State of Oregon Hepatitis C Strategic Plan

RECOMMENDATIONS
OF THE
STATEWIDE
VIRAL HEPATITIS
PLANNING GROUP



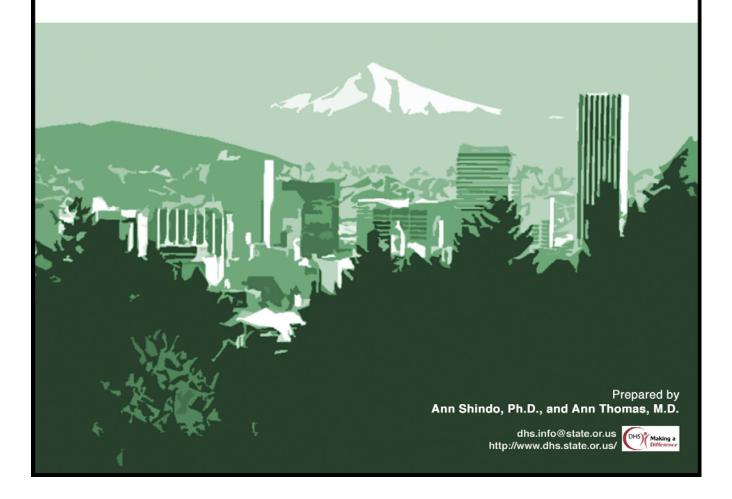


Table of Contents

Introductory Letter	4
Abbreviations Used in State Viral Hepatitis C Strategic Plan	5
Executive Summary	7
Mission, Vision, and Guiding Principles	11
Acknowledgements	12
Introduction	14
Recommendations	18
Education	19
Prevention	21
Management	23
Surveillance and Research	26
Legislation, Policy, Grants	28
Conclusion	30
Appendix A - Management of Hepatitis C	31
Guiding Principles of Interferon-based Antiviral Therapy	32
Guiding Principles of Complementary and Alternative Medicine (CAM)	34
References	35

If you need this in an alternate format, please contact Barbara Danel at 503-731-4029.

January 1, 2005

Dear Colleague:

I am pleased to present the State of Oregon's Hepatitis C (HCV) Strategic Plan. This document is in response to House Bill 2451, which requested the Oregon Department of Human Services (DHS) to design a plan for statewide education efforts concerning HCV, and for prevention and management of the disease. Led by the Acute and Communicable Disease Prevention Program in the Office of Disease Prevention and Epidemiology, the Statewide Viral Hepatitis Planning Group (SVHPG) met monthly from January to September 2004 to develop these recommendations. I would like to acknowledge the hard work of the members of the planning group, who volunteered many hours and made invaluable contributions to this effort to address the HCV epidemic in Oregon.

HCV is one of Oregon's most important public health problems. It is estimated that 64,000 Oregonians are infected with the virus, and many of them are unaware of their illness or unable to access appropriate medical care. Implementation of this plan is critical for the State to begin meeting their needs.

The SVHPG designed the action steps built into this strategic plan to address the multidimensional nature of HCV needs in our state. Ranging from basic education of all Oregonians to comprehensive and holistic care of people living chronically with this disease, this strategic plan provides guidelines for HCV interventions that can be used by any local or state agency or organization providing service to individuals with HCV or at-risk for HCV. Ultimately multidisciplinary partnerships, like those developed to write this plan, will be necessary to ensure that a comprehensive, inclusive, and culturally appropriate approach is taken to coping with HCV in Oregon.

Please use this plan to develop programs, support grant requests, set programmatic priorities and identify activities that will help us reduce the toll of HCV in Oregon.

Sincerely,

Melvin A Kohn, MD, MPH

Welia Fol HOMPY

State Epidemiologist

Abbreviations Used in State Viral Hepatitis C Strategic Plan

Abbreviation	Definition
AASLD	American Association of the Study of Liver Disease
ACDP	Acute and Communicable Disease Prevention
Advocates	Members of the general population advocating on behalf of persons living with HCV
Advisory Group	A ten-member statewide HCV stakeholders group that will oversee plan implementation
AETC	AIDS Education and Training Centers
ALF	American Liver Foundation
ALT	Alanine Aminotransferase
CAM	Complementary and Alternative Medicine
CAREAssist	A program designed to support the medical needs of people living with HIV
CBOs	Community-Based Organizations
CDC	Centers for Disease Control and Prevention
CLHO	Conference of Local Health Officials
CME	Continuing Medical Education
CSTE	Council of State and Territorial Epidemiologists
DHS	Department of Human Services
DOC	Department of Corrections
EIA	Enzyme Immunoassay
ELC	Epidemiology and Laboratory Capacity grant
HBV	Hepatitis B Virus
HCC	Hepatocellular Carcinoma
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HMOs	Health Maintenance Organizations
IDUs	Injection Drug Users

Abbreviation	Definition
Kaiser	Kaiser Permanente Northwest – Hepatology Division
LA	Legislative Advocates
LHDs	Local Health Departments
LHRC	Local Harm Reduction Coalition
NCNM	National College of Natural Medicine
NIH	National Institutes of Health
ODE	Oregon Department of Education
ODPE	Office of Disease Prevention and Epidemiology
OHSU	Oregon Health and Sciences University
OMAP	Office of Medical Assistance Program
OMHAS	Office of Mental Health and Addictions Services
OSPHL	Oregon State Public Health Laboratory
PCR	Polymerase Chain Reaction
PI	Pharmaceutical Industry
RIBA	Recombinant Immunoblot Assay
RNA	Ribonucleic Acid
SVHPG	Statewide Viral Hepatitis Planning Group
VA	Veteran's Administration Hospital
VA Clinician's Panel	A multidisciplinary team of health care providers that comprise the VA's NW HCV Resource Center
VFC	Vaccine for Children

Executive Summary

Introduction

Hepatitis C (HCV) is the most common chronic blood-borne viral infection in the United States with an estimated 3.9 million people infected, of whom 2.7 million are chronically infected. It is estimated that nearly 64,000 Oregonians are infected with HCV, many of whom may not know they are infected. Hepatocellular carcinoma (HCC) and cirrhosis are two life-threatening sequelae of chronic HCV infection, and between 8,000 - 10,000 people die each year due to complications from HCV infection.² Hepatitis C is also the primary reason for liver transplant in the U.S. National data projections estimate that the need for liver transplantation will increase fivefold and liver-related deaths will double by 2008, highlighting the increasing burden of HCV on the U.S. health care system.³

Legislative Background

Prior to 2003, there was no statewide guidance or consistent approach to the prevention and management of HCV in Oregon. In that year, the Centers for Disease Control and Prevention (CDC) awarded Oregon Department of Human Services (DHS) funding to hire a HCV coordinator to: 1) conduct an ongoing communitybased needs assessment; 2) create a clearinghouse of HCV information and resources; and 3) develop training modules for persons doing HCV counseling and testing. Recognition of the need for further public health action precipitated adoption of an HCV-related budget note in House Bill 2451 in August of 2003. This budget note, within the DHS Appropriation and Expenditure Limitation report, stated:

By January 2005, the Department of Human Services (DHS) is to design a plan for statewide education efforts concerning Hepatitis C, and for prevention and management of the disease. In developing the plan, the Department shall consult with the public, patient groups and organizations, state agencies, service providers and suppliers, local public health departments, public health and clinical laboratories, research scientists, health care associations and others involved with Hepatitis C.

The development of this plan became the responsibility of the Acute and Communicable Disease Program (ACDP) in the Office of Disease Prevention and Epidemiology (ODPE). ACDP staff applied for and received funding from the Council of State and Territorial Epidemiologists (CSTE) to support the planning process, specifically to provide support for a series of meetings of the stakeholders requested by the legislature.

The Planning Process

To assist in the development of the plan, the ACDP recruited advisors from the State HIV Prevention Program, Immunization Program, Multicultural Health Program, the Public Health Laboratory, and the Department of Corrections Medical Services and Blood-borne Pathogens Programs, as well as several outside agencies and partners. The first Statewide Viral Hepatitis Planning Group (SVHPG) was convened in early 2004 and was comprised of allopathic physicians, naturopathic physicians, local health departments, and representatives from the tribal health board, drug companies, health plans, community-based organizations, and people living with HCV. The SVHPG identified five priority areas by reviewing national and Oregon HCV data and HCV plans from other states, and formed task groups to address each priority. The priority areas were: 1) Education; 2) Management; 3) Prevention; 4) Surveillance and Research; and 5) Legislative, Policy,

and Grants. During the nine-month process each task group developed a primary goal, several prioritized objectives addressing the primary goal, and specific action steps to address each of these objectives. With best practices and the current public health infrastructure in mind, each task group developed timelines, measurable outcomes, and prioritized objectives based on the most recent research literature where available. Additionally, SVHPG members utilized their own professional experience and judgment in this decision-making process.

Health Services administration, CSTE, and CDC stakeholders were apprised of the progress, edited drafts, and provided guidance throughout the course of the planning process. Additional public health administrators, physicians, advocates, and people living with HCV who were not a part of the planning process reviewed a final version to ensure completeness, inclusiveness, and cultural appropriateness.

The following are the goals and associated objectives described within the Oregon State Viral Hepatitis C Strategic Plan:

Education

Goal. Promote HCV education that is comprehensive, consistent, accurate, and targeted for specific and general audiences throughout the State of Oregon.

Objective 1. Synthesize HCV educational information from peer-reviewed literature and guidelines published by nationally-recognized sources to develop a core set of educational messages addressing: disease education, risk assessment, behavior modification, treatment options, educa-

tional awareness, as well as primary and secondary prevention, addictions services, and harm reduction strategies.

Objective 2. Package core educational messages into appropriate modules for different educational target audiences.

Objective 3. Review and evaluate HCV counseling and testing protocols that are currently in use to ensure appropriate educational messages.

Prevention

Goal. Decrease new HCV infections among people at risk for contracting the disease and decrease HCV-related liver disease complications among people who are already HCV-positive.

Objective 1. Use primary prevention strategies to decrease new HCV infections through education, screening and testing of persons of all socioeconomic, racial, and ethnic groups who are at high-risk of HCV infection.

Objective 2. Promote safer injection practices in the injection drug use community.

Objective 3. Use primary and secondary prevention strategies to decrease the transmission of HCV and minimize the progression and complications of chronic liver disease.

Management

Goal. Identify reasonable, effective, accessible, and affordable case management and treatment

services to prevent or limit the progression and complications of HCV infection and improve affected individuals' quality of life.

Objective 1. Research and identify comprehensive models for an evidence-based process for prevention and management of HCV that is based on solid medical principals, recommendations, and guidelines.

Objective 2. Develop education and training opportunities for the evaluation and long-term clinical management of HCV for licensed clinical providers, both allopathic and complementary and alternative (CAM).

Objective 3. Develop materials for providers to give to HCV-positive patients with information about living with HCV, evaluation plans, and long-term management options and recommendations.

Objective 4. Increase continuity of care for HCV patients who are transitioning between health plans or differing geographic areas, especially those actively taking medication that should not be interrupted.

Objective 5. Establish and implement an integrated and comprehensive care structure for the management of HCV patients that will include HCV education, testing, treatment, and referrals to medical and social services.

Surveillance and Research

Goal. Improve HCV surveillance in order to better understand HCV in Oregon and develop a means of evaluating the effectiveness of HCV prevention programs.

Objective 1. Develop a surveillance system for chronic HCV infection.

Objective 2. Assess the need for medical, preventive, and mental health services for persons with HCV.

Objective 3. Evaluate prevention and control efforts.

Objective 4. Periodically revise surveillance plan based on acquired data.

Legislative, Policy, and Grants

Goal. Ensure adequate resources for prevention and control of HCV in Oregon.

Objective 1. Educate state legislators and key health policymakers about HCV issues.

Objective 2. Revise existing Oregon administrative rules and statutes to include language for prevention and control of HCV where appropriate.

Objective 3. Identify potential funding sources for HCV plan implementation including public, private, and in-kind resources.

Objective 4. Identify the costs and potential benefits of implementing a comprehensive, inclusive, and culturally appropriate HCV plan in the State of Oregon.

Objective 5. Ensure resources for hepatitis A and B vaccine integration into existing programs that reach HCV at-risk populations.

Objective 6. Develop collaborations with agencies funding and providing services to person co-infected with HIV and HCV to promote integration of medical and prevention services.

Inherent in the vision of the SVHPG is the recognition that many people are marginalized within our society and may be at high-risk for acquiring HCV. People who are on the fringes of mainstream society due to race, ethnicity, sexual or gender identification, low socioeconomic status, or people with a history of homelessness, incarceration, or injection drug use may be examples of such high-risk groups. Strategies for the implementation of the SVHPG plan will include as many representatives from high-risk groups as possible as well as other partners who may work with them.

Responsibility for Implementation

Although DHS has been the nexus for completing this work, it will be necessary for all relevant stakeholders to assume responsibility for implementation. DHS, and specifically the State HCV Coordinator, will coordinate and facilitate the work of a ten-member Statewide HCV Advisory Group. As envisioned by the SVHPG, the Advisory group will take primary responsibility for implementation oversight and the development of adhoc committees that will address specific recommendations of the five task groups. Multidisciplinary partnerships, like those developed to write this plan, will be necessary to ensure timely, comprehensive, inclusive, and culturally appropriate implementation of this plan.

Mission, Vision, and Guiding Principles

Mission

The purpose of the Viral HCV Plan is to:

- Stop the spread of HCV;
- Minimize the progression and complications of chronic liver disease in people infected with HCV in urban and rural Oregon; and
- Promote comprehensive viral hepatitis policy and advocacy.

Vision

The vision of the Oregon SVHPG is to develop a systematic and coordinated approach to HCV education, prevention, and management through public and private partnerships designed to:

- Promote HCV education that is comprehensive, consistent, accurate, and targeted for specific and general audiences throughout the state of Oregon;
- Decrease new HCV infections among people at risk for contracting the disease and decrease HCV-related liver disease complications among people who are already HCV-positive;
- Identify reasonable, effective, accessible, and affordable case management and treatment

- services to prevent or limit the progression and complications of HCV infection and improve affected individuals' quality of life;
- Improve HCV surveillance in order to better understand HCV in Oregon and develop means of evaluating the effectiveness of HCV prevention programs; and
- Ensure adequate resources for prevention and control of HCV in Oregon.

Guiding Principles

To realize this vision we must:

- Recognize that program implementation necessitates sustained collaboration and funding.
- Respect the inherent worth and dignity of all HCV-positive individuals independent of route of transmission.
- Acknowledge that hepatitis C disproportionately affects some groups of people and focus resources accordingly.
- Identify existing program infrastructures in which to integrate HCV programs.

Acknowledgements

Education Task Group

Karen Beauchamp, ODS Health Plan Phyllis Beck, Hepatitis C Awareness Project John Bergland, Hepatitis C Awareness Project Debora Bowers, Roche Laboratories, Inc. Darcy Edwards, Oregon Department of Corrections

Michael Hurley, Glaxosmithkline Gene Mask, HCV Survivor and Advocate M. Jay Platt, HCV Survivor and Advocate Scott Sigmon, Schering-Plough Susan Yirku, National College of Natural Medicine

Mitchell Zahn, Department of Human Services, HIV Prevention Program

Prevention Task Group

Maria Bonnacci, Partnership Project
Mike Bunyard, HIV Resource Center
Heidi Eidler, Eastern Oregon Center for
Independent Living
Jenny Lee, Department of Human Services,
Multicultural Health Division
J. Bruin Rugge, CareOregon
Ann Shindo, Department of Human Services,
Acute and Communicable Disease Prevention,
HIV Prevention
Donna Standing Rock, Cascade AIDS Project
Anna Vail, Department of Human Services, HIV
Prevention Program

Management Task Group

Laurie Ammerman, Tillamook County Health Department John Buchanan, CareOregon Melissa Davis, Schering-Plough Kelly M. Fitpztrick, Naturopathic Physician, National College of Natural Medicine & Private Practice Leslie Horn, Quest Diagnostics David Indest, NW Hepatitis C Resource Center, Portland Veterans Affairs Medical Center
Ken Ingram, Oregon Health and Sciences
University
Keivan Jinnah, National College of Natural
Medicine, Naturopathic Physician and Licensed
Acupuncturist, Private Practice
Michelle Koder, Oregon State University
College of Pharmacy
James Mackay, Providence Health Plan
Jim Phelps, PsychEducation.org
Steven Shelton, Oregon Department of
Corrections
Brian Willis, Kaiser Northwest
Atif Zaman, Oregon Health and Sciences
University

Surveillance and Research Task Group

Jim Beggs, Cascade Comprehensive Care, Inc. Chris Biggs, Oregon State Public Health Laboratory

James Calvert, Merle West Center for Medical Research

Hilary Gillette, Department of Human Services, Immunization

Joshua Jones, Northwest Portland Area Indian Health Board

Virginia Schmitz, Multnomah County Health Department

Diane Seyl, Jefferson County Health Department Holly Starr, Umatilla County Health Department Ann Thomas, Department of Human Services, Acute and Communicable Disease Prevention

Legislative, Policy, and Grant Writing Task Group

Mary Durbrow, Department of Human Services, Immunization

Lorren Sandt, Hepatitis C Caring Ambassadors Program

Lisa Scott Gilliam, The Gilliam Group

Hasina Squires, Western Advocates, Inc. Tom Turek, Oregon Department of Human Services

Additional Reviewers

Marylin Carter, Douglas County Health Department Paul Cieslak, Department of Human Services, Acute and Communicable Disease Prevention Carole Fenton, Douglas County Health
Department
Thomas Holt, Oregon State Pharmacy Association
Barry Kast, Department of Human Services,
Health Services
Katy King, Department of Human Services
Melvin Kohn, Department of Human Services
Maura Toole, Roseburg Veteran's Administration
Medical Center

Introduction

Overview of Hepatitis C

Hepatitis C is the most common chronic bloodborne viral infection in the United States. It is estimated that 3.9 million people (1.8% of the population of the U.S.) have been infected with the hepatitis C virus (HCV), and 74% of these individuals, or 2.7 million, are chronically infected.¹ The majority of affected individuals have no symptoms when they first acquire the disease and may not develop symptoms until 10-20 years later. Of those chronically infected, 50% - 60% will develop evidence of chronic liver disease (manifested by elevated liver function tests), 10% - 20% will develop cirrhosis, and 1% - 5% will die from hepatocellular carcinoma or complications from chronic liver disease.^{1,2} Risk factors for more rapid progression to cirrhosis include male gender, age greater than 40 years at time of infection, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), obesity, and alcohol use. 4 HCV has become the most frequent indication in the U.S. for liver transplant, accounting for 37% of liver transplants in 2000.³ In 1997, the direct and indirect costs of HCV in the U.S. were estimated at \$5.46 billion (comparable to the 5.8 billion spent on asthma in 1994).5

According to the CDC, risk factors for HCV include contact with blood or body fluids from a person infected with HCV. This exposure can occur from sharing injection drug use equipment, blood transfusions, or solid organ transplants before July 1992, receipt of clotting factor(s) made before 1987, and long-term kidney dialysis.² In the period of 1995 – 2000, 68% of newly-acquired cases in the U.S. occurred among injection drug users, 18% were reported to be sexually acquired, and 4% occurred in occupational settings.⁶

The current standard of care for treating HCV involves interferon-based therapy, which is success-

ful in eradicating the virus nearly 50% of the time. Successful drug-based treatment is defined as a lack of measurable virus 6 months after the conclusion of therapy (known as *sustained virologic response*) and varies by genotype. Of the six genotypes identified, treatment for type 1, the most common genotype in the U.S., is successful in eradicating the virus 30% - 40% of the time. Response rates with genotypes 2 and 3 are much higher, approaching 80%.

Hepatitis C Screening and Diagnosis

The basic screening test for HCV is offered in medical settings and by most local health departments. The initial screening test is an inexpensive test (approximately \$15) called the enzyme immunoassay (EIA), which detects HCV antibody. In settings where the prevalence of infection is low, up to 20% to 50% of positive EIA test results may be falsely positive. 8 The recombinant immunoblot assay (RIBA), another antibody detection test, is more specific than the EIA and can be used to rule out false-positive EIA tests. The polymerase chain reaction (PCR) test measures HCV RNA, signifying that a person has circulating virus. These confirmatory tests are much more expensive than the initial screening test and are usually performed by a primary care physician or gastrointestinal specialist.

When a person initially acquires HCV, circulating virus is present (and measurable by PCR) within 1-2 weeks, and circulating antibodies are usually present 7-8 weeks post-infection. There is also an increase in liver enzymes such as alanine aminotransferase (ALT). About one-third of people develop symptoms of hepatitis, such as jaundice. If RNA is present 6 months after infection, the individual is considered to

have chronic HCV infection.

Serum ALT levels can be used for assessing disease activity. Persistently elevated ALT levels suggest the development of chronic liver disease and the need for further work-up, such as genotype identification or biopsy. The measurement of ALT levels during antiviral treatment is also an important means of monitoring response to treatment.

The genotype test identifies HCV genotypes and subtypes. There are 6 genotypes and >90 subtypes of HCV known. In the U.S., 70% of HCV infection is caused by genotypes 1a or 1b. Knowledge of the genotype can be used to predict

the response to treatment. For example, patients with genotype 2 and 3 are more likely to have a sustained virologic response to interferon alpha than those with genotype 1a or 1b.⁷

A liver biopsy is performed on individuals with chronic HCV infection to detect the level of physical damage to the liver. A biopsy is performed in a medical setting on an outpatient basis and determines both the severity of liver disease and the degree of fibrosis, or scar tissue, in the liver. A liver biopsy also serves to rule out other forms of liver disease such as steatosis (fatty liver), cirrhosis related to chronic alcoholism, liver injury, or damage due to iron overload.

The CDC recommends screening for people who:

- were notified that they received blood from a donor who later tested positive for hepatitis C;
- have ever injected illegal drugs, even if only one time many years ago;
- received a blood transfusion or solid organ transplant before July, 1992;
- received clotting factor(s) made before 1987;
- have ever been on long-term kidney dialysis; or
- have evidence of liver disease (e.g. persistently abnormal ALT levels).

Available from: http://www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm

Hepatitis C in Oregon

Based on national prevalence data, it is estimated that 64,000 Oregonians are currently infected with HCV. However, tracking the number of acute (newly-acquired) cases of HCV that occur each year in Oregon is problematic. Although acute cases of HCV are reportable to the state, only 15 – 20 cases are reported each year, which is most likely a vast underestimate. Most patients with HCV have no symptoms at the time of initial infection. Other reasons for under-reporting are that patients may not seek health care even if they do have symptoms, practitioners are often unaware of acute case reporting requirements, and local health departments (LHDs) have no easy way to distinguish between acute and chronic infections based solely on laboratory reports. However, despite the lack of data on the number of new infections that occur annually, several studies in Multnomah County and in the state of Oregon have provided insight into the HCV epidemic in Oregon.

In 2000, the Multnomah County Health Department offered HCV testing and evaluated risk factors for HCV among clients seeking HIV testing. They found that 55% of persons who admitted to injection drug use were positive for HCV, while the prevalence of HCV was much lower in persons who only reported household or sexual contacts with an infected person. Similarly, a 1998 study of inmates entering the Oregon State Penitentiary found that 30% of inmates had antibody to HCV, and 62% of persons who had used injection drugs had antibody to the virus.

In 2000 – 2001, a CDC-funded study in Multnomah County found that 70% of patients with chronic liver disease seen by gastroenterologists were HCV-positive, of whom 70% had a history of injection drug use at some time in their past. Thirteen percent of these HCV patients had most likely acquired HCV from a transfusion, and 5% reported high-risk sexual activity as their only risk factor.

In summary, studies in Oregon have confirmed what researchers in the rest of the U.S. have also seen, that the prevalence of HCV is particularly high among injection drug users and much lower in patients reporting high-risk sexual behaviors. The corrections population also is at high risk, similar to what has been observed elsewhere.

Hepatitis Prevention in Oregon

Within DHS, three programs - (ACDP, Immunizations, and the Human Immunodeficiency Virus, Sexually Transmitted Disease and Tuberculosis program [HIV/STD/TB]) - each have some responsibility for hepatitis prevention or oversight of programs that have interaction with populations at risk for hepatitis. ACDP is primarily responsible for surveillance for acute cases of hepatitis A, B, and C, and ACDP staff have been involved in several CDC-funded studies looking at the epidemiology of chronic liver disease and the prevalence of HCV in high-risk populations. The Immunization Program emphasizes outreach and distributes vaccine statewide to eligible providers, county health departments, and delegate agencies. The program manages the perinatal hepatitis B program and provides hepatitis A and B vaccine to children eligible for Vaccine for Children (VFC) funds, and distribute vaccine to additional children and certain categories of high-risk adults through funds from the CDC. In 2003, the program funded 29 pilot projects in local health departments (LHDs) and correctional facilities around the state that provided hepatitis A and B vaccine to high-risk adults. The responsibilities of the HIV/STD/TB Program include management of HIV education and service delivery, patient care and outreach, incarcerated persons education and outreach programs, and harm reduction programs throughout the state. As such, they have contact with many of the populations also at risk for HCV infection.

Prior to 2003, there was no statewide guidance or consistent approach to the prevention and management of HCV in Oregon. With funding through the CDC's Epidemiology and Laboratory Capacity (ELC) cooperative agreement, Dr. Ann Shindo was hired as the state HCV Coordinator in August 2003. Housed in ACDP, she has primarily been involved in developing and conducting a state HCV needs assessment among LHDs, mental health, and addiction programs. While conducting this assessment, Dr. Shindo has begun assisting counties in identifying and building on existing HIV and STD resources and facilitating integration of HCV services into appropriate public health programs. Doing this has provided counties with guidance for infrastructure development that fulfills county-specific needs. By no means complete, these first steps to HCV program development at the local level have been helpful in determining the strengths and gaps within the current HCV resource base across the state.

Results from the needs assessment of LHDs show that 30 (85%) of 35 LHDs are conducting some HCV screening. Many will only provide screening to clients who can afford the \$15 - \$20 fee, and only two have comprehensive testing and counseling procedures recommended in the CDC Viral Hepatitis Screening protocols. Eighty percent of LHDs refer HCV-positive clients to at least one of the following: primary care physicians, the Oregon Health Plan, mental health or addictions services, and social support groups. Only 26% of those LHDs who report some type of referral indicated that they thought the client would receive good or appropriate care, and only two suggested that care would be excellent, or impressive. Few of these LHDs collaborate with local agencies that could support HCV-positive people. Resources (e.g. money and staff costs) and the lack of an appropriate referral infrastructure were the most cited barriers that prevented counties from conducting comprehensive HCV testing and counseling.

Thus, it is clear that some HCV screening and referring to appropriate resources is occurring in Oregon. Unfortunately, this is not universal and the ability of many LHDs to offer screening and referrals to providers or other support services in their community is limited due to the lack of resources.

The hiring of a state HCV coordinator and the 2003 legislation calling for the development of a statewide plan have led to increased collaboration between ACDP, Immunization, and HIV/STD/TB at the state level. The participation of all three programs in the statewide planning process has created a foundation for better integration of the three programs that will ideally lead to the integration of HCV counseling and testing into HIV settings and increase the likelihood that people living with HCV are targeted for hepatitis A and B vaccine. The three programs have created an inhouse hepatitis taskforce that will meet monthly to coordinate and oversee some of the recommendations by the SVHPG. Additionally, a ten-member statewide HCV advisory group will be formed in January 2005. This group will consist of members from the original SHVPG and representatives from minority communities most affected by HCV in Oregon. The role of this group will be to oversee implementation of action steps within the strategic plan, increase partnerships necessary for implementation, and promote inclusion of diverse people into the implementation process. In addition, this group will oversee evaluation and advocacy. This group will meet bimonthly for the first year after the plan is submitted to the legislature and as needed thereafter.

Recommendations

For each strategic area identified by the SVHPG there is one goal with several objectives, action steps and measurable outcomes, and a proposed time frame for development and implementation. It is very clear that implementation of this plan, or portions of this plan, will depend not only on strategic collaboration among multiple stakeholders and DHS, but also on funding from private, local, state, and federal sources.

Central to the vision of the SVHPG is the recognition that groups who may be marginalized within our society are at particular risk for acquiring HCV and will likely pose the greatest challenge for intervention. People diverse in relation to race, ethnicity, sexual or gender identification, socioeconomic status, or people with a history of homelessness, incarceration, or injection drug use are examples of such high-risk groups. Where possible, the task groups have tried to formulate education-, prevention- and disease managementspecific strategies that will take into account the needs of these communities. In implementing the SVHPG plan, our intent is to include as many representatives from these groups as possible, as well as other partners who may aid in reaching them, such as families of individuals living with HCV and faith-based communities.

Throughout this document, we refer to various clinical providers. Our intention is that those who implement this plan should consider all providers who participate in the care of people with, or at risk for, HCV. This includes but is not limited to: allopathic and CAM physicians, physician's assistants, nurse practitioners, nurses, pharmacists, psychiatrists, psychologists, counselors, social workers, health educators, public health professionals, outreach workers, case managers, and addictions service providers.

The timeline for implementation of components of this plan is differentiated by year one, two, and year three timeframes. This particular timeline was chosen as it lends opportunity to utilize current infrastructure for some components of the plan, yet address more long-term components in a timely fashion. Thus, those tasks that can be undertaken in year one are those that are most feasible within the context of the existing public health infrastructure, while portions of the plan designated for implementation in years two and three are more likely to require additional resources for implementation. An * is used to denote tasks that can be undertaken using existing resources, and ** denotes tasks that will require funding to implement.

Education

Goal: Promote HCV education that is comprehensive, consistent, accurate, and targeted for specific and general audiences throughout the State of Oregon.

Objective 1

Synthesize HCV educational information from peer-reviewed literature and guidelines published by nationally-recognized sources to develop a core set of educational messages addressing: disease education, risk assessment, behavior modification, treatment options, educational awareness, as well as primary and secondary prevention, alcohol and drug addictions services, and harm reduction strategies.

Action Steps:

During year one:

- Review guidelines published by the CDC, American Association for Liver Disease (AASLD),
 National Institute of Health (NIH), Veteran's Administration (VA) Treatment Guidelines and
 other credible evidence based sources for the most accurate and up-to-date research on HCV
 (Advisory Group Member, Representatives from Oregon Health Sciences University [OHSU],
 National College of Natural Medicine [NCNM], and the Oregon Public Health Degree Program).
- Review appropriate research and clinical journal articles for recent data on the epidemiology, natural history, prevention, and treatment of HCV (DHS, Advisory Group).**
- Review harm reduction, addiction intervention models, motivational interviewing, and other appropriate behavior-change theories to serve as a foundation for educational messages (DHS HIV Prevention and ACDP, Advisory Group).**
- Develop core educational behavior-modification messages based on current scientific evidence, best practices, and national standards of care, synthesized from the various above sources (Advisory Group, National HCV Trainers, National HCV Advocacy Council, DHS ACDP).**

Objective 2

Package core educational messages into appropriate modules for different educational target audiences:

- Target Group 1: Corrections Staff, Social Workers/Addiction Counselors, Alcohol and Drug
 Treatment Center (inpatient and outpatient), Behavioral/Mental Health Providers, LHD staff,
 AIDS Education and Training Center Staff (AETC) (AETC, Conference of Local Health Officials [CLHO], DHS ACDP and HIV, Office of Mental Health and Addictions Services
 [OMHAS], Advisory Group).**
- *Target Group 2*: Persons at risk for contracting HCV (persons who engage in high risk behaviors, persons who are incarcerated and homeless persons) (Advisory Group, American Liver Foundation [ALF], AETC, Oregon Department of Corrections [DOC], Local Harm Reduction Coalition [LHRC], Patient Advocates, DHS ACDP, HIV, and Office of Multicultural Health).**
- *Target Group 3*: Persons who are currently HCV positive (Patient Advocates, Advisory Group, ALF, DHS HIV, ACDP, and Office of Multicultural Health).**
- Target Group 4: General adult population in Oregon (AETC, DHS ACDP and HIV, ALF, Private organizations and insurers and health maintenance organizations [HMOs], Office of Medical Assistance Program [OMAP]).**
- Target Group 5: Children and youth engaged in school systems, schools teachers (K-12) (Oregon Department of Education [ODE], DHS ACDP and HIV, Parent Teacher Associations, School Based Health Centers).**

Action Steps:

During year one:

- Gather comprehensive list of social workers, addiction counseling centers, alcohol and drug treatment centers, behavioral/mental health providers (AETC, OMHAS, DHS).**
- Develop appropriate educational written and audio-visual materials for each target group above (DHS, Advisory Group, LHRC, NCNM, OHSU).**
- Evaluate all existing materials available through outside sources (e.g. New York Health Department Videos, OASIS video series, HCV Advocate Web sources, and others) for cultural sensitivity, availability to access in different languages, accuracy and cost (Advisory Group, DHS, LHRC).*
- Synthesize relevant counseling messages from HIV and STD fields (DHS, Advisory Group).*

Action Steps:

During year two:

- Gather a comprehensive list of K-12 schools in the State of Oregon (DHS, Oregon Department of Education [ODE]). *
- Work with ODE to incorporate HCV education and prevention into school curriculums for elementary, middle school and high schools health programs (DHS, ODE).**
- Investigate means of engaging the identified target groups using current outreach programs, widespread media campaigns, and public service announcements (DHS, Advisory Group, LHDs, LA, ALF).**
- Investigate potential funding sources from the CDC, State of Oregon legislature, pharmaceutical industry, private corporations, and non-profit organizations for grants to support educational efforts (DHS, Advisory Group, Advocates).*

Objective 3

Review and evaluate HCV counseling and testing protocols that are currently in use to ensure appropriate educational messages.

Action Steps:

During year one:

- Review nationally-recommended counseling and testing protocols (DHS, Advisory Group). *
- Develop or adopt appropriate risk assessment tools for target educational audiences 1-5 (DHS, ODE, Advisory Group, LHDs).*
- Develop core educational counseling and testing messages based on the literature review resources, including theories of harm reduction, addiction intervention models, behavioral modification and motivational interviewing (DHS, Advisory Group, NCNM, OHSU). **
- Ensure that consistent counseling and testing protocols are utilized at screening sites throughout the State of Oregon (DHS, Advisory Group, LHDs, Community-Based Organizations [CBOs]). **

Action Steps:

During year two:

• Develop standard counseling and testing protocols to be used throughout the State of Oregon to ensure best practices and quality assurance (DHS, Advisory Group, LHDs, CBOs). **

Prevention

Goal: Decrease new HCV infections among people at risk for contracting the disease and decrease HCV-related liver disease complications among people who are already HCV-positive.

Objective 1

Use primary prevention strategies to decrease new HCV infections through education, screening and testing of persons of all socioeconomic, racial, and ethnic groups who are at high-risk of HCV infection.

Action Steps:

During year two:

- Integrate HCV awareness into appropriate existing public health service programs (DHS, LHDs, CBOs, Advisory Group).*
- Implement standardized risk assessment screening and counseling protocols in high-risk target communities (DHS).**
- Implement harm reduction strategies within existing public health service programs and highrisk target communities to encourage screening and counseling (LHDs, CBOs, Advisory Group).
- Conduct peer-based risk reduction counseling with people who inject drugs (LHDs, CBOs, LHRC).**
- Work with community liaisons and peers to conduct street-based outreach in diverse high-risk target communities (DHS, LHDs, CBOs, LHRC).**

During year three:

- Promote on-site and on-demand financially accessible HCV screening at needle exchanges, alcohol and drug treatment centers, social service agencies, medical facilities, and during mobile outreach (DHS, LHDs, CBOs, Advisory Group, LHRC).***
- Evaluate behavior changes among those at greatest risk for HCV to evaluate the impact of prevention strategies on HCV incidence (DHS, Advisory Group).**

Objective 2

Promote safer injection practices in the injection drug use community.

Action Steps:

During year one:

- Promote access to a continuum of addictions services (DHS, LHDs, CBOs, LHRC).**
- Develop and distribute statewide up-to-date syringe exchange program schedules through internet and print media (DHS, CBOs, LHRC).*
- Develop and distribute consistent HCV education and prevention materials targeted for needle exchange clientele (DHS, CBOs, LHRC).**
- Increase awareness of the need for syringe accessibility (DHS, Advisory Group).*
- Educate state and local law enforcement groups about public health benefits of state laws supporting needle exchange and syringe access (DHS, LHDs, CBOs, Advisory Group).**
- Evaluate processes related to action steps (DHS).*

During year two:

- Work with injection drug use social networks to educate peers about HIV, STD and hepatitis transmission; syringe access; and skills to prevent disease acquisition (LHDs, CBOs).**
- Increase street-based and mobile syringe disposal and exchange accompanied with appropriate harm reduction and addiction services education throughout the state (DHS, LHDs, CBOs).**

During year three:

- Increase access to disease prevention related injection drug equipment at alcohol and drug outpatient facilities and pharmacies statewide (DHS, CBOs, LHRC, Advisory Group).**
- Develop and implement safe syringe exchange vending machines in limited venues through the state (DHS, Advisory Group, CBOs).**
- Develop and implement safe injection sites throughout the state (DHS, LHDs, CBOs, Advisory Group, LHRC).**

During years one, two, and three:

- Develop and implement ongoing evaluation efforts of the effectiveness of prevention programs with target populations (DHS).**
- Evaluate processes related to action steps (DHS).*

Objective 3

Use primary and secondary prevention strategies to decrease the transmission of HCV and minimize the progression and complications of chronic liver disease.

Action Steps:

During year two:

- Educate HCV-positive people about how to reduce transmission of HCV (LHDs, CBOs).**
- Partner with multidisciplinary treatment teams to promote harm reduction strategies for preventing liver damage from alcohol and liver-toxic medications, and support diet and exercise (DHS, Advisory Group, LHDs, CBOs).**
- Promote and provide hepatitis A and B vaccination among persons with HCV (DHS, LHDs, CBO).**

During year three:

- Integrate HCV case management into appropriate public health programs (DHS, LHDs, CBOs).
 **
- Advocate for stable, subsidized health care coverage to improve access to care for low-income HCV-positive persons (DHS, Advisory Group, Health Plans, OMAP).**
- Ensure that all HCV-positive people have increased access to a full range of HCV treatment options such as interferon-based therapies, CAM disease management options, mental health, addictions services, social support, health plan coverage, housing, and other needed resources (DHS, Advisory Group, Health Plans, OMAP, LHDs, CBOs).**
- Evaluate processes related to action steps (DHS).*

Management

Goal: Identify reasonable, effective, accessible, and affordable case management and treatment services to prevent or limit the progression and complications of HCV infection and improve affected individuals' quality of life.^I

Note: Viral eradication is the goal of allopathic drug-based therapies and interventions. Long-term support and reduction of disease burden on the individual is the goal of Complimentary and Alternative Medicine (CAM) interventions.

Objective 1

Research and identify comprehensive models for an evidence-based process for prevention and management of HCV that is based on solid medical principles, recommendations and guidelines.

Action Steps:

During year one:

 Convene a panel to review medical guidelines, protocols, and recommendations for the medical management of HCV, and develop recommendations for management of HCV in Oregon¹ (DHS, Advisory Group, OHSU, Kaiser, VA Clinician Panel, NCNM, gastroenterologists and hepatologists).*

During years two and three:

- Use the panel's recommendations and findings to develop educational and training materials for licensed clinical providers^{II} for the management of HCV patient care (OHSU, Kaiser, VA Clinician Panel, NCNM, gastroenterologists and hepatologists).*
- Review recommendations on an annual basis or as needed to incorporate the most up-to-date information (OHSU, Kaiser, VA Clinician Panel, Advisory Group, NCNM).*

Objective 2

Develop education and training opportunities for the evaluation and long-term clinical management of HCV to licensed clinical providers, both allopathic and complementary and alternative.

Action Steps:

During year one:

- Identify curriculum development committee (Advisory Group, OHSU, NCNM, Kaiser). *
- Create appropriate educational curricula based on the major management points^I for each of the following (Advisory Group, OHSU, NCNM, Kaiser):**
 - Natural history, evaluation and management of HCV for all licensed clinicians and practitioners involved in concurrent co-morbidity care (e.g. mental health and addictions service providers).
 - Advanced HCV management for medical providers who treat patients with HCV.

Prevention of disease is the best management;

Prevention of complications or progression is the next best management;

Self-care is important to all patients living with HCV and should be emphasized; and

Though appropriate for some patients, viral eradication is not for everyone.

^I Major management points considered in this plan (See Appendix A for guiding principles):

II Clinical providers include allopathic and licensed CAM practitioners, pharmacists, and licensed mental health providers.

During year two:

- Make education curricula available through multiple continuing education channels (e.g. conferences, grand rounds, meetings, mailings, publications, web-based Continuing Medical Education [CME], web-based resources, and others) (OHSU, DHS, Pharmaceutical Industry [PI], NCNM).**
- Identify and train primary care clinicians to provide HCV treatment in those areas of the state with poor access to care (OHSU, NCNM).**
- Create collaborative educational sessions among allopathic and CAM providers to promote effective integration and coordination of medical therapies thought to provide optimal care for HCV patients (OHSU, NCNM, DHS, PI).**

During years two and three:

- Ensure educational information is periodically revised in keeping with current information (Advisory Group, OHSU, NCNM, Kaiser, VA Clinician Panel).*
- Evaluate effectiveness of educational programs (Advisory Group, OHSU, NCNM, Kaiser, VA Clinician Panel).*

Objective 3

Develop materials for providers to give to HCV-positive patients with information about living with HCV, evaluation plans, and long-term management options and recommendations.

Action Steps:

During year one:

Based on the work of the Education task group, identify or develop educational materials in a
variety of formats designed for patients and their families on the natural history, transmission,
prevention, and management of HCV infection (Advisory Group, OHSU, NCNM, Kaiser, VA
Clinician Panel, PI).**

During year two and on-going:

- Widely disseminate patient educational materials to providers to assist patients in evaluating life-style choices, decision-making for living with chronic HCV infection, minimizing the effects of HCV infection, and undergoing viral eradication or other therapies (OHSU, DHS, NCNM, Advisory Group).**
- Develop a statewide resource list (for both providers and patients) for access to HCV disease information and referrals to appropriate resources (OHSU, DHS, NCNM, Advisory Group).*
- Ensure that information sources are revised to reflect the most current information (Advisory Group, OHSU, NCNM, Kaiser, VA Clinician Panel, LHRC).*

Objective 4

Increase continuity of care for HCV patients who are transitioning between health plans or differing geographic areas, ^{III} especially those actively taking medication that should not be interrupted.

III Many people living with HCV may not have medical insurance coverage.

Action Steps:

During year one and two:

- Promote partnerships with corrections and jail health services, health plans, provider groups, LHDs, CBOs, and advocacy groups to design processes for the transition of HCV patients between incarceration settings and the community (DHS, OMAP, DOC, CBOs, LHDs).**
- Design a plan to assure continuous treatment for patients transitioning from one insurance plan to another (DHS, Advisory Group, Health Plans, Provider Groups, OMAP, LHDs, CBOs, LHRC).**

During year three:

Implement the plan for continued coverage from one insurance plan to another, and from incarceration to community health systems (DHS, Advisory Group, Health Plans and Third Party Payers, OMAP).**

Objective 5

Establish and implement an integrated and comprehensive care structure for the management of HCV patients that will include HCV education, testing, treatment, and referrals to medical and social services.

Action Steps:

During years one, two, and three:

- Partner with health plans, provider groups, local health departments, community-based organizations, and advocacy groups to identify statewide medical and social services supportive of HCV prevention and management (DHS, Advisory Group, DOC, OMAP, OHSU, NCNM).**
- Integrate HCV testing and referrals into local addictions services and needle exchange programs, HIV/AIDS/STD programs, local health departments, correctional settings, veteran services, community health, mental health, and other relevant social service agencies (DHS, Advisory Group, DOC, LHDs, CBOs).**
- Promote the development of a comprehensive infrastructure to provide support to HCV-positive persons, using a case-management approach to ensure access to mental health and substance abuse treatment, health insurance coverage, employment and housing (DHS, Advisory Group, OMAP, LHDs, CBOs). **

During years two and three:

Include hepatitis A and B testing, vaccinations, and appropriate medical care through local addiction services and needle exchange programs, HIV/AIDS/STD programs, LHDs, correctional settings, veteran services, community health, mental health, and/or other relevant agencies for non-HCV seropositive people who are at high-risk for infection (DHS, Advisory Group, OMAP, DOC, VA, LHDs, Pharmacists). **

Surveillance and Research

Goal: Improve HCV surveillance in order to better understand HCV in Oregon and develop means of evaluating the effectiveness of HCV prevention programs.

Objective 1

Develop a surveillance system for chronic HCV infection.

Action Steps:

During year one:

- Make all positive HCV tests reportable by laboratories to the State of Oregon (DHS, Legislation, CLHO).*
- Offer free HCV screening tests at local health departments to any person with risk factors for HCV (DHS ACDP, HIV, LHDs, CLHO, Oregon State Public Health Laboratory [OSPHL], PI).
 ** IV
- Develop pilot protocol for interested counties for investigation of cases and standardized case report form (DHS ACDP, Advisory Group, LHDs, CLHO, OSPHL).*
- Develop a standardized demographic and risk factor data collection form (based on existing form in use for HIV testing) to use for every HCV test performed at the OSPHL in Oregon (DHS ACDP, HIV, Advisory Group, OSPHL).*

During years two and three:

 Develop and implement standard protocols for follow-up of HCV-positive individuals, to include standardized counseling, vaccination with hepatitis A and B vaccine, contact tracing, and referrals to health care and other support services (DHS ACDP, Immunization, CLHO, LHDs, CBOs).***

Objective 2

Assess need for medical, preventive and mental health services of persons with HCV.

Action Steps:

During year three:

Institute ongoing surveys of persons with HCV identified through chronic HCV surveillance system to estimate needs for such services as primary medical care, need for hepatitis A and B vaccination, addiction services, and mental health services (DHS ACDP, Immunization, HIV, CLHO, may also consult representatives from DOC, Native American Tribal Health Organizations, Northwest Area Indian Health Board, Hispanic-based migrant health and other CBOs as necessary).**

CDC recommends HCV screening for anyone who: 1) has ever injected drugs; 2) has persistently elevated liver function tests; 3) has ever been on long-term hemodialysis; 4) received a blood transfusion or solid organ transplant prior to July 1992 or clotting factor before 1987; or 5) was notified that they received blood from a donor who later tested positive for HCV.

Objective 3

Evaluate prevention and control efforts.

Action Steps:

During year two:

- Analyze surveillance data on ongoing basis (DHS ACDP).**
- Monitor annual incidence of hepatocellular carcinoma and mortality from viral hepatitis (DHS ACDP).**
- Disseminate data from state HCV acute and chronic surveillance and special studies via such channels as DHS web site and *CD Summary* (DHS ACDP).**

During year three:

Assess ongoing transmission through targeted seroprevalence studies in high-risk populations, with emphasis on frequent re-testing of HCV-negative persons (DHS ACDP, OSPHL, LHDs, may also consult representatives from DOC, Native American Tribal Health Organizations, Northwest Area Indian Health Board, Hispanic-based migrant health and other CBOs as necessary).***

Objective 4

Periodically revise surveillance plan based on acquired data.

Action Steps:

During year three:

- Analyze surveillance data for gaps and strengths (DHS ACDP, Advisory Group).**
- Develop and promote appropriate changes to data gathering protocols (DHS ACDP, CLHO, LHDs, Advisory Group, OSPHL).**

Legislation, Policy, Grants

Goal: Ensure adequate resources for prevention and control of HCV in Oregon.

Objective 1

Educate state legislators and key health policymakers about HCV issues.

Action Steps:

During year one:

- Develop legislative information packets rooted in evidence-based epidemiological data (Legislative Advocates [LA]).*
- Conduct training for legislative advocates who participated in the statewide viral hepatitisplanning group (DHS, Advisory Group).*
- Identify legislative leadership and key health policy makers (DHS, LA).*
- Schedule and conduct educational informational sessions with legislatures and policy makers (DHS, LA).*
- Identify individuals from the SVHPG to serve as spokespeople (DHS, LA).*

Objective 2

Revise existing Oregon administrative rules and statutes to include language for prevention and control of HCV where appropriate.

Action Steps:

During year one:

• Identify administrative rules and statutes where HCV language inclusion is practical and appropriate (e.g. existing HIV and HBV statues) (LA, DHS).*

Objective 3

Identify potential funding sources for HCV plan implementation including public, private, and in-kind resources.

Action Steps:

During year one:

- Research current grant options from the following sources: federal, state, and local governments, non-profit organizations, and private corporations (DHS).*
- Advocate for stable, ongoing funding sources for HCV education, prevention and management programs implemented as a result of this planning process (LA).*

Objective 4

Identify the costs and potential benefits of implementing a comprehensive, inclusive and culturally appropriate HCV plan in the State of Oregon.

Action Steps:

During years two and three:

- Review cost-benefit evaluation analyses conducted by other state HCV Coordinators (LA, DHS).**
- Review published scientific literature on costs and benefits of different facets of HCV prevention (e.g., hepatitis A and B vaccination, harm reduction programs, medical treatment of HCV) (LA, DHS, Advisory Group).**

Objective 5

Ensure resources for hepatitis A and B vaccine integration into existing programs that reach HCV atrisk populations.

Action Steps:

During year one:

- Identify existing programs appropriate for vaccine integration efforts (LA, DHS ACDP, Immunization, LHDs, CBOs).*
- Develop collaborative partnerships to strengthen vaccination resources (LA, DHS).*
- Secure stable vaccine supply (DHS, LA, LHDs, PI).**

Objective 6

Develop collaborations with agencies funding and providing services to persons co-infected with HIV and HCV to promote integration of medical and prevention services.

Action Steps:

During year one:

- Identify current CAREAssist (medical expense augmentation program for people living with HIV or AIDS) and Ryan White funding and delivery mechanisms (LA, DHS HIV).*
- Identify current Department of Corrections guidelines and funding regarding co-infection (LA, DHS, DOC).*
- Identify integration practices and gaps in such practices (DHS, Advisory Group, LA, DOC).**

Conclusion

HCV is one of Oregon's most important public health issues. Tens of thousands of Oregonians may unknowingly be infected with this virus and may be progressing toward liver disease or continuing to spread the virus. Comprehensive, inclusive, and culturally appropriate education, prevention, and management strategies must be employed to reduce the number of new infections per year and decrease the probability that persons already infected will develop serious and costly health outcomes.

Recognition of the need for public health mobilization around HCV was driven by a legislative mandate and stakeholder group advocacy. The 2003 Oregon Legislature requested that a strategic plan addressing HCV education, prevention, and management be developed with the assistance of multiple stakeholder groups. This process has brought together some of the most creative minds in Oregon's HCV community to identify priorities for addressing the HCV epidemic.

The SVHPG designed the action steps built into this strategic plan to address the multidimensional

nature of HCV needs in our state. Ranging from basic education of all Oregonians to comprehensive and holistic care of people living chronically with this disease, this strategic plan provides guidelines for HCV interventions that can be used by any local or state agency or organization providing service to individuals with HCV or at-risk for HCV. The need to move forward in a direction that fully addresses all HCV needs will require continued collaboration and partnership between private, public, and community HCV stakeholders. Efforts to implement this strategic plan will take creative investment of both time and money and will require political as well as community support. The success of this plan will involve community-based coalitions that will take the implementation reins and develop programs that are consistent with their community's needs and values. Ultimately multidisciplinary partnerships, like those developed to write this plan, will be necessary to ensure that a comprehensive, inclusive, and culturally appropriate approach is taken to coping with HCV in Oregon.

Guiding Principles of Interferon-based Antiviral Therapy

Management of chronic HCV, with the specific goal of viral eradication, should be evidence-based and reflect understanding of the natural history of the infection as well as the limitations of current therapy. Decision-making should follow these principles:

Though very appropriate for some, viral eradication treatment is not for everyone.

- Treatment is costly and often associated with significant adverse effects.
- In many cases, viral eradication is not necessary, safe, or appropriate.

Selection of patients for treatment with the intent to eradicate HCV should be highly individualized.

- A careful benefit to risk analysis should always be done, incorporating both patient and disease factors
- Final decision to treat should be predicated minimally on: 1) the severity of liver disease; 2) the likelihood of response; 3) the potential for serious adverse effects of therapy; and 4) patients' level of motivation for therapy.

Although current drug-based therapy is effective in clearing HCV in about one half of those treated, only 15-20% of chronically infected, untreated individuals will develop cirrhosis. Thus, therapy may be safely deferred for the following patients:

- Individuals with absent or minimal fibrosis on biopsy, especially if genotype 1.
- Patients whose progression of liver disease is slow, often taking years to progress, especially if in an early stage at the time of initial evaluation.
- Interval liver biopsy approximately 5 years after the first is prudent in the follow-up of those not treated.

The following patient conditions are associated with either: 1) high risk for serious iatrogenic problems; 2) low response rates; or 3) potential lack of adherence to therapy. Treatment of these patients should be pursued on a case-by-case basis by providers with high patient volume and expertise in treating these conditions:

- Active use of alcohol (continued alcohol use during therapy adversely affects response to treatment)
- Active injection drug use (although injection drug use does not adversely affect response to treatment and concurrent methadone use is not a contraindication to therapy, there is only limited data available on the feasibility of treating IDUs)
- Decompensated cirrhosis (response to treatment is lower than in patients without cirrhosis).
- Certain pre-existing inadequately controlled medical or psychiatric conditions that carry a higher risk of harm if treated.

Specific suggestions related to viral eradication therapy should be evidence-based and approximate published guidelines (e.g. AASLD Practice Guideline: Diagnosis, Management, and Treatment of Hepatitis C. Strader DB et al. Hepatology 2004;39(4):1147-1171., NIH Consensus Conference Development Statement: Management of Hepatitis C - 2002, June10-12, 2002. etc.)

Management of Chronic Hepatitis C, with the goal of long-term maintenance or support, should follow these principles:

- The long-term value of agents commonly prescribed for viral eradication remains unproven.
- Emphasis should be placed on the avoidance of alcohol, selection of the least hepatotoxic alternatives among medications

- prescribed for other conditions, pursuit of ideal body weight, nutrition, and vaccination for hepatitis A and B (if not already immune).
- A number of agents and modalities within the scope of CAM may be of value:
 - Agents known to be associated with hepatotoxicity should be investigated and their use discouraged. Milk Thistle (silymarin) in pure preparation has proven safety.
- Use of over-the-counter agents directed at liver support should be discouraged unless used under the supervision of a licensed allopathic or naturopathic clinician knowledgeable about HCV.

CAM modalities of all types should be taken only under guidance of a licensed CAM provider with expertise in liver disease.

Guiding Principles of Complementary and Alternative Medicine (CAM)

Goals

Consider CAM therapies in conjunction with interferon-based treatment:

- to enhance effectiveness of conventional therapy; and
- to reduce side effects of conventional therapy in order to increase likelihood of completing full duration of interferonbased treatment.

Consider CAM therapies when interferon-based treatment is refused, withheld, unavailable, inappropriate, or unsuccessful. 10-12

Enhance patient quality of life through:

- education about nutritional optimization, lifestyle improvements, and stress reduction;
- *decongestion* of the liver and reduction of systemic toxicity;
- enhanced nutrient absorption and assimilation:
- decreased systemic inflammation; and
- enhanced functioning of elimination pathways of the body.

Recommendations for CAM Management of HCV

Identify and evaluate CAM treatment protocols for the management of HCV in the above areas.

Train CAM providers through an approved CE class in the management of HCV to ensure a high level of familiarity and competence in CAM treatment of HCV.

List on web site those providers that have completed the CAM CE class so that patients and referring physicians seeking a CAM provider can choose someone with competence in this area.

Educate both allopathic doctors and naturopathic doctors to allow effective integration and coordination of therapies to provide optimal care for HCV patients.

Educate lay public in the use of over-the-counter natural medicines.

References

- 1. Alter MJ, Kruszon-Moran D, Nainan OV, McQuillan GM, Gao F, Moyer LA, et al. The prevalence of hepatitis C virus in the United States, 1998 through 1994. N Engl J Med 1999;341:556-62.
- 2. CDC. Recommendations for prevention and control of hepatitis C virus (HCV) and HCV-related chronic disease. MMWR 1998; 47(RR-19): 1-39.
- 3. Kim WR. The burden of hepatitis C in the United States. Hepatology 2002;36:S30-34.
- 4. Seef LB. Natural history of chronic hepatitis C. Hepatology 2002;36:S35-46.
- 5. Leigh JP, Bowlus CL, Leistikow BN, Schenker M. Costs of hepatitis C. Arch Intern Med 2001;161:2231-2237.
- 6. Alter MJ. Prevention of spread of hepatitis C. Hepatology 2002;36:S93-S98.
- 7. DiBisceglie AM, Hoofnagle JH. Optimal therapy of hepatitis C. Hepatology 2002;36:S121-S127.
- 8. Hyams KC, Riddle J, Rubertone M,

- Trump D, Alter MJ, Cruess DF, et al. Prevalence and incidence of hepatitis C virus infection in the US Military: A seroepidemiologic survey of 21,000 troops. Amer Epidemiol 2001;153:7694-7770.
- 9. CDC. Viral hepatitis counseling 2003. Atlanta, GA: Centers for Disease Control and Prevention, Viral Hepatitis Branch.
- 10. Milliman WB, Lamson DW, Brignall MS. Hepatitis C: A retrospective study, literature review, and naturopathic protocol. Alternative Medicine Review, 2000; 5 (4):355-370.
- 11. Flora K, Hahn M, Rosen H, Benner K. Milk thistle (Silybum marianum) for the therapy of liver disease. Am J Gasteronterology 1998; 93:139-143.
- 12. Von Herbay A, Stahl W, Niederau C, Sies H. Vitamin E improves the aminotransferase status of patients suffering from viral hepatitis C: A randomized, doubleblind placebo-controlled study. Free Radic Res 1997; 27:599-605.



Oregon Department of Human Services Oregon Health Services

800 NE Oregon St Ste 1105 Portland, Oregon 97232

Phone: 503-731-4029 Fax: 503-731-4608