United States General Accounting Office

GAO

Report to the Chairman, Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives

January 2003

VA HEALTH CARE

Improvements Needed in Hepatitis C Disease Management Practices

GAO-03-136

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GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-03-136, a report to the Chairman, Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives

Why GAO Did This Study

In 1998, the Department of Veterans Affairs (VA) launched an initiative to screen and test veterans for hepatitis C—a chronic blood-borne virus that can cause potentially fatal liver-related conditions. Since 2001, GAO has been monitoring VA's hepatitis C program. This year GAO was asked to report on VA's hepatitis C disease management practices. GAO surveyed 141 VA medical facilities about their processes for notifying veterans concerning hepatitis C test results and evaluating veterans' medical conditions regarding potential treatment options. In addition, GAO reviewed medical records of 100 hepatitis C patients at 1 facility and visited 4 other facilities that used unique hepatitis C disease management processes.

What GAO Recommends

GAO recommends that VA direct facilities to make special arrangements to notify veterans about hepatitis C test results when veterans' next scheduled appointments are longer than 30 days away and to ensure that providers are promptly alerted about test results. In addition, GAO recommends that VA encourage facilities to increase reliance on primary care providers and other nonspecialists to initially evaluate the medical condition of hepatitis C-infected veterans while continuing to consult with specialists, when appropriate. VA concurred with these recommendations.

www.gao.gov/cgi-bin/getrpt?GAO-03-136.

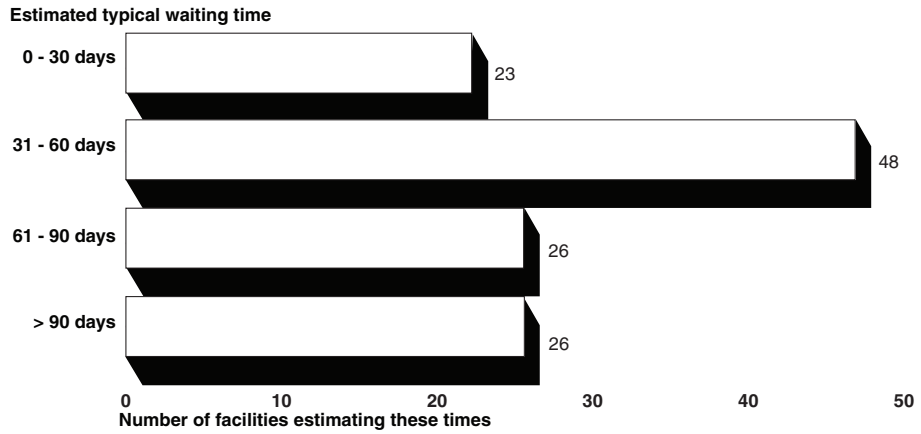
To view the full report, including the scope and methodology, click on the link above. For more information, contact Cynthia A. Bascetta, (202) 512-7101.

What GAO Found

There is considerable variation among VA facilities in the time it takes to notify veterans that they have hepatitis C. For example, 29 VA medical facilities estimated that veterans were typically notified within 7 days of testing while 16 estimated that notification times exceeded 60 days. At facilities with longer notification times, primary care providers generally notified veterans at their next regularly scheduled appointments—sometimes more than 4 months away. In contrast, facilities with shorter notification times generally scheduled special appointments focused on hepatitis C notification or notified veterans by telephone or mail. Longer notification times increase the risk that veterans may unknowingly infect others or continue to engage in behaviors, such as alcohol use, that could accelerate the damaging effects of hepatitis C on their livers.

VA medical facilities also varied considerably in the time that veterans must wait before physician specialists evaluate their medical conditions concerning hepatitis C treatment recommendations. For example, 23 facilities estimated that veterans waited 30 days or less for appointments with physician specialists while 52 facilities estimated that veterans waited over 60 days. At facilities with longer waiting times, primary care providers frequently referred all veterans to physician specialists for evaluations. In contrast, facilities with shorter waiting times often relied on nonspecialists, such as primary care providers, to conduct initial hepatitis C evaluations, referring only those with certain conditions, such as liver injury, to specialists for additional evaluations.

Estimated Waiting Times for Appointments with VA Physician Specialists for Hepatitis C Evaluations



Source: GAO.

Note: This information is from our survey of VA medical facilities. Of the 141 surveyed facilities, 18 used providers other than physician specialists to perform evaluations.

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ALT alanine aminotransferase
NIH National Institutes of Health
VA Department of Veterans Affairs

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United States General Accounting Office
Washington, DC 20548

January 31, 2003

The Honorable Christopher Shays
Chairman
Subcommittee on National Security, Veterans Affairs,
and International Relations
Committee on Government Reform
House of Representatives

Dear Mr. Chairman:

Hepatitis C is a chronic blood-borne virus that can cause potentially fatal liver-related conditions. In 1998, the Department of Veterans Affairs (VA) launched a major initiative to screen all veterans who received care in its health care system for hepatitis C risk factors and conduct diagnostic blood tests for those at risk of infection. Since 1999, VA included a total of $700 million in budgets submitted to the Congress to screen and test veterans, as well as treat those with hepatitis C. In fiscal year 2002, VA expected about 4.7 million veterans to use its health care system. VA reports that its initiative had identified almost 160,000 veterans infected with hepatitis C as of the end of fiscal year 2002.

Since 2001, we have been monitoring VA's efforts to screen, test, and treat veterans with hepatitis C. Unless tested, veterans infected with the virus could unknowingly spread it to others. Once diagnosed, veterans face complex decisions about the best course of treatment they should follow to protect their health. Last year, we testified before your subcommittee that VA missed opportunities to screen and test many veterans for hepatitis C when they visited VA's medical facilities.[1] In response to our work, VA has begun to improve screening and testing procedures. Subsequent to the hearing, you asked us to focus on VA's efforts to (1) notify veterans concerning their hepatitis C test results and (2) evaluate veterans' medical conditions regarding potential treatment options.

[1]U.S. General Accounting Office, *Veterans' Health Care: Standards and Accountability Could Improve Hepatitis C Screening and Testing Performance*, GAO-01-807T (Washington, D.C.: June 14, 2001).

To do our work, we surveyed 141 VA medical facilities (accounting for the care provided at most of VA's 1,013 health care delivery locations) about their hepatitis C notification and disease management processes. We also conducted a case study at VA's Washington, D.C., medical facility, including a review of 100 medical records of patients who tested positive for hepatitis C during the first 6 months of fiscal year 2001. We visited 4 other VA facilities that, in response to our survey, reported unique processes for notifying veterans and evaluating their medical conditions when making treatment decisions. In addition, we interviewed representatives from veterans' advocacy groups and the American Liver Foundation to gain their perspectives on the timeliness and adequacy of VA's notification and disease management processes. For a complete description of our scope and methodology, see appendix I. Our review was conducted from July 2001 through January 2003 in accordance with generally accepted government auditing standards.

Results in Brief

There is considerable variation among VA facilities in the time it takes to notify veterans that they have hepatitis C. For example, in response to our survey, 29 facilities estimated that veterans are typically notified within 7 days after test results are available, while 16 estimated that notification times exceeded 60 days. At facilities with longer notification times, primary care providers generally notified veterans at their next regularly scheduled appointments, which, in some cases, were more than 4 months away. In contrast, at most facilities with shorter notification times, providers generally scheduled special appointments focused on hepatitis C notification, or notified veterans by telephone or mail. Longer notification times increase the risk that veterans may unknowingly infect others or continue to engage in behaviors, such as alcohol use, that could accelerate the damaging effects of hepatitis C on their livers.

There is also considerable variation among VA facilities in the time that veterans must wait before physician specialists evaluate their medical condition concerning hepatitis C treatment recommendations. For example, in response to our survey, 23 facilities estimated that veterans waited 30 days or less while 52 facilities estimated that veterans waited over 60 days, including 26 that had waits exceeding 90 days. At facilities with longer waiting times, primary care providers frequently referred all veterans to physician specialists for evaluations. In contrast, facilities with shorter times (30 days or less) usually relied on nonspecialists to evaluate patients. In these cases, primary care physicians, nurses, or nurse practitioners evaluated veterans and referred only selected veterans, such

as those with liver injury or those who were candidates for antiviral drug therapy, to specialists.

We are recommending that VA direct facilities to use special arrangements to notify veterans when veterans' next scheduled appointments are longer than 30 days away and to ensure that providers are promptly alerted about test results. In addition, we recommend that VA develop referral guidelines to encourage the use of nonspecialists to conduct initial evaluations of veterans diagnosed with hepatitis C, while continuing to consult with specialists, when appropriate. VA concurred with our recommendations.

Background

Hepatitis C was first recognized as a unique disease in 1989. It is the most common chronic blood-borne infection in the United States.[2] The virus causes a chronic infection in 85 percent of cases. 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] While hepatitis C antibodies generally appear in the blood within 3 months of infection, it can take 15 years or longer for the infection to develop into cirrhosis. Blood tests to detect the antibody, which became available in 1992, helped to virtually eliminate risk of infection through blood transfusions and curb the spread of the virus. However, many were already infected and, because they had no symptoms, were unaware of their infection.

Early detection of hepatitis C is important for several reasons. First, undiagnosed persons miss opportunities to safeguard their health. Those who have hepatitis C infections could unknowingly behave in ways that speed the progression of the disease. For example, alcohol use can hasten the onset of cirrhosis and liver failure. Vaccinations prevent those with hepatitis C from contracting hepatitis A and B, other infections that could further damage the liver. Second, persons carrying the virus pose a public health threat because they could infect others. Specifically, as a blood-borne virus, hepatitis C can be spread to family members through sharing of razors; to health care workers through blood exposure, such as

[2]W. Ray Kim, MD. M.Sc., M.B.A., "The Burden of Hepatitis C in the United States," *NIH Consensus Development Conference: Management of Hepatitis C: 2002* (Bethesda, Md.: National Institutes of Health, 2002), 23.

[3]R. Cheung, "Epidemiology of Hepatitis C Virus Infection in American Veterans," *The American Journal of Gastroenterology*, vol. 95, no. 3 (March 2000), 740.

needlestick injuries; and to others who come in contact with contaminated blood, such as intravenous drug abusers.

In the last few years, considerable research has been done concerning hepatitis C. The National Institutes of Health (NIH) held a consensus development conference on hepatitis C in 1997 to assess the methods to diagnose, treat, and manage hepatitis C. NIH convened a second hepatitis C consensus development conference in June 2002[4] that reviewed the most recent developments in the management of the disease and the treatment options available and identified directions for future research. This panel concluded that there have been substantial advances in the effectiveness of antiviral drug therapy for chronic hepatitis C.

VA's Public Health Strategic Healthcare Group coordinates VA's hepatitis C program, which calls for universal screening of veterans when they visit VA facilities for routine medical services and conducting blood tests for veterans identified by the screening as being at risk[5] or who want to be tested. VA has developed guidelines intended to assist health care providers who screen, test, and counsel patients for hepatitis C. Providers are to educate veterans about their risk of acquiring hepatitis C, notify veterans of hepatitis C test results, and provide education to those infected with the virus to help facilitate behavior changes to reduce veterans' risk of transmitting hepatitis C. In addition, providers are to evaluate the medical condition of those diagnosed with hepatitis C. An evaluation could include a medical history, blood tests to measure liver functions and virus genotype or strain, and a liver biopsy. VA has also developed guidance for providers to use when conducting such evaluations based on recommendations of NIH and the Centers for Disease Control and Prevention.

[4]NIH Consensus Development Conference, *Management of Hepatitis C: 2002*, June 2002. The 12-member consensus panel is an independent, nonadvocate and nonfederal panel including representatives from internal medicine, gastroenterology, infectious diseases, family practice, and the public. The panel heard presentations from 28 hepatitis C experts and reviewed an extensive body of medical literature and a report prepared by the Johns Hopkins University School of Medicine Evidence-based Practice Center.

[5]VA identifies veterans at risk for hepatitis C infection as those who have one or more of the following 11 risk factors: Vietnam-era veteran; blood transfusion before 1992; past or present intravenous drug use; unequivocal blood exposure of skin or mucous membranes; history of multiple sexual partners; history of hemodialysis; tattoo or repeated body piercing; history of intranasal cocaine use; unexplained liver disease; unexplained/abnormal alanine aminotransferase, which is an enzyme that is present in high concentration in the liver and other organs; and intemperate or immoderate use of alcohol.

Through such evaluations, providers are to identify veterans who have the greatest risk of progressive liver disease—abnormal alanine aminotransferase (ALT) blood tests or liver biopsies showing fibrosis[6]—and who may benefit from an antiviral therapy regimen consisting of injections of interferon plus ribavirin (an oral antiviral agent) capsules. The effectiveness of this therapy to rid—"clear"—a patient of the virus has been shown to vary from a 30 to 80 percent success rate depending on the genotype of the virus, the extent of the infection, and the type of interferon used. Genotype 1, the most common genotype found in VA patients, is the genotype least responsive to antiviral therapy. The recommended duration of antiviral therapy for patients with genotype 1 is 48 weeks compared to 24 weeks for patients with other genotypes.

Also, providers' evaluations are expected to identify veterans with hepatitis C who are not considered to be candidates for antiviral therapy because they have co-morbid conditions that contraindicate therapy. Veterans with coronary artery disease, uncontrolled diabetes, or chronic obstructive pulmonary disease, for example, are often not candidates for antiviral therapy because of the reduced life expectancy from the underlying co-morbid condition in addition to the potential for increased side effects from antiviral therapy. In addition, veterans with active drug or alcohol abuse may not be candidates for antiviral therapy because of potential toxic effects of the antiviral therapy and compliance problems with the antiviral regimen, which requires adherence to a regular schedule of interferon injections and doses of ribavirin. Additionally, interferon-based therapies may worsen the psychological problems of patients with uncontrolled, severe psychiatric disorders—particularly depression and suicide risk. However, the recent NIH consensus conference expanded the scope of patients eligible for treatment to include some patients with substance abuse problems.

Providers may also recommend watchful waiting—monitoring the disease status without antiviral treatment—because the risks of drug therapy outweigh the potential benefits. Antiviral drugs have severe side effects, such as depression, flu-like symptoms, and intense itching, which patients sometimes find unbearable. Providers may make such a recommendation to older veterans with slowly advancing disease and minimal liver injury and encourage those veterans to lead healthy lifestyles and receive

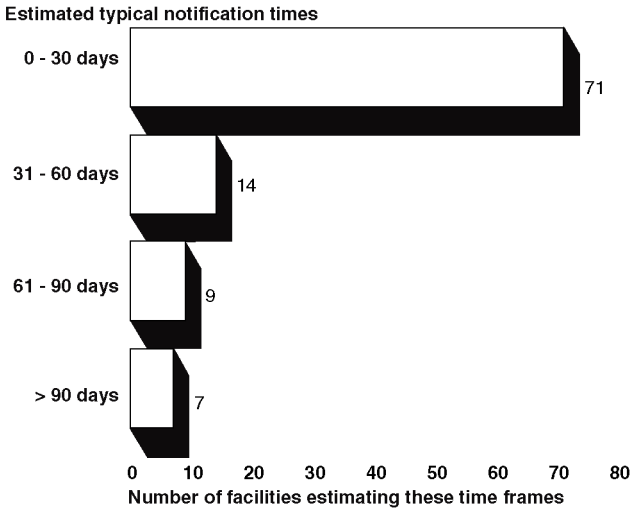
[6]Fibrosis is an increase in fibrous tissue in the liver that can progress to a more severe stage called cirrhosis.

periodic liver evaluations to assess the progression of their disease. In these cases, if the disease advances, a more effective antiviral therapy may have become available or the patient's health may be at a point where it may be worth the risk of undergoing drug therapy.

Hepatitis C Notification Time Frames Vary

There is considerable variation among VA facilities in the time it takes to notify veterans that they have hepatitis C. Systemwide, 71 facilities, in response to our survey, estimated typical notification time frames of 30 days or less, including 29 facilities with estimates of 7 days or less. In contrast, 30 facilities estimated that notification typically took longer than 30 days, including 7 facilities that estimated time frames of 90 days or longer.[7] (See fig. 1.)

Figure 1: 101 VA Facilities' Estimated Typical Time Frames for Notifying Veterans That They Have Hepatitis C



Source: GAO.

Note: This information is from our survey of VA medical facilities.

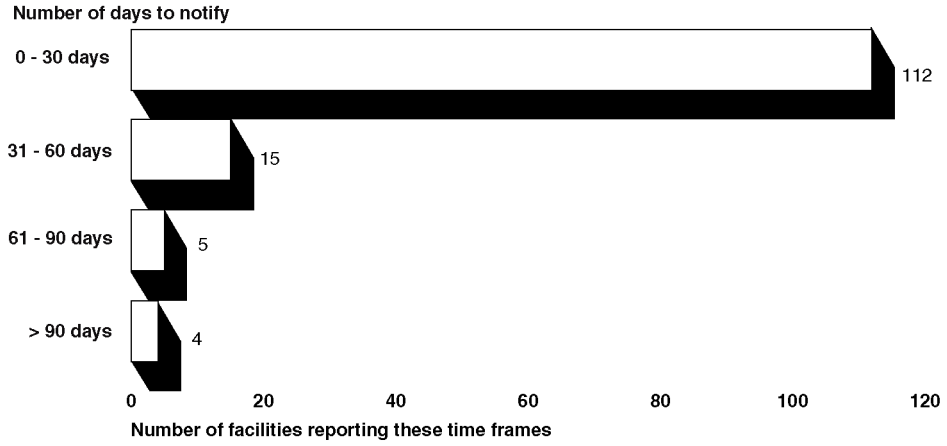
VA has delegated responsibility for establishing a hepatitis C notification process to local facilities, including when veterans will be notified. VA

[7]Forty facilities did not estimate typical notification time frames when responding to our survey. Many of these facilities told us they did not know how long it typically took to notify veterans.

hepatitis C guidance suggests that providers schedule a return date for veterans to meet with them to discuss hepatitis C test results, but does not designate a time frame within which veterans should be notified of their hepatitis C test results. Also, VA does not specifically require facilities to monitor notification of veterans concerning their hepatitis C test results.

In addition, most facilities do not provide guidance to their providers regarding notification time frames, responding to our survey that notification was left to provider discretion. However, when we asked facilities what would be a reasonable time frame for notifying veterans, 112 of 136 survey respondents (about 80 percent) reported that veterans should be notified in 30 days or less from the day the hepatitis C test results are available. [8] (See fig. 2.)

Figure 2: Reasonable Time Frames to Notify Veterans of Hepatitis C Test Results Reported by VA Medical Facilities



Source: GAO.

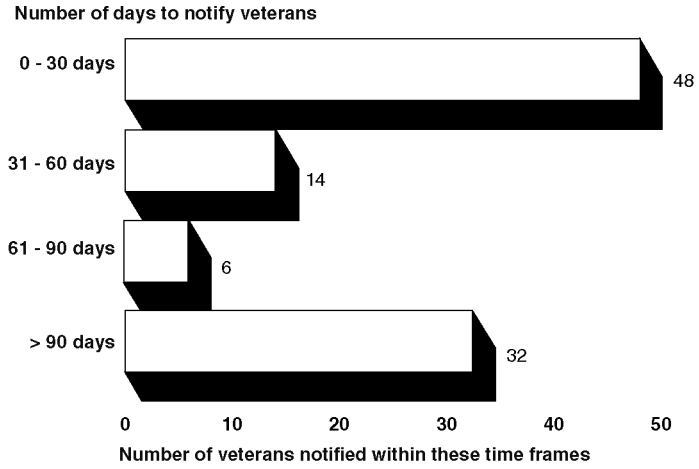
Note: This information is from our survey of VA medical facilities. Of the 141 surveyed facilities, 136 responded to this question.

Facilities estimating longer notification times (over 30 days) generally relied on primary care providers to notify veterans at their next regularly scheduled appointments, often more than 30 days away and, in some

[8] In addition, we asked a representative from the American Liver Foundation what would be a reasonable notification time frame, and he suggested that 2 to 4 weeks would be a reasonable time frame within which to notify veterans that they have hepatitis C.

cases, longer than 4 months away. At our case study facility—Washington, D.C.—we analyzed medical records of veterans who tested positive for hepatitis C from October 1, 2000, through March 31, 2001. Our analysis of 100 medical records showed that although many veterans were notified in 30 days or less, it took longer than 30 days to notify over half. Thirty-two of these veterans had to wait over 90 days to be notified. (See fig. 3.)

Figure 3: Time to Inform Veterans That They Had Hepatitis C at the Washington, D.C., VA Medical Facility



Source: GAO.

Note: This information is from our analysis of medical records sampled from the universe of veterans who tested positive for hepatitis C from October 1, 2000, through March 31, 2001, at the Washington, D.C., facility. At the time of our review (fall 2001), the 32 veterans whose notification took longer than 90 days included 19 veterans who had waited 256 to 425 days without being notified. We provided the Washington, D.C., facility with the names of these veterans so that they could be notified.

Headquarters officials told us that providers may wait to notify veterans at their next regular appointments because hepatitis C is a slowly advancing disease, and as such, waiting until the next appointments should not significantly affect veterans' medical conditions. In the meantime, however, veterans with hepatitis C could unknowingly infect others or continue to engage in behaviors, such as alcohol use, that could accelerate the damaging effects of hepatitis C on their livers.

In contrast, most of the 29 facilities with the shortest estimated notification times—7 days or less—generally established special processes for notifying veterans, rather than waiting until the next regularly scheduled appointments. For example, providers at 4 facilities scheduled special appointments to discuss hepatitis C test results with veterans, and

providers at 17 facilities notified veterans by telephone or mail. To facilitate these special processes, these facilities also made other adjustments. For example, 16 facilities used a computerized "alert" system that reminds providers to notify veterans as soon as the providers log onto VA's computerized patient record system and before they access individual patient records. This system proactively reminds primary care providers to notify veterans. Previously, hepatitis C test results were placed in a patient's medical record, and providers would only learn the results by accessing the record, which was generally only done at the time of the veteran's next regularly scheduled visit.[9]

In addition, 6 of the 29 facilities with shorter time frames established special systems whereby the laboratory notified a designated person directly of the hepatitis C test results. For example, the San Francisco facility has a full-time registered nurse who each week receives a list of veterans—directly from the laboratory—whose hepatitis C test results are available. She attempts to notify these veterans by telephone. If unsuccessful, she tries to notify the veterans in person at upcoming appointments in outpatient clinics. If the nurse is unable to notify a veteran, she documents this in the veteran's medical record and e-mails the veteran's primary care provider to make him or her aware that the veteran has not yet been notified. She told us that it could be difficult to notify veterans who are homeless or who do not have telephones.

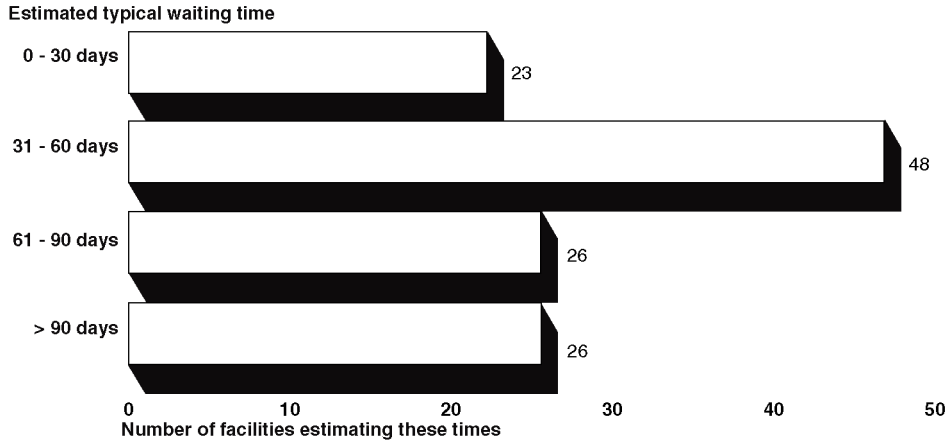
About one-third of the 141 surveyed facilities have established oversight processes to monitor providers' notification performance. For example, the hepatitis C coordinator at the Wilmington VA facility receives all hepatitis C test results directly from the laboratory and checks the medical records of veterans with hepatitis C, reminding primary care providers to notify veterans if records indicate that veterans were not notified. Since the start of our medical record review, our Washington, D.C., case study site has modified its notification processes and has hired a hepatitis C coordinator who monitors primary care providers' notification of veterans to ensure that all veterans found to be infected with hepatitis C are notified.

[9]In addition to these 16 facilities, another 47 report that they use the alert system to notify providers that hepatitis C results are available for veterans whose tests are completed. Of these, 40 reported notification times ranging from 8 to 30 days.

Evaluations of Medical Conditions of Veterans with Hepatitis C Hampered by Waits for Physician Specialist Appointments

Almost all VA medical facilities involved physician specialists[10] in evaluating veterans with hepatitis C to determine a treatment recommendation, but waiting times for appointments with physician specialists varied considerably. Twenty-three facilities, in response to our survey, estimated that veterans typically waited 30 days or less for appointments with physician specialists. By contrast, 100 facilities estimated that veterans typically waited more than VA's 30-day standard to see physician specialists including 26 that had waits exceeding 90 days. (See fig. 4.)

Figure 4: VA Facilities' Estimated Typical Waiting Times for Appointments with Physician Specialists



Source: GAO.

Note: This information is from our survey of VA medical facilities. Of the 141 surveyed facilities, 18 used providers other than physician specialists to perform evaluations.

Moreover, the level of involvement of physician specialists in evaluating veterans to determine treatment recommendations for veterans diagnosed with hepatitis C varies by facility. For example, 62 facilities refer all veterans diagnosed with hepatitis C to physician specialists to decide whether antiviral therapy should be started. By contrast, it is the customary practice at most other facilities surveyed to refer only certain

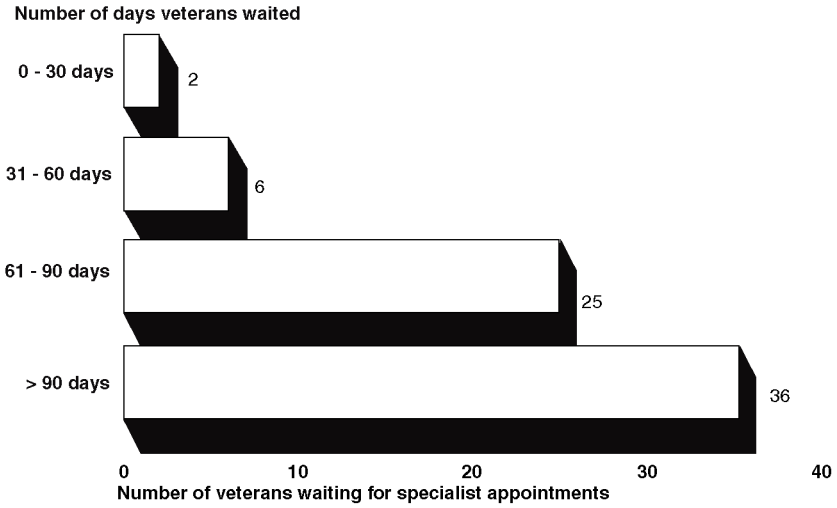
[10]We have used the term physician specialists to mean gastroenterologists, hepatologists, and infectious disease specialists, all of whom provide care for hepatitis C patients in the VA health care system.

veterans diagnosed with hepatitis C for specialists to evaluate, such as those with evidence of liver injury or those who were candidates for antiviral drug therapy.

Since 1999, VA's efforts to screen and test all veterans for hepatitis C have significantly increased the volume of veterans who need physician specialist appointments, therefore creating a bottleneck at many specialty clinics. This is especially true for the 62 facilities that refer all veterans with hepatitis C to physician specialists—80 percent of which estimated waiting times exceeding 30 days. For example, at Washington, D.C., where it is the customary practice to refer all veterans with hepatitis C to physician specialists, our analysis of medical records of 69[11] veterans who were notified that they had hepatitis C and should have been referred to physician specialists showed that only 2 veterans received appointments with physician specialists within VA's 30-day standard for a specialty appointment. Sixty-one veterans waited longer than 60 days, and we could find no evidence that 13 of these veterans ever received appointments with physician specialists to begin the evaluation process. (See fig. 5.)

[11]We reviewed 100 medical records of veterans with hepatitis C. Thirty-one veterans were not candidates for referral to physician specialists because 19 were not notified that they had hepatitis C, 9 received evaluations from primary care physicians, and 3 stopped using this VA facility. If a veteran received an appointment with a physician specialist and did not keep it, we kept that veteran in the analysis using the original appointment date.

Figure 5: Waiting Times for Veterans to See Physician Specialists at the Washington, D.C., VA Medical Facility



Source: GAO.

Note: This information is from our analysis of medical records sampled from the universe of veterans who tested positive for hepatitis C from October 1, 2000, through March 31, 2001, at the Washington, D.C., facility. At the time of our review (fall 2001), the 36 veterans who waited over 90 days for appointments included 13 veterans for whom we could find no evidence of appointments with physician specialists.

However, some facilities with shorter waiting times have found that it is not necessary for all veterans diagnosed with hepatitis C to see physician specialists and have assigned responsibility for hepatitis C evaluations to additional providers—not just physician specialists. Sixteen of the 23 facilities estimating waiting times of 30 days or less indicated that primary care providers or hepatitis C coordinators—often nurses or nurse practitioners—evaluate hepatitis C patients to determine who should be referred to physician specialists. For example, at the San Francisco facility, a nurse practitioner is responsible for evaluating all veterans diagnosed with hepatitis C except those whose disease is very complex, whom she refers to a physician specialist.[12] At the Boston VA facility, primary care providers order diagnostic tests so that results are available when veterans diagnosed with hepatitis C receive evaluations by the

[12]The nurse practitioner operates under a protocol set up by the hepatologist, and a physician specialist approves all treatment decisions that she makes. In cases where the hepatitis C is advanced, the evaluation is conducted by the hepatologist.

hepatitis C coordinator—a physician assistant. She evaluates veterans with guidance from the physician specialist. Likewise, the hepatitis C coordinator at the Wilmington facility, a nurse practitioner, evaluates all veterans with hepatitis C, referring only those with more complex symptoms to the physician specialist.

Conclusions

VA has invested considerably in its efforts to identify and treat veterans with hepatitis C. However, there is wide variation across VA in the time it takes to notify and recommend a course of action for veterans with hepatitis C. When veterans are not promptly notified that they have hepatitis C, they could unknowingly spread the disease to others or engage in activities, such as alcohol use, that could worsen the effect of hepatitis C on their livers. In addition, many veterans must wait too long for their disease to be evaluated by physician specialists.

VA can look to successes within its own system to improve processes and timeliness outcomes systemwide. Promoting best practices for notifying veterans about their hepatitis C test results would encourage providers to think of alternate ways of notifying veterans—such as by telephone or mail—when a veteran's next scheduled appointment is more than 30 days away. Other best practices such as the use of a computerized alert reminding providers to notify veterans would further improve VA's hepatitis C program. Likewise, using clinical guidelines to help providers other than physician specialists evaluate certain veterans with hepatitis C would shorten the time that veterans wait to learn what may be the best course of treatment for their disease. In addition, using providers other than physician specialists could help better allocate the expertise of physician specialists across VA locations. Systemwide use of such best practices that are already being used successfully at some VA facilities would benefit all veterans.

Recommendations for Executive Action

To continue to improve the management of hepatitis C, we recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to

- direct facilities to use special arrangements, such as mail or telephone when appropriate, to notify a veteran rather than waiting until the next regularly scheduled visit if it is more than 30 days away;
- direct facilities to modify their computerized patient record systems so that providers are alerted to positive hepatitis C test results as soon as possible; and

- help facilities improve the timeliness of evaluations for veterans diagnosed with hepatitis C by encouraging facilities to use nonspecialists to conduct initial evaluations, and develop clinical guidelines for when to refer veterans to physician specialists for additional consultations.

Agency Comments

In commenting on a draft of this report, VA agreed with our findings and conclusions and concurred with our recommendations. VA's letter is reprinted in appendix II.

Regarding timely notification of veterans, VA identified several activities that are expected to improve performance in this area. These include collecting data on notification times systemwide, investigating notification issues, and piloting electronic reminder systems to encourage providers to make prompt notifications. VA mentions that it is considering a directive from the Under Secretary for Health to more effectively target the specific settings and circumstances in which notification is delayed.

Regarding notifications to providers, VA has informed facilities that a system for calling a clinician's attention to diagnostic test results is a high priority because hepatitis C testing is frequently done in outpatient settings on patients who appear clinically well. Because of the diversity of its facilities, VA suggested three possible methods for ensuring prompt notifications: (1) laboratories generating phone calls to providers, (2) facilities modifying their computerized patient record systems so that providers are alerted to positive hepatitis C test results as soon as possible, or (3) laboratories reporting all test results to a single designated individual, such as a hepatitis C coordinator, primary care case manager, or another locally designated individual. The designated individual has responsibility for ensuring that patients with positive test results are notified and that proper clinical assessments take place. VA noted that the optimal process will vary depending on local workload, resources, and environment. VA describes these methods in the Under Secretary for Health's Information Letter (mentioned in VA's letter as enclosure 2), which is available on the Web at www.va.gov/publ/direc/health/infolet/10200219.pdf.

Regarding the use of nonspecialists to conduct initial evaluations and development of clinical guidelines for referral to physician specialists, VA stated that it has developed an educational program for primary care providers regarding the initial evaluation of hepatitis C patients as well as a training program to improve the skill of providers who work with liver specialists. In addition, VA is developing templates to standardize and

streamline referral to specialists when appropriate. To measure the effect of these efforts, VA has begun to collect data on the time between a positive test and the point at which a disease management decision is made.

As agreed with your office, unless you publicly announce its contents earlier, we will plan no further distribution of this report until 30 days after its date. At that time, we will send copies to interested congressional committees and other parties. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov. If you or your staff have any questions about this report, please call me at (202) 512-7101. Another contact and key contributors are listed in appendix III.

Sincerely yours,

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

Appendix I: Scope and Methodology

To achieve our objectives, we reviewed and analyzed the Department of Veterans Affairs' (VA) hepatitis C program documents and guidance, including VA's *Hepatitis C Testing and Prevention Counseling Guidelines* and *Treatment Recommendations for Patients with Chronic Hepatitis C*. We interviewed officials from VA's Public Health Strategic Healthcare Group. We also reviewed and analyzed the current literature pertaining to hepatitis C.

We conducted an E-mail survey to obtain information on hepatitis C notification and disease management processes and practices throughout the VA system, including evaluating veterans' medical conditions regarding potential treatment options. We asked each of VA's 22 regional clinical managers to identify the provider most knowledgeable about the hepatitis C program at each medical facility in his or her region. We received the names of hepatitis C providers located in 141 VA medical facilities (accounting for the care provided at most of the 1,013 health care delivery locations within the VA system). We e-mailed a survey to each identified provider. Our survey response rate was 100 percent, although not every location responded to each question.

We conducted a case study at VA's Washington, D.C., facility in the fall of 2001 to understand the complexity of managing a hepatitis C program. We interviewed primary care providers, liver clinic physician specialists and nurses, the chief of laboratory services, and hospital administrators. As part of our case study, we reviewed the medical records of a sample of veterans who tested positive for hepatitis C for the first time during the first 6 months of fiscal year 2001. We selected our sample from a facility-provided list of 346 veterans who had a positive hepatitis C test during this period. To ensure that we examined an adequate number of veterans who had evidence of liver damage (as measured by high levels of alanine aminotransferase (ALT)), we separated the names into two groups—veterans with tests showing high ALT levels (n=149) and those with tests showing normal levels (n=197)—and randomly selected names from each group resulting in a sample of 100 veterans: 53 with high ALT levels and 47 with normal ALT levels. In reviewing the medical records, we discovered that some of the veterans sampled had tested positive prior to October 1, 2000. These veterans were excluded from our sample and other veterans were randomly selected. This discrepancy in the sampling list and the oversampling of the high ALT group may limit the generalizability of our findings.

To obtain information about unique hepatitis C notification and disease management processes that could serve as best practices, we conducted

site visits to 4 other VA facilities: San Francisco, Wilmington, Boston, and Minneapolis. We selected these facilities based on their responses to our survey. At each site we interviewed hepatitis C physician specialists and coordinators and reviewed their hepatitis C notification and disease management processes.

To gain their perspectives on the timeliness and adequacy of VA's hepatitis C notification and disease management processes, we conducted interviews with representatives from four veterans' advocacy groups: American Legion, Vietnam Veterans of America, Veterans Aimed Toward Awareness, and Disabled American Veterans. We also interviewed a representative from the American Liver Foundation. Our review was conducted from July 2001 through January 2003 in accordance with generally accepted government auditing standards.

Appendix II: Comments from the Department of Veterans Affairs

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

December 30, 2002

Ms. Cynthia Bascetta
Director, Health Care—Veterans'
Health and Benefits Issues
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Bascetta:

The Department of Veterans Affairs (VA) has reviewed your draft report, ***VA HEALTH CARE: Improvements Needed in Hepatitis C Disease Management Practices*** (GAO-03-136) and agrees with your findings and conclusions and concurs with your recommendations. The Veterans Health Administration (VHA) will continue to give priority attention to assure that more timely notification of test results to both providers and patients is achieved.

As the General Accounting Office (GAO) observed, VA has many positive accomplishments in the field of hepatitis C counseling, testing, and clinical care. Recent medical record reviews indicate that performance in screening and testing meet or exceed established targets. VHA continues to work diligently to ensure that quality of care is consistent by developing comprehensive treatment recommendations, implementing the new Hepatitis C Registry, offering extensive educational programs, and creating the Hepatitis C Resource Center Program.

The National Hepatitis C Program Office, the Hepatitis C Resource Center Program, and the Employee Education Service are actively involved in developing educational programs for clinical providers, particularly regarding the initial evaluation of patients with hepatitis C. In addition, the computerized medical record is being enhanced to expedite both the patient notification and referral processes.

Enclosure (1) describes actions VHA has taken as well as its plans to improve its hepatitis C disease management. VHA is already engaged in several activities to meet its improved notification goals. These efforts include focused review by the External Peer Review Program to identify better the extent of notification delays and electronic reminder systems to encourage prompt notification and documentation of results. Also, recently, VHA distributed a national Information Letter, Enclosure (2), that provides suggested algorithms for the diagnosis of hepatitis C and notification of related test results.

Ms. Cynthia A. Bascetta

Thank you for the opportunity to comment on your draft report.

Sincerely yours,

Anthony J. Principi

Enclosure

Enclosure 1

DEPARTMENT OF VETERANS AFFAIRS'
COMMENTS TO GAO DRAFT REPORT
VA HEALTH CARE: Improvements Needed in Hepatitis C Disease Management Practices
(GAO-03-136)

To continue to improve the management of hepatitis C, GAO recommends that the Secretary of Veterans Affairs direct the Under Secretary for Health to:

- **Direct facilities to use special arrangements, such as mail or telephone when appropriate, to notify veterans rather than waiting until the next regularly scheduled visit to notify them if the next regularly scheduled visit is greater than 30 days;**

Concur – The Veterans Health Administration (VHA) is engaged in several activities to define better the identified problems with notification. Beginning in fiscal year 2003, the External Peer Review Program (EPRP) will collect data during chart reviews pertaining to the time between testing and documentation of notification. The National Hepatitis C Program Office is also partnering with the Office of the Medical Inspector to investigate issues related to patients not being informed in a timely manner of positive test results. In addition, the Hepatitis C Resource Center Program, in coordination with VA's Office of Information, is developing and piloting electronic reminder systems to encourage prompt notification and better documentation of the notification process. VHA believes that these activities will lead to improved performance in this area. A directive from the Under Secretary for Health is one possible solution that VHA will consider along with others that may more effectively target the specific settings and circumstances in which notification is delayed.

- **Direct facilities to modify their computerized patient record system so that providers are alerted to positive hepatitis C test results as soon as possible;**

Concur - VHA agrees with GAO that this recommendation is a high priority to improve its hepatitis C program. On December 13, 2002, the Under Secretary's office distributed to field facilities an Information Letter (IL 10-2002-019,) that outlines diagnostic testing algorithms and systems to ensure that providers are notified of test results. It provides information on how to configure laboratory test file entries so that they can trigger "view alerts." Three possible notification algorithms are suggested, all of which will accomplish the goal of notifying providers promptly. Because of the diversity of VA's system, the optimal process will vary depending on local workload, resources and environment. Adoption of

Enclosure 1

DEPARTMENT OF VETERANS AFFAIRS'
COMMENTS TO GAO DRAFT REPORT
VA HEALTH CARE: Improvements Needed in Hepatitis C Disease Management Practices
(GAO-03-136)
(Continued)

any of the three algorithms of the Information Letter will accomplish the goal that GAO recommended. The Office of Information will continue to work with the clinical business/program users to ensure that the information technology systems support the notification process.

- **Help facilities improve the timeliness of evaluations for veterans diagnosed with hepatitis C by encouraging facilities to use non-specialists to conduct initial evaluations; and develop clinical guidelines for when to refer to physician specialists for additional consultations.**

Concur – Recently, the National Hepatitis C Program Office, the Hepatitis C Resource Center Program, and the Employee Education Service developed an educational program for primary care and other front line providers regarding the initial evaluation of patients identified with hepatitis C. Pocket guides, slide presentations, and training notes are being developed and will be distributed through local hepatitis C lead clinicians for training non-specialists who test, counsel, and evaluate patients with hepatitis C. In addition, the Hepatitis C Resource Center Program is developing templates for use in the electronic medical record to streamline and standardize the process of referral to liver specialists when appropriate. Training programs are also being set up to improve the skill of mid-level providers who work with liver specialists so that their time may be better devoted to truly specialized services. VA expects that all of these efforts will improve timeliness and quality of initial evaluations. To support and measure the effect of these efforts, EPRP is collecting data beginning in fiscal year 2003 on the time between a positive test and the point at which a disease management decision is made.

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Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Paul Reynolds, (202) 512-7109

Acknowledgments

In addition to the contact named above, Cheryl Brand, Irene J. Barnett, Frederick Caison, Deborah L. Edwards, Martha A. Fisher, Susan Lawes, Gay Hee Lee, and Clare Mamerow made key contributions to this report.

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