1993 to 2,182 in September 1997. The sum paid out increased from $436,008 per month in September 1993 ($5,232,096 per year) to $2,301,229 per month in September 1997 ($27,614,748 per year). In addition, there are another 690 monthly recipients of Dependency and Indemnity Compensation based upon section 1151 awards. The monthly payout on these cases is $595,454 which amounts to $7,145,448 per year.

Question 2: Roughly, how much does VA spend to measure and monitor quality in the health care system? Do you have any idea on how its spending on measures to enhance quality compare to spending for other health care providers?

Answer: It is not possible to fully answer your question because measuring and monitoring quality is an inherent responsibility of all caregivers and managers in the system, but the specific time or percent of their effort devoted to such efforts varies by position and over time.

Within VHA headquarters, two offices are specifically devoted to measuring and monitoring quality: the Office of Performance and Quality (105A) and the Office of the Medical Inspector (10MI). For FY 1998, total salary costs for these two headquarters offices are approximately $1,426,000. The Office of Performance and Quality also monitors quality through field programs, special contracts, and grants. These include for FY 1998:

Patient Advocacy Program at Danville, IL VAMC	$188,000
Data Resource Center at Durham VAMC	1,345,000
National Customer Feedback Center at W. Roxbury, MA VAMC	1,304,000
External Peer Review Contract	7,300,000
Joint Commission on Accred of Healthcare Orgs Contract	2,800,000
Interqual (Utilization Management) Contract	245,000
Functional Status Project	413,000
Total Field, Contract, and Grant	13,595,000

Total travel costs to support all of these programs are approximately $760,000, and the bulk of this goes to field sites to support travel by field staff. Total Headquarters costs identified for the two offices whose mission is to monitor and measure quality of care for FY 1998 are as follows:

Headquarters Salary	$1,426,000
Field Programs, Contracts, and Grants	13,595,000
Travel	760,000
Total	$15,781,000

These costs do not include the oversight responsibilities of other Headquarters elements such as Patient Care Services (11) where a substantial amount of staff time is spent in activities that could be defined as monitoring and measuring quality of care. Further, these costs do not include the many field staff who devote their time to monitoring and measuring quality of care. Currently, the Office of the Inspector General is conducting a review of VHA's quality management programs, with part of that review involving an effort to determine the amount of staff time spent in monitoring and measuring quality activity. We understand that the OIG review is scheduled for completion in December 1997. VHA is not able to compare its costs with the private sector, since this information is considered proprietary and is not publicly available. My personal impression, as a former state regulator of over 5,000 healthcare facilities, as a private consultant on healthcare quality issues, as a senior faculty member involved in quality of care issues at a large academic health center, and as a medical practitioner in a wide variety of settings is that VA devotes considerably more resources and efforts in this regard than most other healthcare systems.

Question 3: We heard testimony from three of your facilities that are tragic examples of preventable deaths. Are you generally satisfied with the manner in which these directors reviewed and corrected systemic deficiencies that lead to the dire incidences that occurred?

Answer: I am never satisfied when events like those which you reference occur. Having said this, I should also say that the directors at the three VA Medical Centers who testified at the House Veterans Affairs Committee Hearing on October 8, 1997, thoroughly reviewed the incidents and implemented corrective actions. These actions were directed at preventing future similar incidents from occurring. Each of the medical centers established interdisciplinary teams to conduct the intensive investigations. The investigations and resultant action plans focused on systems and process defects that allowed the incidents to occur. While the manner in which each of the directors reviewed and corrected the systemic deficiencies leading to the incidents was satisfactory, four additional enhancements of the process have been implemented to further assist them:

1. The new Risk Management Directive (VHA Handbook 1051, 9/25/97) provides additional guidance to VA facilities in the process of analysis of adverse events.

2. A Risk Management Oversight Committee meets biweekly at VHA Headquarters to review all of the investigations of these serious events carried out by VA medical centers. The Committee provides feedback to them regarding the need for any additional information. The Committee along with the medical center and the respective network identifies and develops "lessons learned," as appropriate for distribution throughout the VHA system. A Lessons Learned Intranet database is being developed for application of information VA wide.

3. A Sentinel Event Registry has been established for the benefit of the entire VHA system. The Chief Network Officer maintains the registry in VHA Headquarters. All serious adverse events are logged and tracked electronically, so that, in time, staff at each medical center may access trended data to determine possible patterns.

4. The Office of the Medical Inspector (OMI) also reviews each Board of Investigation and Focused Review, for compliance with policy, for completeness, for timeliness,

for trending, for further review, for identifying a need for an OMI investigation, and for any additional lessons learned.

I believe these four enhancements will improve the process by which each serious adverse event is used for future systemic improvements, and hopefully help to reduce the overall number of serious adverse events to a minimum.

Question 4: Please briefly describe how VHA's new risk management plan differs from the plan that was previously in place.

Answer: There are many significant differences between the new policy and the previous one. Some of the most important are that the new policy is based on the most rigorously conducted research on patient safety, emphasizes identifying and revising system designs that have led, or that may lead, to practitioner errors and adverse events, establishes a clearly defined oversight role for the networks and Headquarters in the risk management process, and includes a mechanism for sharing lessons learned from the review of adverse events between facilities. The requirement in the new policy that most clearly differentiates it from the previous policy is the implementation of a systematic monitoring process, involving the facilities, networks, and Headquarters. This monitoring process is described in the response to Question 5.

Question 5: VA's Risk Management directive indicates that it will establish a systematic monitoring process. What does this entail?

Answer: The systematic monitoring process involves facility review of all adverse events with significant consequences (as well as near-misses) to identify the underlying causes and needed system redesigns. Facilities are required to address 10 specific questions that focus on improving patient safety in their assessment of each adverse event. The assessments are reviewed by the VISNs and the Risk Management Oversight Committee in Headquarters to trend the frequency with which particular care delivery systems have been problematic, identify needed changes in policies and procedures, and identify system redesigns requiring further review and development. Insights gained from this process that may be useful to other facilities are shared through VHA's Lessons Learned Database on the VA Intranet. In addition, all adverse events and subsequent reviews will be transmitted to a central data repository that will be regularly analyzed by VISN and Headquarters staff.

Question 6: Have you thought of how VA will balance correcting problems (which sometimes implies punitive action) while ensuring that employees are encouraged to report adverse data?

Answer: In a 1996 national conference, "Errors in Health Care," Lucian Leape, a Harvard physician, educator, and researcher, stated in his keynote address that frequently errors are made by the best people—the best trained, the best educated, the best performing. It has been an unstated belief, according to Stahultz and Gosbee in the August 1996 edition of American Medical News, that through medical education and practice, medical professionals can be trained to be "infallible." The truth is unfortunately otherwise; humans have measurable limitations in memory, attention span, and physiological and mental endurance. Stahultz and Gosbee go on to say, "...medical educators and clinicians must understand that human performance is not perfect and cannot be perfected by training. Then they must be taught to look for opportunities to modify systems...." That is the direction of the new VA—focusing on correcting systems and not on punitive action toward individuals.

While there are errors caused directly by willful acts of an individual, these are the extreme exception rather than the rule. The real gains to be made in the reduction of errors in health care are through identification and repair of systems errors. These systems errors are frequently the cause of why the best people commit errors, according to Leape. Within the document, Journey of Change, the need for VHA to be an exceptionally accountable organization is stressed. Within that need for accountability, reporting of errors is part of the individual ethical behavior expected of all VHA workers.

It is only through identification and reporting of errors that we can begin the process of reducing them.

Within the VHA, the Office of the Medical Inspector is frequently involved in reporting error and making recommendations to reduce error. That office never recommends individual sanctions, but, instead, focuses on the systemic causes. This is a philosophy we hope is spreading throughout the VHA.

Having said these things, any suggestions that you might have to facilitate the right balance would be welcome.

Question 7: Your policy cites a study that found that 18% of all hospitalizations are subject to an adverse event resulting in serious injury. Are there any data to indicate how VA compares to the private sector in the occurrence of adverse events.

Answer: There are no studies that have applied the same definitions and data collection procedures to VA and private sector care to compare the rates of adverse events. VHA has analyzed data on adverse events reported in its Risk Management program during FY 1994 to 1997 and compared these rates to findings from research conducted in the private sector. A copy of this analysis is attached. Again, my personal impression (based on my past experience as noted in the answer to question 2) is that VA's experience compares very favorably.

Question 8: How does VA ascertain that its patients who are harmed due to medical negligence or malpractice are informed about the error in their treatment?

Answer: VA's new RM policy requires that staff inform patients and their families about all injuries resulting from adverse events, not just those adverse events involving medical negligence or malpractice, and also about their remedial options if the adverse event involves potential organizational liability. The Office of the Medical Inspector and the Office of the Inspector General are responsible for determining whether this and other policy requirements are being implemented by facilities. This is a change from prior policy.

Question 9: How many networks have developed policies for reporting adverse events? How are you ensuring that the policy is developed and implemented? Do any networks offer models? What is VHA Headquarters role in overseeing the effective development and use of these policies?

Answer: At the time of the October 8, 1997 hearing, not all VISNs had issued a VISN Risk Management policy. Some were awaiting the issuance of the Risk Management Handbook which was issued by VHA Headquarters on September 25, 1997. Some VISNs have simply adopted the national risk management policy at the VISN level. The VISNs are in the process of setting up mechanisms to implement the risk management policy. Several have developed their own model risk management programs. These will be reviewed by the Risk Management Oversight Committee (RMOC) in Headquarters and shared with other VISNs.

Many VISNs have designated a lead Risk Manager for the VISN to ensure consistent implementation of policy. The data is reviewed by the Chief of Staff/Clinical Advisory Council or Executive Leadership Council.

Risk Management is a topic that has been discussed on the Clinical Managers' weekly conference calls as well as their face to face meetings. To underscore the importance of risk management, the Network Directors' performance contract for FY 98 contains a performance measure on risk management.

VHA Headquarters' role at present is providing guidance to the VISNs and field regarding the expectations of the risk management policy. A Sentinel Events registry has been established and reporting of events is being facilitated by the use of MS Exchange which is now available at the facility level. The Risk Management Oversight Committee reviews each incident to identify the adequacy of the facility review, the prevalence of

incidents and commonalties, system redesigns that should be adopted and shared throughout the system, and to identify lessons learned that can be shared on the Intranet database. To date, several facilities have been asked to develop lessons learned based on how they handled specific incidents.

If you have specific suggestions on how you think this process should work, I would welcome your suggestions. We also are working with a consultant on this matter.

Question 10: How does headquarters review and compare data rolled up at the national level? Do you feel that this is a timely and effective means of identifying potential problems?

Answer: Currently, Headquarters analyzes aggregate data based on incident reports that are sent to the Hines Chief Information Officer Field Office. However, the value of these analyses is somewhat limited by the incident reports only including variables derived from the preceding RM policy. In addition, access to these data is limited to a small number of staff at the Hines Field Office. These problems will be remedied when the incident reporting software is upgraded. The upgrade will establish a national database that includes all relevant variables needed to adequately describe the adverse event as well as the results of the review that was conducted to assess the adverse event. This database, which will be located at the Austin Automation Center, will be accessible to Headquarters and VISN staff as well as HSR&D researchers.

These data should provide a timely and effective means of identifying RM issues requiring further evaluation and national efforts at system redesign. The data will also flag facilities with unusually high or unusually low adverse event rates for further assessment. Because of the difficulties involved in determining whether a high rate of reported adverse events represents poor quality of care or unusually good reporting (See response to Question 12), it will usually not be possible to definitively identify facilities providing poor quality care from these data alone. Intensive assessment of the facility, usually involving site visits, will often also be necessary.

Question 11: Describe the role of the sentinel event registry in ensuring quality care.

Answer: The sentinel event registry tracks those adverse events for which reporting to Headquarters within 48 hours is required; this includes sentinel events and adverse events likely to generate substantial negative publicity or to lead to a JCAHO Visit for Cause. The registry is used by the Office of the Chief Network Officer to identify adverse events that require immediate alerts being sent to field facilities or that need to be brought to the attention of the Under Secretary or Deputy Under Secretary. It also enables that office to track whether appropriate review activities have been performed for these serious adverse events. In addition, the sentinel event registry is used by the Risk Management Oversight Committee to identify adverse events and system failures that have repeatedly occurred within VHA and require national efforts at system redesign.

Question 12: Do you have an expected number of adverse events which helps you understand where facilities may be under-reporting? For example, if 0 reports were filed for a facility, would your reaction be, this facility is doing a great job or this facility is not identifying its adverse events? How do you know?

Answer: Since the available studies indicate that adverse events are common in all healthcare settings, a report of 0 adverse events for an extended period of time would certainly suggest under reporting. Since the research literature also indicates that under reporting is extremely frequent, it would not be immediately clear whether a large number of reported incidents signified unusually good reporting or poor quality of care. Intensive study, probably including a site visit, and other evaluation, would be required and would be the approach taken by VA. Based on the research literature, under reporting probably occurs at all healthcare facilities and, thus, it is not necessary to establish a threshold to identify it.

When the Risk Management directive was issued June 6, 1997, there were many areas that required clarification based on field concerns. The recently issued Handbook

provides clarification, examples that provide clear guidance to facilities on what incidents should be reported. In addition, guidance is provided by Headquarters on the monthly Risk Management conference calls.

Question 13: What is the private-sector standard for reporting practitioners to the National Practitioner Data Bank? Is VA's any different? If so, how so?

Answer: The private-sector standard for reporting to the National Practitioner Data Bank (NPDB) is set forth in the Health Care Quality Improvement Act of 1986, Title IV of Public Law 99-660, and further delineated in Department of Health and Human Services (DHHS) regulations 45 CFR, Part 60, entitled National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners.

There are two types of reports:

1. Adverse Action Report – this report is filed when an action (reduction or revocation) which exceeds 30 days is taken against a practitioner's clinical privileges.
2. Medical Malpractice Payment Report – this report is filed when a malpractice payment is made on behalf of a Licensed Health Care Practitioner.

The VA makes both types of reports. The only difference is with regard to Malpractice payment reporting. The process for VA is different. For a private sector practitioner, when his/her malpractice insurance company makes a payment on a claim filed against the practitioner, the company which makes the payment also immediately files the form for NPDB reporting because the practitioner is the named defendant in the action. Because malpractice claims in VA are Tort claims with the defendant being the United States government, the VA performs a post-payment peer review to determine:

a. the practitioner(s) responsible for the act/omission for which payment was made AND
b. whether that act/omission constitutes substandard care, professional incompetence, or professional misconduct.

Although the legislation establishing the NPDB was not binding on Federal Agencies, the VA voluntarily entered into a Memorandum of Understanding with the DHHS in November 1990, to participate in support of the spirit and intent of the legislation.

Question 14: Systems design is to blame for most adverse events. For what systems has VA taken steps to improve design? (How many of the references in your Appendix A is VA implementing?)

Answer: Based on the work of a national task force established to look at blood transfusion errors in the operating room, Dr. Kizer has recently approved a plan to implement bar coding procedures to match blood products against the patient's ID wrist bracelet prior to operating room transfusions. VHA expects to quickly expand this system redesign to all blood transfusions and is developing a plan to also implement bar coding in the medication administration process, because of its known effectiveness in reducing medication errors. We are also developing plans to have physician orders entered directly into computer terminals. We anticipate that this step, combined with the use of bar coding in medication administration, will significantly reduce the number of adverse drug events in our medical centers.

At the facility and VISN levels, plans are being developed to redesign a large number of other systems. These plans are to some extent being driven by the Risk Management Performance Measure in the FY 1998 Network Directors' Performance Agreement that requires each VISN to implement a number of system redesigns of their care delivery systems to enhance patient safety. We anticipate that most of the issues listed in Appendix A of our Risk Management policy, as well as many other system issues, will have been addressed either nationally or by a number of VISNs by September 1998, which marks the end of the assessment period for the FY 1998 performance agreements.

Question 15: How are you assuring that every layer of VHA knows that you, as its leader, are deeply committed to ensuring quality for the veterans who are your patients?

Answer: As you know, I have made it a hallmark of my tenure as Under Secretary for Health to insist that veterans receive the highest quality health care available, and a consistent message to that effect has gone out to all VA employees. This message was first promulgated in 1995 in the "Vision for Change," a document that described the restructuring of the VA health care system. This was followed in 1996 by the "Prescription for Change," a document that laid out the five Mission Goals that are the strategic underpinnings of change in VHA:

- Provide Excellence in Healthcare Value
- Provide Excellence in Customer Service
- Provide Excellence in Education and Research
- Be an Organization that is Characterized by Exceptional Accountability
- Be an Employer of Choice

In 1997, the "Journey of Change" was published. This document describes the systematic approach being taken to meet strategic and annual targets set for the 22 VHA Networks. This document outlines the Domains of Value that provide the framework for defining and measuring Excellence in Healthcare Value and Customer Service.

All of the initiatives described in these documents come to life in annual performance agreements with the Network Directors. The requirements in these performance agreements filter through the organization and literally touch every employee. A primary mechanism for ensuring that my commitment to quality reaches all levels of the organization is the existence of performance measures in these performance agreements that require all employees to address the quality of their work—whether it be meeting the customer service standards or the rigorous technical requirements of complex surgical procedures. The message is getting there. For example, in a recent survey of VHA employees, fully 75% identified the delivery of excellent customer service as a critical component of VA's mission. We cannot be satisfied until 100% answer that way, but 75% is a good start.

In addition, I have personally lectured to staff on this subject and have effected a number of other policy and program changes aimed at enhancing and standardizing quality of care. Exemplative of these are the June 1997 requirements for board certification for physicians and, more recently, a similar requirement for medical center directors, associate directors and other VHA executive personnel; the "Clinical Programs of Excellence" program; various incentive awards; participation in the Institute of Medicine's National Roundtable on Quality; increased use and support for VA's National Bioethics Committee; and implementation of the Chronic Disease Index and Prevention Index. A number of other such efforts are currently at various stages of development.

POST-HEARING QUESTIONS
CONCERNING THE OCTOBER 8, 1997
HEARING ON VHA'S RISK MANAGEMENT
POLICY AND PERFORMANCE

FOR DR. ELWOOD HEADLEY
DIRECTOR, VA MEDICAL CENTER, BOSTON, MA
DEPARTMENT OF VETERANS AFFAIRS

FROM THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Question 1: I fear that something must first go horribly wrong before VA assesses how to redesign systems to improve patient safety. Has your facility undertaken any other re-engineering studies since your root cause analysis of the events that led to your patient being transfused with the wrong blood type?

Answer: The Boston VA Medical Center, and VHA nationally, have historically been very aggressive in developing a risk management program that systematically collects data to identify areas that place patients, visitors and staff at risk. Data are tracked, trended and analyzed so that measures can be taken to redesign systems as appropriate to facilitate environmental safety. In many instances the data are computerized to facilitate local, network, and national trending and comparison. It is because of this type of ongoing systematic approach to risk assessment and management that sentinel events are a rare occurrence. Our goal has always been to minimize clinical risks to patients. When systems do fail, causing patient injuries, we very quickly conduct a comprehensive root cause analysis to identify and correct deficiencies to eliminate recurrence. While these unfortunate incidents clearly identify systems issues that warrant immediate action, they are by no means the only source of such information or impetus for process improvements.

Long before the unfortunate error occurred, the medical center developed processes to systematically review designated aspects of care known to pose significant risks to patients such as: complex pharmacy and therapeutic agents; operative, invasive and other procedures; and transfusion medicine. Interdisciplinary committees systematically review and evaluate the quality and appropriateness of care using a proactive approach to risk assessment and management. We recognize that there are certain risks inherent in what we do and value the lives of each veteran we serve. In addition to internal review, each group tracks sentinel events that occur in private healthcare systems so that lessons can be learned before similar events occur locally. For example:

a. Patients on multiple medications are at risk for the drugs adversely interacting with each other. For years, the medical center has identified polypharmacy as an area of significant clinical risk to patients, especially the elderly veteran population. Systems have been put in place to identify patients and medications at risk for drug-drug interactions. The system is computerized so that all patients receiving more than eight medications are automatically identified and medications are reviewed. These patients may be referred to a Pharmacy Clinic for medication review and extensive patient teaching to minimize the risk of complications from the medications and enhance the patient's understanding to assure that the medications are appropriately taken. In addition, regardless of the number of medications prescribed, certain drugs or combinations of medications are automatically flagged in the pharmacy computer system and reviewed before the prescriptions are filled, thereby minimizing the risk of an adverse event. Prescribing guidelines are readily available to all providers via the computer. Physician orders are initiated via the computer and the system is structured to limit dosing based on established guidelines which further decreases the risk for error or adverse reactions. Finally, there are stringent guidelines and monitoring processes for certain complex medications, such as chemotherapeutic agents, to avoid overdosing and causing devastating complications or death, such as that which was reported to occur in a

well known local private hospital. Our physicians report that there is currently no comparable system available in private health care facilities in the Boston area.

b. The literature shows that procedures in which any type of sedation or anesthesia are involved also pose known clinical risks. There have been several unfortunate complications reported in the media, especially within the private sector's pediatric and elderly population. The medical center has extensive processes in place to assure that care is uniform and safe in all areas in which procedures are performed and/or sedation administered. Our Invasive Procedure Committee, for example, has established stringent guidelines to define minimum standards of care and practice to assure the appropriateness of indications for procedures and the selection of sedative agents; assessment of patients; monitoring patients during procedures; and providing follow-up care after procedures. Recognizing that medical technology and pharmacology change rapidly, and that illness within the veteran population is extremely complex, there was a redesign of systems to enhance patient care aimed at further minimizing clinical risks associated with sedation. These changes were done although the unexpected outcomes and complications observed at our hospital were minor in nature and represented a complication rate of less than 1% historically.

A comprehensive educational program was developed for all staff involved in the administration of sedation or monitoring of patients who receive conscious sedation. Course content focuses heavily on the assessment of each patient's health status, pharmacology and airway management. All members of the medical staff must successfully complete the course and a post test to demonstrate competency before privileges are approved in this area. Because airway obstruction or compromise is known to occur in a percentage of cases, competency in airway management is an essential component of our educational and monitoring process. The use of sedation is closely monitored by the Invasive Procedure Committee, in conjunction with the Committee on Therapeutic Agents, so that any need for further system redesign is identified in a timely manner. We have developed provider profiles to track and trend individual performance regarding operative, invasive and other procedures.

The medical center also participates in a VHA-national Surgical Quality Improvement Program. There are local and national data on major operative procedures that is tracked and trended to identify possible systems issues that place patients at risk for complications. The data are reviewed through our surgical case review process. Findings may result in system changes or in identifying topics for more comprehensive research designed to enhance patient care. Our surgical staff are integrally involved in research initiatives.

c. The transfusion of blood and blood products is also known to have certain clinical risks. Although extensive monitoring processes associated with transfusion were in place, our systematic internal review did not identify any significant issues that would have warned us of the transfusion error prior to its occurrence. Our review systems were consistent with established community and JCAHO standards and there were no trends regarding lapses in policy or procedure known to contribute to such an error. We have since expanded the scope of our systematic review and have redesigned systems to avoid recurrence and facilitate the identification of risks, as previously reported. The review and evaluation of systems is ongoing through our Transfusion Committee and we will continue to be aggressive in pursuing opportunities for improvement.

Question 2: Besides the steps you took to remedy the systems that failed in the scenario you described in testimony, are there any other quality initiatives Boston has undertaken that you would like to share with the committee?

Answer: Examples of quality initiatives, other than for blood transfusion, are provided in the response to question number one. However, there is supplemental information that you may be interested in regarding last year's sentinel event. In addition to the risk management initiatives undertaken as result of the initial root cause analysis, ongoing review by the Transfusion Committee has resulted in other comprehensive assessment and process changes to further minimize clinical risks to patients.

(1) There is a two-person verification of patient identification required at the time that any blood specimen is obtained for cross-matching and transfusion as well as prior to the transfusion of any blood or blood product.

(2) We have consulted specialists in the area of transfusion medicine to work with us as we continue our aggressive review of all aspects of care in this field such as: ordering; distribution and handling; administration; and effectiveness of systems in identifying and managing risks.

(3) As a result of a VHA-national initiative, bar coding will be implemented to eliminate human errors in transfusion that are associated with inaccurate verification of patient identification.

Question 3: Please indicate how you believe the new Risk Management policy will be applied at the local level. What specific changes are planned for your facility or network as a result of this new directive?

Answer: The new risk management policy should not have any significant impact on the operations of the Boston VA Medical Center. It should be noted that the 'new' policy represents the updating of preexisting policy to reflect systems changes or modifications rather than the development of policy that was not previously in existence. The VA has had such guidelines and directives in place since its inception. The most significant change in the policy is the integration of multiple aspects of risk management into one document rather than separate policies. We agree with this concept and functionally have operated in this manner for quite some time. We believe that quality cannot be adequately assured without integrating the ongoing assessment and management of risk into the day-to-day operations of a health care organization.

To demonstrate commitment to a proactive versus reactive approach to risk management, VHA has integrated the identification of risks and system redesign into its performance measurement and improvement processes nationally. There has always been opportunity to share lessons learned throughout our system. The process will be expanded to become more comprehensive, inclusive, and formally reported as a result of this new performance improvement initiative.

The systems described above are merely a few examples of how we integrate risk assessment and management into the day-to-day operations of the Boston VA Medical Center. Similar examples of systems assessment and redesign can be found in all services and at all levels of the organization. We routinely assess the quality, appropriateness and timeliness of the services we provide so that we can take measures to minimize patient injury. Our proactive approach to risk assessment and management was acknowledged during our recent JCAHO survey. The internal review and evaluation of the effectiveness of systems continues to be ongoing.

POST-HEARING QUESTIONS
CONCERNING THE OCTOBER 8, 1997
HEARING ON VHA'S RISK MANAGEMENT
POLICY AND PERFORMANCE

FOR T.C. DOHERTY
DIRECTOR, VA MEDICAL CENTER, MIAMI, FL
DEPARTMENT OF VETERANS AFFAIRS

FROM THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Question 1: The case you presented today is greatly disturbing to me, not only because of the tragic event that occurred due to clinical mismanagement, but because of the obvious cultural problems within your organization that must have existed to allow the attempted cover-up and failures to report to higher management levels to occur. Has your facility gone through any type of cultural audit to determine what the source of these problems is?

Answer: Without question, the death of patient John Martin while receiving dialysis treatment at the Miami VA Medical Center was tragic, especially in view of the fact that the caregivers had several opportunities to initiate a medical response after they realized their mistake. The tragedy was compounded by the fact that the caregivers elected to cover up the mistake. In your inquiry, you mentioned "obvious cultural problems" and asked if we had done a cultural audit to determine the source of these problems. In response, I have to respectfully disagree that there are obvious cultural problems throughout the Miami VAMC. I readily agree that there were cultural issues within the Dialysis Unit. These issues were identified during the Root Cause Analysis (RCA) that we conducted following the incident. From the RCA, it was quite clear that the cultural issues arose within the Dialysis Unit because the unit had, over time, become somewhat isolated, functioning in a relatively independent fashion. As you are aware from the RCA, this is no longer the case, in that we have a brand new unit, an almost entirely new staff, and a Dialysis Unit environment where communication and team work are fostered and praised.

In answer to your question regarding cultural audit, we have not conducted anything that we termed as an organization-wide cultural audit, but indeed we have conducted multiple reviews and staff surveys in order to ensure that we continually know and understand the opinions, thoughts, and ideas of our staff; and to ensure that we fully understand our organizational environment and culture. From our careful analysis of these reviews and surveys, we do not believe the culture within the organization is one that fosters cover-ups and failures in reporting to higher authority. The Miami VAMC is a very complex and culturally diverse Medical Center where all minority groups are recognized and valued for their contributions. These groups have worked together, learned together and supported each other through a number of significant events. Here again, there is not any evidence to suggest cultural differences played a role in this tragic event nor is there evidence that cultural diversity lead to cover-ups or failures to report to higher authorities.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) conducted a Survey for Cause at our Medical Center in May of this year because of the Dialysis incident. The JCAHO surveyor reviewed our RCA and did his own assessment of the issues surrounding the event. As was reflected in the JCAHO report we received after the survey, the surveyor also recognized culture issues within the Dialysis Unit and our Medical Center received recommendations from the JCAHO, accordingly. The recommendations affirmed our opinion that this was an issue of cultural separateness on the part of one specific unit within our organization, and in no way was indicative of an organization-wide cultural problem. We had a second follow-up survey conducted by the JCAHO on October 27, 1997. The surveyor did a thorough and complete review and

concluded that we were in 100% compliance with applicable JCAHO standards, that we had met all of the recommendations of the JCAHO, and had no further recommendations for the organization.

Question 2: I fear that something must first go horribly wrong before VA assesses how to redesign systems to improve patient safety. Has your facility undertaken any other re engineering studies since the root cause analysis of the event in your dialysis unit took place?

Answer: Rendering quality health care and ensuring patient safety are our top priorities. Nothing has to go horribly wrong before we reassess our systems and processes. Continuous assessment is on going in everything we do. Strong evidence of this is the fact that several hundred thousand procedures are ordered and completed annually and few, if any, have had outcomes similar to the one observed in the John Martin case.

As stated previously, we have conducted multiple reviews and staff surveys. Many of them have been conducted to determine what is good and bad about our facility. From the 1,000+ responses received, there was no evidence of any disregard for patient safety. Nor was there any evidence of fear of reprisal for reporting out-of-line situations. In a recent "One VA" Employee Survey conducted by the former Secretary of the Department of Veterans Affairs, the Miami VAMC received an extremely high score by employees for faith and confidence in top management for trying to implement quality improvements within the Medical Center. The effort to improve does not stop, even with the level of confidence expressed in these kinds of responses.

You asked if we have undertaken any other re-engineering studies since the root cause analysis of the event in our Dialysis Unit took place. The answer is "Yes." While the Dialysis Unit was the recipient of intense team building exercises and numerous re-engineering efforts, the same type of focus is also underway or being planned for the rest of the Medical Center. A consultant has been hired to do an assessment of our organization's readiness to change. Information gained from this consultant will help us to more clearly understand what our barriers to re-engineering are. We are currently planning intense customer service training for our staff that will help guide us towards enhanced customer relations and help us to become an even more customer-focused organization. Recently, we began a major re-engineering effort related to the way we assess employee competency. Dozens of key supervisors and managers participated in a two-day seminar conducted by outside consultants on the subject of employee competency. As a result of this seminar, we will be totally changing our employee competency assessment process and will be establishing organization-wide competencies that every employee must possess in order to satisfactorily perform within the Miami VAMC. We are also reorganizing our employee training and development program in order to make it more responsive to Medical Center goals and objectives. Funds will be spent on programs that have the greatest potential for organizational impact involving the largest number of employees. A new multidisciplinary Education Council is being selected to establish operational guidance for the education and training process. All of these re-engineering efforts can only positively support our initiatives to become an organization on the cutting edge, relative to systems and processes that are geared toward providing quality healthcare and patient safety.

Question 3: How are you taking steps to communicate your commitment to risk management to your staff and what if any steps are you taking to encourage staff to report?

Answer: A number of efforts have been initiated or are underway to improve communications among the staff and leadership, including town-hall meetings, enhanced E-mail access, weekly newsletters, etc. Additionally, management is making a comprehensive effort to communicate its goals and objectives and is making effective use of multidisciplinary group exercises to address process improvement problems. I re-emphasize that without the direct employee input we already receive about problem or process areas of concern, we would not be able to effectively identify all of the areas that need focused attention. A majority of our employees recognize their role in reporting problems and/or areas of concern because they realize that this is the only way to

effectively initiate change and to work as a team. Most employees readily understand and acknowledge that no one has lost their job at the Miami VAMC because they reported an out-of-line situation.

I will continue to utilize the multidisciplinary workgroups to develop effective solutions to identify problem areas. Our Quality Leadership Council will continue to be the main body for organizational input and development of process improvements. Through our extensive communications network, I will continue to encourage input from all employees, patients and families on how we can make our organization better, more effective, and more responsive to our customers. Through our Quality Management and Performance Improvement program, I will continue to implement the components of the VA, VISN and VAMC Miami Risk Management policies and procedures. Further, I will continue to encourage use of the Medical Center Risk Management Hotline which has been established to foster easy, timely, non-threatening reporting of all adverse incidents occurring within the organization.

POST-HEARING QUESTIONS
CONCERNING THE OCTOBER 8, 1997
HEARING ON VHA'S RISK MANAGEMENT
POLICY AND PERFORMANCE

FOR BILLY M. VALENTINE
DIRECTOR, VA MEDICAL CENTER, MUSKOGEE, OK
DEPARTMENT OF VETERANS AFFAIRS

FROM THE HONORABLE LANE EVANS
RANKING DEMOCRATIC MEMBER
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

Question 1: I fear something must first go horribly wrong before VA assesses how to redesign systems to improve patient safety. Has your facility undertaken any other re-engineering studies since your root cause analysis of the events that led to your patient being transfused with the wrong blood type?

Answer: Your question refers to a patient being transfused with the wrong blood type. This did not occur at the Muskogee VAMC. However, regarding our incident of a patient death at a construction site we have continued to implement and monitor activities based on findings from our root cause analysis. Our Facility Safety Manager meets weekly and as needed with the contractors for the Replacement Bed Tower to ensure that a safe environment in and around the construction site is maintained.

Question 2: Have you assessed any other opportunities for system re-engineering since you implemented the new policies responding to the Board of Investigations and the Medical Inspector?

Answer: Assessment and reassessment for system re-engineering is a continuous effort at the Muskogee VA Medical Center. This is accomplished through patient and staff education, drills, and critiquing; however, no additional needs have been identified, although letters to patients, visitors and employees visiting the medical center have been issued regarding dangers of construction. We have implemented the new national "Risk Management" policy.

Question 3: Do you believe that your organization would have either taken proactive steps to prevent this accident or responded any differently had VA had its new risk management plan in place in the wake of the incident you just shared with the Subcommittee? Please discuss your response.

Answer: Any further restriction of mentally competent, physically mobile patients would infringe on the patients' rights. This incident did not occur as a result of risk-taking behavior by any employee. While it may have changed the outcome in our particular incident, implementation of the new policy, with a Lessons Learned Intranet Database, would have certainly implemented system-wide communication to facilitate systems redesign where needed. Had this incident occurred at another facility, and those experiences shared, we may have been prompted to conduct more frequent sweeps of the construction area to include specific issues addressed in others experiences. For example this patient entered the construction site by taking apart a barrier fence. Sharing this information with other sites engaged in construction, and with Headquarters facilities staff who are responsible for ensuring construction documents contain appropriate safety precautions, will hopefully prompt them to more closely scrutinize barrier fences.

Attachment to Question #1
from Hon. Lane Evans to Dr. Kizer

VA MEDICAL MALPRACTICE EXPERIENCE
FISCAL YEARS 1988 THRU 1997

ADMINISTRATIVE CLAIMS

FY	Claims Filed	Claims Settled	Amt. Paid in Claims Settled
88	844	206	$ 9,304,783
89	692	182	$ 7,726,483
90	676	168	$ 9,854,744
91	672	152	$ 9,868,960
92	749	183	$ 13,284,344
93	801	188	$ 16,640,350
94	978	257	$ 19,640,022
95	1,084	252	$ 18,820,625
96	1,039	203	$ 20,492,247
97	1,117	258	$ 21,129,995
TOTAL	8,652	2,049	$146,762,553

LITIGATION

FY	FILED	DISMISSAL	Jgt. U.S.	Jgt. PLAINTIFF	SETTLEMENTS/AMT.
88	350	77	34	15/$ 3,348,274	150/$ 16,514,057
89	272	80	26	6/$ 2,005,650	169/$ 16,907,393
90	248	75	17	6/$ 1,872,045	179/$ 20,090,593
91	239	75	39	17/$ 6,631,498	130/$ 20,916,550
92	228	61	26	18/$ 9,089,489	141/$ 18,427,452
93	219	61	17	14/$ 3,722,467	114/$ 21,070,888
94	155	53	22	12/$ 3,596,292	127/$ 30,628,483
95	222	56	34	14/$ 7,040,024	107/$ 22,227,467
96	185	74	38	14/$ 5,125,155	127/$ 27,830,873
97	211	58	20	11/$13,834,638	121/$ 27,062,891
TOTAL	2,329	670	273	127/$56,265,532	1,365/$221,676,647

AMOUNT PAID IN VA MEDICAL MALPRACTICE CASES
FISCAL YEARS 1983 thru 1997

FY	ADMINISTRATIVE SETTLEMENTS	LITIGATION SETTLEMENTS	JUDGMENTS	TOTAL
83	$ 4,482,520	$ 9,195,011	$ 2,374,656	$ 16,052,187
84	$ 5,692,487	$ 8,059,466	$ 4,229,897	$ 17,981,850
85	$ 14,464,433	$ 13,055,818	$ 7,484,353	$ 35,004,604
86	$ 10,361,648	$ 17,454,963	$ 5,140,419	$ 32,957,030
87	$ 11,392,261	$ 17,752,838	$ 5,241,132	$ 34,386,231
88	$ 9,304,783	$ 16,514,057	$ 3,348,274	$ 29,167,114
89	$ 7,726,483	$ 16,907,393	$ 2,005,650	$ 26,639,526
90	$ 9,854,744	$ 20,090,593	$ 1,872,045	$ 31,817,382
91	$ 9,868,960	$ 20,916,550	$ 6,631,498	$ 37,417,008
92	$ 13,284,344	$ 18,427,452	$ 9,089,489	$ 40,801,285
93	$ 16,640,350	$ 21,070,888	$ 3,722,467	$ 41,433,705
94	$ 19,640,022	$ 30,628,483	$ 3,596,292	$ 53,864,797
95	$ 18,820,625	$ 22,227,467	$ 7,040,024	$ 48,088,116
96	$ 20,492,247	$ 27,830,873	$ 5,125,155	$ 53,448,275
97	$ 21,129,995	$ 27,062,891	$13,834,638	$ 62,027,524
TOTAL	$193,155,902	$287,194,743	$80,735,989	$561,086,634

VA MEDICAL MALPRACTICE LITIGATION
FISCAL YEAR 1997

Cases Closed	210
Closed With Payout	132 (63%)
Settled	121 (58%)
Judgment for Plaintiff	11 (5%)
Closed Without Payout	78 (37%)
Dismissed	58 (27%)
Judgment for U.S.	20 (10%)
Cases Tried (To Summary Judgment or Beyond)	31 (15%)
Judgment/U.S. as % of trials	65%
Judgment/Plaintiff as % of trials	35%
Amount Paid in cases Settled	$27,062,891
Average Settlement	$ 223,660
Amount Paid in Judgment/Plaintiff	$13,834,638
Average Judgment	$ 1,257,694
Total Amount Paid in Litigation	$40,897,529
Average Award	$ 309,829

VA MEDICAL MALPRACTICE CLAIMS
FISCAL YEAR 1997

Claims Closed	758
Settled	258 (34%)
Denied	500 (66%)
Denied without suit following	289 (58%)
Cases Finally Closed Administratively	539 (72%)
Amount Paid on Claims Settled	$21,129,995
Average Settlement	$ 81,899

Attachment to Question 7
from Hon. Lane Evans to Dr. Kizer

Frequency of Adverse Events Identified for Review at VA Medical Facilities

Adverse events are unexpected and undesirable events that may or may not lead to negative consequences. The VA requires its clinical and non-clinical staff to report all such adverse events. The VA reviews them to identify possible errors or design defects in care delivery systems in order to improve patient care. Table 1 shows how frequently 14 categories of adverse events occurred at VA medical facilities from FY 1994 to FY 1997. The definitions of the 14 categories are in Appendix 1.

Adverse events requiring review that led to death were separately analyzed. For each year from FY 1994 through FY 1997, we determined the proportion of acute care inpatients treated within VA hospitals who died as a result of any of these adverse events requiring review.

FY 1994 – 2.3 per 1,000 inpatients treated
FY 1995 – 1.8 per 1,000 inpatients treated
FY 1996 – 1.4 per 1,000 inpatients treated
FY 1997 – 1.2 per 1,000 inpatients treated

The most comparable data available from non-VA hospitals come from the widely respected Harvard Medical Practice Study[1], which examined the care received by 30,000 randomly selected acute care patients hospitalized in New York State in 1984. In this study 5.0 per 1,000 inpatients treated experienced an adverse event that caused their death. A second relevant study, the California Medical Insurance Feasibility Study[2], assessed the care given to 20,000 California inpatients in 1974. The authors reported that 4.5 of every 1,000 patients studied died as a result of their health care management.

References

1. Leape LL, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. New England Journal of Medicine. 324:370-376, 1991.

2. California Medical Association. Report of the Medical Insurance Feasibility Study. San Francisco: California Medical Association, 1977.

Table 1

Number of Adverse Events Requiring Review in VHA FY 1994 - FY 1997

Category*	FY 94 #	FY 94 Rate Per 1,000 Patients Treated	FY 95 #	FY 95 ** Rate Per 1,000 Patients Treated	FY 96 #	FY 96 Rate Per 1,000 Patients Treated	FY 97 #	FY 97 Rate Per 1,000 Patients Treated
No informed consent	94	0.0334	36	0.0125	46	0.0157	41	0.0135
Medication errors	120	0.0427	104	0.0360	101	0.0344	101	0.0332
Wandering patient	82	0.0292	112	0.0388	99	0.0337	18	0.0059
Transfusion errors	5	0.0018	6	0.0021	3	0.0010	1	0.0003
Falls	1026	0.3650	1003	0.3470	883	0.3006	663	0.2178
Patients involved in fires	4	0.0014	12	0.0042	16	0.0054	7	0.0023
Patient abuse	998	0.3550	762	0.2637	564	0.1920	395	0.1298
Assaults	50	0.0178	55	0.0190	37	0.0126	39	0.0128
Sexual assault	42	0.0149	41	0.0142	51	0.0174	64	0.0210
Suicide attempts	848	0.3017	837	0.2896	764	0.2601	562	0.1847
Suicide	281	0.1000	245	0.0848	220	0.0749	168	0.0552
Homicide	3	0.0011	11	0.0038	15	0.0051	13	0.0043
Deaths requiring review	897	0.3191	674	0.2332	417	0.1420	274	0.0900
Miscellaneous injury	538	0.1914	499	0.1727	394	0.1342	299	0.0982
TOTALS	4988	**1.7745**	4397	**1.5214**	3610	**1.2291**	2645	**0.8691**

*See Appendix 1 for definitions of 14 categories.

**Rate of adverse event, where 1.0 would be 1 patient per 1,000 patients treated and 0.10 would be 1/10th of 1 patient per 1,000 patients treated. Total number of patients treated for FY 1994 – FY 1997: FY 1994 – 2,810,975; FY 1995 – 2,890,157; FY 1996 – 2,937,000; FY 1997 – 3,043,449

Appendix 1

Definitions of 14 Adverse Events

1. No Informed Consent:

Informed consent is not obtained for any invasive procedures or for any patient participating in a research protocol.

2. Medication Errors:

An administration or dispensing of medication that deviates from the physician's order as written in the patient's medical record or as written on an outpatient prescription form or which deviates from standard medical center policies and procedures for administering and dispensing medications and results in a significant injury or death. Prescribing errors that result in a significant injury* or death are also included.

3. Wandering Patient:

A search for a patient who disappears from the patient care area for any length of time, even if found or the patient returns on his/her own, if the patient has a court-appointed legal guardian, is considered a danger to self or others, is legally committed, or lacks cognitive ability to make decisions.

4. Transfusion Errors:

Blood administered to the wrong patient, administered when not ordered, administered using the wrong product, incorrectly administered, or an error occurred in the type/cross match process.

5. Falls:

All falls whether observed or not that result in a significant injury or death.

6. Patients Involved in Fires:

Includes patients who set a fire, are burned, experience smoke inhalation, or are otherwise involved in a fire.

7. Patient Abuse:

Acts against patients, which involve physical, psychological, sexual or verbal abuse. Employee "intent" to abuse is not a requirement.

8. Assaults:

Unwanted physical contact that results in a significant injury.

9. Sexual Assault:

Sexual contact without consent with or without penetration and regardless of gender.

10. Suicide Attempts:

Self-destructive act requiring inpatient medical or surgical care or behavior which carries a high risk for severe injury or death by patients currently receiving inpatient or outpatient care or who had a VA clinical encounter or visit within 30 calendar days.

11. Suicide:

Taking of one's own life by patients currently receiving inpatient or outpatient care or who had a VA clinical encounter or visit within 30 calendar days.

12. Homicide:

The death of a patient or staff member intentionally caused by a patient or the death of a patient intentionally caused by another individual.

13. Deaths Requiring Review:

Deaths that occur in the operating room, in the recovery room, during induction of anesthesia (including in procedure rooms), within 48 hours of surgery, within 24 hours of a procedure, or during use of a medical device; also, deaths due to equipment malfunction, deaths reportable to and accepted by the medical examiner, and deaths of patients who are on the medical center grounds but not necessarily being treated at the time.

14. Miscellaneous Injury:

Significant injury or death to a patient resulting from an adverse event not specifically addressed elsewhere is included in this category.

*A significant injury is an injury that requires medical or surgical intervention or increased hospital stay, or is disabling or disfiguring so that the patient will have any degree of permanently lessened function or quality of life.

HARVARD SCHOOL OF PUBLIC HEALTH

Department of Health Policy and Management

Lucian L. Leape, M.D.

November 25, 1997

Hon. Lane Evans
U.S. House of Representatives
Committee on Veterans' Affairs
335 Cannon House Office Building
Washington, DC 20515

Dear Rep. Evans:

Thank you for the opportunity to answer your questions about improving safety in the Veterans' Health Administration. Here are my replies. If there are further questions, do not hesitate to get in touch with me. I appreciate your efforts on behalf of all of us to make health care safer in the VA, and, by example, to encourage the private sector to do likewise.

Yours sincerely,

Lucian L. Leape, MD

677 Huntington Avenue Boston, Massachusetts 02115 617 432-2008 Fax: 617 432-4494

Post-Hearing Questions for Dr. Lucian Leape

1. Based on your knowledge of the VA and other health care systems, are VA patients any more likely than patients of other systems to experience an adverse event that results in injury or death?

1. I never practiced in the VA health system so my knowledge of patient care in the VA is severely limited. In addition, I am a pediatric surgeon, and I have been out of clinical practice for 11 years, further limiting my knowledge. However, my general understanding is that VA patients in general are older and tend to have more severe disease than the average patient in non-VA acute care hospitals. If that is true, then they may well be more likely than other patients to experience adverse events since our studies in the private sector have shown that adverse events are more common in both the elderly and those with complicated illnesses.

2. Your testimony describes an approach to risk management which centers on re-designing systems to control for human fallibility. Can you identify the types of system breakdowns health care facilities are most likely to experience that result in adverse outcomes? Does VS have different problems than other providers?

2. We don't know the answer to this question because the nature and extent of systems failures in health care has not been examined extensively. Most studies have concentrated on the medication system, in which systems failures have been demonstrated at every stage, but most extensively in the physician prescribing stage and in the nurse medication administration stage. Other areas that are known to have higher than average adverse event rates that probably are due to systems failures are emergency rooms, intensive care units, and operating rooms. I do not know if VA has different problems than other providers.

3. VA has a series of general approaches to system redesign listed in Appendix A of its Risk Management Handbook. These approaches, such as "standardize", "reduce reliance on memory", "use protocols" sound like pretty practical advice. Are you familiar with the approaches in Appendix A and if so do you think they are generally sound? If these general approaches based on medical literature are sound and useful in preventing injury or death, why do you believe VHA would be reluctant to recommend them to its facilities?

3. The approaches described in Appendix A of the VA Risk Management Handbook are indeed sound - they represent the application of human factors principles that have been proven effective in other industries, and, to a limited extent, in health care. I have not heard that VHA is reluctant to recommend them and if it is I do not know why.

4. What can VA do to encourage its clinicians to report adverse outcomes quickly and honestly?

4. Quit punishing them for reporting. While I recognize that efforts are being made to develop a non-punitive environment within the VA, the need to punish people when they make mistakes is very deeply ingrained in all of us. That is, the concept that an error - particularly an egregious one, such as removal of the wrong organ - results from systems failures is difficult for most people to accept. Not only is it counter-intuitive, it offends our sense of justice somehow. Certainly, we think, SOMEONE should pay. So, even in a system that tries to be non-punitive, a fair amount of punishment will seep through - sending a loud message to all that it is better not to report events that aren't obvious. It is not a matter of dishonesty, it is a matter of self-preservation. And it is universal.

   A critical ingredient in changing this culture of blame is developing the recognition that the cause of an error is almost always multifactorial. Therefore, understanding the "root cause" requires extensive investigation and analysis. An error is never just one person's fault. Creating a safe environment requires attention to all aspects - education and training, process design, team training, working conditions, leadership, etc. - that are known to induce individuals to make errors. Management has responsibility to stimulate and require all members of the health care team to examine these issues and create safer systems.

   Until the culture is changed so that everyone feels it is safe to report and discuss errors, attempts to monitor errors and adverse events will always fail. A wise alternative that would probably improve patient safety more would be to monitor the use of safe practices. That is, we should insure that known safety measures are in place and operative (see below).

5. Are there any "quick fixes" to improve patient safety within VA's health care system or other health care system you study? What are the easiest types of systems to fix?

5. Yes. The major systems changes that have the greatest potential to rapidly and substantially reduce errors in health care are in information processing. Specifically, computerized physician order entry has the potential to cut the rate of medication errors in half. Similarly, the computerized medical record, which permits timely and accurate access to all pertinent patient information by all parties who need to know, has great potential to reduce all kinds of errors in patient care.

   "Tried and true" systems changes from the past that if not already in place should be implemented promptly include: unit dosing, 24-hour availability of the pharmacist, central IV-admixture, protocols for ER management of trauma, myocardial infarction, etc., protocols and preprinted orders for chemotherapy and other hazardous drugs such as insulin, removal of concentrated potassium chloride from floor stock in ICUs and regular units, weight-based heparin dosing, and anticoagulation services run by nurses or pharmacists.

Experience in other industries suggest other changes that would improve patient safety, such as prohibition of double shifts or 12-hour shifts, standardization of processes, simplification of processes, use of checklists, etc.

We don't know which are the easiest types of systems to fix. It is undoubtedly easier to change processes (such as various components of the medication system) than to re-engineer a whole system (although the latter is urgently needed for the medication system). And it is probably easier to change processes than traditions (such as long hours and double shifts), or practices (such as not functioning in teams). However, if one is serious about safety, all of these should be pursued simultaneously.

I commend you for your attention and concern about safety in the VA. We need these kinds of efforts throughout our health care system, but why not start here? Good luck!

Lucian L. Leape, MD
November 25, 1997

NOV 1 1 1997

The Honorable Lane Evans
Ranking Minority Member
Committee on Veterans' Affaire
House of Representatives
Washington, DC 205155

Dear Congressman Evans:

I am please to respond to your October 30, 1997 letter requesting answers to the questions you asked in reference to the Subcommittee on Health's hearing on October 8, 1997. I have enclosed my response.

Thank you for your interest in the Department of Veterans Affairs.

Sincerely

JOHN H. MATHER, M.D.

Enclosure

Post-Hearing Questions for Dr. John H. Mather

Assistant Inspector General for Healthcare Inspections (54),

Office of the Inspector General

Department of Veterans Affairs

1. In your statement you indicate that there may have been somewhat clearer reporting lines when the VA health care system was organized under the four Regions. Do you want to elaborate on this statement and indicate where VHA, under its current organizational structure, could take steps to ensure clear lines of communication in the event of an adverse outcome?

Answer:

The guidance for the four Regions and the twenty-two VISNs that have replaced them, in regard to VHA's Risk Management (RM) Policy, have been clear and explicit. The exception was the interim Risk Management Directive VHA Directive 97-029 that was issued June 6, 1997 and replaced just over three months later with the present Risk Management Directive, VHA Directive 1051, September 25, 1997. This interim RM Directive was a most unfortunate issuance since it gave authority and responsibility to the VISNs with very little guidance. The VISNs were expected to develop and issue VISN-wide guidance, which had the great potential for twenty-two different RM programs. If this RM Directive had not been changed it would have been very difficult, if not impossible, to have any consistency in the data that would be collected, monitored and tracked, analyzed for trends, and system-wide corrective actions taken. The present RM Directive should provide sufficient guidance.

In addition, there will need to be a continued emphasis in the VISNs to monitor the VAMCs and their investigations of adverse events either as focused reviews or Administrative Investigations. The VISNs have an augmented responsibility in these matters as compared to the guidance previously followed by the four Regions. This will be a particular challenge since the VISNs are sparsely staffed to cover a large spectrum of responsibilities such as fulfillment of Performance Plans that include the execution and allocation of resources [VERA], Annual Strategic Planning and so forth.

Ultimately, when an adverse event is identified and current explicit instructions are not followed or remain ambiguous, VHA should recognize the problems and issue additional guidance and education. The Office of Healthcare Inspections is committed to monitoring the implementation of the present RM Directive and will make further recommendations for guidelines wherever deficits in the present RM Directive occur.

2. You indicate that of the 15 reports you reviewed for this Committee, most VA medical centers have taken active steps to identify the cause of sentinel events—and further that those inclined to report to external organizations, such as the Joint Commission on Accreditation of Healthcare Organizations, seem especially invested in investigating the root cause of their problems. Should, in addition to their internal reporting requirements, all VA medical centers also be required to report to an external quality assurance group?

Answer:

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is, in broad definition, an external quality assurance group. Its accreditation standards do not actually require the reporting of "sentinel" events, but they strongly urge that its accredited healthcare facilities report such adverse events. The JCAHO does monitor, independently of voluntary reports, other sources of information and may self-initiate a site visit team to investigate. The result may be a curtailing of the healthcare facility's accreditation status. Wherever external quality assurance groups encourage or mandate the reporting of sentinel events then, VAMCs should fulfill these requirements. These external reviewers may be comprised of other Federal regulatory agencies such as the Centers for Disease Control and the Food and Drug Administration. It is unclear as to whether there is a master list of external quality assurance groups VHA to which sentinel or adverse events need to be reported.

3. With regard to VHA's Medical Inspector, it is sometimes said that no man can serve two masters. Is this the case with the Medical Inspector responding to both you and VHA? Are you aware of any plans to change the mission or activities associated with that office? Have you spoken with the Secretary or Under Secretary about why has there been a delay in fully staffing this office:

Answer:
The Medical Inspector reports to the Undersecretary for Health and, by statute, its operations are overseen by the Inspector General (IG). The IG has delegated this oversight responsibility to the Office of Health Care Inspections (OHI). All OMI inspection reports are submitted to OHI in draft and we provide comments as to the adequacy of the inspection and the reasonableness of the conclusions and recommendations. The Undersecretary for Health has contracted with Abt. Associates to conduct a broad-based analysis of the role, functions, and responsibilities of the OMI. This contractor should be finishing its work this month and we anticipate conferring with the USH on the results of this outside inquiry by Abt Associates momentarily. Ever since we issued our Oversight Report on the OMI, February 16, 1997 [OIG Report No: 5H1-A28-039] we have sought resolution of the three recommendations. Only one has been resolved and this concerned the receipt by the OMI of all VAMCs' Boards of Investigation reports. The other two recommendations relate to the staffing levels of the OMI. The USH has chosen to defer making a final response to our recommendations until after he has received the Abt Associates report and can clarify the mission for the OMI. Even so, a certain amount of influence on the USH has been exerted and the OMI is projected to achieve a staffing level equivalent to just under half of what used to be considered necessary. This contrasts with the remaining VHA Headquarters organization that have lost between 25 and 30 % of their previous staffing levels.

4. You indicated that a couple of VA facilities presented documentation from their Boards of Investigations that did not convey the same level of concern as others over sentinel events. How would you handle these responses?

Answer:
The expectation is that the current RM Directive will require the VISNs to carefully review all Boards of Investigations (BOI) and make a determination as to their completeness and sufficiency. Then each will be forwarded to VHA headquarters where several offices, including the OMI, will further review the BOI reports. In OHI, if we were referred a BOI or had, in the course of an inspection of a veteran's complaint about poor quality of medical care received at a VAMC, an opportunity to review a BOI we would conduct a thorough review. The BOI report would be scrutinized for deficient investigations of the issue(s) and, if necessary, additional evidence would be collected through requesting additional documents, conducting interviews by telephone or on-site. Depending on how severe a threat to 'life and limb' the issue was, a more in-depth inspection would be conducted and a report filed with the VAMC and VHA headquarters that may include a number of recommendations which need to be implemented.

5. Does your office have sufficient staff to sustain the IG's mission and your caseload?

Answer:
The staffing level designated for the OHI is 25 FTE but due to funding restrictions the authorization has had to be limited to 20 full-time staff. OHI's staffing is insufficient to maintain a balance in its product lines of program review, hotline inspections and Quality Program Assistance reviews as the number of veteran complaints concerning a perceived poor quality of care, received at VAMCs, increases. These complaints, which are frequently received from Congressional and other sources, such as VHA itself or the Veterans Service Organizations, are becoming more and more complex due to companion issues such as personnel or possible fraudulent activities. The effect of this increase in number and complexity of hotline inspection activity is to restrain OHI's ability to complete its other product lines in a timely manner. The deficient OHI staffing level has been recognized and the Department has made representation to the Office of Management and Budget to increase the assigned FTE in the President's Fiscal Year 1999 budget request.
The Statute requires the VA's OIG to maintain a floor of 417 FTE, but OMB has submitted a legislative initiative to Congress requesting abolition of this FTE floor. Current FTEE levels are significantly below the statutory floor, creating a situation where the OIG's ability to cover VA programs is vulnerable.

6. The IG's Strategic Plan indicates that your office, working with VHA, intends to conduct a review of VHA's Medical Inspector and Quality Management (QM) activities. Has this review begun? Can you share any preliminary findings?

Answer:
The OIG statute provides that all of VA's programs are subject to review. Public Laws 99-166 and 100-322 require the OIG to give particular emphasis in its work to overseeing the OMI and VHA's quality Assurance activities. Our ongoing review of the OMI is discussed in the answer to Question 3. In addition to OHI's regular ongoing review of VHA's quality assurance activities we have initiated two reviews.
One initiative is at the request of the Senate Veterans Affairs Committee to conduct a complete, detailed evaluation of VHA's quality assurance program. We are assessing the changes in the quality assurance program over the last five years with regard to its scope, administration and staffing at the VAMC, VISN and headquarters levels. This program review will be completed very early on in 1998.
The second initiative is the development of a Quality Program Assistance (QPA) review program, which is designed to assess the ability of a VAMC to provide high quality of care to the veterans it serves. This initiative is in its final phase of piloting and it is anticipated that upon completion of an evaluation of its effectiveness as a mechanism for fulfilling our oversight function, the QPA program will go operational early in 1998.

7. Do you believe that VHA's guidance to the field on risk management policy is sound? Are there improvements you might recommend?

Answer:
The present RM Directive is sound and consistent with contemporary notions of what a RM program should be. The real concern has to be whether it will be adequately and properly implemented, and whether the VISNs and VHA headquarters will consistently and vigorously ensure that the policy is followed. In the past there have been reasonably good RM policies espoused by VHA leadership, which have not been fully complied with. The USH has stated that he thought certain aspects of the RM policy had been going on but he found that they had been forgotten or ignored. In particular, he was referring to the collection of information on adverse events in VHA headquarters, the tracking and trending of these sentinel events, and the issuance to the VISNs and VAMCs of instructions on systematic changes that were needed. Now the intent is to conduct such an activity through the VHA headquarters RM Oversight committee and to issue guidance through various means on "Lessons Learned". Also, the USH has aligned the VA with several other organizations to approach the issue of preventing medical errors more broadly, and it is anticipated that further actions will come from this collaboration.

8. Your office operates a hotline. Please describe any procedures you have in place for communicating with the VHA's Central Office following a Class I Hotline Call.

Answer:
The OIG operates a Hotline and Special Inquiries Office which is the central focal point for receipt of complaints and inquiries. OHI works very closely with this office. There are many complaints and inquiries that involve issues related to quality of care received by veterans. The less serious of these complaints can be handled through a referral to VHA without the involvement of OHI, and an appropriate response to the complainant can often be made upon review of the response from VHA. Some other complaints clearly require OHI's immediate involvement because of a Congressional inquiry or the apparent serious nature of the issues involved, such as patient abuse or unusual deaths. If VHA's OMI is already aware or even involved in the issue, OHI may assume the responsibility for the case to be more evidently assured of an independent inquiry, or the OMI will continue the inspection with close monitoring from OHI. The coordination and cooperation has worked well over the past several years although it does require a high level of confidence in the OMI's capabilities, and amount of staff resources in the OHI to aggressively conduct these inspections in a timely manner.

○

ISBN 0-16-056429-8

90000

9 780160 564291