STATEMENT OF
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BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
December 3, 2014

Thank you for the opportunity to discuss VA's commitment and efforts in providing timely access to high-quality Hepatitis C Virus (HCV) care for Veterans, including their pharmaceutical treatment. I am accompanied today by David Ross, M.D., Ph.D. Director of VA's HIV, Hepatitis, and Public Health Pathogens Program.

VA has approximately 174,000 Veterans in care with HCV, making it the largest single HCV provider in the U.S. VA has had a comprehensive national HCV program since 2001. Like the rest of the country, VA has treated only a portion of Veterans for HCV because treatment and cures have been difficult to achieve due to low efficacy and high toxicity of standard drug therapies.

Overview

Chronic infection with hepatitis C virus (HCV) is the most common blood-borne infection in the world and is a major public health problem facing not only the Veterans Health Administration (VHA) but the United States in general. Complications that may result from untreated HCV infection include progressive liver damage leading to cirrhosis (also known as Advanced Liver Disease, ALD), hepatocellular carcinoma (HCC), and other life-threatening conditions. Although many of these complications are treatable or even preventable, they may occur because only half of the individuals with HCV infection in the U.S. are aware they are infected. The epidemic of HCV in the U.S. has also affected VA, and we are capitalizing on the availability of new therapies to improve access to and quality of HCV care.

VHA is a leader in the U.S. in HCV infection care, including screening, treatment, and prevention. Between 2002 and 2013, the percentage of Veterans in VHA care with at least one outpatient visit who had ever received screening for HCV infection more

than doubled from 26.9 percent to 56.0 percent. Individuals born between 1945 and 1965 are at higher risk for HCV infection due to exposure to the virus; as of 2013, almost two-thirds of Veterans in VHA care born between these years have been screened for HCV infection. VHA is also developing an electronic clinical reminder to improve screening rates among Veterans in the 1945-1965 birth cohort and others with risk factors. Similar improvements were seen in confirmatory testing after an initial positive screening result, which increased to 96 percent across the system by 2013. VHA's HCV care is implemented at VA medical facilities across the country and uses a comprehensive approach that includes:

- Universal assessment for risk of hepatitis C infection
- Testing and counseling for those at risk, particularly those in the 1945-1965 birth cohort
- Education for patients and their families
- Giving providers access to the best available information about hepatitis C
- Excellence in clinical care
- Support for research to improve clinical care
- Ongoing quality improvement

Screening for HCV

Increased screening for HCV is a critical component of early identification and linkage to care. Under VHA Handbook 1120.05, *Coordination and Development of Clinical Preventive Services,* screening is defined as an examination or testing of a person with no symptoms of the target condition to detect disease at an early stage when treatment may be more effective, or to detect risk factors for disease or injury. The current VA HCV screening policy recommends offering HCV testing to any Veteran born between 1945-1965, to any Veteran who has a risk factor for HCV infection such as Vietnam-era service (defined by dates of service in 1964-1975,) or a blood transfusion or organ transplantation prior to 1992, or to any Veteran wishing to be tested. This policy closely follows the 2013 US Preventive Services Task Force recommendation for screening for HCV in persons at high risk for infection and also offering one-time

screening for HCV infection to adults born between 1945 and 1965 (B recommendation).

As most Veterans with HCV infection were infected decades ago and fewer than 22,000 new HCV infections in the U.S. occur annually, the increase in the number of HCV-infected Veterans in VHA care largely represents expanded screening and identification of individuals with pre-existing HCV infection rather than new infections. Entry of previously diagnosed patients into VHA care may also have contributed to this increase. It is important to remember that the cohort of HCV-infected Veterans in VHA care changes from year to year due to new diagnoses, deaths, and Veterans with HCV infection moving into or out of VHA care.

Treatment for HCV

In the past three years, significant gains have been made in the therapeutic options available to cure HCV infection, with further gains expected in the very near future. In 2013, the U.S. Food and Drug Administration (FDA) approved two antiviral medications for use as part of combination regimens which offer shorter treatment durations and decreased side effects in addition to increased cure rates. Several other new agents and combinations of agents are expected to receive FDA approval in 2014-15, making additional treatment regimens available for patients. The evolution of management and treatment of HCV infection will make it possible to cure an increasing proportion of HCV-infected Veterans with fewer side effects.

VHA has moved rapidly to deploy new, more effective, less toxic HCV treatments and has been able to negotiate significant discounts for these newer therapies. For example, VA has negotiated a price of $594 per dose for Sofosbuvir (the commercial price is $1000 per dose) and $413 per dose for Simeprevir (the commercial price is $790 per dose). When the VA Pharmaceutical Prime Vendor negative distribution fee of 9.15% is factored in, VA's net price for Sofosbuvir is $539 per dose and is $375 per dose for Simeprevir. In FY 2014, VHA treated over 5,400 Veterans with HCV with these new treatments. VA spent over $370 million in drug costs alone on these new treatments in FY 2014. VA is actively planning for the deployment of more effective

HCV treatments becoming available in later this year and we plan to move aggressively to treat patients with these drugs, based on clinical need.

Veterans infected with HCV in VHA care receive primary care through their local VHA medical center or VHA community-based outpatient clinic. However, some Veterans may need to travel to another VHA facility to receive the full spectrum of specialized HCV care. Increasingly, telemedicine platforms, such as telehealth and Specialty Care Access Network-Extension for Community Outcomes (SCAN-ECHO), are being used to deliver care to Veterans in remote areas or to Veterans with conditions that limit mobility.

Current Challenges and Future Directions

As the largest single provider of care for HCV infection in the U.S., VHA is charged with addressing an epidemic of life-threatening complications among Veterans with HCV infection. The challenge is increased by the likelihood that some Veterans with HCV infection remain undiagnosed, while others do not accept treatment or may not be treatment candidates because of co-existing medical conditions. The introduction of very costly, highly effective and less toxic anti-viral therapies, which are easier to administer than older treatments, holds the promise of eradicating this disease in infected Veterans. VA redirected funding for the increased cost of the newer medications for Fiscal Year 2014 and is doing so in 2015. For future budget submissions, VA will incorporate the cost of these new therapies into the Enrollee Health Care Projection Model (EHCPM) estimates. However, addressing the cost of these agents remains a major challenge. In addition, the synthesis of a population health approach to HCV infection with system redesign will improve access to high-quality HCV care for Veterans. System redesign refers to analysis of barriers that may affect patients' access to care, followed by design and execution of changes to overcome such barriers. VHA is currently developing a VISN-centered system redesign approach that will coordinate care of HCV and its complications across a wide area. The application of system redesign principles to HCV diagnoses, treatment, and care promises to substantially improve access to, quality of, and efficiency of care. Finally,

the experience, expertise, and dedication of VHA providers and pharmacists will allow VA to deliver the excellent care that Veterans with HCV deserve.

Conclusion

VHA is committed to providing evidence-based care to ensure the continual improvement of VHA care for Veterans with HCV infection. We recognize that our future work to improve the quality of HCV care will be based in large part on understanding and addressing variation in HCV care structures, processes, and outcomes. We are happy to respond to any questions you may have.