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October 13, 2000

The Honorable Terry Everett
Chairman
Subcommittee on Oversight
and Investigations
Committee on Veterans' Affairs
House of Representatives

Subject: Response to Questions From Hearing on Patient Safety and Quality of Care at VA Facilities

Dear Mr. Chairman:

The enclosed information responds to your follow-up questions on our July 27, 2000, testimony for the Subcommittee on Oversight and Investigations hearing concerning VA's Patient Safety and Quality of Care. We will make copies of this correspondence available to other interested parties upon request.

If you have any questions or would like to discuss this information further, please contact me at (202) 512-7101.

Sincerely yours,

Cynthia A. Bascetta
Director, Health Care – Veterans' Health and
Benefits Issues

Enclosure

SUPPLEMENTAL INFORMATION ON VA'S PATIENT SAFETY INITIATIVES

This enclosure presents your questions and our responses, which supplement information in our testimony before the Subcommittee on Oversight and Investigations, VA Patient Safety: Initiatives Promising but Continued Progress Requires Culture Change (GAO/T-HEHS-00-167, July 27, 2000).

1. Regarding VA's four Patient Safety Centers of Inquiry, how does their role and research focus relate to the work conducted by VA's Office of Research and Development? In what way does the work of the centers address the principal adverse and sentinel events that were disclosed in VA's 1999 Office of the Medical Inspector's report?

The Patient Safety Centers of Inquiry and VA's Office of Research and Development are not directly linked organizationally. The four Centers of Inquiry do not report to and are not funded by the Office of Research and Development. Rather, the Directors of the four centers report to either the Veterans Integrated Service Networks (VISN) or Medical Center manager where they are located. The Office of Research and Development staff assisted the Under Secretary for Health in developing the Centers of Inquiry request for proposals and subsequently helped in rating and ranking the proposals submitted. The centers were then chosen by the Under Secretary for Health and received $500,000 per year in funding from medical care funds. Some staff associated with the Centers of Inquiry also have active projects funded by Health Services Research and Development (HSR&D), which is part of the Office of Research and Development. In addition to these projects, HSR&D funds other patient safety research projects that are not directed by the centers and is currently funding four projects that overlap with the work of the centers. Two of these focus on selected aspects of adverse drug reactions, and the other two address fall prevention in the hospital and home environments. As the patient safety effort develops, VA told us that it expects to articulate clear linkages between these efforts to maximize the efficiency of this research effort.

The work at the Centers of Inquiry address some but not all of the known principal adverse and sentinel events at VA medical facilities. In December 1999, a report by VA's Medical Inspector disclosed that between June 1997 and December 1998, the top five categories of adverse events reported by VA facilities were patient falls, suicide and attempted suicide, other unplanned occurrences, and patient abuse (not in rank order). Adverse events in these five categories account for 69 percent of reported events during the timeframe reviewed by the Medical Inspector. The Patient Safety Center of Inquiry at the Tampa VA medical center is studying fall prevention and injury reduction related to patient falls in high-risk populations that have mobility problems. The Center in White River Junction is currently working to reduce medication errors (ranked seventh on the Medical Inspector's list) using a collaborative technique. Not targeted by the

centers are unplanned occurrences, patient abuse, and suicide and suicidal behavior.

Although none of the centers is currently studying suicide prevention, VA has undertaken a variety of suicide prevention efforts since the 1970s, including most recently its March 1, 2000, suicide summit called "Suicide: Recognizing Risks Across Treatment Settings."[1] This program was designed to encourage caregivers to screen patients for risk of suicide; share resources regarding suicide awareness, prevention, and treatment; and recommend proper treatment and referral. Suicide risk assessment pocket cards were also printed and distributed to clinicians to use in their daily activities. VA has also implemented depression screening in nonmental health care settings to identify veterans at risk for suicide and to get them help from a mental health professional. There are also 12 VA facilities with active projects related to improved prevention and management of suicidal behavior.

“Unplanned occurrences” is a general category for events that do not fit neatly into one of the other categories used by VA. To work in this area, the events would need to be further categorized. VA is no longer handling cases of alleged patient abuse under the patient safety program and instead has mandated that facilities take immediate administrative steps to investigate these incidents.

2. Given GAO’s early assessment of VA’s efforts to improve patient safety, what obstacles or other problems might VA have to overcome to ensure continued progress?

As we testified, VA’s initiatives to improve patient safety mirror some of those suggested by the Institute of Medicine (IOM), but VA faces significant challenges to ensure the success of its patient safety efforts. The key challenges include setting goals, planning, and communicating the priority of patient safety to its employees. Beyond that, VA needs to overcome obstacles that impede the move from a “blame and shame” way of handling adverse events to a culture of safety that looks openly at how and why adverse events occur and how systems can be improved to prevent them in the future. To make a major change in patient safety, VA must convey the message to all its employees that patient safety is everyone’s responsibility and then put this belief into practice by making it an integral part of everyday work. Safety experts agree that management officials—many of whom have been trained to look for the person responsible for an error—need to focus instead on the systems that allowed the adverse event to occur. They must also be able to create a nonpunitive work environment in which employees feel safe enough to report and investigate adverse events and, even more important, close calls (situations in which an adverse event could have occurred but did not). Because successful culture change takes years, we believe that patience and sustained commitment in the event of leadership changes should also be a top priority. Also, once the culture change has taken root, VA leadership at all levels

[1]In VA, a summit is a series of educational and networking events designed to share best practices across the VA health care system.

of the organization must remain committed to continuous improvement in the effort to drive the medical error rate to zero.

It is also important to point out that, in the short run, if the culture change is successful, we would expect to see an increase in the number of reported adverse events, and we should view this increase as a positive result of VA's efforts. As reports of adverse events increase and more errors come to light, managing the potential negative reaction of skeptics and highlighting the fact that staff are able to learn from these errors will be critical to ensuring that the patient safety program stays on track.

3. Much has been said about VA's patient safety program and some people point to it as a model for the private sector to follow. Does GAO believe that it is a model program?

Because VA's patient safety program has not been fully implemented, it is too early to predict whether, in the final analysis, it will be a model for other health care organizations. While some of VA's patient safety initiatives are clearly exemplary, such as removing concentrated potassium chloride from wards and bar-coding medications, these initiatives preceded the broader patient safety program that VA is now trying to put in place. In other words, more fundamental than such stand-alone initiatives is VA's effort to create a systemwide culture of safety. In this key endeavor, VA is not yet a model. While VA leads the rest of the health care sector in adopting the right concepts and consulting with appropriate experts, we believe that it is too early to predict if VA will be successful in creating a culture that promotes patient safety. Until VA demonstrates results attributable to the processes it is putting in place, others will be unable to emulate them. In our view, therefore, calling VA a model would be premature.

4. VA's National Center for Patient Safety promises to have a pivotal role in the development of new systems that will be used to analyze and report on sentinel and adverse events. If the Center's new processes are successful, what will be the likely impact on the number of patient safety events that are reported?

In the short run, if the processes instituted by the National Center for Patient Safety are successful, there should be a rise in the number of reported adverse events at VA facilities. We believe an increase in reported events will reflect a willingness on the part of employees to report events that have been occurring all along, not a real increase in the number of adverse or sentinel events. In fact, we would be suspicious that the system is not working well if the number of events is too low. The magnitude of this potential increase is unknown but could be steep. Increased reporting will offer employees a chance to learn from adverse events, especially close calls, and will provide an opportunity to propose changes that can prevent such events from happening again in the future. In the long run, more reports should lead to a drop in preventable adverse events as proposed solutions and action plans are disseminated systemwide to reduce or prevent occurrences.

5. In addition to more definitive goal setting and measurement, comprehensive planning, and communicating the importance of the program to all its employees, are there other actions VA can take to ensure the success of its patient safety program?

Reporting adverse events—one of the most important steps VA is taking to improve patient safety—depends on the cooperation and participation of VA employees. However, a reporting system is not enough. In its training for employees on VA's new method for reporting and analyzing the root causes of patient safety problems, the National Center for Patient Safety emphasizes the importance of feedback to all employees who are participating in the process—from the individual who reports the adverse event or close call to the team of employees selected to perform the root cause analysis or aggregate review. We believe that motivating employees by involving them in these processes will enhance the success of VA's efforts even more than setting goals and communicating patient safety as a top priority. The importance of providing feedback to teams and disseminating findings throughout VA cannot be overemphasized. Managers must be willing not only to find time for employees to participate in the root cause analysis but must also support the implementation of recommendations made by the teams. We believe that only when these processes run smoothly and employees participate fully as part of their everyday work will the full benefits of the culture of safety be realized.

6. The VA Office of Inspector General's Combined Assessment Program (CAP) reports often identify critical nursing staff shortages. Can you comment on how these shortages have an impact on patient safety?

The nursing shortage—a national problem affecting VA and private sector hospitals alike—is projected to worsen in the coming years. GAO has not conducted an evaluation of the adequacy of nursing staff ratios in VA. We therefore cannot comment directly on the potential effect that any nursing shortage may have on patient safety. However, in 1998, VA and Kaiser Permanente jointly sponsored a public/private sector focus group of health care professionals to identify perceived barriers to patient safety. These care providers, including VA participants, identified inadequate staffing as the largest barrier to patient safety. Not surprisingly, they reported that inadequate staffing leads to employee fatigue and frustration. Other industries, such as aviation, have established strict rules that prevent flight crews, for instance, from working without adequate rest periods. VA is currently doing research in this area to determine the applicability of this preventive measure in health care delivery situations.

7. The VA points to its bar-coding system for medications as one of its great success stories. I understand the implementation of this system has encountered problems in operating rooms and in interfacing with VA's computerized patient record system. Would you please elaborate on these difficulties?

VA reports that it has implemented bar code medication administration (BCMA) in over 60 percent of its inpatient care areas. For BCMA to work, the physician order entry package, which is part of the Computerized Patient Record System (CPRS), must be functioning. One reason for the slippage in the BCMA schedule is that CPRS is not uniformly available in all facilities, even though VA tells us that the software has been installed at all VA facilities. We are unaware of any specific interface problems between BCMA and CPRS, but VA has experienced hardware and training problems in some locations that have prevented full implementation of CPRS.

VA did not indicate that problems in operating rooms were occurring. However, there are some problems in intensive care units (ICUs), where the situation is more complex. VA told us that ICUs, in which about 70 percent of medications are administered intravenously, are further behind other inpatient care areas in implementing BCMA. Specifically, only about 40 ICUs had implemented BCMA, as of the end of June 2000. According to VA officials, the original BCMA computer package was intended primarily for administration of oral medications and not for intravenous therapy. VA tells us that the Version 2 upgrade of the software, scheduled for 2001, will resolve this problem.

8. What evidence have you seen of VA's senior management participation or commitment to the ambitious safety training programs being conducted throughout the VA system?

There has been little participation by VA senior management in its safety training programs. We asked the National Center for Patient Safety to provide a breakout of the job titles of those employees who attended one of the 3-day patient safety improvement training sessions. On July 19, 2000, VA told us that, until then, no VISN or medical center director had participated in the training sessions. The highest level managers who did attend included 41 chiefs of staff, 49 service chiefs, and 83 associate directors for patient care services or nurse executives. According to VA, of the nearly 600 employees trained, the majority were facility risk managers or quality managers.

9. Has VA identified the highest priority areas for medical errors, and have they developed a standardized system for measuring the reduction of these errors?

VA can use its adverse event registry to categorize adverse events that occur most frequently and that would merit priority attention, such as falls, suicides, and medication errors. VA has not yet developed a standardized system for measuring a reduction in medical errors, and we are not aware of any VA plans to do so. However, before VA can target the patient safety problems that most need attention, it will have to put in place a well-functioning reporting system and establish an accurate baseline from which to measure change systemwide. Until VA's new system is fully in place and operating for some time, VA will use the root

cause analysis process to provide a standardized tool for assessing the causes of errors and to compare analyses across all VA facilities.

10. The IOM report uses the Harvard Medical Practice Study in New York, which states that adverse events occurred in 2.9 percent of hospitalizations. This is a widely respected peer reviewed study. The VA reported 2,927 adverse events in a 19-month period. The July 17, 2000, *U.S. News and World Report* cited the Johns Hopkins Hospital in Baltimore, Maryland, as the highest rated hospital in America for several years running. Johns Hopkins had 69,603 inpatients in FY 1999. If you use IOM's 2.9 percent times 69,603, Johns Hopkins would have had just over 2,000 adverse events. This is just one hospital. How can the entire VA hospital system only report 2,927 adverse events? Using the same formula, one would predict 21,802 possible adverse events. Can GAO try to explain this phenomenal discrepancy?

We do not know if Johns Hopkins has a reporting system, or, if it does, the number of adverse events it contains. Nevertheless, this example underscores the growing consensus in the health care industry, including the VA system, that underreporting of adverse events is a serious problem. The percentage reported by the IOM is based on limited research in two states and represents a national estimate not intended for application to individual health care systems. Moreover, other researchers have made compelling but contradictory arguments that the IOM report overstates and understates the extent of underreporting. Nevertheless, experts agree that underreporting is a problem and that there is inadequate data to estimate the degree of underreporting with much precision. So, whether 22,000 adverse events is the "right" number or not is impossible to say. During fiscal year 2000, VA will be conducting a survey to establish a baseline measurement of how employees feel about reporting adverse events. If employees report that they do not feel safe enough to report adverse events, then we can assume that underreporting will continue to be a problem. However, determining the magnitude of this problem will continue to be difficult.

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