

# State of Care for Veterans with Chronic Hepatitis C

**Department of Veterans Affairs** 

**Veterans Health Administration** 

**Office of Public Health and Environmental Hazards** 

**Public Health Strategic Health Care Group** 







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#### **Preface**

The purpose of this report is to characterize the state of care of the population of Veterans with chronic hepatitis C (HCV) within the US Department of Veterans Affairs' (VA) Veterans Health Administration (VHA). The first step in providing responsive care is to learn about the affected population. This report describes the distribution of Veterans with chronic HCV within VHA and provides basic demographic data on this population. Additionally, the report describes pharmacologic treatment, other conditions commonly seen in Veterans with chronic HCV, and indicators of healthcare quality including screening, monitoring, and outcomes assessment. This report contains information that can be used to assess and guide interventions to improve the quality of care VHA delivers to Veterans with chronic HCV.

The report has a series of chapters, each covering a limited aspect of VHA care for Veterans with chronic HCV. Please refer to the Table of Contents for a quick reference to key sections within each chapter. The report contains summary information at the national, regional (Veterans Integrated Service Network, or VISN), and local healthcare system levels. To improve readability, large tables appear in the Appendix; smaller tables and figures appear within the text. References and general methods are described at the end of each chapter.

This is the first comprehensive summary report on Veterans with chronic HCV produced by the Public Health Strategic Healthcare Group (PHSHG). PHSHG was assigned responsibility for the National Hepatitis C Clinical Program in 2001. Since then, PHSHG has initiated numerous educational, training, and quality initiatives, the majority led by the National Hepatitis C Resource Centers, targeting various VHA providers responsible for hepatitis C care. In 2006, PHSHG, in conjunction with the Office of Information Technology, launched a new population management tool, the Clinical Case Registry (CCR), which greatly expanded access both locally and nationally to medical information for Veterans with chronic HCV. Data from the CCR serves as the foundation for this report. Where available, comparisons are made between Veterans with chronic HCV in care recently and during earlier periods.

With the goal of continual improvement in VHA care for Veterans with chronic HCV, PHSHG is committed to making these data available to front-line clinicians, VHA policy makers and researchers. This report would not be possible without the efforts of VHA staff located at VHA facilities across the county. PHSHG staff who are responsible for review of the quality of HCV care and who were instrumental in the development of this report are listed in the acknowledgements section. This report is dedicated to them and to the Veterans we serve.

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#### **Executive Summary**

The Department of Veterans Affairs (VA), Veterans Health Administration (VHA) is the largest single provider of hepatitis C (HCV) care in the United States. According to Clinical Case Registry data, between 2000 and 2008, 287,410 Veterans in VHA care screened positive for antibodies to HCV and 189,065 (65%) were identified with chronic HCV infection. In 2008, VHA clinicians cared for over 147,000 Veterans with chronic HCV; these Veterans were cared for in every one of VHA's 21 Veterans Integrated Service Networks (VISNs) and at every one of the 128 VHA local healthcare systems across the United States. Of the 5.6 million Veterans in VHA care in 2008, one of every 38 (2.6%) had a diagnosis of chronic HCV. The number of Veterans with chronic HCV in VHA care has been relatively stable over the past 5 years with approximately 8% entering VHA care and approximately 8% leaving (including deaths) VHA care each year. In 2008, caseloads of Veterans with chronic HCV ranged from 2,480 to 14,019 across VISNs and from 26 to 4,476 across local VHA healthcare systems. In 2008, the typical Veteran with chronic HCV was White (49%), 56 years old, male (97%), with a history of comorbidities including hypertension (63%) and depression (56%). This group has a significant history of tobacco use (62%) and alcohol use (54%), complicating the management of chronic HCV. More than one in eight had a history of cirrhosis and over 900 new cases of hepatocellular carcinoma (HCC) were diagnosed in 2008. The proportion of those in care with advanced liver disease, including cirrhosis and liver cancer, has grown significantly over the past 8 years.

Nationally, Veterans with chronic HCV receive high quality care at the VHA as reflected in rates of guideline-concordant HCV-specific care, recommended prophylaxis, screening for conditions important to public health, and outcomes measures; however room for improvement exists. National VHA rates of providing guideline-recommended clinical preventive services for Veterans with chronic HCV receiving care in 2008 included: confirmation of hepatitis B immunity or vaccination 70%, confirmation of hepatitis A immunity or vaccination 65%, HIV testing 56%, influenza vaccination 46%, and screening for HCC in Veterans with chronic HCV and cirrhosis 45%. By 2008, over 31,000 had received antiviral therapy for HCV; they represent one-fifth of the Veterans with chronic HCV in VHA care in 2008. Attainment of a successful HCV antiviral treatment outcome, referred to as sustained virologic response (SVR), was lower in VHA compared to drug registry trials, as might be expected due to differences in patient population.

As the report shows, VHA has made significant improvements over the past 8 years in many areas of HCV population management including patient identification, testing, and in quality of care indicators. These improvements coincide with the establishment of a National Hepatitis Clinical Program Office and the Hepatitis C Resource Centers. Programmatic efforts

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have included the development of educational materials, development and dissemination of successful models of care, various training programs and quality improvement initiatives. This document provides a descriptive report; it is not meant to be exhaustive nor is it to provide the type of statistical analyses that allow inferences to be drawn. The PHSHG uses these data to understand HCV prevalence, burden of disease, and care outcomes regionally and locally in order to design targeted interventions and identify topics requiring additional investigation, thus assisting in improving care for our nation's Veterans. Geographic variability across VISNs and local healthcare systems exists on all the quality indicators covered in this report, providing an opportunity for the PHSHG, administrators, local champions, and VHA researchers to identify gaps, barriers, and best practices to improve care.

## Chapter 1 – Background and Perspective

#### **1.1** Department of Veterans Affairs, Veterans Health Administration

The Department of Veterans Affairs (VA) Veterans Health Administration (VHA) is a federal comprehensive healthcare system serving eligible, enrolled US Veterans. Organizationally, the VHA is divided into 21 geographic regions called Veteran Integrated Service Networks or VISNs, each of which encompasses a number of local healthcare systems. These 128 local healthcare systems include over 1,100 facilities consisting of medical centers, community based outpatient clinics (CBOCs), domiciliaries, extended care facilities, hospices, and specialty centers for mental health, blind rehabilitation, spinal cord injury, polytrauma and traumatic brain injury. In federal fiscal year 2008, there were 7.8 million VHA enrollees and 5.6 million (72%) of them received care at a VHA facility. Nationwide, VHA inpatient care involved 641,000 discharges (70% of which were for acute care) totaling 4.3 million bed days of care. That year, the average daily census in nursing homes was 33,782 Veterans. Over 67 million outpatient visits were provided by the VHA in fiscal year 2008, 13.7 million of which were at CBOCs. Additional information on the general Veteran population can be found at http://www1.va.gov/vetdata/.

#### **1.2** Overview of Program Office and Quality Initiatives

The Office of Public Health and Environmental Hazards improves Veterans' health through prevention, outreach, treatment and surveillance. It focuses on specific populations of Veterans including women Veterans, Veterans with HIV/AIDS, Veterans with hepatitis C (HCV), and Veterans exposed to hazardous materials during military service. The Office also manages VHA's medical response to emergencies and protects the safety and health of VHA employees. Additional information on the Office of Public Health and Environmental Hazards is available at <u>www.publichealth.va.gov</u>.

#### Public Health Strategic Health Care Group

PHSHG Public Health Strategic Health Care Group

The Public Health Strategic Health Care Group (PHSHG) is an organizational unit within the Office of Public Health and Environmental Hazards. PHSHG's mission is to improve the health of Veterans through the development of sound policies and programs related to several major public health concerns including: HCV infection, HIV infection, seasonal influenza, smoking and tobacco use, and emerging infections of public health significance including healthcare associated infections. PHSHG strives to promote the highest quality, comprehensive care for Veterans and to have that care recognized as the standard by which all healthcare in the United States is measured. PHSHG efforts include patient care activities, clinician education, patient education, prevention activities, policy development, and research directed at continuous improvement of medical and preventive services delivered to Veterans. Additional information on the PHSHG is available at

http://www.publichealth.va.gov/about/pubhealth/index.asp.

#### Clinical Public Health Programs Office

The Clinical Public Health Program Office (CPHP), a component of PHSHG, oversees the VA National Hepatitis C Program. The Hepatitis C Program works to ensure that patients with or at risk for HCV receive the highest quality healthcare services. Led by PHSHG and carried out by providers at VA medical facilities across the country, the program takes a comprehensive approach to HCV that includes:

- Universal screening for risk of HCV infection
- Effective counseling and testing for those at risk
- Education for patients and their families
- Prevention and harm reduction
- Clinician training on the latest information regarding the management of HCV including antiviral therapy
- Promotion of excellence in clinical care
- Proactive research to improve clinical care
- Data-based quality improvement

#### Hepatitis C Resource Centers



The Hepatitis C Resource Center (HCRC) network is an integral part of VA's National Hepatitis C Program and is overseen by CPHP. Initially funded in 2002, the four HCRCs,

located in Minneapolis, San Francisco, Seattle/Portland, and West Haven, work closely with CPHP and other elements of PHSHG to develop best practices in HCV prevention, clinical care, patient and provider education, and program evaluation for use within VA as well as within other medical care systems. Projects of the HCRCs include:

- Improving screening and testing methods
- Development of patient education materials
- Assessing impact of co-morbidities on chronic HCV treatment decisions (e.g. mental illness, substance abuse, or concurrent HIV infection) and piloting effective models of care to address these challenges
- Development and dissemination of models of interdisciplinary care to optimize effective management of chronic HCV
- Training of VA healthcare providers on hepatitis C diagnosis and care, including reduction of risk from co-morbidities and management of complications of chronic HCV infection
- Surveying HCV clinicians to better understand HCV care delivery in VHA
- Development and dissemination of clinical standards for managing patients with all stages of HCV
- Development of telehealth models of care to improve access to care for Veterans with chronic HCV

Over the period covered by this report, the HCRC program was instrumental in developing treatment guidelines, educational materials for Veterans and providers, and numerous products and staff educational programs with the goal of improving the quality of care for Veterans with chronic HCV. Additional information on the HCRC program including access to guidelines and educational materials for both Veterans and clinicians can be found on the internet at <a href="http://www.hepatitis.va.gov">http://www.hepatitis.va.gov</a> and within VHA at <a href="http://www.hepatitis.va.gov">http://www.hepatitis.va.gov</a>

Center for Quality Management in Public Health



The Center for Quality Management in Public Health (CQMPH), also a component of the PHSHG, is based at the VA Palo Alto Health Care System. CQMPH oversees the Clinical Case

Registry (CCR) for HCV. CQMPH's mission is to catalyze continual innovation and improvement in VHA clinical care via the use of quality management techniques and the strategic use of clinical information systems. This work is possible because of the unique VHA electronic medical record (EMR). Taking advantage of clinical data from the VHA's EMR, CQMPH develops centralized patient registries, and enhances local registry functions to provide clinicians useful information about their populations of Veterans with HCV. CQMPH staff members provide support to VHA clinicians and administrative staff to enhance their ability to use the CCR. CQMPH also provides other electronic tools such as optional Clinical Reminders. All these efforts are designed to enhance the quality of care delivered to Veterans.

#### **1.3 Electronic Medical Records, the Clinical Case Registry, and CCR Reports**



VHA has a state of the art electronic medical record (EMR) covering all aspects of healthcare delivery and documentation. Electronic tools use healthcare data to provide clinicians with patient-centric reminders and guidance related to care delivery including safety functions such as drug-drug interaction and allergy checks, reminders to provide vaccinations, laboratory tests and screenings, and alerts regarding abnormal results or procedures. The VHA EMR also includes population management tools, such as the Clinical Case Registry (CCR). The CCR software, deployed throughout VHA, provides a registry at every VHA facility to support local care delivery and populates a national clinical database. Staff members at VHA facilities serve as local registry coordinators, reviewing the medical records of Veterans with laboratory results and/or diagnosis codes reflecting potential infection with HCV and in cases of chronic infection, confirming their addition to the local CCR. Addition of a Veteran to a local registry triggers his or her addition to the national CCR, which is created through extraction of specific clinical data from the local EMR. Data elements extracted to the national CCR include information on allergies, demographics, diagnoses, inpatient stays, laboratory tests, outpatient visits, prescriptions, procedures, and radiology.

Using data from all VHA facilities, periodic summary reports are created on the population of Veterans with chronic HCV receiving care in the VHA. These reports use the latest available data and provide information at the national, VISN, and local healthcare system levels to VHA clinicians, administrators, and researchers. Each report is based on an extract of CCR data on a specific date. In each extract, CCR historical data is updated with current data for

Veterans already in the CCR and with historical and current data for Veterans recently added to the CCR. Because CCR data collection is dynamic, reports covering the same period using extracts created on different dates are not necessarily identical. Nonetheless, comparison of information from reports created in different periods is useful for monitoring trends. The ultimate goal of these reports is to provide information to guide clinical, quality improvement, and administrative activities directed to assuring safe, effective and efficient care for Veterans with chronic HCV.

In addition, local healthcare system staff have access to population management reporting tools in their local CCR software. While such local reports are based only on data from the local healthcare system (as opposed to the national CCR) they permit the user to examine a variety of process and outcome related questions.

Examples of valuable ways the local and national CCR supports clinical practice include:

- Measurement of patient volume and disease severity to inform decisions about how care is delivered, allocation of staff and other resources
- Assessment of adherence to national guideline recommendations or medication criteria for use
- Identification of trends over time, such as screening practices, hepatocellular carcinoma (HCC) diagnosis, vaccination, or monitoring of treatment
- Describing patient demographic characteristics and co-morbidities to assess types of services likely to be required, such as treatment for age-related issues or chronic conditions.
- Measurement of treatment outcomes and effectiveness of current practices, protocols or guidelines including production of reports from the national CCR by PHSHG
- Performing ongoing comparison across VISNs or healthcare systems of like size to identify variation that may indicate quality issues or opportunities for improvement

Feedback reporting is a fundamental strategy that PHSHG employs to achieve its mission to assure the highest quality, comprehensive care to Veterans. This State of Care Report joins PHSHG's efforts in clinical surveillance, patient care activities, clinician education, patient education, prevention activities, and research directed at continuous improvement of medical and preventive services delivered to Veterans with chronic HCV.

## **Chapter 2 – Veterans with Chronic HCV**

The diagnosis of chronic hepatitis C (HCV) includes both screening for historical exposure to HCV and confirmatory testing for the presence of chronic infection with HCV. Completion of confirmatory testing as a measure of quality of care is discussed in Section 6.1. Approximately 15% to 20% of those exposed to HCV will naturally clear the infection and do not experience chronic infection.<sup>1</sup> Those with chronic HCV should be linked to care for baseline assessment, education, implementation of risk reduction strategies (e.g., vaccinations, counseling and assistance on decreasing alcohol use), and assessment for antiviral therapy. This report focuses on Veterans with evidence of chronic HCV (e.g., a measurable HCV viral load); these patients are referred to as Veterans with chronic HCV.

#### 2.1 Number in Care

Nationally, in 2008 there were 147,352 Veterans in VHA care with chronic HCV. Based on sampling performed in 1999 to 2002, the prevalence of chronic HCV in the general U.S. population was estimated to be 1.3% by the Centers for Disease Control and Prevention (CDC).<sup>2</sup> With 5.6 million Veterans receiving VHA care in 2008, a crude estimate of known prevalence of chronic HCV in VHA for 2008 was 2.6% - twice the rate reported by the CDC. The number of Veterans in VHA care identified with chronic HCV has increased from 111,521 in 2000 to 147,352 in 2008 (Figure 1). In 2001, VHA established performance goals to increase risk assessment and testing for HCV. The identification of an additional 30,000 Veterans with chronic HCV was likely related to the establishment of those goals and not to new infections.



#### Figure 1. Number of Veterans with Chronic HCV in VHA Care by Year

#### 2.2 Location of Care

Figure 2 shows each of the 21 VISNs. The number of Veterans with chronic HCV in VHA care per VISN in 2008 ranged from 2,480 in VISN 2 to 14,019 in VISN 16 (Figure 3). Nine of the VISNs each had over 7,000 Veterans with chronic HCV in VHA care (VISNs 4, 6-8, 11, 16, 20-22). For information on the number of Veterans with chronic HCV in VHA care in each VISN in earlier years, see Appendix A.



Figure 2. VHA VISN Map

Figure 3. Number of Veterans with Chronic HCV in VHA Care in 2008 by VISN



Although the total number of Veterans with chronic HCV in VHA care changed little from 2005 to 2008, there was a geographic shift in their distribution toward VISNs in the Southeast. Comparing 2005 to 2008, VISNs with increases of at least 200 Veterans with chronic HCV included VISNs 7 (+455), 6 (+453), and 8 (+270). In contrast, VISNs 3 (-523), 22 (-465), 16 (-386), and 11 (-351) each decreased by more than 300 patients. The shift in geographic distribution may be due in part to Veterans transferring care within VHA and expanded screening and testing for hepatitis C; however additional investigation is required to further understand this geographic shift.

At the local healthcare system level, Veterans with chronic HCV were seen at each of the 128 local systems which are responsible for reporting on all local VHA health care. In 2008, HCV patient caseload by healthcare system ranged from 26 to 4,476, with the majority of healthcare systems caring for between 700 and 1,500 Veterans with chronic HCV.

Figure 4 depicts the distribution of the 128 VHA healthcare systems by caseload. The 41 healthcare systems with large HCV caseloads (over 1,500) care for 60% of all Veterans with chronic HCV. Healthcare systems with chronic HCV caseloads between 501 and 1,500 (n=60) care for 35% of the chronic Veteran population and the 24 facilities with HCV caseloads less than 501 care for 5% of the population.



Figure 4. Percent of VHA Healthcare Systems by HCV Caseload in 2008

Almost 12% of Veterans with chronic HCV received care at more than one healthcare system and 3.5% received care at more than one VISN during 2008. A complete listing of the

number of Veterans with chronic HCV at each local healthcare system can be found in Appendix A.

#### **2.3 Demographics**

#### <u>Sex</u>

The majority of Veterans with chronic HCV were men (97%); nonetheless, the VHA provides care to a substantial number (over 4,200) of women Veterans with chronic HCV. Although the proportion of Veterans with chronic HCV in VHA care who were male has remained stable over the past five years, as the percentage of female Veterans in VHA care increases, the number of HCV infected female Veterans may also increase. According to CDC estimates, the prevalence of HCV in American females is one-half that of men.<sup>2</sup>

#### Race/Ethnicity

In 2008, Whites comprised almost half of Veterans with chronic HCV in VHA care (49%, Figure 5). Blacks comprised 31% of the VHA population with chronic HCV - a substantially greater proportion than the overall Veteran population in VHA care in which 11% were identified as Black.<sup>3</sup> Just over five percent of Veterans with chronic HCV identified themselves as Hispanic or Latino, which is very similar to the 5.7% Hispanic population served by the VHA overall. Less than 1% of HCV infected Veterans were American Indian, Alaskan Native, Asian, Native Hawaiian, or Pacific Islander. Because reporting of race and of ethnicity among Veterans in VHA care is not complete, the actual percentages may vary from those reported.



Figure 5. Race/Ethnicity for Veterans with Chronic HCV in VHA Care in 2008

<u>Age</u>

A comparison of the age by decade of life of Veterans with chronic HCV in VHA care in 2000, 2004 and 2008 is presented in Figure 6. Since 2000, the mean age of Veterans with chronic HCV has increased from 49.8 to 56.3 years. In 2008, 88% of Veterans with chronic HCV in VHA care were age 50 or older and more than one in four Veterans with chronic HCV was over the age of 60.



Figure 6. Veterans with Chronic HCV in VHA Care in 2000, 2004 and 2008 - Age by Decade of Life

Since 2003, incidence rates of acute HCV in the US have generally remained stable within each age group, increasing only slightly among persons aged 25 - 39 years and those aged > 40 year.<sup>4</sup> According to the CDC, peak prevalence of acute HCV infection in the general US population in 2007 occurred among persons aged 40-49<sup>2</sup>. In VHA, there are no data on the incidence of acute HCV.

The impact of HCV disease on the long-term management of other chronic conditions common in the elderly and vice versa is still largely unknown. As the affected population ages, HCV will complicate the management of other co-morbid conditions to a greater degree. VHA is in the unique position of caring for a large older Veteran population with chronic HCV; much can be learned about their care. This report describes the prevalence of some of the other chronic conditions common in the elderly in Veterans with chronic HCV in Chapter 4.

#### 2.4 Deaths

According to CDC information from 1998, chronic HCV causes 8,000-10,000 deaths each year and accounts for almost half of the approximately 4,000 liver transplantations done each year.<sup>1</sup> Since death from HCV liver disease usually occurs 20 or more years after the initial infection, CDC expects deaths from chronic HCV to rise sharply in the next 10 years.<sup>5</sup> VHA has already begun to see an increase in deaths from all causes among Veterans with chronic HCV. Between 2000 and 2008, the annual number of all cause deaths recorded for Veterans with chronic HCV rose from 1,259 (1,129 per 100,000 in VHA care) to 5,967 (4,049 per 100,000 in VHA care), respectively. The PHSHG is acutely interested in understanding the causes associated with this increase in deaths including the impact of chronic hepatitis C.

#### Methods:

- 1. In Care. A Veteran is considered in VHA care for this report if they had at least one outpatient visit or an inpatient stay or filled an outpatient prescription in the defined time period.
- 2. Demographics. Age was calculated at the midpoint of the time period under evaluation. Race is classified using the Office of Management and Budget (OMB) categories published in the Federal Register on July 9th, 1997 and include American Indian or Alaskan Native, Asian or Pacific Islander, Black, and White. For Ethnicity, persons were classified as of Hispanic origin or not. For the race/ethnicity, Hispanic Veterans (of any race) were identified first based on the Veteran's ethnicity field. We then used the race field for remaining Veterans to identify if they should be mapped to Black, White, and Other. The "Other" group includes "American Indian or Alaskan Native" and "Asian or Pacific Islander".
- 3. Deaths. Dates of death were obtained from both Veterans Health Administration and the Veterans Benefits Administration files.

#### References:

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## **Chapter 3 – Services Provided to Veterans with Chronic HCV**

The 147,352 Veterans with chronic HCV in VHA care in 2008 generated over 60,000 inpatient stays, over 5 million outpatient visits and over 5.3 million prescription fills. Compared to data from fiscal year 2008 for the overall VHA population, Veterans with chronic HCV had higher use of some VHA services including hospitalizations and outpatient visits (Table 1).

	Veterans with Chronic HCV CY 2008	All Veterans in Care FY 2008
Number of Veterans	147,352	5.6 million
Inpatient Discharges (#/1000 Veterans)*	410	115
Outpatient Visits (#/1000 Veterans)	33,932	11,982
Prescription Fills (#/1000 Veterans)	35,968	43,661

Table 1. Healthcare Utilization for Veterans with Chronic HCV and All Veterans

\* Includes acute and non-acute discharges. Abbreviations: CY calendar year; FY, federal fiscal year

Over twenty thousand (23,762) Veterans with chronic HCV had one or more of the 60,359 inpatient discharges in 2008. Their average length of stay was 17.9 days with a median of 5 days. Mental health diagnoses were the most common primary inpatient diagnosis at 19.5% for Veterans with chronic HCV and 14% for the general VHA population (Table 2). Compared with the overall VHA population, Veterans with chronic HCV had a higher percent of discharges for diseases of the digestive system (11.9% vs. 8.4%) and substance use disorders (14% vs. 6.1%). The general VHA population had a higher percentage of hospitalizations for diseases of the circulatory system than Veterans with chronic HCV at 18.7% versus 9.7%, respectively. The percentage of discharges with a primary diagnosis of cirrhosis was 4.4% in Veterans with chronic HCV compared to 0.9% of the general population of Veterans nationwide. With one exception, there was little difference in incidence of primary discharge diagnosis between 2005 and 2008 for Veterans with chronic HCV. The exception is that substance use disorder among Veterans with chronic HCV decreased from 18% of all primary discharges in 2005 to 14% in 2008.

Major Diagnostic Group	Veterans with Chronic HCV CY 2005*	Veterans with Chronic HCV CY 2008*	All Veterans FY 2008*
Mental Disorders	20.8%	19.5%	14.1%
Substance Use and Disorders	18.0%	14.0%	6.1%
Diseases of the Digestive System	11.3%	11.9%	8.4%
Diseases of the Circulatory System	9.2%	9.7%	18.7%
Signs and Symptoms**	6.9%	6.7%	7.0%
Diseases of the Respiratory System	4.9%	5.6%	8.4%
Health Status Factors***	3.2%	4.9%	5.2%
Injury, Poisoning, Drug Toxicity	5.2%	4.9%	4.9%
Neoplasms	3.6%	4.6%	6.4%
Diseases of the Musculoskeletal System and Connective Tissue	2.8%	3.2%	4.2%
Endocrine, Nutritional and Metabolic Diseases, and Immunity Disorders	3.3%	3.2%	3.5%
Diseases of the Skin and Subcutaneous Tissue	3.2%	2.8%	2.5%
Kidney and Urinary Tract	2.2%	2.8%	4.2%
Infectious and Parasitic Diseases	2.2%	2.6%	1.6%
Diseases of the Nervous System and Sense Organs	1.3%	1.7%	2.4%
Diseases of the Blood and Blood-Forming Organs	0.9%	1.3%	1.4%

Table 2. Percent of Primary Discharge Diagnosis by VHA Major Diagnostic Group

\* Percent of all discharges in that year. Subgroups with at least 1% in any year are presented and ranked by Veterans with chronic HCV in CY 2008

\*\* Includes discharges for signs and symptoms including fever, shortness of breath, fainting and other symptoms requiring evaluation and observation.

\*\*\* Includes discharges related to prosthetic or orthopedic aftercare and rehabilitation.

Abbreviations: CY, calendar year; FY, fiscal year

With regard to outpatient care, depending on the local healthcare system, Veterans with chronic HCV may be seen for their HCV infection in Gastrointestinal (GI), Hepatology, Primary Care, or a combination of these clinics. Veterans with chronic HCV were actively engaged in VHA care; in 2008; 52% of Veterans had between 2 and 6 visits to GI clinic, Hepatology, or Primary Care, 20% had between 7 and 12 visits, 8% had 13 visits or more, while 20% had one visit or less (Figure 7).

Figure 7. Percent of Veterans with Chronic HCV by Number of GI, Hepatology or Primary Clinic Visits in 2008



The numbers of prescription fills for Veterans with chronic HCV were lower than those without chronic HCV. The cost of antiviral therapy and the management of associated toxicities likely results in higher overall prescription costs per Veteran with chronic HCV. This increased cost is contrasted with the potential for cost avoidance associated with prevention of progression of liver disease and early death. With new, more effective treatments for chronic HCV on the near horizon, it will be important for healthcare administrators to understand the overall cost impact of chronic HCV care over the next two decades.

Methods:

<sup>1.</sup> VHA data. The data on the entire Veteran population can be found at <u>http://www1.va.gov/vetdata</u>.

Major Diagnostic Group. The distribution of admissions by major diagnostic group was determined using the primary discharge code for each hospitalization categorized by the 17 groups created by the Classification of Diseases and Injuries version ICD-9-CM. Distribution of discharges for the National VA population is based on data from the VA's Decision Support System.

<sup>3.</sup> Outpatient Visits. Only one visit is counted for a Veteran for each clinic and date of visit even if multiple practitioners (i.e. nurse practitioner and physician) saw a given patient.

### **Chapter 4 – Other Diseases and Conditions**

#### 4.1 Other Diseases and Conditions Seen in Veterans with Chronic HCV

Concurrent health issues, or co-morbidities, add to the complex health needs of Veterans with chronic HCV. PHSHG compiles information on the rates of co-morbid conditions in Veterans with chronic HCV in VHA care both for those who have ever had the co-morbid condition and those who have a new diagnosis in the year. Understanding the number of existing and new cases of various co-morbid conditions is important for administrators preparing workload and budget projections and for providers who must assess how these conditions affect the management of HCV. For example, the level of healthcare utilization for an otherwise healthy Veteran with chronic HCV may be very different than for someone with diabetes, a substance use disorder, and depression as well as chronic HCV.

In 2008, several co-morbid conditions requiring chronic medical management were present in approximately 25% or more of the population with chronic HCV in VHA care at VHA: hypertension (63%), dyslipidemias (34%), esophageal disease (30%) and diabetes (26%). Mental illness, another important clinical condition impacting HCV care was also highly prevalent in Veterans with chronic HCV; depression (56%), neuroses or anxiety disorders (33%), and Post Traumatic Stress Disorder (PTSD) (26%). Substance use was also quite prevalent in the HCV infected Veteran population with 55% reporting a history of alcohol abuse, 39% with a history of illicit drug use and almost 62% reporting a history of tobacco use. Tobacco use will be addressed in greater detail in Section 6.5. The substantial percentage of Veterans with chronic HCV affected by co-morbid conditions highlights the need for consistent preventive care and routine monitoring. Several of these conditions can be exacerbated or caused by HCV itself and/or by HCV antiviral medications. That may be the case for the 21% of Veterans with chronic HCV with anemia and the 26% with diabetes. It may also be the case for more than half of Veterans with chronic HCV who were affected by mental illness and substance use. Of the co-morbid conditions first diagnosed for Veterans with chronic HCV in 2008, anemia and depression were among the most common. Table 3 presents the rates of co-morbid conditions first diagnosed or ever diagnosed by VHA among Veterans with chronic HCV in VHA care in 2008.

Hepatitis B co-infection was present in approximately 8% of Veterans with chronic HCV while 3.8% were known to be co-infected with HIV. The prevalence of chronic hepatitis B and HIV infection and screening rates for HIV infection are discussed in more detail in Chapter 6.

Co-morbid Condition Group	Co-morbid Condition	Percent with <i>First</i> VHA Diagnosis of Condition in 2008	Percent with VHA Diagnosis of Condition <i>Ever</i> *
Cardiovascular	Cardiomyopathy	0.3%	2.2%
	Cerebral Vascular Conditions	0.4%	2.5%
	Conduction Disorders / Dysrhythmias	1.2%	10.3%
	Congestive Heart Failure	0.8%	5.1%
	Hypertension	4.1%	63.0%
	Ischemic Heart Disease	1.2%	15.0%
Gastrointestinal	Esophageal Disease	2.6%	30.4%
	Pancreatic Disease	0.5%	4.4%
	Ulcers	0.4%	5.9%
Hematologic	Anemia	3.0%	20.5%
Liver Disease	Cirrhosis	1.9%	12.0%
	Decompensated Liver Disease	1.2%	5.3%
Malignancy	Colon / Rectum	0.2%	0.9%
	Hepatocellular Carcinoma	0.6%	1.5%
	Kidney / Renal Pelvis	0.1%	0.6%
	Leukemia	0.0%	0.3%
	Lung / Bronchus	0.3%	1.0%
	Lymphoma	0.1%	0.7%
	Melanoma of the Skin	0.0%	0.4%
	Oral Cavity / Pharynx	0.1%	0.8%
	Pancreatic	0.1%	0.1%
	Prostate	0.0%	1.1%
	Urinary Bladder	0.1%	0.5%
Mental Illness	Bipolar Disorder	0.7%	11.7%
	Depression	3.1%	56.0%
	Neuroses and Anxiety States	1.7%	33.3%
	PTSD	1.5%	25.8%
	Schizophrenia	0.3%	10.1%

Table 3. Rates of Co-morbid Conditions for Veterans with Chronic HCV in VHA Care in 2008

Co-morbid Condition Group	Co-morbid Condition	Percent with <i>First</i> VHA Diagnosis of Condition in 2008	Percent with VHA Diagnosis of Condition <i>Ever</i> *
Metabolic	Diabetes, Type I	0.1%	5.2%
	Diabetes Type II and Unspecified	2.1%	25.5%
	Dyslipidemias	3.3%	34.3%
	Male Hypogonadism	0.2%	1.0%
Pulmonary	Asthma	0.4%	6.5%
	COPD	1.8%	18.4%
	Emphysema	0.2%	2.6%
Renal	Renal Failure, Acute	1.6%	5.4%
	Renal Failure, Chronic	1.2%	6.1%
Substance Use	Alcohol Use	2.5%	54.5%
	Illicit Drug Use	1.7%	39.3%
	Other and Unspecified Drug Use	1.5%	31.6%
	Tobacco Use	4.3%	61.5%
Viral Diseases	Hepatitis B	0.5%	7.7%
	HIV Infection	0.1%	3.8%

\* Refers to the percent of those Veterans with chronic HCV in care in 2008.

#### 4.2 Cirrhosis and Associated Complications

According to the CDC, 5-20% of those infected with chronic HCV will develop cirrhosis over a period of 20 to 30 years and 1-5% will die from liver cancer or cirrhosis.<sup>1</sup> The risk of cirrhosis is further increased by alcohol use. Based on the epidemiology of HCV in the US and age of Veterans with chronic HCV, the majority of Veterans with chronic HCV in VHA care in recent years were likely infected during the Vietnam War era (1964 – 1975). Given the natural history of chronic HCV, one would expect to see increasing numbers of conditions related to progression of liver disease including cirrhosis.

Cirrhosis is an important cause of morbidity and mortality in HCV disease and represents the end stage of chronic liver disease. The main complications of cirrhosis are related to the development of liver insufficiency and portal hypertension and include ascites, variceal hemorrhage, jaundice, hepatic encephalopathy, and hepatorenal and hepatopulmonary syndromes. Once a patient with cirrhosis develops signs of decompensation, duration of survival is significantly reduced.<sup>2,3</sup> Given that many patients with liver disease are asymptomatic for a long period of time, it is very difficult to accurately establish its prevalence and incidence both in the general population and among Veterans. Nevertheless, in 2006, chronic liver disease and cirrhosis was the 12<sup>th</sup> leading cause of death in the U.S.<sup>4</sup> To understand the prevalence and impact of cirrhosis and its associated complications, PHSHG reports on Veterans with new diagnoses of cirrhosis (first VHA diagnosis in the year) and Veterans with existing diagnoses of cirrhosis (ever had a diagnosis of cirrhosis) (Figure 8).

Figure 8. Number and Percent of Veterans with Chronic HCV with First and Existing Diagnosis of Cirrhosis in VHA care



In 2008, there were over 19,000 Veterans with chronic HCV in VHA care who also had a diagnosis of cirrhosis ever, representing 13% of Veterans with chronic HCV in care. At the VISN level, the caseload of Veterans with chronic HCV *and* cirrhosis ever ranged from 364 to 1,950 (Table 4) and percentage of Veterans with chronic HCV *and* cirrhosis ever ranged from 9% to 19%. At the local healthcare system level, the comparable caseload ranged from 1 to 683 cases and the comparable percentage ranged from 4% to 30%.

	Number in Care	# in VHA Care with First Diagnosis of Cirrhosis	# in VHA Care with Diagnosis of Cirrhosis Ever
Nation	147,352	3,061	19,012
VISN (number)	I		
VA New England Healthcare System (1)	5,126	107	778
VA Healthcare Network Upstate New York (2)	2,480	42	364
VA NY/NJ Veterans Healthcare Network (3)	6,952	128	808
VA Healthcare (4)	7,745	177	1,136
VA Capitol Health Care Network (5)	6,281	87	539
VA Mid-Atlantic Health Care Network (6)	8,164	176	1,164
VA Southeast Network (7)	9,583	205	1,231
VA Sunshine Healthcare Network (8)	13,392	304	1,950
VA Mid South Healthcare Network (9)	6,933	136	903
VA Healthcare System of Ohio (10)	5,170	111	689
Veterans in Partnership (11)	7,003	141	812
VA Great Lakes Health Care System (12)	5,913	108	751
VA Heartland Network (15)	5,384	100	700
South Central VA Health Care Network (16)	14,019	264	1,565
VA Heart of Texas Health Care Network(17)	6,313	218	1,207
VA Southwest Health Care Network (18)	6,703	153	999
Rocky Mountain Network (19)	4,046	82	490
Northwest Network (20)	8,607	196	1,282
Sierra Pacific Network (21)	8,670	173	1,194
Desert Pacific Healthcare Network (22)	10,899	240	1,296
VA Midwest Health Care Network (23)	5,126	107	608

Table 4. Diagnoses of Cirrhosis in Veterans with Chronic HCV in VHA Care in 2008

The percentage of cases of cirrhosis in Veterans with chronic HCV has increased by one to two percentage points per year over the past 8 years. Work by the PHSHG to prepare VHA for this increasing caseload of Veterans with cirrhosis is underway. Resources for these Veterans, ranging from materials on screening for hepatocellular carcinoma (see Section 4.3) to

pre- and post- liver transplant care will need to be increased to meet future demand. Materials for both clinicians and Veterans can be found at <u>http://www.hepatitis.va.gov</u>.

#### 4.3 Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) accounts for 80-90% of all liver cancers, is more common in men than women and currently is generally seen in those between the ages of 50 and 60. Annually, approximately 1% to 2% of persons with chronic HCV and cirrhosis develop HCC. The incidence of HCC in the US as well as in the VHA has been increasing and this is likely due to the large pool of people with longstanding HCV infection.<sup>5</sup> Over 4,824 cases of HCC were diagnosed in Veterans with chronic HCV between 2000 through 2008. The number of new diagnoses, the number receiving ongoing care, and the cumulative number of cases recorded in VHA are presented in Figure 9.



Figure 9. HCC Cases in Veterans with Chronic HCV in VHA Care

The cumulative number of new HCC diagnoses continues to increase at a rate that exceeds the increase in patients receiving ongoing care for their chronic HCV and HCC. The divergence of these trends is mainly due to limited treatment options for HCC, resulting in a one-year survival rate of less than 50%.<sup>6</sup> Additional information on screening for HCC can be found in Section 6.6.

In 2008, new cases of HCC among Veterans with chronic HCV were diagnosed in all VISNs and in all but 10 of the 128 local healthcare systems. One and a half percent (1.5%) of all

Veterans with chronic HCV in VHA care in 2008 had been diagnosed with HCC (see table 3). PHSHG is working on a number of initiatives to assist VHA clinicians in screening, diagnosing and treating HCC. One particular area of future quality assessment for the PHSHG is to understand access to HCC treatment given the need to coordinate Hepatology, Diagnostic Radiology, Interventional Radiology, Oncology, Surgery, Liver Transplant, and Palliative care activities.

#### Methods:

- 1. Diagnosis. For the analysis of co-morbid conditions, cirrhosis, and HCC, a Veteran is considered to have a diagnosis if he or she had at least one diagnosis (ICD-9) from an admission (of any rank) or from two outpatient encounters occurring on separate dates. For more information, contact the PHSHG. In the case of outpatient coding, if the two dates were in different years, then the condition is recorded as first ever in the earlier year.
- 2. Cirrhosis. Includes ICD-9 codes for cirrhosis and complications associated with this chronic condition (esophageal varices, spontaneous bacterial peritonitis, hepatic coma, portal hypertension, hepatorenal syndrome).

#### References:

- 1. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#section1, viewed March 23, 2009.
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- 5. Davila JA, Morgan RO, Shaib Y, McGlynn KA, El-Serag HB Hepatitis C infection and the increasing incidence of hepatocellular carcinoma: a population-based study.Gastroenterology. 2004 Nov;127(5):1372-80.
- 6. Cabibbo G, Enea M, Attanasio M, Bruix J, Craxì A, Cammà C. A meta-analysis of survival rates of untreated patients in randomized clinical trials of hepatocellular carcinoma. Hepatology. 2010, Apr; 51(4): 1274-83]

## **Chapter 5 – Antiviral Therapy for Chronic HCV**

The current standard of pharmacologic treatment of chronic HCV, which received Food and Drug Administration (FDA) approval in 2001, consists of weekly subcutaneous pegylated interferon injections in combination with daily oral ribavirin. This therapy is typically completed in 24 to 48 weeks, although shorter or longer durations are sometimes indicated. The duration of therapy is determined by the HCV genotype and, increasingly, by the patient's virologic response during therapy. Infections due to genotype 1 HCV strains (the most common genotype among Veterans with chronic HCV in VHA care) require longer durations of therapy and are associated with lower response rates. In cases where poor adherence, lack of tolerance, or early treatment failure is detected, Veterans may not complete a full treatment course. Therapy may need to be repeated in cases of virologic failure after treatment discontinuation or in the rare occurrence of re-infection with HCV.

Historically, the FDA-approved treatment options for chronic HCV have included interferon monotherapy, interferon plus ribavirin, pegylated interferon monotherapy, consensus interferon, and the current combination of pegylated interferon plus ribavirin. All FDA-approved alfa-interferon products, including pegylated interferon products, and ribavirin have been included on the national VHA formulary and are currently available to Veterans with chronic HCV. Figure 10 shows the cumulative use of these agents between 2000 and 2008.



Figure 10. Cumulative Number of Veterans with Chronic HCV with HCV Antivirals

Through the end of 2008, over 31,500 Veterans with chronic HCV had received at least one course of HCV treatment at VHA, including 21% of those in VHA care in 2008 (Figure 11). The number of those in VHA care who received their first ever HCV antiviral treatment regimen increased 2.5-fold from 1,367 in 2000 to 3,393 in 2008. The same magnitude of increase was seen in overall caseload on therapy, which increased from 2,402 in 2000 to 6,325 in 2008. Figure 11. Number and Percent of Veterans with Chronic HCV in VHA Care Treated with HCV Antivirals



Across VISNs, the percentage of Veterans with chronic HCV who ever received HCV antiviral therapy ranged from 16% to 31% (Table 5). Some Veterans with chronic HCV may not be candidates for antiviral treatment. Though general guidelines exist on treatment considerations for HCV infected patients, most treatment decisions continue to be individualized.<sup>1,2</sup> Factors which may prevent Veterans from receiving HCV antiviral therapy include low blood cell counts, advanced cirrhosis, or the presence of certain medical conditions or mental health conditions, including ongoing substance abuse. Alternatively, because response rates to the currently available treatments are less than ideal (see Section 6.8) and because the medications are poorly tolerated, clinicians and patients may postpone treatment until newer, more effective agents become available. Newer agents for the treatment of HCV that significantly increase response rates are expected to become available in 2011 and will likely be used in combination with pegylated interferon and ribavirin. PHSHG is exploring various models of care delivery in anticipation of the increased demand for newer HCV antiviral treatments.

	Number in Care	Number Receiving HCV Antivirals In 2008	Number Ever Receiving HCV Antivirals from VHA
Nation	147,352	6,325	31,541
VISN (number)			
VA New England Healthcare System (1)	5,126	315	1,589
VA Healthcare Network Upstate New York (2)	2,480	115	556
VA NY/NJ Veterans Healthcare Network (3)	6,952	224	1,228
VA Healthcare (4)	7,745	404	1,762
VA Capitol Health Care Network (5)	6,281	269	1,160
VA Mid-Atlantic Health Care Network (6)	8,164	422	1,839
VA Southeast Network (7)	9,583	344	1,634
VA Sunshine Healthcare Network (8)	13,392	517	3,289
VA Mid South Healthcare Network (9)	6,933	287	1,584
VA Healthcare System of Ohio (10)	5,170	223	1,105
Veterans in Partnership (11)	7,003	261	1,358
VA Great Lakes Health Care System (12)	5,913	190	1,326
VA Heartland Network (15)	5,384	225	1,397
South Central VA Health Care Network (16)	14,019	596	2,977
VA Heart of Texas Health Care Network (17)	6,313	278	1,304
VA Southwest Health Care Network (18)	6,703	317	1,657
Rocky Mountain Network (19)	4,046	131	773
Northwest Network (20)	8,607	353	1,508
Sierra Pacific Network (21)	8,670	486	1,963
Desert Pacific Healthcare Network (22)	10,899	472	1,690
VA Midwest Health Care Network (23)	4,235	183	1,200

Table 5. Number of Veterans with Chronic HCV in VHA care in 2008, the Number Receiving HCV Antivirals in 2008, and the Number that Ever Received HCV Antivirals from VHA by VISN

Table 5 also shows the number and percent of Veterans with chronic HCV in VHA care by VISN who received antiviral therapy in 2008. Regardless of HCV caseload, in each VISN close to 4% of Veterans with chronic HCV were on antiviral therapy that year. In 2007, PHSHG led a survey of local healthcare system HCV providers that included questions to assess local antiviral treatment management. Findings from this VA-wide survey of HCV clinicians indicate that multiple issues related to patient characteristics (e.g., ongoing substance abuse), clinician and facility factors (e.g., staff turnover) may influence the numbers of patients on antiviral therapy. Information learned from this survey has and will be incorporated into educational and training initiatives that include expanding antiviral therapy where indicated and appropriate. Engaging and maintaining Veterans in HCV care and discussing available treatment options, including risks versus benefits, remain important objectives within VHA.

#### Methods:

References:

<sup>1.</sup> HCV antiviral therapy – All FDA approved medications are included in this report. Medication use is reported from the VHA outpatient prescription files.

<sup>1.</sup> Yee HS, Currie SL, Darling JM, Wright TL. Management and treatment of hepatitis C viral infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center program and the National Hepatitis C Program office. Am J Gastro 2006; 101:2360-2378.

<sup>2.</sup> Ghany MG, Strader DB, Thomas DL, Seeff LB. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology 2009. 49: 1335-1374.

## **Chapter 6 – Assessing Quality of Care in Veterans with Chronic HCV**

In 2006, PHSHG began drawing on data from the CCR to construct measures for selected clinical topics important in caring for Veterans with chronic HCV. These measures were developed using existing treatment recommendations and clinical practice guidelines from the PHSHG and from professional societies. The following clinical topics have been used to assess the quality of care delivered to Veterans with chronic HCV in VHA care: confirmation of chronic HCV, hepatitis A and B screening and vaccination, HIV testing, influenza vaccination, and tobacco cessation pharmacologic treatment. In addition, rates of screening for HCC among Veterans with chronic HCV and cirrhosis and of non-selective beta-blocker use in Veterans with chronic HCV hospitalized with esophageal variceal hemorrhage were assessed. Sustained virologic response rates were assessed for Veterans with chronic HCV treated with pegylated interferon and ribavirin. To permit assessment of trends over time, data on each clinical topic are presented for the years 2000 through 2008 where available.

Although the majority of the data are complete and accurate, these quality measures are limited by data quality. Data not captured by the EMR, captured in a non-standard fashion, or using non-standard terms is not available for CCR based assessments and may lead to underestimates of performance. VHA providers who document diagnoses, outside VHA medications, and other activities only within progress notes, will not have that information counted in a report such as this one. These data limitations impact our care ascertainment and should be kept in mind while reading this chapter.

#### 6.1 Confirming Chronic HCV Infection.

Blood tests for HCV antibodies were first approved by the FDA in 1992. HCV viral load testing for chronic infection became available a few years later. While national HCV antibody or viral load testing rates in all Veterans in VHA care over time are not available, we can observe the uptake of both HCV antibody and viral load testing among Veterans in the CCR (Figure 12).



Figure 12. Cumulative Number of Veterans in the CCR Tested for HCV Antibodies and Viral Load.

Since up to 20% of all persons infected with HCV will naturally clear active viral disease, a HCV viral load test is required to assess the presence of chronic infection.<sup>1</sup> The percent of Veterans in the CCR with a positive HCV antibody test result who had HCV viral load testing has increased from 81% in 2000 to 89% in 2008 (Figure 13).



Figure 13. Percent of Veterans in the CCR with a Positive HCV Antibody Test who had HCV Viral Load Testing

To address the remaining gap in testing for chronic hepatitis C infection, PHSHG has established a policy requiring "reflex testing" or the completion of screening and confirmatory testing, including tests for chronic infection with a single blood draw. This policy and others developed by the PHSHG can be found at <u>http://www.hepatitis.va.gov</u>.

#### 6.2 Hepatitis A and Hepatitis B Infection

Many patients who have acquired HCV infection may be at risk for acquiring hepatitis A or B, both of which are preventable diseases. These patients could benefit from effective hepatitis A and hepatitis B vaccination. Screening for hepatitis A and B and subsequent vaccination, if indicated, is important in providing comprehensive HCV medical care and is recommended by the Advisory Committee on Immunization Practices (ACIP).<sup>2,3</sup> VHA guidelines on the management and treatment of hepatitis C infection published in 2006 recommend testing for hepatitis A and B in all Veterans with chronic HCV to evaluate for past infection with hepatitis A and hepatitis B, chronic hepatitis B infection and to assess the need for hepatitis A and/or B immunization.<sup>4</sup> In 2007, the VHA began reporting the number of HCV infected Veterans who were vaccinated against hepatitis A and hepatitis B where there was no evidence of chronic hepatitis B or past exposure to hepatitis A or hepatitis B. PHSHG also measures the overall rate of screening for immunity to these two viral diseases; however this information is not routinely posted online.

#### Hepatitis A

The overall rates of screening for immunity to hepatitis A increased from 33% to 76% among Veterans with chronic HCV in VHA care between 2000 and 2008. Over this period, Veterans with chronic HCV without documented immunity to hepatitis A were vaccinated at increasing rates, from 20% in 2000 to 53% in 2008. In addition, an increasing number of Veterans with chronic HCV were vaccinated for hepatitis A without testing for hepatitis A immunity; in 2008, 24% of those without hepatitis A antibody testing received a hepatitis A vaccination. Together, the percent of Veterans with chronic HCV immune to or vaccinated against hepatitis A increased from 18% to 65% between 2000 and 2008 (Figure 14).



Figure 14. Rates of Hepatitis A Antibody Testing and Vaccination in Veterans with Chronic HCV

Twelve VISNs had documented testing rates of 75% or more for hepatitis A antibodies in 2008. In two VISNs, at least 75% of Veterans with chronic HCV in VHA care in 2008 had documented immunity to or were vaccinated against hepatitis A. Table 6 provides VISN level data for hepatitis A immunity/vaccination for 2008.

#### <u>Hepatitis B</u>

While the overall rates of screening for past exposure to hepatitis B were higher than hepatitis A, screening rates for hepatitis B, like those for hepatitis A, increased between 2000 (59%) and 2008 (89%). Veterans with chronic HCV not found immune to or chronically infected with hepatitis B were vaccinated at increasing rates, from 21% in 2000 to 48% in 2008. In addition, an increasing number of Veterans with chronic HCV were vaccinated without testing for hepatitis B immunity; 15% of those without hepatitis B antibody testing received a hepatitis vaccination. Together, the percent of Veterans with chronic HCV immune to or vaccinated against hepatitis B increased from 39% in 2000 to 70% in 2008 (Figure 15).



Figure 15. Rates of Hepatitis B Antibody Testing and Vaccination in Veterans with Chronic HCV

All VISNs had documented testing rates for hepatitis B antibodies higher than 75%. In six VISNs, at least 75% of their Veterans with chronic HCV in VHA care in 2008 had documented immunity to or were vaccinated against hepatitis B (Table 6).

Table 6. Hepatitis A and Hepatitis B Immunity and Vaccination Rates in Veterans with Chronic HCV in VHA Care in 2008

	Number in Care	Percent with VHA HAV Immunity or Vaccine	Percent with VHA HBV Immunity or Vaccine*
Nation	147,352	65%	70%
VISN (number)	•		·
VA New England Healthcare System (1)	5,126	66%	75%
VA Healthcare Network Upstate New York (2)	2,480	57%	73%
VA NY/NJ Veterans Healthcare Network (3)	6,952	59%	82%
VA Healthcare (4)	7,745	71%	78%
VA Capitol Health Care Network (5)	6,281	76%	83%
VA Mid-Atlantic Health Care Network (6)	8,164	64%	71%
VA Southeast Network (7)	9,583	54%	59%

	Number in Care	Percent with VHA HAV Immunity or Vaccine	Percent with VHA HBV Immunity or Vaccine*
Nation	147,352	65%	70%
VISN (number)			1
VA Sunshine Healthcare Network (8)	13,392	67%	72%
VA Mid South Healthcare Network (9)	6,933	61%	64%
VA Healthcare System of Ohio (10)	5,170	58%	67%
Veterans in Partnership (11)	7,003	57%	63%
VA Great Lakes Health Care System (12)	5,913	60%	70%
VA Heartland Network (15)	5,384	64%	64%
South Central VA Health Care Network (16)	14,019	62%	65%
VA Heart of Texas Health Care Network (17)	6,313	77%	77%
VA Southwest Health Care Network (18)	6,703	61%	64%
Rocky Mountain Network (19)	4,046	66%	66%
Northwest Network (20)	8,607	71%	73%
Sierra Pacific Network (21)	8,670	82%	77%
Desert Pacific Healthcare Network (22)	10,899	67%	77%
VA Midwest Health Care Network (23)	4,235	53%	61%

\* Percent is calculated among Veterans with chronic HCV in VHA care eligible to HBV vaccine and excludes those Veterans co-infected with hepatitis B. Abbreviations: HAV, hepatitis A virus; HBV, hepatitis B virus

For Veterans with chronic HCV in 2008, the national rate of co-infection with chronic hepatitis B in those who were assessed for HBV status (70%) was approximately 8% (as indicated by a VHA laboratory record of positive hepatitis B surface or 'e' antigen or detectable hepatitis B viral load).

As evidenced by the wide variation in rates observed among VISNs , improved screening and vaccination for hepatitis A and B deserves attention. Efforts to educate primary care and substance use providers on the recommendations and benefits of hepatitis A and B

screening and vaccination should be undertaken as one means to improve these rates. The significant number of Veterans who received vaccination without the determination of immune status may be due to the co-formulation of hepatitis A and B in a single vaccine product and to questions regarding the cost effectiveness of hepatitis A screening relative to vaccine cost and risk of vaccination. VHA providers might benefit from a cost benefit analysis of this issue.

#### 6.3 HIV Testing

Several national guidelines, including those from the American Association for the Study of Liver Diseases (AASLD) and the VHA Hepatitis C Resource Center Program and National Hepatitis C Program Office, recommend that all HCV infected patients be tested for HIV infection.<sup>4,5</sup> HCV and HIV co-infection increases the risk of HCV-related liver damage, can lengthen the duration of HCV therapy in HCV genotype 2 and 3, and lowers HCV treatment response rates. Thus the need for HIV diagnosis and treatment in these individuals is high.

In 2008, 56% of Veterans with chronic HCV in VHA care had been tested for HIV infection, an increase from 39% in 2000. (Figure 16). In 2008, the highest HIV testing rate at any VISN was 71%. Five VISNs had HIV testing rates in Veterans with chronic HCV less than 50% (Table 7). More than 5,800 Veterans with chronic HCV in VHA care in 2008 have been identified as HIV positive.



Figure 16. Maximum and Minimum HIV Testing Rates in Veterans with Chronic HCV over Time by VISN

	Number in Care	Percent with VHA HIV Test Ever
Nation	147,352	56%
VISN (number)		1
VA New England Healthcare System (1)	5,126	53%
VA Healthcare Network Upstate New York (2)	2,480	56%
VA NY/NJ Veterans Healthcare Network (3)	6,952	65%
VA Healthcare (4)	7,745	53%
VA Capitol Health Care Network (5)	6,281	68%
VA Mid-Atlantic Health Care Network (6)	8,164	71%
VA Southeast Network (7)	9,583	53%
VA Sunshine Healthcare Network (8)	13,392	60%
VA Mid South Healthcare Network (9)	6,933	53%
VA Healthcare System of Ohio (10)	5,170	53%
Veterans in Partnership (11)	7,003	49%
VA Great Lakes Health Care System (12)	5,913	52%
VA Heartland Network (15)	5,384	46%
South Central VA Health Care Network (16)	14,019	57%
VA Heart of Texas Health Care Network (17)	6,313	66%
VA Southwest Health Care Network (18)	6,703	47%
Rocky Mountain Network (19)	4,046	45%
Northwest Network (20)	8,607	46%
Sierra Pacific Network (21)	8,670	58%
Desert Pacific Healthcare Network (22)	10,899	64%
VA Midwest Health Care Network (23)	4,235	48%

Table 7. HIV Testing Rates in Veterans with Chronic HCV in VHA Care in 2008

Although emphasis has been placed on HIV testing for Veterans with HCV, testing rates remain low. PHSHG believes that this is due in part to the historical barriers requiring written informed consent for HIV testing in VHA. As of August 2009, Federal law and regulations were changed and VHA policy updated replacing the requirement written informed consent for HIV testing for all veterans not just those with identifiable risk factors for HIV. With these policy changes in place, PHSHG has begun a broad campaign to increase HIV testing among Veterans in VHA care, in collaboration with VHA stakeholders in primary care, mental health, medicine, nursing, women's health, and other disciplines.

#### 6.4 Influenza Vaccination

Each year, VHA conducts a nationwide campaign to maximize influenza vaccination among Veterans and healthcare providers. The VHA bases the influenza vaccination program on recommendations of the U.S. Advisory Committee on Immunization Practices (ACIP). One target group for annual influenza vaccination in these recommendations has been persons with chronic liver disease.<sup>6</sup> Forty-six percent of Veterans with chronic HCV in VHA care during the 2007/2008 influenza season had documentation that they received an influenza vaccination from VHA. This percentage represents an increase over previous influenza vaccination campaigns; vaccination rates of 28%, 37% and 40% were observed in 2001/2002, 2003/2004, and 2005/2006, respectively. Across VISNs, the documented rate of influenza vaccination in 2007/2008 for Veterans with chronic HCV ranged from 37% to 59% (Table 8).

	Number Eligible for Influenza Vaccination	Percent with VHA Influenza Vaccine during 2007/2008 Influenza Season
Nation	138,146	46%
VISN (number)		
VA New England Healthcare System (1)	4,791	45%
VA Healthcare Network Upstate New York (2)	2,352	45%
VA NY/NJ Veterans Healthcare Network (3)	6,340	50%
VA Healthcare (4)	7,119	53%

Table 8: Influenza Vaccination Rates in Veterans with Chronic HCV in VHA Care in 2007/2008 Influenza Season

	Number Eligible for Influenza Vaccination	Percent with VHA Influenza Vaccine during 2007/2008 Influenza Season
Nation	138,146	46%
VISN (number)		
VA Capitol Health Care Network (5)	5,801	54%
VA Mid-Atlantic Health Care Network (6)	7,592	50%
VA Southeast Network (7)	8,784	50%
VA Sunshine Healthcare Network (8)	12,365	48%
VA Mid South Healthcare Network (9)	6,355	43%
VA Healthcare System of Ohio (10)	4,847	37%
Veterans in Partnership (11)	6,595	42%
VA Great Lakes Health Care System (12)	5,479	48%
VA Heartland Network (15)	5,078	50%
South Central VA Health Care Network (16)	13,005	45%
VA Heart of Texas Health Care Network (17)	5,837	59%
VA Southwest Health Care Network (18)	6,138	44%
Rocky Mountain Network (19)	3,705	47%
Northwest Network (20)	7,908	42%
Sierra Pacific Network (21)	8,013	45%
Desert Pacific Healthcare Network (22)	10,003	42%
VA Midwest Health Care Network (23)	3,949	46%

Influenza vaccination rates documented in the EMR and thus generated from the CCR likely underestimate the number of Veterans with chronic HCV actually vaccinated. VHA providers may not consistently document that a Veteran received influenza vaccination outside of VHA (such as in a community program or pharmacy) or may not document it in a standard manner that is accessible to the CCR. VHA assesses national influenza vaccination rates by age group (50-64 years and 65 years and older) and Veterans with spinal cord injury (SCI) through an

automated and manual electronic medical record audit performed at each local healthcare system and reports on Veterans in these groups.<sup>7</sup> The documented national rate of influenza vaccination for those 50 – 64 years old, those 65 and older, and those with an SCI for the 2008/2009 influenza vaccination period were 69%, 83% and 80%, respectively. These national influenza vaccination rates for Veterans who meet ACIP guidelines for vaccination were higher than the 46% observed in Veterans with chronic HCV, one other group recommended by ACIP to receive influenza vaccination.

#### 6.5 Tobacco Cessation

Tobacco dependence is prevalent among Veterans with chronic HCV. Sixty-two percent of these Veterans had a diagnosis of tobacco use at some time while in VHA care, and 37% had a current diagnosis of tobacco dependence in 2008, which was substantially higher than the 22% prevalence in the overall Veteran population and the 21% prevalence in the general population.<sup>8</sup>

The 2008 Update of the *Public Health Service Clinical Practice Guideline: Treating Tobacco Use and Dependence* states that it is essential for clinicians and healthcare delivery systems to consistently identify and document tobacco use status and provide tobacco cessation treatment to every tobacco user seen in a healthcare setting. Just over 46% of Veterans with chronic HCV who had a VHA diagnosis of tobacco use had ever received a medication to treat tobacco dependence, and 20% received tobacco cessation medications in 2008. VISN rates for cessation treatment in 2008 ranged between 13% and 29% (Table 9). Additional work is needed to determine how to assist VHA healthcare providers and Veterans with chronic HCV in managing tobacco dependence.

	Number in Care	Percent with VHA Diagnosis of Tobacco Use Ever	Percent with VHA Diagnosis of Tobacco Use in 2008	Percent with VHA Pharmaco- therapy Ever	Percent with VHA Pharmaco- therapy in 2008
Nation	147,352	62%	37%	46%	20%
VISN (number)					
VA New England Healthcare System (1)	5,126	64%	41%	54%	26%

 Table 9. Tobacco Use and Pharmacotherapy Rates in Veterans with Chronic HCV in VHA Care in 2008

	Number in Care	Percent with VHA Diagnosis of Tobacco Use Ever	Percent with VHA Diagnosis of Tobacco Use in 2008	Percent with VHA Pharmaco- therapy Ever	Percent with VHA Pharmaco- therapy in 2008
Nation	147,352	62%	37%	46%	20%
VISN (number)					
VA Healthcare Network Upstate New York (2)	2,480	68%	42%	50%	22%
VA NY/NJ Veterans Healthcare Network (3)	6,952	52%	30%	42%	19%
VA Healthcare (4)	7,745	61%	38%	52%	19%
VA Capitol Health Care Network (5)	6,281	56%	32%	51%	22%
VA Mid-Atlantic Health Care Network (6)	8,164	61%	38%	46%	21%
VA Southeast Network (7)	9,583	61%	35%	48%	22%
VA Sunshine Healthcare Network (8)	13,392	59%	36%	41%	18%
VA Mid South Healthcare Network (9)	6,933	63%	38%	45%	20%
VA Healthcare System of Ohio (10)	5,170	76%	50%	53%	23%
Veterans in Partnership (11)	7,003	65%	41%	48%	20%
VA Great Lakes Health Care System (12)	5,913	66%	42%	50%	23%
VA Heartland Network (15)	5,384	66%	41%	50%	22%
South Central VA Health Care Network (16)	14,019	64%	36%	49%	20%
VA Heart of Texas Health Care Network(17)	6,313	56%	31%	45%	18%
VA Southwest Health Care Network (18)	6,703	65%	38%	41%	16%
Rocky Mountain Network (19)	4,046	63%	40%	50%	23%
Northwest Network (20)	8,607	66%	41%	52%	21%
Sierra Pacific Network (21)	8,670	62%	39%	44%	18%
Desert Pacific Healthcare Network (22)	10,899	55%	31%	35%	13%

	Number in Care	Percent with VHA Diagnosis of Tobacco Use Ever	Percent with VHA Diagnosis of Tobacco Use in 2008	Percent with VHA Pharmaco- therapy Ever	Percent with VHA Pharmaco- therapy in 2008
Nation	147,352	62%	37%	46%	20%
VISN (number)					
VA Midwest Health Care Network (23)	4,235	68%	44%	60%	29%

## 6.6 Screening for Hepatocellular Carcinoma in Veterans with Chronic HCV and Cirrhosis

The VHA Hepatitis C Practice Recommendations recommend screening patients with HCV and cirrhosis for hepatocellular carcinoma (HCC) using alpha-fetoprotein (AFP) and abdominal imaging every six to twelve months.<sup>9</sup> The annual rate of VHA screening with *both* AFP and imaging in Veterans with chronic HCV and cirrhosis increased from 29% in 2000 to 45% in 2008. The annual rates for AFP alone and for imaging studies alone remained relatively stable at approximately 11% each over these years (Figure 17). Data from the CCR does not allow differentiation of tests performed specifically for screening for HCC from tests performed for other reasons. The sum of rates for any type of screening test (either AFP or imaging or both) performed increased from 54% to 68% from 2000 to 2008.



Figure 17. Rates of AFP Testing and/or Abdominal Imaging in Veterans with Chronic HCV and Cirrhosis

In 2008, the percentage of Veterans with chronic HCV and cirrhosis receiving both an AFP and abdominal imaging ranged across VISNs from 35% to 60% (Table 10). Four VISNs provided both tests to at least 50% of such Veterans.

	Number with Cirrhosis in Care	Percent with AFP Only	Percent with Imaging Only	Percent with Both	Percent with Either
Nation	16,014	11%	12%	45%	67%
VISN (number)				1	
VA New England Healthcare System (1)	676	9%	10%	45%	64%
VA Healthcare Network Upstate New York (2)	322	13%	15%	35%	63%
VA NY/NJ Veterans Healthcare Network (3)	680	13%	10%	47%	70%
VA Healthcare (4)	963	10%	13%	48%	71%
VA Capitol Health Care Network (5)	453	12%	10%	46%	68%
VA Mid-Atlantic Health Care Network (6)	994	10%	8%	57%	75%
VA Southeast Network (7)	1,033	9%	15%	40%	64%
VA Sunshine Healthcare Network (8)	1,651	12%	12%	49%	73%
VA Mid South Healthcare Network (9)	768	9%	18%	41%	68%
VA Healthcare System of Ohio (10)	581	12%	12%	38%	62%
Veterans in Partnership (11)	678	11%	14%	41%	66%
VA Great Lakes Health Care System (12)	646	11%	14%	41%	66%
VA Heartland Network (15)	602	10%	12%	48%	70%
South Central VA Health Care Network (16)	1,304	12%	11%	43%	66%
VA Heart of Texas Health Care Network(17)	990	12%	8%	55%	75%
VA Southwest Health Care Network (18)	846	11%	12%	38%	61%

 Table 10. Percent of Veterans with Chronic HCV with Cirrhosis in VHA Care in 2008 Who Were

 Screened for Hepatocellular Carcinoma

	Number with Cirrhosis in Care	Percent with AFP Only	Percent with Imaging Only	Percent with Both	Percent with Either
Nation	16,014	11%	12%	45%	67%
VISN (number)					
Rocky Mountain Network (19)	413	7%	16%	48%	71%
Northwest Network (20)	1,091	8%	12%	43%	63%
Sierra Pacific Network (21)	1,023	13%	9%	51%	73%
Desert Pacific Healthcare Network (22)	1,059	12%	12%	46%	70%
VA Midwest Health Care Network (23)	512	6%	8%	60%	74%

Though room for further improvement exists, HCC screening efforts have improved over the past eight years. During this time, VHA has focused on educating providers to increase their awareness of the importance of HCC screening.

As described above, the prevalence of advanced liver disease, including cirrhosis, has increased to 13% of chronic HCV Veteran patients in care. VHA leadership should be aware of the workload impact of full adherence to the HCC screening guidelines and the likelihood for increased utilization of VHA health care resources with the increase in the number of Veterans with chronic HCV, cirrhosis, and HCC.

## 6.7 Use of Non-Selective Beta Blockers in Veterans with Chronic HCV Admitted with Esophageal Variceal Hemorrhage

Esophageal varices are present in about 50% of cirrhotic patients and the presence of esophageal varices correlates with the severity of liver disease.<sup>10</sup> Patients with esophageal varices develop variceal hemorrhage at a rate of about 12% to 15% per year. The mortality rate associated with each episode of esophageal variceal hemorrhage (EVH) is approximately 15% to 20%.<sup>10</sup> Hence, one of the main prophylactic measures in the care of a patient with cirrhosis is the prevention of the first EVH (primary prophylaxis).

Two therapies are currently accepted for the prevention of the first EVH: non-selective beta-blockers (NSBBs) and endoscopic variceal ligation. In patients with esophageal varices, NSBBs (propranolol and nadolol) have been shown to significantly reduce the incidence of first

EVH and mortality. In patients with small varices that are not at a high risk of hemorrhage, NSBBs have been effective in delaying variceal growth, and thereby preventing EVH.

The VHA Hepatitis C Resource Centers currently recommend use of NSBBs in patients with cirrhosis who have medium or large varices to prevent primary and recurrent EVH.<sup>10</sup> PHSHG reports on the use of NSBBs in Veterans with chronic HCV who were discharged from a VHA hospital with a first diagnosis of EVH. For this population, PHSHG assesses whether the Veterans were receiving NSBBs 120 days prior to the admission, during that hospital stay, at the time of discharge, and at 180 days after discharge. Because NSBBs are contraindicated in some patient (for example, due to asthma and lack of tolerance), this population includes some Veterans for whom NSBBs would not be prescribed. From 2000 to 2006, the most recent period with data available for this analysis, the number of Veterans admitted for their first EVH in VHA care increased from 328 to 690. The percent of Veterans with chronic HCV in care with a first EVH increased from 0.29% in 2000 to 0.46% in 2006.

As mentioned above, there is significant mortality following an EVH. Figure 18 shows the percent of Veterans with chronic HCV alive at discharge and 180 days following first admission for EVH. Nationally, there was no change between 2000 and 2006 in the percentage alive at hospital discharge while the percent alive 180 days after discharge declined from 81% in 2000 to 71% in 2006.



Figure 18. Percentage of Veterans with Chronic HCV Alive Following First Admission for EVH

Among Veterans with chronic HCV, the rates of NSBBs use prior to, during, and following admission for a first EVH from 2000 through 2006 are shown in Figure 19. Rates of NSSB use were highest during the hospital stay. Between 2000 and 2006, rates of NSBB use increased before, during, and after admission. During this period, NSBB use increased from 21% to 29% prior to the first admission for variceal hemorrhage and from 49% to 57% during the stay. In 2000, 37% of Veterans with chronic HCV with a first EVH were discharged with a prescription for a NSBB, compared with 41% in 2006. The percent of those on a NSBB at 180 days after such a hospital discharge increased from 38% to 46% between 2000 and 2006.

Figure 19. Rates of NSBB Use Prior to Admission, During Hospitalization, and Following a First Admission for EVH in Veterans with Chronic HCV



Across VISNs, the number of VHA admissions for first EVH in 2006 ranged from 7 (VISN 2) to 59 (VISNs 8 and 20). Across VISNs with at least 10 cases, the rate of NSBB use prior to the admission for first EVH in Veterans with chronic HCV ranged from minimum of 19% to a maximum of 43%, while the NSBB rate during such hospitalizations ranged from 41% to 75% (Figure 20 and Table 11).



Figure 20. Maximum and Minimum VISN Rates for NSBB Use by VISN in Veterans with Chronic HCV and First Admission for EVH in 2006

Table 11. Use of Non-Selective Beta Blockers (NSBB) in Veterans with Chronic HCV Hospitalized with First Esophageal Variceal Hemorrhage (EVH) in 2006

VISN Number	Number with EVH Admission	Percent on NSBB prior to Admission	Percent on NSBB During Admission	Number Alive at Discharge	Percent on NSBB at Discharge	Number Alive 180 Days after Discharge	Percent on NSBB on 180 Days after Discharge
National	690	29%	55%	629	37%	492	46%

VISN Number	Number with EVH Admission	Percent Receiving NSBB During 120 Days Before Admission	Percent Receiving NSBB During Inpatient Stay	Number Alive at Discharge	Percent Receiving NSBB Upon Discharge	Number Alive at Day 180 After Discharge	Percent Receiving NSBB on Day 180 After Discharge
1	20	40%	50%	19	37%	17	65%
2	7	NR	NR	NR	NR	NR	NR
3	28	25%	54%	26	31%	19	42%
4	35	31%	63%	33	39%	30	33%
5	16	38%	75%	15	40%	10	70%
6	25	20%	56%	23	44%	19	47%

VISN Number	Number with EVH Admission	Percent on NSBB prior to Admission	Percent on NSBB During Admission	Number Alive at Discharge	Percent on NSBB at Discharge	Number Alive 180 Days after Discharge	Percent on NSBB on 180 Days after Discharge
National	690	29%	55%	629	37%	492	46%
VISN Num	ber*	1		1	1	•	
VISN Number	Number with EVH Admission	Percent Receiving NSBB During 120 Days Before Admission	Percent Receiving NSBB During Inpatient Stay	Number Alive at Discharge	Percent Receiving NSBB Upon Discharge	Number Alive at Day 180 After Discharge	Percent Receiving NSBB on Day 180 After Discharge
7	46	24%	52%	43	42%	28	25%
8	59	29%	41%	51	29%	41	51%
9	31	19%	52%	27	44%	24	42%
10	25	32%	52%	22	32%	19	42%
11	33	33%	64%	30	33%	21	43%
12	23	30%	61%	22	41%	18	61%
15	23	30%	61%	21	24%	17	59%
16	56	27%	59%	52	46%	38	45%
17	36	39%	67%	33	33%	26	54%
18	31	32%	45%	26	39%	20	30%
19	24	42%	54%	22	41%	17	41%
20	59	25%	59%	55	46%	45	42%
21	53	28%	57%	49	33%	38	45%
22	41	20%	51%	36	33%	27	56%
23	19	21%	42%	18	28%	15	53%

\*Please refer to the other VISN level tables in this report for the full VISN name.

Abbreviation: NR, not reported if less than 10 cases in the year.

Though NSBB use has increased recently, greater attention is needed to the initiation of NSBBs before, during, and after admission for first EVH for Veterans with chronic HCV. Large variation exists between VISNs in use of NSBBs. The number of first ever diagnoses of EVH among Veterans with chronic HCV increased from 2000 to 2006. This trend is continuing; there were 800 admissions for first EVH in Veterans with chronic HCV in 2008. There is significant all-

cause mortality during hospitalization and in the 6 months following discharge among patients with chronic HCV and EVH and mortality rates have increased in recent years. More work is needed to understand the reasons why mortality has trended higher over time.

#### 6.8 Sustained Virologic Response after HCV Antiviral Treatment

The goal of HCV antiviral therapy is to eradicate the HCV virus in hopes of reducing complications and death from HCV infection. Effectiveness of treatment is evaluated by assessing virologic response. A sustained virologic response (SVR) is defined as an undetectable HCV RNA level 24 weeks after the end of treatment. As indicated above, the current standard of care for HCV treatment is the combination of pegylated interferon and ribavirin. In randomized, controlled trials of pegylated interferon plus ribavirin that were the basis for FDA approval, an SVR was observed in 42% to 46% of those infected with HCV genotype (GT) 1 and in 76% to 82% of those infected with HCV GT 2 or 3.<sup>11-13</sup> Ninety-five percent of Veterans with chronic HCV in VHA care have one of these three genotypes, with the majority having GT1.

For this report, a Veteran was considered to have attained a SVR if he or she had an undetectable HCV viral load on all HCV viral load tests after the end of HCV antiviral treatment, at least one of which was a minimum of 12 weeks after ending treatment. HCV viral load tests taken 12 weeks after the end of treatment were accepted because 98% of relapses occur within the first 12 weeks after ending treatment<sup>14,15</sup> and because of the scheduling variability of routine medical care. Tests taken more than 12 weeks after the end of treatment were also accepted because of the scheduling variability of routine medical care.

Among the 20,477 Veterans with chronic HCV who initiated their first VHA course of pegylated interferon and ribavirin between 2002 and 2006, the SVR rate was 26%, 62%, and 52%, for genotypes 1, 2 and 3, respectively. When comparing the year 2002 to the year 2006, there was an increase in SVR rates from 21% to 27% for those with HCV GT1, from 57% to 60% for HCV GT2, and from 43% to 53% for HCV GT3 (Figure 21). The year-to-year trend in SVR rates for all three genotypes increased from 2002 to 2003, followed by a leveling off from 2003 to 2006. Cumulative numbers treated and SVR rates for the nation along with VISN ranges are presented in Table 12. The highest VISN SVR rates were 32% for HCV GT1, 77% for HCV GT2 and 63% for HCV GT3.

Figure 21. SVR Rates in Veterans with Chronic HCV after First VHA Course of Pegylated Interferon and Ribavirin Treatment Initiated between 2002 and 2006



Table 12. SVR Rates by VISN in Veterans with Chronic HCV Initiating First VHA Pegylated Interferon and Ribavirin between 2002 and 2006

	GT1 Number Treated	GT1 Percent with SVR	GT2 Number Treated	GT2 Percent with SVR	GT3 Number Treated	GT3 Percent with SVR
Nation	15,424	26%	3,062	62%	1,961	52%
VISN (Number)	1	1				1
VA New England Healthcare System (1)	756	23%	194	60%	112	51%
VA Healthcare Network Upstate New York (2)	316	28%	49	55%	34	59%
VA NY/NJ Veterans Healthcare Network (3)	664	20%	115	55%	51	55%
VA Healthcare (4)	929	25%	137	63%	82	52%
VA Capitol Health Care Network (5)	672	22%	68	65%	19	63%
VA Mid-Atlantic Health Care Network (6)	802	26%	123	60%	68	46%
VA Southeast Network (7)	752	22%	132	56%	59	49%
VA Sunshine Healthcare	1,643	25%	306	59%	191	44%

	GT1 Number Treated	GT1 Percent with SVR	GT2 Number Treated	GT2 Percent with SVR	GT3 Number Treated	GT3 Percent with SVR
Nation	15,424	26%	3,062	62%	1,961	52%
VISN (Number)	1			1		1
Network (8)						
VA Mid South Healthcare Network (9)	563	22%	106	52%	60	57%
VA Healthcare System of Ohio (10)	591	24%	102	62%	54	50%
Veterans in Partnership (11)	647	23%	124	66%	82	54%
VA Great Lakes Health Care System (12)	708	29%	102	77%	76	54%
VA Heartland Network (15)	740	30%	158	60%	88	50%
South Central VA Health Care Network (16)	1,517	26%	301	67%	183	60%
VA Heart of Texas Health Care Network (17)	507	23%	127	60%	77	51%
VA Southwest Health Care Network (18)	699	31%	168	64%	121	54%
Rocky Mountain Network (19)	275	28%	67	57%	51	49%
Northwest Network (20)	521	31%	180	63%	139	55%
Sierra Pacific Network (21)	844	32%	214	69%	184	55%
Desert Pacific Healthcare Network (22)	660	24%	139	65%	119	45%
VA Midwest Health Care Network (23)	618	32%	150	61%	111	43%

There are likely several reasons why SVR rates among Veterans in VHA care were lower than those reported in clinical trials. First, the Veteran population is a real-world population which is very different than the cohort of patients enrolled in HCV clinical trials. Second, clinical trials likely have greater resources to encourage and actively support adherence and on-therapy retention than are available in routine clinical practice. Third, VHA has a higher proportion of HCV-infected African-Americans (the majority with HCV GT1), a population known to have lower SVR rates and Veterans with multiple co-morbidities including mental illness and substance abuse which have been shown to decrease response rates.<sup>16,17</sup>

There are few published data on SVR rates for groups outside of clinical trials making it difficult to place VHA rates in the appropriate context. However, it is possible to assess regional variability across VHA by assessing rates at the VISN level. Variation in SVR rates across VISNs may offer an opportunity to identify best practices for treating various Veterans populations (e.g. those with concurrent mental illness) from sites with high SVR rates. Further studies are necessary to understand the Veteran, healthcare provider and system variables that influence clinical evaluation and treatment practices, including the offer of HCV antiviral therapy and its acceptance.

#### Methods:

- 1. HCV Confirmatory testing: Veterans with a detectable HCV viral load or a HCV genotype test with a genotype identified (e.g., genotype 1) qualifies as having completed HCV confirmatory testing.
- 2. Hepatitis A (HAV) and Hepatitis B (HBV): Veterans with an outpatient visit, admission, or outpatient prescription fill in 2008 were first assessed for the receipt of testing for HAV or HBV exposure or previous vaccination (antibodies to HAV or HBV surface or core antigens) or for active hepatitis B infection (positive result for HBV viral load, e antigen, or surface antigen). Next, those with no evidence of past immunity to HAV or HBV or active HBV disease were assessed for the receipt of HAV or HBV vaccine. Inpatient and outpatient prescription records and procedure codes were reviewed for receipt of HAV or HBV vaccine or combination products during and prior to 2008.
- 3. HIV: Veterans with an outpatient visit, admission, or outpatient prescription fill in 2008 were assessed for the receipt of a laboratory test for HIV during or prior to 2008.
- 4. Influenza vaccination: Veterans with an outpatient visit, admission, or outpatient prescription during the 2007/ 2008 influenza vaccination campaign were assessed for the receipt of vaccination, refusal of vaccination, history of allergy to the vaccine or eggs, or documentation of vaccination outside of VHA.
- Tobacco cessation: Veterans with an outpatient visit, admission, or outpatient prescription fill in 2008 were assessed for a history of a tobacco use diagnosis from ICD-9 codes linked to outpatient visits or admissions. Medications for tobacco cessation included nicotine replacement therapy, bupropion (FDA-approved formulations and strengths), and varenicline,
- 6. HCC screening in cirrhotics: Veterans with an outpatient visit, admission, or outpatient prescription fill in 2008 were assessed for a diagnosis of cirrhosis using ICD-9 diagnosis codes. Receipt of AFP testing or abdominal imaging was identified by a CCR record for these tests with a test date in 2008 and similarly for abdominal imaging (including ultrasound, computerized tomography, and magnetic resonance imaging).
- 7. Non-selective Beta Blocker use: Veterans were considered to have received NSBB during each of the four time periods of interest if they had an outpatient, or inpatient prescription or unit dose medication record in CCR. "Upon discharge" included a fill date on the discharge date or within 7 days after discharge. "180 days after discharge" included Veterans receiving a NSBB on day 180 after discharge or a drug supply on day 180 carried over from a previous outpatient prescription. NSBBs include oral formulations of propranolol, timolol, or nadolol alone or in combination products.
- 8. Sustained Virologic Response (SVR) rates: Veterans with CCR records that characterized HCV genotype who filled at least one outpatient prescription for pegylated interferon and ribavirin between Jan 1, 2000 and Dec 31, 2006 and had a calculated end of treatment and post treatment evaluation period date on or before Dec 31, 2008 were included. Veterans were identified as having a SVR if they had an undetectable HCV viral load on all HCV viral load tests after the end of HCV antiviral treatment including at least one HCV viral load result a minimum of 12 weeks after the end of their HCV treatment

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### Chapter 7 – Chronic HCV Quality Care in VHA and the Future

#### 7.1 Quality

For the past two years, PHSHG has used CCR data to assess and report internally on a number of quality indicators based on accepted guidelines or treatment recommendations. On a routine basis, reports on patient volume, demographics, rates of common conditions, and selected indicators of quality are disseminated to all VHA HCV providers and posted internally for access by the broad VHA audience. This State of Care Report builds on that foundation and presents an overall view of care for Veterans with chronic HCV. Information reported here supports the mission of PHSHG to improve the health of Veterans. This information, along with assessment of trends over time, has been useful within VHA in planning staffing, projecting cost, and understanding where improvements in VHA care can be made.

The VA is able to provide a real world perspective on the care and treatment of the largest population of individuals with chronic HCV in the US. While there are several aspects of the VHA that make it a unique healthcare system, sharing the VHA HCV experience with the general community is particularly important given the increased prevalence of HCV in our Veteran population. The overall older age of this population can provide insights that may help non-VHA providers understand what to expect as their patients with HCV age in the decades ahead.

Indicators of quality care have been developed and implemented by the PHSHG as part of a national strategy to assess and improve chronic HCV care. The National Quality Forum (NQF), a private, not-for-profit, public benefit corporation established to develop and implement a national strategy for health care quality measurement and reporting has recently endorsed performance measures for chronic HCV care. Many of the endorsed measures are comparable to the current list of quality indicators for chronic HCV care developed by PHSHG. As is done in the case of HIV care, PHSHG will incorporate NQF measures into future quality assessment and improvement efforts.

Data in this State of Care report will help to identify areas for possible improvement, including assessment of national performance rates and examination of variation in performance across geographic regions. Further, this data helps identify and focus the detailed review of care delivery processes needed to identify barriers to achieving higher quality care. Removing barriers can require legislative changes (e.g., consent for HIV testing), VHA policy changes (e.g., the requirement for reflexive confirmatory HCV testing), development or refinement of practice guidelines (e.g., Management and Treatment of Hepatitis C Viral Infection from the VHA HCRC Program), and development of tools for monitoring population health (e.g., CCR software) along with ongoing interventions to assure providers have access to the latest evidence based information on HCV. The PHSHG will continue to assess and address quality of care issues, monitoring for emerging issues and ways to improve quality.

#### 7.2 Future Initiatives

One of the most important trends in the data in this report is the increasing prevalence of advanced liver disease among Veterans with chronic HCV in VHA care. Since the majority of Veterans with chronic HCV in VHA care were exposed during the Vietnam War era, their increasing age translates into a longer duration of chronic hepatitis C and increasing risk of cirrhosis, HCC, and end-stage liver disease. Not surprisingly, the data in Chapter 5 shows increasing caseloads for all of these complications, particularly HCC.

Improving clinical outcomes in patients with chronic HCV – especially those at highest risk for complications – depends on early identification of HCV patient, efficient linkage to care, evidence-based interventions to reduce modifiable risks for disease progression, and use of effective treatments for HCV and its complications. This paradigm is based on emerging data that the risk of advanced liver disease in HCV-infected Veterans can be significantly lowered by addressing co-morbidities and successful antiviral treatment in an interdisciplinary care model<sup>1,2</sup>, while early detection of HCC can allow liver transplantation or other curative therapies.<sup>3</sup>

Clearly, this chain of actions can only be applied to patients who are diagnosed with chronic HCV. Thus, an important goal of the PHSHG is to support and encourage screening for HCV and the initiation of HCV-specific care as soon as a diagnosis of chronic HCV is made. Fundamental to this goal is the confirmation of chronic HCV infection. Timely detection of HCV infection allows the implementation of interventions to reduce further transmission, provide care and treatment to reduce disease progression, provide ongoing monitoring and management of clinical status and potentially, the delivery of pharmacologic therapy. Recent change in VHA regulation requiring reflex confirmatory testing for all Veterans who are HCV antibody positive is expected to significantly decrease unconfirmed cases in the future.

It is important to know more about the stage at which Veterans are first identified with HCV infection and at what stage they seek VA HCV care. Ideally, Veterans with chronic HCV should not have that diagnosis made at the time they present with advanced liver disease or liver cancer. Education, targeting healthcare system staff that work in areas of high HCV prevalence (primary care, mental health, substance abuse and homeless outreach programs) about the natural history of chronic HCV including the need for screening and testing is key to

early identification, prompt referral and linkage to appropriate HCV care. The Clinical Public Health Programs Office (CPHP) has been actively engaged in addressing this fundamental component of a comprehensive HCV disease management program.

By the same token, effectively addressing HCC and other complications of chronic HCV infection requires early recognition and referral for therapy as soon as possible. Again, education of providers, particularly in primary care, about these issues is a central part of improving clinical outcomes for patients with more advanced liver disease, along with use of decision support tools such as clinical reminders. CPHP is overseeing projects by the Hepatitis C Resource Centers to improve clinical surveillance rates and timely diagnostic work-ups for patients with suspected HCC. The CCR reports on cirrhosis, HCC caseloads, and mortality will be extremely helpful in gauging the effects of such interventions.

Given the size, age, and racial diversity of VHA's HCV population, VHA can provide information on this population that will be of value both within VA and to the HCV treating community in general. As the Veteran HCV population with cirrhosis and its associated complications continues to grow, it will be important to identify and address specific challenges to ensure the best care possible. Issues related to the availability of new HCV treatments and adherence to them, the management of multiple co-morbidities, and the consequences of advanced liver disease will add to the complexity of caring for HCV. Activities such as the development of quality indicators specific to HCV care helps capitalize on the knowledge and insight of HCV providers with years of experience and is a source of guidance for future providers. Recent changes in VHA regulations requiring reflex confirmatory testing for all Veterans who are HCV antibody positive is expected to significantly decrease the number of unconfirmed cases in the future. PHSHG will continue efforts to support and educate primary care providers to co-manage the aging population of Veterans with chronic HCV and to adapt their practices as newer therapies become available.

The increase in chronic liver disease underscores the need to ensure that each new generation of Veterans has the knowledge and skills to prevent HCV infection and recognizes, the importance of being tested for HCV for those at risk. There is a continuing need for efforts to promote HCV testing and for Veteran targeted programs that increase awareness of HCV prevention, testing and management.

Future work to improve the quality of HCV care will be based in part on understanding of the variation in VHA care between VISNs and healthcare systems. The information presented in this State of Care Report on antiviral therapy and on quality of care measures indicates that the potential exists to learn more about which approaches are successful and which are not from those facilities with high and low performance rates. To better understand local models of care, PHSHG recently completed a survey of clinicians providing HCV care. Linking survey information to various measures of treatment and quality presented in this report will begin the process of identifying characteristics associated with better outcomes. Additional work will be required by the PHSHG to more clearly understand care delivery at the local VHA healthcare system level. Then, PHSHG team will develop and assist VHA in the effective dissemination and implementation of products and models of care designed to address specific quality issues. Such products will support VHA providers as they develop solutions to local issues in the provision of HCV care. Such solutions may be exportable to other disease states or to other VHA facilities.

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The Hepatitis C Resource Centers (HCRC) have conducted a number of education and training initiatives covering HCV over the past 8 years including the publication of treatment recommendations and guidelines. The impact of their work is likely shown in the improvements in the quality of care indicators over the past 8 years. HCRC leadership was involved in the initial formulation of indicators for quality care contained in this report and provided review of this document:

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## Appendix

Table A.1 and A.2 show the number of Veterans with chronic HCV in VHA care by VISN and local healthcare system, respectively, in three recent years. To be counted in a given year, a Veteran must:

- Exist in the Clinical Case Registry for HCV and
- Have a history of measurable HCV viral load and
- Have a hospitalization, outpatient visit, or prescription filled in the VISN (healthcare system) during the calendar year of interest. A Veteran was counted in each VISN (healthcare system) providing him or her care during the year.

	2000	2004	2008
National	111,521	145,261	147,352
VA New England Healthcare System (1)	4,488	5,295	5,126
VA Healthcare Network Upstate New York (2)	2,090	2,674	2,480
VA NY/NJ Veterans Healthcare Network (3)	7,076	7,658	6,952
VA Healthcare (4)	5,971	7,596	7,745
VA Capitol Health Care Network (5)	5,347	6,548	6,281
VA Mid-Atlantic Health Care Network (6)	5,199	7,447	8,164
VA Southeast Network (7)	6,470	8,888	9,583
VA Sunshine Healthcare Network (8)	9,370	12,808	13,392
VA Mid South Healthcare Network (9)	4,850	6,492	6,933
VA Healthcare System of Ohio (10)	3,829	4,956	5,170
Veterans in Partnership (11)	5,240	7,168	7,003
VA Great Lakes Health Care System (12)	5,096	6,034	5,913
VA Heartland Network (15)	3,073	5,247	5,384
South Central VA Health Care Network (16)	10,243	14,304	14,019
VA Heart of Texas Health Care Network(17)	4,363	6,246	6,313
VA Southwest Health Care Network (18)	5,006	6,715	6,703
Rocky Mountain Network (19)	2,690	3,805	4,046
Northwest Network (20)	6,277	8,511	8,607
Sierra Pacific Network (21)	6,563	8,531	8,670
Desert Pacific Healthcare Network (22)	9,346	11,540	10,899

Table A.1. Chronic HCV Caseload by VISN for 2000, 2004 and 2008

	2000	2004	2008
National	111,521	145,261	147,352
VA Midwest Health Care Network (23)	3,185	4,284	4,235

Table A.2. Chronic HCV Caseload by Main Healthcare System City and State, 2000, 2004 and 2008

State	Main Healthcare System City	2000	2004	2008
National	·	111,521	145,261	147,352
AL	Birmingham	1,350	1,616	1,701
AL	Montgomery	770	1,117	1,116
AL	Tuscaloosa	248	327	244
AK	Anchorage	473	546	552
AZ	Phoenix	1,676	2,218	2,110
AZ	Prescott	418	646	644
AZ	Tucson	818	1,055	1,100
AR	Fayetteville	603	1,033	1,114
AR	Little Rock	1,390	1,731	1,603
CA	Fresno	580	758	798
CA	Loma Linda	1,207	1,742	1,733
CA	Long Beach	1,490	1,861	1,800
CA	Los Angeles	4,335	4,947	4,319
CA	Martinez	2,219	2,955	3,008
CA	Palo Alto	1,617	2,146	2,222
СА	San Diego	1,524	1,948	1,890
CA	San Francisco	1,636	2,007	1,967
со	Denver	1,260	1,794	1,861
СО	Grand Junction	135	190	235
СТ	West Haven	1,153	1,354	1,319
DE	Wilmington	639	836	835
DC	District of Columbia	1,930	2,498	2,392
FL	Bay Pines	1,498	2,117	2,170

State	Main Healthcare System City	2000	2004	2008
National	*	111,521	145,261	147,352
FL	Gainesville	1,474	2,440	2,969
FL	Miami	1,832	2,190	2,038
FL	Tampa	2,954	4,263	4,476
FL	West Palm Beach	762	1,049	1,050
GA	Atlanta	1,701	2,442	2,663
GA	Augusta	642	968	1,039
GA	Dublin	393	582	670
н	Honolulu	329	465	478
ID	Boise	372	502	580
IL	Chicago	2,164	2,296	2,161
IL	Danville	370	579	590
IL	Hines	1,122	1,375	1,313
IL	Marion	456	720	726
IL	North Chicago	635	663	552
IN	Indianapolis	1,455	1,907	1,793
KY	Lexington	507	674	768
KY	Louisville	824	951	1,006
LA	Alexandria	475	737	698
LA	New Orleans	1,251	1,659	1,278
LA	Shreveport	826	1,160	1,230
ME	Togus	328	491	526
MD	Baltimore	2,842	3,357	3,105
МА	Bedford	494	559	474
МА	Boston	1,588	1,710	1,572
MA	Northampton	351	443	478
МІ	Ann Arbor	733	1,080	978
МІ	Battle Creek	777	1,053	1,053
МІ	Detroit	1,633	2,169	1,963
МІ	Iron Mountain	152	188	185
МІ	Saginaw	364	539	576

State	Main Healthcare System City	2000	2004	2008
National		111,521	145,261	147,352
MN	Minneapolis	1,087	1,510	1,506
MN	St. Cloud	418	483	482
MS	Jackson	552	777	814
MS	Biloxi	1,302	1,922	1,696
МО	Kansas City	1,768	3,096	3,071
МО	St. Louis	1,313	2,178	2,347
MT	Fort Harrison	364	588	605
NE	Omaha	1,342	1,844	1,738
NV	Las Vegas	1,184	1,595	1,552
NV	Reno	684	828	784
NH	Manchester	261	353	307
NJ	East Orange	1,670	1,918	1,805
NM	Albuquerque	1,197	1,503	1,405
NY	Buffalo	2,090	2,674	2,480
NY	Bronx	1,508	1,574	1,400
NY	Montrose	746	819	781
NY	Northport	634	711	654
NY	New York City (Manhattan, Brooklyn)	3,047	3,215	2,891
NC	Asheville	515	723	864
NC	Durham	999	1,395	1,463
NC	Fayetteville	718	1,103	1,184
NC	Salisbury	704	1,209	1,445
ND	Fargo	170	251	275
ОН	Columbus	416	589	645
ОН	Chillicothe	406	555	523
ОН	Cincinnati	910	1,167	1,173
ОН	Dayton	637	812	825
ОН	Cleveland	1,689	2,183	2,259
ОК	Muskogee	595	919	925
ОК	Oklahoma City	1,188	1,613	1,611

State	Main Healthcare System City	2000	2004	2008
National		111,521	145,261	147,352
OR	Portland	1,528	2,401	2,600
OR	Roseburg	542	786	779
OR	White City	552	878	887
PA	Altoona	161	257	279
PA	Butler	142	235	259
PA	Coatesville	898	1,166	909
PA	Erie	134	167	203
PA	Lebanon	668	838	883
PA	Philadelphia	2,417	2,819	2,639
PA	Pittsburgh	1,011	1,505	1,614
PA	Wilkes-Barre	502	689	732
PI	Manila	7	18	26
PR	San Juan	1,190	1,271	1,213
RI	Providence	593	708	716
SC	Charleston	792	1,088	1,192
SC	Columbia	1,023	1,537	1,643
SD	Fort Meade	249	364	317
SD	Sioux Falls	193	244	264
TN	Memphis	1,063	1,399	1,365
TN	Mountain Home	686	954	1,323
TN	Nashville	1,408	2,088	2,132
ТХ	Amarillo	565	768	771
ТХ	Big Spring	340	497	529
ТХ	Dallas	1,097	1,548	1,475
ТХ	El Paso	323	480	488
ТХ	Houston	2,496	3,456	3,585
ТХ	San Antonio	1,798	2,551	2,672
ТХ	Temple	1,657	2,421	2,356
UT	Salt Lake City	689	936	964
VT	White River Junction	289	362	345

State	Main Healthcare System City	2000	2004	2008
National	National		145,261	147,352
VA	Hampton	995	1,362	1,387
VA	Richmond	1,038	1,461	1,556
VA	Salem	487	687	666
WA	Seattle	2,414	2,903	2,754
WA	Spokane	564	776	744
WA	Walla Walla	304	424	417
WV	Beckley	173	210	207
WV	Clarksburg	208	288	331
WV	Huntington	477	603	586
WV	Martinsburg	872	1,111	1,111
WI	Madison	420	629	656
WI	Milwaukee	957	1,255	1,261
WI	Tomah	229	326	313
WY	Cheyenne	168	218	229
WY	Sheridan	169	272	324

Please note that the geographic coverage of a given VISN or main healthcare system can cross state lines and that a Veteran can be seen in multiple VISNs and/or healthcare systems.

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