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VETERANS' HEALTH CARE

Standards and Accountability Could Improve Hepatitis C Screening and Testing Performance

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the Department of Veterans Affairs' (VA) efforts to identify veterans who have hepatitis C—a chronic bloodborne virus that can cause potentially fatal liver-related conditions. This year, VA expects 3.8 million veterans to use its health care system, which consists of over 700 facilities located in 22 service delivery networks.

Three years ago, VA characterized hepatitis C as a serious national health problem that needs early detection to reduce transmission risks, ensure timely treatment, and prevent progression of liver disease. In a 1998 information letter, the Under Secretary for Health provided background information on hepatitis C and stated that all patients will be evaluated for risk factors and have assessments documented in their patient charts. He also outlined the process clinicians should use when (1) screening veterans for known risk factors for exposure to hepatitis C and (2) ordering tests to detect antibodies and diagnose hepatitis C infection. He also recommended testing of those with the presence or history of any risk factor or at the patient's request.

Subsequently, VA included a request for $195 million and $340 million for hepatitis C screening, testing, and antiviral drug treatment in its fiscal year 2000 and 2001 budget submissions, respectively. In doing so, VA noted that hepatitis C has particular importance because of its prevalence among VA's enrolled population. Specifically, VA cited its one-day survey of over 26,000 veterans (on March 17, 1999) that documented an infection rate of 6.6 percent[1], compared with 1.8 percent in the general population.

My comments today will focus on VA's progress in screening and testing veterans for hepatitis C during fiscal years 1999 and 2000 and ways that performance could be enhanced. Our assessment of VA's efforts to treat infected veterans remains ongoing and results will be available early next year.

[1] Department of Veterans Affairs, Office of the Assistant Secretary for Financial Management, *FY 2001 Budget Submission, Medical Programs* (Volume 2 of 6, February 2000), p. 2-28.

Our review of VA's hepatitis C screening and testing was conducted from November 2000 through May 2001 in accordance with generally accepted government auditing standards. It included:

- reviews of relevant VA documents, including a sample of electronic medical records, budget justifications, policy documents and practice guidelines;
- interviews with over 100 VA officials, including the Under Secretary for Health, the former and current Hepatitis C Directors, and officials in seven VA health care networks; and
- visits to seven medical facilities that conducted hepatitis C screening and testing.

In summary, VA missed opportunities to screen as many as 3 million veterans when they visited medical facilities during fiscal years 1999 and 2000, potentially leaving as many as 200,000 veterans unaware that they have hepatitis C infections. Most remain undiagnosed primarily because local managers adopted restrictive hepatitis C screening practices. Moreover, of those screened, an unknown number likely remain undiagnosed because of flawed procedures. Clinicians at facilities we visited, for example, frequently did not (1) order blood tests for screened veterans who had known hepatitis C risk factors or (2) follow up to ensure that ordered tests were completed.

During fiscal year 2001, VA has taken important steps to enhance hepatitis C screening and testing performance, such as a better communication process that includes lead clinicians at each medical facility. Although the pace of screening and testing appears to be improving, many currently undiagnosed veterans may not be identified expeditiously unless VA (1) establishes early detection of hepatitis C as a standard for care and (2) holds managers accountable for timely screening and testing of veterans who visit VA medical facilities. Communicating more effectively with local managers about the availability of funding for screening, testing, and treatment could also reduce concerns about resources as a barrier to improved performance.

Background

Hepatitis C virus infection is the most common chronic bloodborne infection in the United States.[2] It develops into a chronic infection in 85

[2]Miriam Alter, et al.,"The Prevalence of Hepatitis C Virus Infection in the United States, 1988 Through 1994," *New England Journal of Medicine* (Vol. 341, August 19, 1999), p. 560.

percent of the cases, through a slow process that is often without symptoms for 20 years or more. Hepatitis C antibodies, however, generally appear in the blood within 3 months of infection. Undiagnosed hepatitis C can eventually lead to liver cancer, cirrhosis (scarring of the liver), or end stage liver disease, which is the leading indication for liver transplantation.[3]

Hepatitis C (previously referred to as non-A, non-B hepatitis) was first recognized as a unique disease in 1989. In 1992, blood tests became available to detect the antibody. This discovery helped curb the rapid spread of the virus by allowing effective screening of blood products to virtually eliminate contamination.[4] Many, however, had already become infected through transfusions and were unaware of their infection because they had no symptoms.

Early detection is important for several reasons. Those who have hepatitis C infections could unknowingly behave in ways that speed up the progression of the disease. For example, alcohol use can hasten the onset of cirrhosis and liver failure. Equally important, undiagnosed persons are missing opportunities to safeguard their health. For example, vaccinations could help those with hepatitis C avoid contracting hepatitis A and B. In addition, some could benefit from antiviral drug therapies.

Early detection is also important because persons carrying the virus could infect others, posing a serious public health threat. Specifically, as a bloodborne virus, hepatitis C can be spread between family members through sharing of razors; to health care workers through unequivocal blood exposure, such as needlestick injuries; and to others who come in contact with contaminated blood such as intravenous drug abusers. The Centers for Disease Control and Prevention also reported potential risks associated with tattooing under certain circumstances, such as in unregulated settings.

Given that the prevalence of hepatitis C may be 3 times greater in the veteran population than the general population, this disease has particular

[3]R. Cheung, "Epidemiology of Hepatitis C Virus Infection in American Veterans," *The American Journal of Gastroenterology* (Vol. 95, March 2000), p. 740.

[4]Centers for Disease Control and Prevention, U. S. Department of Health and Human Services, "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease," *MMWR* (Vol. 47, October 16, 1998), p. 1.

importance for VA's health care system. For example, hepatitis C now accounts for over half of the liver transplants needed by VA patients—costing as much as $140,000 per transplant. In addition, VA treats many other veterans for hepatitis C-related conditions, including some which frequently require hospital stays, costing as much as $40,000 per patient. Also, drug therapy to treat hepatitis C is costly—about $13,000 for a 48-week treatment regimen.

Most Infected Veterans Likely Remain Undiagnosed

VA estimates that about 800,000 veterans were screened for hepatitis C during fiscal years 1999 and 2000[5]—about 20 percent of all veterans (4 million) making outpatient visits to VA medical facilities in those years. Moreover, screening and testing practices were sometimes flawed. As a result, the majority of veterans with hepatitis C who visited VA facilities may remain undiagnosed. For example, while the true hepatitis C prevalence rate for the 3.2 million unscreened veterans is unknown, as many as 200,000 could have hepatitis C infections if VA's estimated 6.6 percent prevalence rate is accurate.[6] By contrast, VA has identified about 75,000 veterans with hepatitis C during this time period.

Restrictive Screening Practices

During VA's hepatitis C screening process, providers are to determine, generally through a series of questions, whether veterans who visit VA facilities have any risk factors for hepatitis C. Figure 1 shows the 11 risk factors, as stated in VA's guidelines to providers.

[5] Department of Veterans Affairs, Veterans Health Administration, *White Paper to Inform Congress of Decisions for Hepatitis C Funding* (April 10, 2001), p. 7.

[6] During congressional testimony last year, VA representatives and others informed members that the prevalence rate could be as high as 10 percent. VA is conducting a study over the next year to determine the prevalence of hepatitis C in its veteran population.

Figure 1: VA's Risk Factors for Hepatitis C

1. Vietnam-era veterans[a]
2. Blood transfusion before1992
3. Past or present intravenous drug use
4. Unequivocal blood exposure of skin or mucous membranes
5. History of multiple sexual partners[b]
6. History of hemodialysis
7. Tattoo or repeated body piercing (circumstances most important)
8. History of intranasal cocaine use
9. Unexplained liver disease
10. Unexplained/abnormal ALT (alanine transaminase)
11. Intemperate or immoderate use of alcohol[c]

[a]As currently determined by dates of service or in the age range of 40 to 55 years
[b]Defined as more than 10 lifetime sexual partners
[c]Defined as more than 50g of alcohol per day for ten or more years (roughly 10-14 grams of alcohol = 1 beer)

Source: U. S. Department of Veterans Affairs, Veterans Health Administration, Hepatitis C Testing and Prevention Counseling - Guidelines for VA Health Care Practitioners.

Local facility managers often adopted restrictive hepatitis C screening practices, limiting screenings to primary care clinics or certain days of the week or letting individual providers use their own judgment regarding who should be screened. At most of the seven facilities we visited, managers stated that their decisions regarding screening practices were based, in part, on concerns about the availability of funding for screening, testing, and treating services.

For example, at four of the seven sites we visited, screenings were almost exclusively limited to veterans who used primary care clinics. However, as many as a third of veterans visiting individual VA outpatient facilities may not use primary care clinics. Instead, they receive care from specialists who work in other clinics such as cardiology, substance abuse, or mental health. Most specialty clinics at the sites we visited did not routinely screen veterans for hepatitis C.

In addition, some facilities opted to limit hepatitis C screenings within primary care clinics. For example, one facility rotated hepatitis C screening among its five primary care clinics so that each clinic conducted screenings only 1 day each week, due in part to concerns about the availability of funding for laboratory services. Another facility phased-in screenings, so that only one of its three primary care clinics screened veterans for hepatitis C during fiscal year 2000, with the other clinics

beginning to screen in early fiscal year 2001, due in part to concerns about the availability of funding for pharmaceuticals.

Moreover, facility managers told us that, during most of fiscal years 1999 and 2000, they left it to the discretion of individual providers to decide who should be screened for hepatitis C. As a result, rather than screening everyone, some providers only screened veterans who had symptoms associated with liver disease or obvious risk factors.

Flawed Screening Procedures

Also, screening procedures used at the sites we visited could result in some veterans with hepatitis C not being identified as at risk. For example, providers at some sites frequently required veterans to identify their specific risk behavior rather than allowing them to generally acknowledge that at least one risk factor applied to them. Such a procedure could embarrass veterans, which could result in some not identifying that they had a risk factor. For example, several staff members responsible for screening at facilities we visited noted that veterans were hesitant to discuss stigmatizing risk behaviors associated with hepatitis C—especially when they were asked to admit their history of sexual behavior and substance abuse—such as alcohol, intranasal cocaine, or intravenous drug use.

In some locations, screening was conducted in areas that lacked sufficient privacy, adding another barrier to obtaining accurate information. For instance, a staff member at one clinic told us that interviews were conducted near the general patient waiting area. She believed this to be problematic when screening veterans, especially those elderly veterans who might be reluctant to answer questions regarding intemperate alcohol use and sexual conduct.

Flawed Testing Procedures

Testing procedures at the sites we visited resulted in many at-risk veterans not being tested despite their being screened. Sometimes tests were not ordered and other times ordered tests were not completed. As a result, any of these veterans with hepatitis C infections would remain undiagnosed.

At four of the seven facilities we visited, we reviewed a random sample of 375 medical records for veterans identified as having at least one risk factor. On average, we found that about 50 percent of those patients were not tested. The percentage of sampled veterans who were not tested at the four facilities ranged between 38 and 84 percent.

Tests were not ordered for a variety of reasons. For example, at one facility, providers thought that veterans would not be eligible for antiviral hepatitis C treatment because of age, psychiatric illness, or substance abuse. At another facility, tests were not ordered for some at-risk veterans who were seen at outlying clinics where providers had not been able to attend training sessions about hepatitis C screening. Also, some screeners were unsure of their authority to order tests. Nursing staff, who were charged with screening veterans at yet another facility, did not order blood tests because they did not think they had the authority to order tests, when in fact they did.

Also, we found that about 7 percent of ordered tests were not completed at the facilities. Staff at those facilities told us that sometimes veterans do not show up at the laboratory to have their blood tested and providers often do not follow up with these veterans during their next visit to reschedule the blood test. These facilities lacked a mechanism for tracking at-risk veterans to ensure that they were tested.

Standards and Accountability Could Improve Hepatitis C Screening and Testing Performance

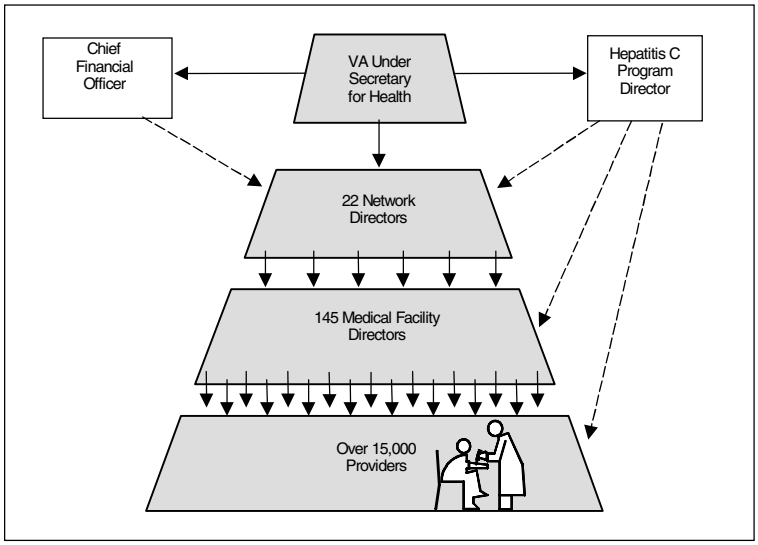
During fiscal year 2001, VA has taken important steps to improve hepatitis C screening and testing performance. For example, VA modified its computerized patient record system to remind providers to screen and document screening results during patients' visits.[7] Also, a new hepatitis C program director was appointed in November 2000 who, among other things, has (1) improved communication processes through the identification of lead clinicians at local medical facilities and (2) convened regional workgroups to identify procedural weaknesses and share best practices.

In VA's management structure, the hepatitis C program director does not have line authority over the providers who screen veterans. Rather, he serves as a catalyst to stimulate ideas and facilitate problem solving. In doing so, he may communicate directly with local managers, but his ability to affect change depends primarily on the level of support provided by managers who have line authority.

[7]When a provider enters a patient name into the computer during a patient visit, the reminder for hepatitis C screening automatically appears on the computer monitor as part of the patient's electronic medical record. When a patient has been screened for hepatitis C, that reminder no longer appears to prompt the physician to screen the veteran, and the provider notes documenting the screening become part of the patient's record.

In that regard, the size and breadth of VA's health care system poses a significant challenge, when trying to address the types of procedural weaknesses noted earlier. As figure 2 shows, policies and guidance must be communicated from the Under Secretary for Health through 22 network directors and 145 facility directors to over 15,000 health care providers who conduct hepatitis C screenings in over 700 locations nationwide.

Figure 2: VA's Management Structure for Hepatitis C Screening and Testing



From our perspective, the pace of screenings appears to be improving, although VA has been unable to provide reliable nationwide data on the number of veterans who were screened this year. Nonetheless, procedural weaknesses noted earlier still persist. This suggests that a more systematic approach may be warranted if all veterans using VA's system are to be screened appropriately and expeditiously. Key steps could include well-defined standards for care and accountability, as well as enhanced communications concerning funding availability.

Establishing Early Detection As A Standard For Care

VA's hepatitis C initiative has operated for almost 3 years with a general policy objective—evaluate all veterans for risk factors and conduct blood tests for the hepatitis C antibody for those with a history of risk factors or who request testing. VA's stated policy, however, does not specify a timeframe for achieving this objective.

Managers at the seven facilities we visited interpreted VA's policy as encouraging, but not requiring, screening and testing each veteran who visits a VA medical facility. As discussed earlier, these managers, when exercising their discretion, frequently adopted restrictive practices for screening and testing veterans, resulting in relatively limited progress.

Establishing early detection of hepatitis C as a standard for care could convey the higher priority that headquarters would expect local managers to place on hepatitis C screening and testing. VA, for example, could direct clinicians to screen veterans during their next visit to any VA medical facility. Likewise, VA could direct clinicians to order blood tests in a timely manner for all at-risk veterans as well as others requesting such tests.

Establishing Accountability For Timely Detection of Hepatitis C

VA's hepatitis C program has operated for almost 3 years without performance targets or adequate management oversight information. Local managers told us that if such targets had been set, and tracked, they would have taken steps to achieve them. Last year, VA told this subcommittee that performance targets for screening were under development. In April of this year, VA stated that performance targets will be available for use in fiscal year 2003.

To motivate local managers to aggressively implement other health screening and prevention initiatives, such as smoking cessation or reducing the risk of colorectal cancer, VA has set performance targets and included them in network managers' performance plans. Also, VA has developed processes for collecting information to measure and report results so that managers can be held accountable.

From our perspective, performance targets are most effective when they are results-oriented and time-sensitive. Specifically, such targets should communicate the percent of a target population that is expected to achieve a desired outcome within a prescribed time period. For example, because the use of tobacco products is the single most preventable cause of disease and death, VA set a national goal to reduce the percentage of patients who use tobacco products to 16 percent by 2004. VA has steadily

reduced the percentage of patients using tobacco each year from 32 percent in 1997 to 25 percent in 2000, heading toward the strategic target of 16 percent.

A comparable performance target could be established to guide hepatitis C screenings. For example, during fiscal year 2002, VA expects almost 3.8 million veterans to visit VA facilities over 40 million times. With these veterans visiting VA facilities so frequently, setting a target to screen 90 percent or more of these veterans during the next 12 months seems reasonable. Such a goal, if achieved, could enable VA to identify most of the previously undiagnosed veterans.

Likewise, a performance target relating to the timeliness of testing could also help improve hepatitis C detection results. Testing, for example, involves electronic ordering of a laboratory analysis, the drawing of a blood sample from a veteran, assessment of the blood sample for hepatitis C antibodies, and electronic reporting of the results to the ordering provider. This process would be considered timely if completed within a specified time frame from the date of initial screening for risk factors.

If VA managers are to be held accountable for achieving such performance targets, timely information on screening and testing results are needed. Currently, VA has no system to provide essential information. To date, when collecting hepatitis C data, VA has relied primarily on its Emerging Pathogens Initiative surveillance system which was designed for the limited purpose of monitoring trends in rates of infectious diseases.

Through this system, VA began to track the number of people tested for hepatitis C and the number with positive tests in 1997. However, it was not able to systematically collect data on the number of veterans screened for hepatitis C until VA's electronic clinical reminder process was implemented last year. Nonetheless, information remains unavailable on the numbers of veterans who should have been screened and tested—information that is essential to hold managers accountable for performance.

Moreover, only one of the seven facilities we visited used the clinical reminder system to track provider performance in screening and testing veterans for hepatitis C. This facility distributed screening results periodically to managers and providers to motivate them to more aggressively screen veterans. While this facility has had great success in increasing the number of veterans screened, managers at the six other facilities had not capitalized on the system's capabilities.

VA agrees that its current sources of data on hepatitis C are inadequate. The new hepatitis C program director is working to address the situation by developing standardized hepatitis C-specific reports to track progress at individual facilities.[8]

Communicating Funding Available for Detection of Hepatitis C

VA told us the $195 million requested for hepatitis C screening, testing and antiviral therapy for fiscal year 2000 and $340 million for this fiscal year were allocated to network managers as part of its general medical care resource distribution; in turn, network managers made allocations to local facilities. However, VA did not clearly communicate how much of each network's allocation it expected would be spent for screening and testing veterans for hepatitis C infections.

Network budget officers, facility managers, and providers we interviewed were generally unaware that they had received funding to screen and test for hepatitis C. Those who thought funds were available were unsure of how much money was available. As noted earlier, such perceived funding inadequacies resulted in some local managers adopting restrictive screening practices, as well as some providers deciding that blood tests were not warranted for certain at-risk veterans.

Our assessment shows that amounts distributed to networks were sufficient to allow local facilities to screen all previously unscreened veterans when they visited VA facilities during those years.[9] Thus, clearer communication regarding available funding could eliminate local managers' and providers' perceptions that resources are a barrier to accelerating their screening and testing efforts.

Concluding Observations

VA established a high priority for hepatitis C screening and testing but failed to follow through, even though funding was sufficient to get the job done. In short, managers and providers at local facilities were afforded too much discretion to decide who and when to screen and test without

[8] Also, VA is designing an electronic database, referred to as a registry, to manage the care and treatment of veterans who, after testing, are diagnosed with hepatitis C infections. This registry, according to VA's hepatitis C program director, will not help managers assess the progress of screening and testing efforts, as it will not contain information on the numbers of veterans who need either screening or testing.

[9] *Veterans' Health Care: Observations on VA's Assessment of Hepatitis C Budgeting and Funding* (GAO-01-661T, April 25, 2001).

adequate senior management oversight. Faced with the serious health care needs of thousands of veterans who remain at risk of having hepatitis C—as well as the urgent public health implications of hepatitis C—senior managers can no longer afford to take a hands-off approach to its screening and testing efforts.

From our perspective, veterans using VA's health care system should be screened and tested as quickly as possible in order to ensure timely prevention of the progression of liver disease as well as to reduce transmission risks to others. Toward that end, senior managers should take immediate action to establish early detection of hepatitis C as a standard for care, set aggressive performance targets, and hold local managers accountable for achieving them.

Last week, we shared our findings with the Under Secretary for Health and the hepatitis C program director. In general, they agreed that additional management action could improve the pace and quality of hepatitis C screening and testing. In that regard, they indicated that VA would take the results of our work into consideration as they modify their national hepatitis C program.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or Members of the Subcommittee may have.

GAO Contact and Staff Acknowledgements

For more information regarding this testimony, please contact me at (202) 512-7101. Key contributors to this testimony include Paul Reynolds, Cheryl Brand, Patricia Jones, and Irene Barnett.

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