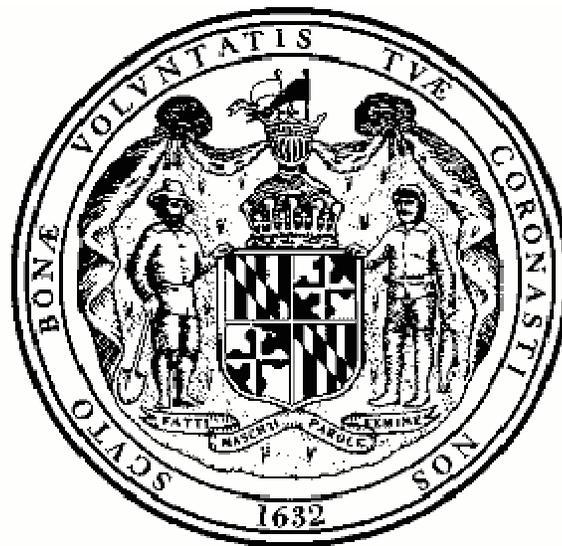


Maryland Department of Health and Mental Hygiene

Maryland Hepatitis C Prevention and Control Plan

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Parris N. Glendening, Governor
Kathleen Kennedy Townsend, Lieutenant Governor
Georges C. Benjamin, M.D., Secretary

Maryland Department of Health and Mental Hygiene

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INTRODUCTION

Hepatitis C virus (HCV) infection is the most common chronic bloodborne viral infection in Maryland as well as in the United States. In November 2000, the Secretary of the Department of Health and Mental Hygiene (DHMH) commissioned the formation of a work group to address this important infection. The Secretary requested that the work group, led by the Epidemiology and Disease Control Program, DHMH and the AIDS Administration, DHMH, develop a plan to address the prevention and control of HCV infection in Maryland.

The ***Maryland Hepatitis C Prevention and Control Plan*** is the work group's response to this request, and includes partnerships and coordination with the Department of Public Safety and Correctional Services, Johns Hopkins Hospital, American Red Cross, Maryland Medical Society, Frederick County Hepatitis Clinic and other federal, state, and private sector entities. Within DHMH, partners include Alcohol and Drug Administration, Laboratories Administration, Local Health Departments, AIDS Administration, Epidemiology and Disease Control Program, Office of Health Care Quality, Office of Maternal and Child Health, among others.

The goals of the ***Maryland Hepatitis C Prevention and Control Plan*** are to lower the incidence of acute hepatitis C in Maryland and reduce the disease burden from chronic HCV infection. Achievement of these goals requires a multi-faceted approach, including the implementation of:

- primary prevention activities that reduce risks for acquiring HCV infection;
- secondary prevention activities that reduce risks for liver and other chronic diseases in HCV-infected persons;
- surveillance to monitor disease trends and to evaluate the effectiveness of prevention activities; and
- professional and public education.

The ***Maryland Hepatitis C Prevention and Control Plan*** was written in advance of the identification of available resources. As resources are identified and become available, implementation of the various Plan objectives can proceed. An implementation time frame is listed for each Plan objective as a targeted milestone and to reflect the importance of addressing HCV infection in Maryland in a timely fashion.

In the face of limited resources, the most effective means to prevent HCV infection and its consequences is to integrate hepatitis C prevention activities into existing clinical services and public health programs, such as those for the prevention and treatment of human immunodeficiency virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), sexually transmitted diseases (STDs) and drug abuse. Similar risk factors place persons at risk for transmission of the major bloodborne viral infections – HIV, HCV, and hepatitis B virus (HBV).

Over the next couple of years, new information about HCV infection will likely accumulate and provide insight into better means of prevention and control. Accordingly, as current knowledge and national public health recommendations change, this Plan will be updated as well.

Questions about the contents of this Plan and its process of development may be referred to the Epidemiology and Disease Control Program, DHMH at 410-767-6700.

BACKGROUND

Hepatitis C Virus Infection in the United States and Maryland

The Centers for Disease Control and Prevention (CDC) underscores the magnitude of the hepatitis C challenge in the following excerpt:

*" ... **Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States.** CDC staff estimate that during the 1980s, an average of 242,000 new infections occurred each year. Since 1989 the annual number of new infections has declined by greater than 80% to 36,000 by 1996. Data from the Third National Health and Nutrition Examination Survey (NHANES III), conducted during 1988-1994, have indicated that **an estimated 3.9 million (1.8%) Americans have been infected with HCV. Most of these persons are chronically infected and might not be aware of their infection because they are not clinically ill.** Infected persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases during the first two or more decades following initial infection. Chronic liver disease is the tenth leading cause of death among adults in the United States, and accounts for approximately 25,000 deaths annually, or approximately 1% of all deaths. Population-based studies indicate that **40% of chronic liver disease is HCV-related**, resulting in an estimated 8,000-10,000 deaths each year. Because most HCV-infected persons are aged 30-49 years, the number of **deaths attributable to HCV-related chronic liver disease could increase substantially during the next 10-20 years** as this group of infected persons reaches ages at which complications from chronic liver disease typically occur. "*

Background: HCV is in the viral family of "flaviviruses", which include the causes of yellow fever and West Nile encephalitis. It was originally known only as hepatitis which differed from hepatitis A and hepatitis B, and was called "hepatitis non-A, non-B." HCV was discovered in 1989 as a distinctive organism that causes hepatitis. A laboratory detection test first became available for use in 1992.

HCV first came to public health's attention about a decade ago, as efforts to improve the safety of the U.S. blood supply focused on eliminating transmissible agents of transfusion-related hepatitis and other infectious diseases, like HIV. The availability of screening tests for donated blood made certain diagnosis possible and widely available, and allowed HCV-contaminated units to be excluded from the blood supply.

Sources of HCV Infection: HCV is transmitted primarily through large or repeated direct percutaneous exposures to blood. In the United States, the relative importance of the two most common exposures associated with HCV transmission, blood transfusion and injecting-drug use, has changed over time. Blood transfusion, which accounted for a

substantial proportion of HCV infections acquired more than 15 years ago, rarely accounts for recently acquired infections. With improved testing and processing of blood since mid-1992, the risk of HCV transmission through the blood supply or transplanted tissue is now virtually zero.

In contrast, since 1992, the majority of new HCV infections have been linked to the practice of sharing needles among injecting drug users and currently accounts for 60% of HCV transmission in the United States. Other sources of infection include sexual exposure (15%), transfusion (before donor screening) (10%), unknown (10%), and other (e.g., hemodialysis, health care work, perinatal) (5%).

Consequences of HCV infection: About 15% to 25% of persons with acute hepatitis C resolve their infection without further problems. The remainder develop a chronic infection and about 60% to 70% of these persons develop chronic hepatitis. Cirrhosis of the liver develops in 10% to 20% of persons with chronic hepatitis C over a period of 20 to 30 years, and hepatocellular carcinoma (liver cancer) in 1% to 5%. For individuals with cirrhosis, however, the rate of development of liver cancer might be as high as 1% to 4% *per year*.

Chronic liver disease is the tenth leading cause of death among adults in the United States. It is estimated that 40% to 60% of chronic liver disease is due to hepatitis C and another 10% to 15% is due to chronic hepatitis B. HCV-associated chronic liver disease is the most frequent indication for liver transplantation among adults. In addition, because alcohol use is one of the most important contributing factors to progression of chronic liver disease among persons with hepatitis C, it is important to counsel infected individuals to limit alcohol consumption.

Treatment for Hepatitis C: Studies are ongoing to determine the best therapies for acute and chronic hepatitis C. At present, the optimal treatment for chronic hepatitis C is a combination therapy with peginterferon and ribavirin, a regimen which yields overall rates of sustained HCV elimination in up to 56% of cases. One recent study of 44 patients found that early treatment of acute hepatitis C with interferon alfa-2b alone prevented the development of chronic HCV infection in almost all patients studied. In addition some patients may have conditions, such as severe cirrhosis, which prohibit treatment. Persons with chronic hepatitis C who continue to abuse alcohol are at risk for ongoing liver injury and antiviral therapy may be ineffective. As such, abstinence from alcohol is recommended during antiviral therapy. In addition, CDC recommends that when patients with past or continuing substance abuse are considered for antiviral treatment, such patients should receive drug treatment or care from substance abuse specialists or counselors.

Persons with HCV-related liver disease should be vaccinated against diseases that may produce further complications or increase their risk of death. Susceptible persons with should receive hepatitis A and hepatitis B vaccine.

HCV Infections in Maryland: Utilizing the national estimate of prevalence at 1.8%, at least 95,400 persons in Maryland are currently estimated to be infected. The majority of these persons are asymptomatic and unaware of their infection. Given that (1) some populations of intravenous drug users have infection rates as high as 90%, and (2) there is evidence from drug treatment program admissions that Maryland may have a disproportionately larger population using heroin (most of which is injected), this number likely represents an underestimate. HCV infection is currently reportable by both Maryland health care providers and medical laboratories and acute symptomatic hepatitis C is considered a nationally notifiable disease. However, the diagnosis of acute versus chronic hepatitis C is difficult because (1) laboratory tests cannot differentiate between acute and chronic infection and (2) 60-70% of acute cases are asymptomatic. Consequently, few cases of acute symptomatic hepatitis C have been reported from Maryland.

PRIMARY PREVENTION ACTIVITIES

SCOPE

Primary prevention activities aim to reduce risks for contracting HCV infection. These activities focus on reducing or eliminating potential risk for HCV transmission from an infected person to an uninfected person.

Primary Prevention Goals and Objectives

Goal 1: The Maryland health care delivery system will be served by a system that screens and tests blood and tissue and employs virus inactivation of plasma-derived products.

Objective 1: By Year 1, the DHMH Office of Health Care Quality will continue to review blood and tissue banks to assess compliance with current standards of safety, and to recommend revisions if necessary.

Objective 2: By Year 1, Local Health Departments (LHDs) will continue to initiate (within 72 hours) investigation of cases of reportable communicable disease, including those related to transfusions.

Goal 2: Maryland residents will be informed about risk reduction strategies to prevent new infections.

Objective 1: By Year 1, DHMH Epidemiology and Disease Control Program (EDCP) will develop and make available through multiple modalities, informational materials about primary prevention targeted to infected and at-risk persons.

Objective 2: By Year 2, various appropriate DHMH agencies will provide HCV educational materials and training opportunities to Community-Based Organizations under contract with DHMH or LHD's that provide services to high-risk populations, to all drug-treatment agencies serving injecting drug users, and to all agencies serving clients with mental illness.

Goal 3: Injecting Drug Users will have access to sterile injection equipment, in conjunction with prevention education and outreach services.

Objective 1: By Year 2, DHMH AIDS Administration will work with State Board of Pharmacy to make sterile injection equipment available in conjunction with prevention education and outreach services through Maryland pharmacies.

Objective 2: By Year 2, DHMH AIDS Administration will pursue programs to make sterile injection equipment available to injection drug users through the expansion of needle exchange programs.

Goal 4: Maryland agencies and health care facilities will implement and maintain appropriate infection control practices.

Objective 1: By Year 2, DHMH EDCP will have documented that LHDs and DHMH facilities maintain compliance with MOSH standards for blood-borne pathogen training and control.

Objective 2: By Year 2, DHMH EDCP will conduct a follow-up survey of public safety agencies for compliance with bloodborne pathogen standards.

SECONDARY PREVENTION ACTIVITIES

SCOPE

Secondary prevention focuses on persons already infected with HCV. These activities aim to reduce risks for liver complications and other chronic diseases. Secondary prevention activities include the testing of individuals most likely to have hepatitis C, and the provision of appropriate counseling about prevention and medical follow-up to HCV-infected persons.

Secondary Prevention Goals and Objectives

Goal 1: Maryland residents who are at-risk for exposure to HCV will be informed about the advantages and disadvantages of HCV testing and offered testing for HCV.

Objective 1: By Year 2, DHMH EDCP will make available information about HCV testing to Maryland residents who were recipients of blood transfusions/organ transplants prior to July 1992, or were recipients of clotting factor concentrates prior to 1987, and who have not yet been tested for HCV infection.

Objective 2: By Year 2, DHMH Family Health Administration will disseminate to all licensed Maryland obstetricians and pediatricians the current national guidelines for screening high-risk pregnant women and children born to HCV-infected mothers.

Objective 3: By Year 2, LHDs will make available information about national HCV screening recommendations and offer testing services to persons in high-risk groups for HCV served by LHD programs (e.g., STD clinics), and public drug and mental health treatment programs.

Objective 4: By Year 2, DHMH EDCP will develop HCV screening guidelines for use in LHD programs that serve high-risk populations.

Objective 5: By Year 2, DHMH EDCP will provide consultation to DHMH institutions in developing criteria for screening of individuals with HCV.

Objective 6: By Year 1, DHMH Laboratory Administration will provide laboratory support for LHD screening programs.

Goal 2: Maryland residents infected with HCV will be counseled about measures to prevent liver complications and other HCV-associated chronic diseases.

Objective 1: By Year 1, DHMH EDCP will develop and make available through multiple modalities, informational materials about secondary prevention targeted to infected persons, in support of counseling efforts.

Objective 2: By Year 1, LHDs will survey their communities to determine existing HCV secondary prevention services that are provided by community-based organizations.

Goal 3: Maryland residents with HCV infection will receive appropriate medical management.

Objective 1: By Year 1, LHDs will survey their communities to determine existing HCV medical treatment services that are provided by community-based organizations.

Objective 2: By Year 1, DHMH will continue to advocate for federal funding and policy initiatives to make HCV treatment services and pharmaceutical agents available to treatment candidates.

Objective 3: By Year 1, DHMH EDCP will continue to advocate for federal funding and policy initiatives for HAV and HBV immunizations for persons infected with HCV.

PROFESSIONAL AND PUBLIC EDUCATION

SCOPE

Control and prevention of HCV infection requires not only well-educated health care professionals but also a well-informed general public. Health education materials should include a) general information about HCV infection; b) risk factors for infection, transmission, disease progression, and treatment; and c) detailed prevention messages appropriate for the targeted population.

Educational Goals and Objectives

Goal 1: Maryland health care providers and other professionals will have a high level of awareness concerning HCV prevention and control, including national recommendations and resources in Maryland for primary and secondary prevention.

Objective 1: By Year 1, DHMH Office of Health Care Quality will provide information about the new State law requiring HCV reporting to all Directors of Laboratories licensed in Maryland to provide medical laboratory testing services.

Objective 2: By Year 2, DHMH EDCP will conduct a survey of a representative sample of Maryland health care providers to assess the percentage of providers who know that HCV infection is a provider-reportable and laboratory reportable disease. This survey will also assess the level of primary and secondary prevention services rendered and perceived barriers.

Objective 3: By Year 2, LHDs will provide to the local medical society in that jurisdiction information on local HCV counseling, testing and referral services.

Objective 4: By Year 2, DHMH Boards of Physician Quality Assurance and of Nursing will provide physicians, nurses and other licensed providers with information about HCV counseling, screening, and case investigation services provided by DHMH EDCP and LHDs.

Objective 5: By Year 1, DHMH EDCP will make national guidelines and other resources available to health care providers via the Internet or other modality.

Objective 6: By Year 1, DHMH EDCP will appoint a liaison to work with agencies serving people at high risk of HCV infection, including Public Safety and Correctional Services.

Objective 7: By Year 2, DHMH AIDS Administration will conduct a survey of a representative sample of staff in Community-Based Organizations that receive funding from the AIDS Administration and provide services to high-risk

populations and drug treatment facilities. The survey will assess knowledge of and educational needs with respect to HCV disease and services.

Objective 8: By Year 2, various appropriate DHMH agencies will provide HCV educational materials and training opportunities to Community-Based Organizations under contract with DHMH or LHD's that provide services to high-risk populations, to all drug-treatment agencies serving injecting drug users, and to all agencies serving clients with mental illness.

Goal 2: The general public in Maryland will have access to accurate and culturally sensitive information about HCV infection along with prevention and control measures.

Objective 1: By Year 1, DHMH EDCP will make available a HCV fact sheet/brochure to provide clear and concise information and guidance to the Maryland public.

Objective 2: By Year 2, DHMH EDCP will, in concert with LHDs, develop a schedule of statewide HCV-related educational events and forums. This schedule will be distributed to all print and broadcast media in the State, and featured on the EDCP website.

Objective 3: By Year 1, DHMH EDCP will make this ***Maryland Hepatitis C Prevention and Control Plan*** available to the general public via the Internet or other modality.

SURVEILLANCE AND EVALUATION

SCOPE

Surveillance concerning HCV infections provides the information necessary to a) identify new cases; b) determine disease incidence and trends; c) determine risk factors for infection and disease transmission patterns; d) estimate disease burden; and e) identify infected persons who can be counseled and referred for medical follow-up. Various surveillance approaches are needed because of limitations of diagnostic tests for HCV infection, the number of asymptomatic patients with acute and chronic disease, and the long time period between infection and chronic disease outcome.

Surveillance and Evaluation Goals and Objectives

Goal 1: Maryland will be served by a DHMH surveillance system that collects laboratory and provider reports of HCV infection and disseminates timely information about HCV morbidity and mortality.

Objective 1: By Year 1, LHDs will have established procedures that ensure timely initiation of HCV case investigations and MERSS (Maryland Electronic Reporting and Surveillance System) data entry within 3 working days.

Objective 2: By Year 1, DHMH EDCP will include in the weekly report of communicable diseases in Maryland a county-by-county breakdown of all Hepatitis C cases.

Objective 3: By Year 2, DHMH Office of Health Care Quality, in concert with EDCP, will begin surveying licensed medical laboratories for compliance with HCV reporting, as part of the annual relicensing procedure.

Goal 2: Maryland's HCV prevention and control program will be reviewed annually to assess program activities and progress, and to recommend future directions.

Objective 1: By Year 1, DHMH AIDS Administration, in conjunction with the Department of Public Safety and Corrections, will conduct a blinded sero-survey of the Department of Corrections in Maryland to assess burden of HIV, HBV, and HCV in this population.

Objective 2: By Year 2, DHMH EDCP will prepare a progress report on HCV prevention and control efforts, including recommendations for future activities, for the Secretary, DHMH and subsequently for public review.

REFERENCES

1. CDC. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR Recommendations and Reports, October 18, 1998 (No. RR-11).
2. CDC. National Hepatitis C Prevention Strategy: A Comprehensive Strategy for the Prevention and Control of Hepatitis C Virus Infection and its Consequences, 2001.
3. National Institutes of Health (NIH). Management of Hepatitis C. NIH Consensus Statement 1997 Mar 24-26; 15(3): 1-41.
4. Manns MP, McHutchison JG, Gordon SC, et al. Peginterferon alfa-2b in combination with ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: results of a randomized trial. *Lancet* 2001;358:958-65.
5. Jaeckel E, Cornberg M, Wedemeyer H, et al. Treatment of acute hepatitis C with interferon alfa-2b. *N Engl J Med* 2001;345:1452-7.

Matrix of Objectives by Time and Lead Agency

	Epidemiology and Disease Control Program	Laboratories Administration	AIDS Administration	Local Health Departments	Office of Health Care Quality
Year 1	Develop and make available through multiple modalities, informational materials about primary prevention targeted to infected and at-risk persons.	Provide laboratory support for LHD screening programs.	Conduct blinded sero-survey of the Department of Corrections in Maryland to assess burden of HIV, HBV, and HCV in this population.	Continue to initiate (within 72 hours) investigation of cases of reportable communicable disease, including those related to transfusions.	Continue to review blood and tissue banks to assess compliance with current standards of safety and to recommend revisions if necessary.
	Develop and make available through multiple modalities, informational materials about secondary prevention targeted to infected persons, in support of counseling efforts.			Survey their communities to determine existing HCV secondary prevention services that are provided by community-based organizations.	Provide information about the new State law requiring HCV reporting to all Directors of Laboratories licensed in Maryland to provide medical laboratory testing services.
	Continue to advocate for federal funding and policy initiatives for HAV and HBV immunizations for persons infected with HCV			Survey their communities to determine existing HCV medical treatment services that are provided by community-based organizations.	
	Make national guidelines and other resources available to health care providers via the Internet or other modality.			Have established procedures that ensure timely initiation of HCV case investigations and MERSS (Maryland Electronic Reporting and Surveillance System) data entry within 3 working days.	

	Epidemiology and Disease Control Program	Laboratories Administration	AIDS Administration	Local Health Departments	Office of Health Care Quality
	Appoint a liaison to work with agencies serving people at high risk of HCV infection, including Public Safety and Correctional Services.				
	Make available a HCV fact sheet/brochure to provide clear and concise information and guidance to the Maryland public.				
	Make this Maryland Hepatitis C Prevention and Control Plan available to the general public via the Internet or other modality.				
	Include in the weekly report of communicable diseases in Maryland a county-by-county breakdown of all hepatitis C cases.				
Year 2	Document that LHDs and DHMH facilities maintain compliance with MOSH standards for bloodborne pathogen training and control.		Work with State Board of Pharmacy to make sterile injection equipment available in conjunction with prevention education and outreach services through Maryland pharmacies.	Make available information about national HCV screening recommendations and offer testing services to persons in high-risk groups for HCV served by LHD programs (e.g., STD clinics), and public drug and mental health treatment programs.	Begin surveying licensed medical laboratories for compliance with HCV reporting, as part of the annual relicensing procedure.

	Epidemiology and Disease Control Program	Laboratories Administration	AIDS Administration	Local Health Departments	Office of Health Care Quality
	Conduct a follow-up survey of public safety agencies for compliance with bloodborne pathogen standards.		Pursue programs to make sterile injection equipment available to injection drug users through the expansion of needle exchange programs.		
	Make available information about HCV testing to Maryland residents who were recipients of blood transfusions/organ transplants prior to July 1992, or were recipients of clotting factor concentrates prior to 1987, and who have not yet been tested for HCV infection.		Conduct a survey of a representative sample of staff in Community-Based Organizations that receive funding from the AIDS Administration and provide services to high-risk populations and drug treatment facilities. The survey will assess knowledge of and educational needs with respect to HCV disease and services.		
	Develop HCV screening guidelines for use in LHD programs that serve high-risk populations.				
	Provide consultation to DHMH institutions in developing criteria for screening of individuals with HCV.				

	Epidemiology and Disease Control Program	Laboratories Administration	AIDS Administration	Local Health Departments	Office of Health Care Quality
	Conduct a survey of a representative sample of Maryland health care providers to assess the percentage of providers who know that HCV infection is a provider-reportable and laboratory reportable disease. This survey will also assess the level of primary and secondary prevention services rendered and perceived barriers.				
	Develop a schedule of statewide HCV-related educational events and forums. This schedule will be distributed to all print and broadcast media in the State, and featured on the EDCP website.				
	Prepare a progress report on HCV prevention and control efforts, including recommendations for future activities, for the Secretary, DHMH and subsequently for public review.				

	Family Health Administration	Various Appropriate DHMH Agencies
Year 1		Continue to advocate for federal funding and policy initiatives to make HCV treatment services and pharmaceutical agents available to treatment candidates.
Year 2	Disseminate to all licensed Maryland obstetricians and pediatricians current national guidelines for screening high-risk pregnant women and children born to HCV infected mothers.	Provide HCV educational materials and training opportunities to community-based organizations under contract with DHMH or LHDs that provide services to high risk populations, to all drug treatment agencies serving injecting drug users, and to all agencies serving clients with mental illness.