Report of the State Advisory Council on Hepatitis C State of Maryland

January 2006

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State Advisory Council on Hepatitis C (SACHC) Final Report: January 2006

Section I: Executive Summary

Introduction: Following its creation in 2003 by an act of the General Assembly, Maryland's State Advisory Council on Hepatitis C (SACHC) has accomplished a number of goals under the direction of its Chair, Dr. Fadia Shaya of the School of Pharmacy of the University of Maryland. The entire Report is designed to provide feedback to the General Assembly and to the Governor about improving attention to this important public health topic.

This Report briefly reviews the major accomplishments of the SACHC, presents a summary of its key findings, and sets out certain key recommendations for further consideration. It is organized into sections:

- I. Executive Summary
- II. Committee Composition, Charge, and Process;
- III. Review of Maryland Hepatitis C Prevention and Control Plan (MHCPCP or "the State Plan"), in terms of the current status of that plan's goals and objectives, as well as a comparison with other states' plans;
- IV. Review of funding opportunities for operationalization of the State Plan; and
- V. Recommendations.

Appendices

The Council acknowledges with great appreciation the participation of its members in its meetings during 2004 and 2005. In addition, staff from the Maryland Department of Health and Mental Hygiene (DHMH) and from the University of Maryland School of Pharmacy pitched in to support Council meetings and other activities, and facilitated the production of this Report.

<u>Summary of Council Activities</u>: The Council met on multiple occasions to consider various aspects of hepatitis C prevention and control in Maryland. On these occasions, the Council encouraged both the reporting of current activities under MHCPCP and heard presentations about future needs. To better investigate the different sections of the plan, the Chair encouraged the formation of subgroups that could concentrate on a specific area (for example, surveillance).

The Council also promoted full discussion about the State Plan. The contributors to that discussion on the Council included stakeholders from university/academic settings, Maryland legislators, DHMH officials, pharmaceutical industry representatives, advocates for improved treatment for hepatitis C patients in the private sector, proponents of groups at high risk for hepatitis C, and leaders of hepatitis C support groups. This diversity of interests reflected the intent of the enabling legislation to engender an open and informative analysis of the needs for hepatitis C public health programs in our State. Presentations about hepatitis C surveillance, outbreak investigation, current programs in the community to provide hepatitis C support

services, and other topics provided an important source of information as the Council considered the various issues addressed by the State Plan.

In particular, the Council reviewed evidence of improvements in hepatitis C surveillance in Maryland:

- An estimated one-third of Maryland residents who were ever infected with hepatitis C virus are now aware of their status; about double the proportion aware of their status as recently as 1999 (before reporting of laboratory evidence of hepatitis C infection was mandated in Maryland).
- Laboratory support for hepatitis C screening is now concentrating on the highestrisk populations in the State.
- Surveillance principles for accurate categorization and counting of hepatitis C cases have been clarified and explained to local health department staff.
- Sensitivity to careful case follow-up has led to the detection of an outbreak of hepatitis C affecting several Maryland jurisdictions in late 2004.

While these indicators of progress are encouraging, much remains to be done to understand the full impact of hepatitis C in our State.

Assessment of the State Plan: Review of the accomplishments of the MHCPCP objectives showed both areas of success, and needs for further action. About two-thirds of the State Plan's objectives have already been accomplished in whole or in part, including a number that are ongoing. However, several objectives were unsuccessful; and certain objectives are contingent on other, currently incomplete objectives.

- a. Some key achievements included:
 - Improved reporting of hepatitis C cases in Maryland;
 - Progress toward integration of hepatitis C screening and counselling into existing programs that serve high-risk groups;
 - Improved attention to infection control within Maryland local health departments and State health facilities;
 - Increased HCV testing by DHMH Laboratories Administration to support screening activities for high-risk groups;
 - Improved understanding, based on a DHMH AIDS Administration survey, of the burden of HCV disease in correctional settings;
 - Presentation of HCV-focused educational sessions to local health department staff; and
 - Continued funding of DHMH HCV Prevention Nurse Coordinator through grants from the Centers for Disease Control and Prevention, as the primary liaison to other State agencies serving high-risk populations.
- b. Other objectives of the State Plan are partly completed, or are now in progress. Among these are:
 - Improved surveillance, including better provider reporting and better investigation of chronic or "lab only" HCV cases;
 - Consistent and uniform outreach to all community-based organizations that serve persons at high-risk for acquiring or transmitting HCV;

- Providing access to culturally sensitive patient-friendly information about hepatitis C; about the need for hepatitis C screening; and about preserving healthy liver function;
- Development of information by all local health departments about hepatitis
 C screening and treatment resources in Maryland jurisdictions;
- Data analysis of survey data reviewing public safety agencies' measures to prevent blood-borne infections; and
- Developing screening guidelines for all local health departments and State agencies providing health care services to high-risk patients.
- c. However, a number of other objectives in the State Plan remain mostly or completely unfinished. No progress toward accomplishing these is expected, given current staff and resource constraints. Some of these may need to be reconsidered or significantly revised:
 - Expanding programs for making sterile injection equipment available to injecting drug users;
 - Improving information available to Maryland healthcare providers to guide them to available local resources for their hepatitis C patients; and
 - Identifying additional financial support from grants.

<u>Recommendations</u>: The Council recommends that the following activities are needed if current progress toward the control and prevention of hepatitis C in Maryland is to continue:

- Seek funding to develop user-friendly web resources for HCV awareness and education, both for healthcare professionals and for the general public.
- Develop recommendations for HCV screening and treatment, and assess compliance of all State and local agencies.
- Support a Maryland-specific needs assessment to identify gaps in public awareness and in professional education.
- Review current surveillance and case follow-up methods, and, if needed, seek
 funding for additional professional and/or clerical resources to ensure complete,
 accurate, and timely case investigation, data entry, and triage of all HCV reports
 in Maryland, and to ensure that all HCV-infected Maryland residents are aware of
 their status and how to access healthcare resources.
- Ensure that a schedule for annual review of the Maryland Hepatitis C Prevention and Control Plan is established, and that this review includes comments solicited from HCV cases and healthcare providers.

In addition, the Council suggests that its report be made available to the public through the web site of DHMH (<u>www.dhmh.state.md.us</u>) and through the website that provides public access to the current hepatitis C plan (<u>www.edcp.org</u>).

<u>For Further information</u>: - Further information about the Report may be obtained through the Council chair, Dr. Fadia Shaya of the University of Maryland School of Pharmacy, or through Dr. John P. Krick of the Office of Epidemiology and Disease Control Programs of the Community Health Administration of DHMH.

Baltimore, Maryland January 2006

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Section II: Composition, Charge and Process of the Council

This section describes the prescribed composition and charge of SACHC, as set forth in its enabling legislation. The section concludes with a review of the major activities of the Council, including a summary of major actions taken at SACHC meetings.

A) Enabling Legislative Action: House Bill 386 (HB386, 2003 Session)

- Background: The principal sponsor of this bill was Del. Shirley Nathan-Pulliam, District 10 (Baltimore City), and there were several dozen co-sponsors. As noted in the Fiscal Note for this bill, prior bills had been submitted during several preceding sessions on similar topics: " ... A bill that would have created a Hepatitis A, B, and C education and prevention program, HB 1035, was introduced in the 2002 session and received an unfavorable report by the Environmental Matters Committee. A bill similar to that one, HB 655, was introduced in the 2001 session and also received an unfavorable report in the Environmental Matters Committee."
- Charge to the Advisory Council: As summarized in the Fiscal Note for this bill, " (t)his bill creates a 16-member State Advisory Council on Hepatitis C to review and recommend changes to the Maryland Hepatitis C Prevention and Control Plan and solicit funds or grants to implement the plan. A copy of the enrolled version of HB386 (including the specific charge) is included (below) as Appendix 1.
- <u>- Composition</u>: The State Advisory Council on Hepatitis C (SACHC) consists of 16 persons with the following requirements:
- A member of the Senate of Maryland;
- A member of the House of Delegates;
- The Secretary of Health and Mental Hygiene or designee;
- The Secretary of Veteran's Affairs or designee;
- The Secretary of Public Safety and Correctional Services or designee; and
- 11 members appointed by the Governor to include:
 - An internist;
 - A hematologist;
 - A hepatologist;
 - A clinical researcher specializing in diseases of the liver;
 - A member of the public;
 - A veteran of the U. S. Armed Forces who has Hepatitis C;
 - 2 representatives from the pharmaceutical industry;
 - A nurse practitioner;
 - A representative of the American Liver Foundation; and
 - A representative of the Baltimore City Health Department.

- <u>- Appointed Members of the Council</u>: The following individuals agreed to accept appointment to SACHC:
 - Dr. Fadia Shaya (Assistant Professor, Outcomes Research, and Associate Director, Center on Drugs and Public Policy, School of Pharmacy, University of Maryland), Chair
 - Sen. Gwendolyn Britt (State of Maryland, Senate)
 - Mr. Steven Holman (Veteran, United States Armed Forces)
 - Dr. John Krick (Program Director, Office of Epidemiology and Disease Control Programs, Department of Health and Mental Hygiene (DHMH))
 - Dr. John Nesbitt (Hematologist)
 - Dr. Michael Rudman (President, Frederick County Hepatitis Clinic, Inc.)
 - Ms. Cindy Cohen, R.N., C.R.N.P. (Johns Hopkins Medical Institutions: Liver program)
 - Del. Robert A. Costa (Maryland House of Delegates)
 - Mr. Larry DeAngelis (Director, Courage to Change, Baltimore, representing transitional program for recovering addicts in Baltimore)
 - Dr. Marianne Githens (Professor of Political Science and International Relations, Goucher College - representing the Washington, D.C. Chapter of the American Liver Foundation)
 - Richard Rosenblatt, JD (Department of Public Safety and Correctional Services)
 - Ms. Pamela Heutte, R.Ph. (Clinical Specialist, Hepatology, Roche Laboratories, Inc.)
 - Ms. Lynette Renee Bradley-Baker (Maryland Pharmacists Association)
 - Dr. Lisa Simonson (Internist, Johns Hopkins Hospital)
 - Dr. Pierre Vigilance (as of 2003, Assistant Health Commissioner, Baltimore City Health Department; more recently, Health Officer, Baltimore County)
 - Catherine Watts (Department of Veterans Affairs)
- <u>- Other aspects of SACHC from HB386</u>: Other aspects of the SACHC's initial charge were also noted in the Fiscal Note:
 - 1. " ... (t)he Department of Health and Mental Hygiene (DHMH) must staff the advisory council. The advisory council must report to the Governor and the General Assembly by April 1, 2005 and annually thereafter. ... "; and
 - 2. " ... The advisory council sunsets September 30, 2005."

B) Committee Activities

- Meetings: The Chair provided a meeting room at the University of Maryland School of Pharmacy. Meetings were held on: 01/14/04; 06/17/04; 10/29/04; 12/17/04; and 05/04/05.

A summary of the topic areas covered at each of the Council's meetings appears as Appendix 2.

- <u>- Council Work Groups</u>: Dr. Shaya asked Council members to form work groups to focus on different areas discussed in the Plan. Each work group was assigned tasks and designated as follows:
 - o Primary prevention: B. Alexander, C. Cohen, L. Bradley-Baker, F. Shaya
 - o Secondary prevention: R. Rosenblatt, L Simonson, F. Shaya
 - o Tertiary care: M. Rudman, P. Heutte, F. Shaya
 - o Provider and general public education: Del. Costa, S. Holman, F. Shaya
 - o Surveillance: J. Krick, P. Vigilance, L DeAngelis, F. Shaya
 - o Administration, legislation, regulatory: Sen. Britt, M. Githens, F. Shaya
- Presentations and Reports: The Council reviewed several reports relating to hepatitis C in Maryland at its meetings. These reports included a summary of the current status of the Maryland Hepatitis C Prevention and Control Plan, and a report on an outbreak of hepatitis C virus infections due to contaminated doses of a radiopharmaceutical used for cardiac imaging.

The Council Chair requested in May of 2005 a report from DHMH on the findings of public health surveillance about cases of hepatitis C in Maryland, based on findings of reported cases in DHMH records. The report, provided to the Chair in early July 2005, is included as Appendix 3.

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Section III: Review of Maryland Hepatitis C Prevention and Control Plan

Part A: Review of Current Status of Maryland Hepatitis C Prevention and Control Plan

In part A of this section, the status of the goals and objectives of the Maryland Hepatitis C Prevention and Control Plan, 2002 ("MHCPCP", reproduced in Appendix 4) are described. In part B, the major features of the Maryland plan are compared with those of selected other states. Both strengths and weaknesses of the plan are reviewed.

A) Current Status, MHCPCP

<u>Overview</u>: In general, the MHCPCP offers goals and objectives by which the State's efforts to prevent and control hepatitis C can be tracked and evaluated. Within the plan, these goals and objectives are organized within four general areas (Primary Prevention, Secondary Prevention, Professional and Public Education, and Surveillance and Evaluation).

The review of the current status of the MCHPCP is therefore organized by these areas. A table, arranged by the status of all objectives in all areas of the plan, is provided below.

Primary Prevention:

Primary Prevention activities aim to reduce risks for contracting HCV infection (for example, by eliminating opportunities for exposure to the virus). Within the Primary Prevention section of the plan, there are four goals, each of which has two objectives:

<u>Goal 1:</u> "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."

Goal 1: 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."

Status: Done. DHMH OHCQ currently surveys Blood Banks and Tissue Banks as a requirement of licensure. These surveys include review of policies and procedures and current records. Also as part of the survey process, OHCQ ensures that Blood and Tissue Banks follow the standards for Testing to Minimize Disease Transmission as listed in COMAR 10.50.01.11(A). Hepatitis C virus is among the disease-causing agents for which prospective blood or tissue donors are tested prior to transfusion or transplantation.

Goal 1, 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."

Status: Done. Based on reports of site visits in each jurisdiction in the State that include reviews of case files of reportable communicable diseases, this objective is being met as stated. LHDs initiate investigation of almost all reportable communicable diseases within 24 - 48 hours.

However, no evidence exists to establish the sensitivity of communicable disease surveillance in detecting cases of hepatitis C related to transfusion. Review of nearly 37,000 MERSS records of HCV reports during the last 5 calendar years (2001 - 2005 to date) showed 20 potentially transfusion-related HCV cases of all types (i.e., 1 acute, 9 chronic, and 10 lab-only). However, the vast majority (99.3%) of these records had no information on possible relationship to transfusion. Given the known variability of LHD follow-up for almost all hepatitis C reports, it is possible that transfusion-related hepatitis C cases may go undiscovered.

<u>Goal 2</u>: "Maryland residents will be informed about risk reduction strategies to prevent new infections."

Goal 2, Objective 1: "By Year 1, DHMH EDCP will develop and make available through multiple modalities, informational materials about primary prevention targeted to infected and at-risk persons."

Status: Done. HCV-related information for the general public is being made available through brochures available in local health department clinics; through fact sheets available through the EDCP website, www.edcp.org; and through public awareness campaigns in Maryland at various times. These public information campaigns include information about primary and other forms of prevention, as well as treatment options.

Goal 2, 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 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."

Status: Partly done and in process. For example, EDCP is working with the Alcohol and Drug Abuse Administration (ADAA) within DHMH to develop and provide train-the-trainer sessions for ADAA staff. This program will address integrating viral hepatitis, STD, and HIV risk factor screening, education and counseling into an expanded evaluation and intake process. The program will be modified and expanded to other appropriate settings - such a Mental Health - and to CBOs providing services to high-risk populations.

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

Goal 3, 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."

Status: Not Done; No Further Progress Expected. According to the DHMH AIDS Administration, there was insufficient support in DHMH or in the State legislature to implement this objective.

Goal 3, Objective 2: "By Year 2, DHMH AIDS Administration will pursue programs to make sterile injection equipment available to injection drug users through the expansions of needle exchange programs."

Status: Not done, no further progress expected. Baltimore City continues to operate and support a needle exchange program, partly funded through DHMH AIDS Administration. However, according to the DHMH AIDS Administration (12/04), a different jurisdiction's County Council rejected a needle exchange program in 2001.

<u>Goal 4</u>: "Maryland agencies and health care facilities will implement and maintain appropriate infection control practices."

Goal 4, 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."

Status: Done. The site visits by DHMH EDCP staff include a review of the LHD blood-borne pathogen training program and procedures for using appropriate measures to protect LHD staff from exposure to blood-borne pathogens (like HCV). Evidence of compliance is documented for each LHD visit in the records of EDCP. DHMH facilities are all JCAHO accredited and therefore are in compliance. Consequently, they receive "deemed" status from DHMH OHCQ.

Goal 4, Objective 2: by Year 2, DHMH EDCP will conduct a follow-up survey of public safety agencies for compliance with blood borne pathogens.

Status: Partly done. This objective is a follow-up to a similar survey performed several years ago. The survey data is awaiting analysis with completion expected by mid-2006.

Secondary Prevention:

Secondary Prevention activities aim to reduce illness from HCV exposure by educating persons at risk about HCV infection; offering screening and counselling for HCV; and (in selected circumstances) implementing appropriate prophylaxis (if available) or early treatment. Within the Secondary Prevention section of MHCPCP, there are three goals, each of which has from two to six 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."

Goal 1, 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.

Status: Done. Information about HCV screening for high-risk groups has been made available in LHDs and in off-site clinic settings. However, based on extrapolations from surveillance findings to late 2005, this need continues, since two-thirds of the estimated total numbers of persons in high-risk categories for HCV transmission have not yet been screened.

Goal 1, 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."

Status: Not done, but in planning stages with Maternal and Child Health program of DHMH Family Health Administration.

Goal 1, 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."

Status: Partly done; implementation varies among LHDs. Integrating HCV screening recommendations within current LHD programs continues to be considered at the agency and program levels pending identification of resources.

Goal 1, Objective 4: "By Year 2, DHMH EDCP will develop HCV screening guidelines for use in LHD programs that serve high-risk populations."

Status: Not done at State level, but in process. However, several LHDs have developed local screening guidelines in their programs serving high-risk persons. Review of existing LHD activities related to this objective is nearly completed; DHMH Hepatitis C Prevention Nurse Coordinator will oversee the development of statewide guidelines for consistent risk factor screening.

Goal 1, Objective 5: "By Year 2, DHMH EDCP will provide consulation to DHMH institutions in developing criteria for screening of individuals with HCV."

Status: Partly done; additional efforts are in process or are planned. Numerous Risk Factor Assessment Tools were distributed to DHMH agencies or programs including the Division of STD Control, ADAA, and AIDS Administration. Discussions are underway regarding integration of risk factor screening into their existing intake processes. Discussions with the Mental Hygiene Administration are planned.

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

Status: Done. DHMH Laboratories Administration has been offering lab screening tests for HCV for a number of years. Screening is also available for persons in the correctional system, for persons with HIV/AIDS, and for mental health and substance abuse programs through Laboratories Administration. However, confirmatory testing lab support has not been resourced.

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

Goal 2, 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 counselling efforts."

Status: Done. Informational pamphlets targeting HCV-infected persons have been made available to LHDs. Additional appropriate materials for use in that population have also been accessed. EDCP website (www.edcp.org) enhancement is underway, and information on the website will include viral hepatitis signs and symptoms, transmission, prevention, testing, treatment and more.

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

Status: Partly done. Although not formally surveyed, non-urban LHDs indicate familiarity with provider needs and with services available for HCV-infected persons in those jurisdictions. The DHMH Hepatitis C Prevention Nurse Coordinator is assembling a summary of such resources.

<u>Goal 3</u>: "Maryland residents with HCV infection will receive appropriate medical management."

Goal 3, Objective 1: "By year 1, LHDs will survey their communities to determine existing HCV medical treatment services that are provided by community-based organizations."

Status: Not done, but in process. DHMH Hepatitis C Prevention Nurse Coordinator continues to gather information from informal communications with LHDs about existing community-based resources for HCV-infected persons. Generally, there are not very many of these available in Maryland. For example, the programs at the facilities of the US Department of Veterans Affairs, or provided through the Frederick County Hepatitis Clinic, Inc., are very valuable resources for qualifying individuals or for persons in that area of the State.

Goal 3, 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."

Status: Done, although need continues. Efforts not successful. Although DHMH efforts to advocate for such treatment services were undertaken during several past years, advice from federal funding sources discouraged such efforts. No funding beyond support for DHMH Nurse Coordinator for HCV received. Targeted fedearl resources are available, based on eligibility criteria, such as programs for HCV/HIV co-infected persons; or through the NIH-funded clinical trials (see clinicaltrials.gov)

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

Status: Done, although need continues; efforts not successful. Federal support for such immunization programs has been limited to provision of vaccine for other priority populations, e.g., children.

Professional and Public Education:

Achieving the goals for increased awareness of HCV among healthcare professionals and among the general public requires sensitive, culturally appropriate, focused programs for each group, based on needs identified. Within the Professional and Public Education section of MHCPCP, there are two goals, with either eight or three associated objectives.

<u>Goal 1:</u> "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."

Goal 1, 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."

Status: Done. Hepatitis C reporting by medical laboratories is now incorporated into the lab reporting statute (Md. Code Ann., Health-General Article, §18-205).

Goal 1, 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."

Status: Not done, but has potential.

Goal 1, Objective 3: "By Year 2, LHDs will provide to the local medical society in that jurisdiction information on local HCV counselling, testing and referral services."

Status: Not done; completion contingent on accomplishment of certain other objectives)

Goal 1, Objective 4: "By Year 2, DHMH Boards of Physician Quality Assurance (ed. note: at this time, it is the Board of Physicians) 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."

Status: Not done. Dependent on completion of other objectives (for example, the provider survey mentioned in the discussion of Objective 3 of this Goal).

Goal 1, 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."

Status: Not done. To be planned with revision of EDCP website information about hepatitis C.

Goal 1, 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."

Status: Partly done; further efforts in planning stages. The DHMH Hepatitis C Prevention Nurse Coordinator has met with officials at the Department of Public Safety and Correctional Services, regarding hepatitis C service requirements in new contracts for inmate health care. Liaison to promote cooperative efforts with other agencies serving high-risk individuals, such as DHMH ADAA and MHA, and first responder organizations, is in the planning stages.

Goal 1, 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 and educational needs with respect to HCV disease and services."

Status: Not done.

Goal 1, 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 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."

Status: Not done. Note that initial communications with DHMH agencies and LHDs are ongoing.

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

Goal 2, 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."

Status: Done; additional efforts are in process. An HCV fact sheet is available on the DHMH EDCP website www.edcp.org. Brochures about HCV for the public are also available through DHMH EDCP. A section on the burden of HCV in Maryland is included with the MHCPCP, also available through www.edcp.org. For Spanish-speaking Maryland residents, accessibility to other culturally sensitive versions of informational materials, including CDC publications, is available or planned.

Goal 2, 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."

Status: Partly done. Initiated, but needs continued effort.

Goal 2, 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."

Status: Done. MHCPCP has been, and is still, available through the www.edcp.org website (since September 2002).

Surveillance and Evaluation:

This section discussed the achievement of MHCPCP's objectives relating to accuracy of HCV case reporting and investigation, determination of disease burden in Maryland, and planning for public health actions to effectively prevent and control HCV infections. Additionally, the HCV prevention and control programs should be re-examined periodically to determine their effectiveness and to find ways to improve their efficiency. Within the Surveillance and Evaluation section of MHCPCP, there are two goals, with three or two objectives respectively.

<u>Goal 1:</u> "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."

Goal 1, 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."

Status: Partly done. Based on evidence from reviews of local health department surveillance practices, this objective is being met at a basic level by many and probably most LHDs. However, due to staff or financial shortfalls, some jurisdictions report that they are unable to provide data entry of reports of HCV infection in their jurisdiction, and to initiate investigations into possible HCV cases.

Goal 1. 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."

Status: Partly done. The current version of EDCP's weekly communicable disease report does include a county breakdown for cases of <u>acute</u> hepatitis C. However, chronic HCV infection, or "Lab only" cases of HCV, are not listed or tabulated by county on a weekly basis.

Goal 1, 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.

Status: Not done. No planning on this item is being done at this time.

<u>Goal 2</u>: "Maryland's HCV prevention and control program will be reviewed annually to assess program activities and progress and to recommend future directions."

Goal 2, Objective 1: "By Year 1, DHMH AIDS Administration, in conjunction with the Department of Public Safety and Correctional Services, will conduct a blinded serosurvey of the Department of Corrections in Maryland to assess burden of HIV, HBV, and HCV in this population."

Status: Done. This survey has been published.

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

Status: Not done. However, this objective has been partially met by the SACHS's efforts and report.

Table: List of objectives by completion status, MHCPCP (12/2005):

Section	Goal	Objective	Status	Comments:			
Primary Prevention	1	1	Done				
Primary Prevention	1	2	Done	See comments under "Status" for this objective.			
Primary Prevention	2	1	Done	Ongoing efforts needed			
Primary Prevention	2	2	Partly Done	Further efforts in process			
Primary Prevention	3	1	Not Done	Unsuccessful. No further efforts currently expected			
Primary Prevention	3	2	Not Done	Unsuccessful. No further efforts currently expected			
Primary Prevention	4	1	Done	See comments under "Status" for this objective.			
Primary Prevention	4	2	Partly Done	Completion planned.			
Secondary Prevention	1	1	Done				
Secondary Prevention	1	2	Not Done	Further efforts are planned.			
Secondary Prevention	1	3	Partly Done	Implementation by LHDs varies			
Secondary Prevention	1	4	Partly Done	Some LHDs have done on their own; no State-level criteria yet.			
Secondary Prevention	1	5	Partly Done	Further efforts are planned.			
Secondary Prevention	1	6	Done	Additional lab support needed.			
Secondary Prevention	2	1	Done	Ongoing efforts needed.			
Secondary Prevention	2	2	Partly Done	See comments under "Status" for this objective.			
Secondary Prevention	3	1	Not Done	Further efforts are planned or in process.			
Secondary Prevention	3	2	Done	Unsuccessful. Further efforts are planned.			
Secondary Prevention	3	3	Done	Unsuccessful.			
Professional and Public Education	1	1	Done				
Professional and Public Education	1	2	Not Done	Further efforts planned.			
Professional and Public Education	1	3	Not Done	Pending completion of other objectives.			
Professional and	1	4	Not Done	Pending completion of			

Public Education				other objectives.
Professional and	1	5	Not Done	Further efforts are
Public Education				planned.
Professional and	1	6	Partly Done	Liaisons for certain
Public Education				agencies have been assigned. Further efforts are planned.
Professional and	1	7	Not Done	
Public Education				
Professional and	1	8	Not Done	
Public Education				
Professional and	2	1	Done	Ongoing efforts needed.
Public Education				
Professional and	2	2	Partly Done	
Public Education				
Professional and	2	3	Done	
Public Education				
Surveillance and Evaluation	1	1	Partly Done	See comments under "Status" for this objective.
Surveillance and Evaluation	1	2	Partly Done	Weekly Surveillance report includes only acute hepatitis C case counts by jurisdiction.
Surveillance and Evaluation	1	3	Not Done	Not currently in planning
Surveillance and Evaluation	2	1	Done	
Surveillance and Evaluation	2	2	Not Done	See comments under "Status" for this objective.

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Section III: Review of Maryland Hepatitis C Prevention and Control Plan

Part B. Comparison with Selected HCV Plans from Other States

Introduction: The Centers for Disease Control and Prevention (CDC) provides links to state plans (www.cdc.gov/ncidod/diseases/hepatitis/partners/state_plans.htm) for hepatitis C prevention and control. Certain state plans incorporate hepatitis C prevention and control within a more general program for the prevention and control of all varieties of viral hepatitis. This section compares the major features of Maryland's plan with those of (selected) other states.

Seven other state plans (whose plans are available through the CDC website above) were chosen as a sample for review. A summary of each state's plan was prepared in a standardized format to enhance comparison. A table at the end of this section lists some major features of Maryland's and other states' plans for comparison.

Generally:

- Other states' plans were developed by a "working group" approach, including internal (State Health Department) staff and selected external partners (other public agencies and private partners).
- Most State plans include lists of action items (some with specific goals and objectives, many derived from prior CDC or NIH recommendations) to serve as guidance for various State agencies to use when planning to integrate hepatitis C services within existing programs.
- Hepatitis C programs, if they exist as separate units of the SHD, are generally assigned to either the HIV/AIDS programs, CD epidemiology programs, or in one case to a state Immunization program.
- An emphasis is placed on improving surveillance, as almost all State plans mention the ongoing need to identify persons who are unaware they have chronic hepatitis C.
- Educational efforts are cited as a key part of most plans, with some states considering family-based educational strategies.
- Funding support for any new services is generally not mentioned in these plans.
 Enabling legislation is mentioned in most plans reviewed.

Some features of these other state plans that might be of interest to Maryland in the future include:

- Several states mentioned their statewide hepatitis C hotline;
- Minnesota's plan emphasized need to survey all stakeholders to assess needs; and provides detailed survey forms for review;
- Several states use Immunization funding to pay for a significant chunk of their programs' costs; and
- Texas' plan includes impact statements from partner State agencies on the feasibility of the State plan.

State: California

Source: www.dhs.ca.gov/ps/dcdc/disb/pdf

Title: Hepatitis C Strategic Plan

Enabling or related legislation: California Senate Bill 1256 (2001)

Year Issued: 2001

Group/Task Force/Developer: A working group developed recommendations for action. Group included CDC, California Medical Association, academic/research groups, CA state agencies including Corrections and Alcohol and Drugs, AIDS, and internal DHS staff.

Implementation as: Integrated among multiple existing agencies: under leadership of CA DHS.

Funding (if noted): Not mentioned

Type of Plan: Series of Recommendations with goals, objectives, timelines

Scope of Plan: DHS and other CA state agencies,

Key Features/Content:

- Enhance hepatitis C surveillance to target plan efforts

- Standardize hepatitis C case investigation across all agencies

- Enhance education for cases, families and providers

State: Colorado

Source: www.cdphe.state.co.us/dc/hepatitis

Title: Viral Hepatitis Strategic Plan (2003 – 2006)

Year Issued: 1999 - 2002

Enabling Legislation: Colorado House Bill 99-1118 (\$200,000 funding)

Group/Task Force/Developer: Working group with internal (state) agencies and external (private sector) partners; facilitated by consultant.

Implementation as: Strategic Plan with general guidelines and goals; to coordinate efforts against all forms of viral hepatitis, and assist agencies in developing their own goals. Specific activities integrated among multiple existing agencies, partners. 8-staff member State agency to coordinate

Funding (if noted): CDC and CSTE funding for State Viral hepatitis Program development. Ongoing funding: mostly through Immunization Program (46%)

Type of Plan: Strategic: strengths and weaknesses are discussed

Scope of Plan: All forms of viral hepatitis

Key Features/Content:

- Improve surveillance
- Behavioral initiatives to reduce transmission
- Outbreak response
- "Team Hep C" private/public consortium

State: Florida

Title: Viral Hepatitis Strategic Plan

Origin:

Year Issued:

Group/Task Force/Developer: Florida Viral Hepatitis Council, cleared through Florida State Health Department, involving multiple partners and stakeholder groups, including community-based organizations, public health, other government agencies, academic/research groups, clinical and medical care providers.

Implementation as: Plan to control all forms of viral hepatitis; [6 goals relate to hepatitis C]. Assigned to existing program: Florida State HIV/AIDS program

Funding (if noted): \$2.5 Million in first year (1999); \$3.5 Million in subsequent years

Type of Plan: Implement specific goals (6 for hepatitis C prevention and control).

Scope of Plan: All viral hepatitis

Key Features/Content:

- Offers general goals for programs: prevention; shared responsibility between public and private partners; feedback from clients about services; better surveillance; with ultimate decrease in morbidity/mortality
- Sets specific goals for screening compliance; self-awareness; percentage of known HCV cases under medical management within State-run care programs (such as Medicaid).
- Example: Reproduce goals on p. 35 (of 66) of FL plan
- Features: State hotline for hepatitis C questions.
 - Review of discharge and death records to pick up hepatitis C cases
 - Audit State health clinics and facilities for compliance with screening guidelines

State: Massachusetts

Source: Recommendations of the Hepatitis C Advisory Committee (to SHD)

Year Issued: 2001

Group/Task Force/Developer: Hepatitis C Advisory Committee

Implementation as: recommendations for implementation by various state agencies

Funding (if noted): Combination of State and Local agency funding

Type of Plan: List of recommendations

Scope of Plan: Action items in several general areas:

- Improve prevention;

- Screening and counseling;

- Improve surveillance;

- Cooperation with other agencies.

Key Features/Content:

State Hepatitis C website and hotline Emphasis on education, training, materials

State: Minnesota

Title: Viral Hepatitis Needs Assessment and Five Year Plan

Origin: SHD STD/HIV section

Year Issued: 2004

Group/Task Force/Developer: mostly internal

Implementation as: not designated

Funding (if noted): CSTE grant for \$20,000

Type of Plan: Strategic Plan with gaps in several areas for attention; especially

coordination among multiple state and local agencies

Scope of Plan: All forms of viral hepatitis

Key Features/Content:

Extensive documentation of surveys of providers, agencies including survey

forms

State: New Mexico

Title: "A Vision and Strategy: Hepatitis C in New Mexico"

Origin: New Mexico Hepatitis C Alliance

Year Issued: 2004 (Developed during 1999 - 2003)

Group/Task Force/Developer(s): State Public Health Division, U. of New Mexico, CDC, State Medical Society, US Indian Health Services, State Medical Review agency, Hepatitis Foundation International, several large healthcare providers (including several medical laboratories), two national laboratories (Los Alamos and Sandia) and community members.

Implementation as: Short-term ("early results") and long-term ("foundation" - 2008) strategies for potential implementation. Outline of community assessment.

Funding (if noted): Not noted specifically. Appears as a "measure of success" in several of the State Hepatitis C strategies.

Type of Plan: Goal-focused plan with both early-results and foundation strategies. Plan identifies core and supporting processes to accomplish strategies. Each early result and foundation strategy has action items to accomplish and has measures of accomplishment.

Scope of Plan: Viral hepatitis C

Key Features/Content:

General content of strategies similar to other states; divided among sections such as: prevention; early detection and screening; public education; professional education; treatment; reducing health consequences; client and caregiver support; surveillance; communications; information technology support; ongoing evaluation; and research.

Portraits of NM residents with hepatitis C Summary of current resources for hepatitis C in New Mexico Outline for assessing community resources State: **Texas**

Title: Hepatitis C Action Plan for Texas

Enabling/Associated Legislation: 1999 House Bill 338

Year Issued: 2002

Group/Task Force/Developer: Texas SHD in lead; stakeholder group of those most affected by the plan (impact statements about plan follow in an appendix to the Texas plan)

Implementation as: (not applicable)

Funding (if noted): Impact statements vary; some agencies doubt any adverse impact or foresee little negative effect

Type of Plan: Strategic plan recognizing lack of coordination; gaps in delivering treatment and prevention services

Scope of Plan: includes (brief) section on general goals for

- Primary Prevention
- Secondary Prevention
- Professional Education

Key Features/Content:

- Summarizes current operations of State agencies providing any hepatitis C services
- State agencies impact statements provided
- Remarkably brief section about the plan itself. (compare: MN)

Table: Key Features of Maryland's Hepatitis C Plan And Selected Other State Plans*

(* - Source of Published State Plans (as of 12/28/2005): CDC)

Topic/Feature Included	MD	CA	СО	FL	MA	MN	NM	TX
Stakeholder Groups Involved	Υ	Υ	Υ	Υ	Υ	N	Υ	Υ
Enabling Legislation Cited	Υ	Υ	Υ	N	N	N	N	Υ
Funding Needs Assessed	N	N	N	N	N	N	N	N^2
Funding Source Identified	N	N	Υ	Υ	N	Y ¹	N	N ²
Type of Plan:								
- Needs Assessment	N	N	N	N	N	Υ	N	N
- Action Items	Υ	Υ	N	Υ	Υ	N	Υ	Υ
- Strategic Plan	N	N	Υ	N	N	N	N	N
- Planning Guideline	N	N	N	N	N	N	Υ	N
Assigned to:				L				
- State HIV (STD) Program	N	N	N	N	N	N	N	N
- State Immunization Program	N	N	N	N	N	N	N	N
- Multiple agencies ³	Υ	N	Υ	Υ	Υ	Υ	N	Υ
- Assignment not specified	N	Υ	N	N	N	N	Υ	N
Scope of Plan								
- Hepatitis C Only	Υ	Υ	N	N	Υ	N	Υ	Υ
- All forms of Viral Hepatitis	N	N	Υ	Υ	N	Υ	N	N
Notes:								
1 MN: CSTE funding of \$20000 for plan development.								

2	TX: Funding needs and resources are assessed to variable degree in impact statements from State agencies. No overall funding needs are quantitated.
3	Either multiple agencies/programs are named, or assignments not given.

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Section IV: Anticipation of Funding Needs, and Review of Potential Sources

Introduction: From Maryland's own experience, corroborated by review of other States' plans, hepatitis C prevention and control programs require substantial financial and technical support. Methods for obtaining financial support vary among State plans reviewed. For example, Florida's State program for hepatitis C is funded at a level of \$3.5 million annually. Other States (including Maryland) use a combination of local, State and federal funding to implement their hepatitis prevention and control efforts.

Limited Federal funding for such programs comes from a variety of sources, including:

- Financial support for existing disease control programs, including the National Immunization Program (primarily hepatitis A and B programs and vaccines), the National Center for Infectious Diseases, and the USPHS/CDC Cooperative Agreements programs.
- Direct Federal technical assistance in providing guidelines and standards, educational programs and materials, and consultations.

[Note: Federal dollars also support care for HCV-infected patients, under Medicare and Medicaid, as well as clinical research programs such as the NIH Clinical Center and contract academic research trials (see the NIH sponsored website at www.clinicaltrials.gov for additional information). A recent (12/21/05) check of this resource lists 26 clinical trials recruiting patients in Maryland, and an additional 5 clinical trials recruiting patients in the District of Columbia.]

Although Maryland programs receive federal funding currently to support many State efforts to prevent or control infectious diseases, attempts to increase federal support for hepatitis C prevention or control programs have generally been unsuccessful. Attempts to expand Federal fiscal support have included

- Requests for additional moneys from the National Immunization Program to provide hepatitis A and hepatitis B vaccines to vaccinate HCV-infected persons;
- Efforts to get more federal support for implementation of advanced diagnostic testing at the DHMH Laboratories Administration for confirmation of positive HCV screening tests;
- Applications to fund the expansion of the capacity of community-based programs to serve HCV-infected individuals, through certain targeted federal grant opportunities; and
- Supporting a grant for enhanced HCV screening and treatment services for incarcerated HCV-infected persons, through the Maryland Department of Public Safety and Correctional Services (DPSCS).

As has been found for other infectious diseases, despite the cost of implementing prevention-focused programs for hepatitis C, the failure to intervene successfully with such programs will result in much higher total costs for medical and surgical therapy for the end-stage complications. This is especially true for patients coinfected with both HCV and HIV. CDC cited this trend of increasing costs in 1998 in its original MMWR recommendations [Source: CDC. MMWR Recommendations and Reports: October 16, 1998, No. 47 (RR-19) pp. 1-39] relating to hepatitis C. This trend has been substantiated by more recent findings.

For example, a recent (2005) article in the journal Hepatology indicates that:

"Chronic hepatitis C virus (HCV) infection affects approximately 3 million people in the United States and places tremendous demands on the health care system. As many observers have predicted, the disease burden continues to grow as the infected population ages. In this study, we analyzed inpatient data from the Healthcare Cost and Utilization Project, outpatient data from the National Ambulatory Medical Care Survey, and drug data from the Verispan Source Prescription Audit. We examined recent growth in the use of health care resources among HCV patients by age group and found average annual increases of 25% to 30% for hospitalizations, charges, hospital days, and physician visits. (Emphasis added). Also, patients co-infected with HIV and HCV in 2001 constituted 7.5 times as many hospitalizations and incurred 2.9 times the charges in 1994, relative to all HIV hospitalizations and charges."

(Source: "Trends in health care resource use for hepatitis C virus infection in the United States". W. C. Grant et al., Hepatology 2005; 42:1406-1413.)

In this section, we briefly summarize potential sources of funding to meet those needs, focusing on the estimated costs of current MHCPCP goals and objectives.

A) Primary Prevention Services: Sources of Current Funding

<u>Goal 1</u>: Screening of Blood and Tissue: Costs needed to reach this goal are generally part of the medical screening process (or the inactivation of plasma derived products) applied to donated blood and tissue.

Notes:

- (Objective 1) OHCQ expenses to review operations at blood and tissue banks may be a non-separable part of its overall costs relating to laboratory inspection and regulation. Costs of viral inactivation of plasma-derived products (such as clotting factor concentrates) are built in to those products by manufacturers.
- 2. (Objective 2) LHD investigations of cases of reportable communicable diseases such as hepatitis C are currently limited to budget support from local funds and targeted general funds, as a portion of overall support for local public health efforts. Categorical general funding is no longer available for HCV case investigation, even though such funds were allocated in FY2001 to coincide with the effective date of House Bill 845, mandating the reporting to public health of laboratory evidence of hepatitis C virus.

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

Notes:

- 1. (Objective 1) Informational materials have been made available generally by DHMH for use by community-based organizations (CBOs). Ongoing costs of updating such materials will be incorporated in current State funding of general communicable disease control through EDCP.
- (Objective 2) Establishing contacts with CBOs will require continued efforts by LHD staff, and by the Maryland Hepatitis C Prevention Nurse Coordinator (a DHMH position funded through the Epidemiology and Laboratory Capacity Cooperative Agreement from USPHS/CDC).

Goal 3: Injecting Drug Users Access to Sterile injection Equipment:

Note: (Objectives 1 and 2) Efforts to establish such programs (outside of Baltimore City) have met with no success over the past 5 years. At this time, funding for the Baltimore City needle exchange program is through the local funding (about two-thirds), and through DHMH AIDS Administration (about one-third).

<u>Goal 4</u>: Appropriateness of infection control practices in Maryland agencies and health care facilities.

Notes:

- (Objective 1) State efforts to assure compliance with blood-borne pathogen standards at LHDs are funded by State general funds. Assessment of compliance with such standards at DHMH facilities is based on communications with infection control professionals at those facilities; as well as regulatory inspections through the State Office of Health Care Quality (also funded through general funds).
- 2. (Objective 2) An initial survey of public safety agencies was funded through State general funds. A repeat of this survey is currently in process, with the same funding source.

B) Secondary Prevention Activities: Sources of Current Funding

Goal 1: Informing at-risk Maryland residents about screening; offering testing.

Notes:

- 1. (Objective 1) Materials about post-transfusion HCV have been prepared and are available through the EDCP website. Costs of publishing and periodic updates are funded as part of State general funds for communicable disease control.
- 2. (Objective 2) When implemented, costs associated with this objective will be covered as part of State general funds for communicable disease control.

- 3. (Objective 3) Funded through State general and local funds; however, as actual compliance by LHDs has so far varied, actual cost is undetermined.
- (Objective 4) No such screening guidelines have yet been developed for Maryland. However, when implemented, support for this activity might require a reprioritization of existing State and Federal (ELC) funds.
- 5. (Objective 5) No such screening guidelines have yet been developed for DHMH institutions. However, support for this activity might require a reprioritization of existing State and Federal (ELC) funds
- 6. (Objective 6) Limited laboratory testing for HCV screening has been supported through State general funds.

Goal 2: Counselling of HCV-infected Marylanders on steps to maintain liver health.

Notes:

- (Objective 1) No such counselling materials have yet been developed to support counselling HCV-infected persons about secondary prevention. However, support for this activity might require a reprioritization of existing State and Federal (ELC) funds.
- 2. (Objective 2) Funded through State general funds; however, actual compliance by LHDs varies; the actual cost is not determined.

Goal 3: Appropriate medical management of HCV-infected Maryland residents

Notes:

- 1. (Objective 1) Funding available through Ryan White Act and other Federal and State programs for HCV/HIV coinfected persons.
- 2. (Objective 2) To a large degree, funding for HCV treatment services depends on the individual case and their available source of healthcare. For incarcerated persons, State general funding is available beginning in FY06 on a limited basis (according to communications with Maryland DPSCS about their draft treatment guidelines). For those with private health insurance, funding for screening, confirmation, counselling, and treatment are available to varying degrees. Funding for Medicaid recipients covers some HCV-related expenses. For those who may meet clinical trial eligibility requirements, funding for therapy may be provided through public and private research organizations, and through private charitable foundations or advocacy groups (American Liver Foundation) (need to check this further).
- 3. (Objective 3) Additional Federal support through Immunization program and through the ELC cooperative grant agreements has been proposed over recent years with little success. (See paragraph on efforts to increase federal funding in the "Introduction" part of this Section (above)). Potential for additional federal funding is judged to be small at this time.

C) Professional and Public Education

<u>Goal 1</u>: Increased professional awareness of national recommendations and Maryland resources for primary and secondary prevention.

Notes:

- 1. (Objectives 1, 5, and 6) No additional funding required at this time.
- 2. (Objectives 2, 3 and 4) If implemented, achievement of this objective may require additional resources for survey of Maryland providers about HCV reporting and prevention.
- (Objective 7) If implemented, will require additional general funds for AIDS Administration survey of CBOs providing treatment to high-risk Maryland residents. Note: some LHDs have already provided this for CBOs in their jurisdictions.
- 4. (Objective 8) If implemented, will require additional local and/or general funds, with participation of (federally funded) Maryland Hepatitis C Prevention Nurse Coordinator to gather and collate such information from State or local resources.

Goal 2: Public access to prevention and control information about HCV infection

Notes:

- 1. (Objective 1) Some general funding required for initial website development and for ongoing upkeep of web-based resources, as well as for periodic updates and for translation into other languages (e.g., Spanish).
- 2. (Objective 2) Additional general funding will be needed to support future educational events in various areas of Maryland.

D) Surveillance and Evaluation

Goal 1: Establishing timely and complete HCV surveillance system for Maryland

Notes:

- 1. (Objective 1) In the absence of categorical federal support, State and/or local funding will be required to ensure comprehensive, accurate, and timely surveillance for HCV cases in Maryland. Because of estimates that 2 out of every 3 Maryland residents who were infected with HCV at any point in their lives do currently not know their HCV status, this is seen as a continuing funding need for the next 5 to 8 years at least. LHD compliance with case investigation based on HCV lab reports varies from extensive to none. Estimates of needed fiscal support at the time of passage of the hepatitis C laboratory reporting law called for eight FTE Nurse Investigators for local case investigation; but this funding is no longer available.
- 2. (Objective 2) Minimal or no general funding will be required for additional programming in MERSS to add total for chronic hepatitis C or lab only cases to the weekly summary of reports of communicable diseases in Maryland.
- 3. (Objective 3) If implemented, will require additional State general funds for education of State laboratory surveyors.

Goal 2: Annual HCV program review and recommendations

Notes:

- 1. (Objectives 1 and 2) No additional funding needed for either objective under this goal. The serosurvey of correctional system clients has already been accomplished through the DHMH AIDS and Laboratories Administrations.
- 2. (Objective 2) Given continued federal support for the HCPCNC, No additional funding is required for the annual review of the State Plan. However, the review of the Plan by this Council was determined by the Council's enabling legislation. Council members and their affiliated agencies and organizations assumed costs for Council staff support.

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Section V: Recommendations

This section describes the recommendations suggested by the Advisory Council to enhance or extend the State's efforts to prevent or control hepatitis C. In addition, the Council suggests that its report be made available to the public through the web site of DHMH (www.dhmh.state.md.us) and through the website that provides public access to the current hepatitis C plan (www.edcp.org).

A) Recommendations for Primary Prevention

 Seek funding to develop user-friendly web resources for HCV awareness and education, both for healthcare professionals and for the general public.

B) Recommendations for Secondary Prevention

 Develop recommendations for HCV screening and treatment, and assess compliance of all State and local agencies.

C) Recommendations for Public and Professional Education

 Support a Maryland-specific needs assessment to identify gaps in public awareness and in professional education.

D) Recommendations for Surveillance and Research

- Review current surveillance and case follow-up methods, and, if needed, seek
 funding for additional professional and/or clerical resources to ensure complete,
 accurate, and timely case investigation, data entry, and triage of all HCV reports
 in Maryland, and to ensure that all HCV-infected Maryland residents are aware of
 their status and how to access healthcare resources.
- Ensure that a schedule for annual review of the Maryland Hepatitis C Prevention and Control Plan is established, and that this review includes comments solicited from HCV cases and healthcare providers.

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Appendices:

- 1. Enabling Legislation for SACHC: House Bill 386, enrolled version (2001 Session of General Assembly)
- 2. Attendance and Topic Summaries, SACHC Meetings, 2004 and 2005
- 3. Summary of Surveillance Findings, Hepatitis C in Maryland, 1994 2004
- 4. Maryland Hepatitis C Prevention and Control Plan September 2002 (DHMH)

Appendix 1: Enrolled version, House Bill 386 (2003 General Assembly Session)

Source: http://mlis.state.md.us, downloaded on December 14, 2005

HOUSE BILL 386

Unofficial Copy 2003 Regular Session (3lr1360)

ENROLLED BILL

-- Health and Government Operations/Education, Health, and Environmental Affairs --

Introduced by Delegates Nathan-Pulliam, Barkley, Benson, Bromwell, Cane, Cardin, Donoghue, Frush, Hammen, Haynes, Hubbard, Jones, Mandel, Marriott, Menes, Morhaim, Murray, Oaks, Patterson, Pendergrass, Redmer, Rosenberg, Taylor, V. Turner, and Zirkin Zirkin, Hurson, Boutin, Costa, Elliott, Goldwater, McDonough, Rudolph, Smigiel, and Weldon

Read and Examined by Proofreaders:
Proofreade
Proofreaded Sealed with the Great Seal and presented to the Governor, for his approval this day of at o'clock,M.
Speaker
CHAPTER
1 AN ACT concerning
2 Disease Prevention - Hepatitis C Advisory Council
3 FOR the purpose of establishing a State Advisory Council on Hepatitis C to provide advice and recommendations to the General Assembly on public awareness, education, screening, and treatment related to benefitis C review, recommend

specifying the membership, terms, removal, chairman, and purpose of the Advisory Council; requiring the Advisory Council to issue certain reports on or

changes to, and solicit funds to implement a certain hepatitis C prevention plan;

before certain dates; requiring the Secretary of Health and Mental Hygiene to

6 7

8

9

- take certain actions in connection with the Hepatitis C Advisory Council; 10
- defining certain terms; <u>providing for the termination of this Act;</u> and generally relating to the Hepatitis C Advisory Council. 11
- 12

1 BY adding to

2

- 2 Article Health General
- 3 Section 18-1001 through 18-1009, inclusive, to be under the new subtitle
- 4 "Subtitle 10. Hepatitis C Advisory Council"
- 5 Annotated Code of Maryland
- 6 (2000 Replacement Volume and 2002 Supplement)
- 7 Preamble
- 8 WHEREAS, Hepatitis C is a silent killer, being largely asymptomatic until
- 9 irreversible liver damage may have occurred; and
- 10 WHEREAS, Hepatitis C has been characterized by the World Health
- 11 Organization as a disease of primary concern to humanity; and
- 12 WHEREAS, Hepatitis C currently infects approximately 4.5 million persons in
- 13 the United States, and each year there are some 30,000 new infections nationwide:
 - 14 and
 - 15 WHEREAS, The federal Centers for Disease Control and Prevention estimate
- 16 that approximately 12,000 persons die annually from the consequences of hepatitis C,
 - 17 and this number continues to grow each year; and
 - 18 WHEREAS, The disease is considered to be such a public health threat that the
 - 19 United States Department of Health and Human Services has initiated a
 - 20 comprehensive plan to address this significant health problem, beginning with the
 - 21 identification of, and notification to, hundreds of thousands of persons who are
- 22 inadvertently exposed to hepatitis C through blood transfusions; and
- 23 WHEREAS, In the absence of a vaccine for hepatitis C, emphasis must be placed
- 24 on other means of awareness and prevention of this disease, including, but not limited
- 25 to, education of persons at high risk for hepatitis C as defined by the federal Centers
- 26 for Disease Control and Prevention, as well as police officers, firefighters, health care
 - 27 workers, and the general public; and
 - 28 WHEREAS, Educating the public and health care community throughout the
- 29 State about hepatitis C will ensure an optimal approach to controlling this lethal

- 30 disease; now, therefore,
- 31 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
- 32 MARYLAND, That the Laws of Maryland read as follows:
- 33 Article Health General
- 34 SUBTITLE 10. HEPATITIS C ADVISORY COUNCIL.
- 35 18-1001.
- 36 THERE IS A STATE ADVISORY COUNCIL ON HEPATITIS C.

- 3
 - 1 18-1002.
 - 2 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 3 INDICATED.
 - 4 (B) "ADVISORY COUNCIL" MEANS THE STATE ADVISORY COUNCIL ON 5 HEPATITIS C.
 - 6 (C) "HCV" MEANS THE HEPATITIS C VIRUS.
 - 7 (D) "SECRETARY" MEANS THE SECRETARY OF HEALTH AND MENTAL 8 HYGIENE.
 - 9 18-1003.
 - 10 (A) (1) THE ADVISORY COUNCIL CONSISTS OF 15 16 MEMBERS.
 - 11 (2) OF THE 15 16 MEMBERS:
- 12 (I) ONE SHALL BE A MEMBER OF THE SENATE OF MARYLAND,
- 13 APPOINTED BY THE PRESIDENT OF THE SENATE:
- 14 (II) ONE SHALL BE A MEMBER OF THE HOUSE OF DELEGATES.
 - 15 APPOINTED BY THE SPEAKER OF THE HOUSE;
- 16 (III) ONE SHALL BE THE SECRETARY OF HEALTH AND MENTAL
- 17 HYGIENE OR THE SECRETARY'S DESIGNEE:
- 18 (IV) ONE SHALL BE THE SECRETARY OF VETERANS AFFAIRS OR THE
 - 19 SECRETARY'S DESIGNEE;
- 20 (V) ONE SHALL BE THE SECRETARY OF CORRECTIONS PUBLIC
- 21 <u>SAFETY AND CORRECTIONAL SERVICES</u> OR THE SECRETARY'S DESIGNEE; AND
- 22 (VI) TEN ELEVEN SHALL BE APPOINTED BY THE GOVERNOR.

23 GOVERNOR	(3)	OF TH	HE TEN <u>ELEVEN</u> MEMBERS APPOINTED BY THE
24		(I)	ONE SHALL BE AN INTERNIST;
25		(II)	ONE SHALL BE A HEMATOLOGIST;
26		(III)	ONE SHALL BE A HEPATOLOGIST;
27 SPECIALIZIN	JC IN	(IV)	ONE SHALL BE A CLINICAL RESEARCHER
28 DISEAS	_	THE	LIVER;
29		(V)	ONE SHALL BE A MEMBER OF THE PUBLIC;
30 ARMED		(VI)	ONE SHALL BE A VETERAN OF THE UNITED STATES
	S WHO	HAS	HEPATITIS C;

- 1 (V) (VII) TWO SHALL BE REPRESENTATIVES OF THE 2 PHARMACEUTICAL INDUSTRY:
- 3 (VII) ONE SHALL BE A NURSE PRACTITIONER; AND
- 4 (VII) (IX) ONE SHALL BE A REPRESENTATIVE OF THE AMERICAN
 - 5 LIVER FOUNDATION; AND
- 6 (VIII) (X) ONE SHALL BE A REPRESENTATIVE OF THE BALTIMORE
 - 7 CITY HEALTH DEPARTMENT.
 - 8 (B) (1) THE TERM OF A MEMBER IS 2 YEARS.
- 9 (2) AT THE END OF A TERM A MEMBER CONTINUES TO SERVE UNTIL A
 - 10 SUCCESSOR IS APPOINTED.
- 11 (3) A MEMBER WHO IS APPOINTED AFTER A TERM HAS BEGUN SERVES
- 12 ONLY FOR THE REST OF THE TERM AND UNTIL A SUCCESSOR IS APPOINTED.
- 13 (C) THE GOVERNOR MAY REMOVE A MEMBER OF THE ADVISORY BOARD FOR
 - 14 INCOMPETENCE OR MISCONDUCT.
- 15 18-1004.
- 16 FROM AMONG THE MEMBERS OF THE ADVISORY COUNCIL THE GOVERNOR
 - 17 SHALL APPOINT A CHAIRMAN.
- 18 18-1005.
- 19 (A) A MAJORITY OF THE MEMBERS SERVING ON THE ADVISORY COUNCIL
- 20 REPRESENTS A QUORUM TO CONDUCT BUSINESS.
- 21 (B) A MEMBER OF THE ADVISORY COUNCIL:
- 22 (1) MAY NOT RECEIVE COMPENSATION; BUT

- 23 (2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE
- 24 STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.
- 25 (C) THE ADVISORY COUNCIL SHALL MEET AT LEAST FOUR <u>TWO</u> TIMES A YEAR,
- 26 AT THE TIMES AND PLACES THAT IT DETERMINES.
- 27 18-1006.
- 28 THE PURPOSE OF THE ADVISORY COUNCIL SHALL BE TO PROVIDE ADVICE AND
- 29 RECOMMENDATIONS TO THE GOVERNOR AND THE GENERAL ASSEMBLY WITH
 - 30 RESPECT TO HEPATITIS C BY:
- 31 (1) DEVELOPING A PROPOSAL FOR A STATEWIDE PROGRAM THAT
- 32 PROMOTES PUBLIC EDUCATION AND OUTREACH TO RAISE AWARENESS OF
- 33 HEPATITIS C AMONG PERSONS AT HIGH RISK FOR HEPATITIS C, AS WELL AS POLICE

- 1 OFFICERS, FIREFIGHTERS, PERSONS EMPLOYED BY CORRECTIONAL FACILITIES.
- 2 EMERGENCY RESPONSE PERSONNEL, AND OTHER HIGH-RISK GROUPS, INCLUDING.
- 3 BUT NOT LIMITED TO, HEALTH CARE PROFESSIONALS AND PERSONS EMPLOYED IN
- 4 PRIMARY CARE SETTINGS OR HEALTH CARE FACILITIES, WHICH SHALL INCLUDE. AT
- 5 A MINIMUM, INFORMATION ON RISK FACTORS, THE VALUE OF EARLY DETECTION.
 - 6 AND THE OPTIONS AVAILABLE FOR TREATING HEPATITIS C:
- 7 (2) PROMOTING PUBLIC AWARENESS ABOUT THE AVAILABILITY OF
- 8 HEPATITIS C SCREENING, PREVENTION, AND TREATMENT SERVICES AMONG
- 9 PERSONS AT HIGH RISK FOR HEPATITIS C AS DETERMINED BY THE ADVISORY BOARD
- 10 BASED ON DATA PROVIDED BY THE FEDERAL CENTERS FOR DISEASE CONTROL AND
- 11 PREVENTION AND OTHER SOURCES OF INFORMATION DEEMED APPROPRIATE BY
- 12 THE ADVISORY BOARD:
- 13 (3) DEVELOPING EDUCATIONAL ACTIVITIES FOR HEALTH CARE
- 14 PROFESSIONALS IN REGARD TO THE EPIDEMIOLOGY, NATURAL HISTORY,
- 15 DETECTION, AND TREATMENT OF HEPATITIS C. WHICH SHALL INCLUDE
- 16 INFORMATION ABOUT COINFECTION WITH HCV AND HIV AND THE IMPLICATIONS OF
 - 17 COINFECTION FOR HIV OR AIDS TREATMENT:
- 18 (4) DEVELOPING EDUCATIONAL AND INFORMATIONAL MEASURES
- 19 TARGETED AT SPECIFIC GROUPS, INCLUDING ACTIVITIES DESIGNED TO EDUCATE
- 20 YOUTH ABOUT THE LONG-TERM CONSEQUENCES OF INFECTION WITH HCV:
- 21 (5) COLLABORATING WITH THE DEPARTMENT OF CORRECTIONS TO
- 22 DEVELOP SCREENING SERVICES TO IDENTIFY HCV-POSITIVE INMATES WHO ARE
- 23 LIKELY TO BE RELEASED WITHIN A PERIOD OF 1 YEAR AND TO PROVIDE

- 24 COUNSELING AND TREATMENT OPTIONS TO REDUCE THE POTENTIAL HEALTH RISK
 - 25 TO THE COMMUNITY FROM THESE PERSONS:
- 26 (6) EVALUATING EXISTING HEPATITIS C SUPPORT SERVICES IN THE
- 27 COMMUNITY AND ASSESSING THE NEED FOR IMPROVING THE QUALITY AND
- 28 ACCESSIBILITY OF THESE SERVICES;
- 29 (7) ESTABLISHING PUBLIC-PRIVATE PARTNERSHIPS TO PROMOTE
- 30 OUTREACH AND INCREASE AWARENESS ABOUT HEPATITIS C AMONG EMPLOYERS.
 - 31 ORGANIZED LABOR, HEALTH CARE PROVIDERS, HEALTH INSURERS, AND
- 32 COMMUNITY-BASED ORGANIZATIONS AND COALITIONS;
- 33 (8) IDENTIFYING FUNDS OR OTHER RESOURCES FROM PRIVATE
- 34 NONPROFIT OR FOR-PROFIT SOURCES OR THE FEDERAL GOVERNMENT
- 35 EFFECTUATE PROGRAMS AND ACTIVITIES DEVELOPED AS PROVIDED FOR IN THIS
- 36 SUBTITLE:
- 37 (9) DEVELOPING A PLAN TO COORDINATE THE ACTIVITIES OF THE
- 38 PROGRAM WITH SERVICES PROVIDED SEPARATELY TO SPECIFIC POPULATIONS.
- 39 INCLUDING VETERANS OF THE UNITED STATES ARMED FORCES, PERSONS
- 40 PARTICIPATING IN PRIVATE OR PUBLIC DRUG ABUSE OR ALCOHOL TREATMENT
- 41 PROGRAMS, AND PERSONS WITH HIV; AND

- 6
- 1 (10) DEVELOPING A PLAN TO COORDINATE THE ACTIVITIES OF THE
- 2 PROGRAM TO PREVENT REDUNDANCIES. THE PURPOSE OF THE ADVISORY COUNCIL
 - 3 SHALL BE TO:
- 4 (1) REVIEW AND RECOMMEND CHANGES TO THE "MARYLAND HEPATITIS
 - 5 C PREVENTION AND CONTROL PLAN"; AND
- 6 (2) SOLICIT ANY FUNDS OR GRANTS FROM ANY FEDERAL, LOCAL.
- 7 PRIVATE, OR OTHER SOURCE TO IMPLEMENT "THE MARYLAND HEPATITIS C
 - 8 PREVENTION AND CONTROL PLAN".
 - 9 18-1007.
 - 10 THE ADVISORY COUNCIL SHALL REPORT ON ITS ACTIVITIES AND
- 11 <u>RECOMMENDATIONS</u> TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF
- 12 THE STATE GOVERNMENT ARTICLE, TO THE GENERAL ASSEMBLY ON OR BEFORE
- 13 APRIL 1, 2005 AND ANNUALLY THEREAFTER AND INCLUDE ADVICE AND
- 14 RECOMMENDATIONS ON HEPATITIS C AS PROVIDED FOR IN THIS SUBTITLE.
- 15 18-1008.
- 16 THE SECRETARY SHALL DESIGNATE THE STAFF NECESSARY TO ASSIST THE
- 17 ADVISORY COUNCIL IN CARRYING OUT ITS FUNCTIONS AS PROVIDED UNDER THIS
 - 18 SUBTITLE.
- 19 18-1009.
- 20 (A) THE PROGRAM SHALL BE FUNDED AS PROVIDED IN THE STATE BUDGET.
- 21 (B) THE FUNDING PROVIDED IN THE STATE BUDGET FOR THE PROGRAM IS

- 22 INTENDED TO COMPLEMENT FUNDING RECEIVED FROM ANY OTHER LAWFUL
 - 23 SOURCE.
 - 24 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
 - 25 October 1, 2003. It shall remain effective for a period of 2 years and, at the end of
 - 26 September 30, 2005, with no further action required by the General Assembly, this
 - 27 Act shall be abrogated and of no further force and effect.

Appendix 2: Attendance and Topic Areas Discussed at Council Meetings:

01/14/04

Members in attendance: Dr. John Krick, Cindy Cohen, R.N., Pamela Heutte, Steven Holman, Marianne Githens, Larry DeAngelis, Pierre Vigilance, Dr. Michael Rudman, Dr. Fadia Shaya. Guests in attendance: Dr. Jeffrey Roche (Chief, Center for Clinical Epidemiology, DHMH), Rosemerry Tasin, R.N. (Hepatitis C Nurse Coordinator, DHMH) **Topics Discussed:**

- Background of the burden of Hepatitis C in Maryland
- Overview of Hepatitis C Plan Development
- Highlights on Progress of Plan Implementation
- Hepatitis screening, prevention, treatments/effectiveness and research
- Long-term impact of HCV
- Public awareness
- HCV & HIV co-infections
- HCV in high-risk populations
- Cost of HCV
- Strategies for control

06/17/04

Members in Attendance: Dr. Fadia Shaya, Marianne Githens, Pamela Heutte, Mr. Steven Holman, Dr. John Krick, Dr. Michael Rudman, Richard Rosenblatt, JD, Dr. Lisa Simonson, Dr. Pierre Vigilance. Guests in Attendance: Dr. Jeffrey Roche (Chief, Center for Clinical Epidemiology, DHMH), Barbara Alexander, RN (Nurse Consultant, Center for Immunization, DHMH), Connie Callahan (Executive Director, Frederick County Hepatitis Clinic, Inc.)

Discussion:

- 2004 Hepatitis Symposium held on 05/07/04 to review Hepatitis activities within the state
- Hepatitis C in the prison System gain access to that group
- Increase awareness of the burden of HCV
- Determine the priorities for the Council's work
- Identify high needs populations not yet getting services
- Focus on primary prevention
- Increase visibility of HCV look at another state's data
- Determine the cost benefit of early identification of infected persons
- Discussion of treatment options, benefits, expected costs
- Seek consultation with experts for determination of low cost/high yield activities and capitalize on existing resources
- Identify local Health Department HCV Reps
- PSAs (public service announcements) to educate the public
- How to make legislators (in general) aware of needs re: HCV control
- Identify areas of interest for each sub-committee member and interested consultants
- Look at Plan deficiencies

10/29/04

Members in attendance: Dr. Fadia Shaya, Sen. Gwendolyn Britt, Del. Robert A. Costa, Dr. Marianne Githens, Mr. Steven Holman, Dr. John Krick, Dr. Michael Rudman and Richard Rosenblatt, JD. Guests in Attendance: Barbara Alexander, RN (Nurse Consultant Center for Immunization, DHMH), Connie Callahan (Executive Director, Frederick County Hepatitis Clinic, Inc.), Nabil Said, MD, (Preventive Medicine Resident, Johns Hopkins University).

Discussion:

- Overview of the Maryland State Hepatitis C Prevention and Control Plan
- Update on statistics on HCV infection rates
- Update on the status of the current contract for inmate medical care, which is due to expire in June 2005 - The DPSC will be requesting an increase of ten million dollars in the current budget to care for HCV infected inmates.
- Reminder from Dr. Shaya to members of the Council's charge She asked them
 to form work groups to focus on different areas discussed in the Plan. Each work
 group was assigned tasks and designated as follows:
- Primary prevention: B. Alexander, C. Cohen, L. Bradley-Baker, F. Shaya
- Secondary prevention: R. Rosenblatt, L Simonson, F. Shaya
- Tertiary care: M. Rudman, P. Huette, F. Shaya
- Provider and general public education: Del Costa, S. Holman, F. Shaya
- Surveillance: J. Krick, P. Vigilance, L DeAngelis, F. Shaya
- Administration, legislation, regulatory: Sen. Britt, M. Githens, F. Shaya

12/17/04

Members in Attendance: Dr. Fadia Shaya, Mr. Larry DeAngelis, Ms. Cindy Cohen, R.N., C.R.N.P., Dr. John Krick, Dr. Michael Rudman, Dr. John Nesbitt; and Dr. Pierre Vigilance. Guests in Attendance: Barbara Alexander, RN (Nurse Consultant, Center for Immunization, DHMH); Connie Callahan, (Executive Director, Frederick County Hepatitis Clinic, Inc.); Debra Collier (Epidemiology and Disease Control, DHMH); Jeffrey Roche, MD (Chief, Center for Clinical Epidemiology, DHMH); and Nabil Said, MD (Preventive Medicine Resident, Johns Hopkins University)

Discussion:

- Overview of the procedures followed during an investigation of a reported case of acute hepatitis C infection
- Work Group Assignments, interim recommendations
- Objectives in the Maryland Hepatitis C Prevention Plan
- Overview of primary prevention activities in the New Mexico, Texas, and California as compared to the Maryland Plan
- The comparison of State plans and suggested that Maryland needs to increase reporting from providers and efficiency for getting information they into the state system as well as providing resources to follow up on reports.
- Report on progress toward primary prevention and educational goals and objectives provided by the AIDS Administration
- Could electronic reporting to be available to practitioners (as in the VA system)?

- Put a "face" on HCV while looking at untapped resources such as the recovering community
- Funding sources private, foundations, banks and tobacco funds that have been provided to the State

05/04/05

Members in Attendance: Dr. Fadia Shaya, Sen. Gwendolyn Britt, Mr. Steven Holman, Dr. John Krick, Dr. John Nesbitt and Dr. Michael Rudman. Guests in Attendance: Barbara Alexander, RN (Nurse Consultant, Center for Immunization, DHMH); Connie Callahan, RN (Executive Director, Frederick County Hepatitis Clinic, Inc.); Kirsten Larson, MPH (Epidemiology and Disease Control DHMH); and Jeffrey Roche, MD (Chief, Center for Clinical Epidemiology, DHMH).

Discussion:

- Presentation by Ms. Kirsten Larson of an extensive investigation into an outbreak of acute hepatitis C that occurred in Maryland during the fall of 2004
- Council activities, review of the Hepatitis C Prevention Plan and comments or changes that need to be included in the upcoming report to the Governor. Suggestions included:
 - Surveillance activities should distinguish what needs to be done when to identify acute infections versus chronic infections.
 - Enhance surveillance so that better data is available.
 - Include how many deaths per year are due to HCV infection.
 - Enhance surveillance in areas with the highest known incidence of injecting drug use and increased heroin use.
 - Develop regulations that would require labs to follow directives for potentially hazardous procedures and update guidelines to protect those at risk.
 - Provide to Dr. Shaya of a summary of hepatitis C cases reported in Maryland over recent years (to be done by Dr. Roche)
 - Recent funding for pilot programs for HCV screening the Governor has approved funding to provide start up for 3 programs (East and West Baltimore, and Frederick) for HCV

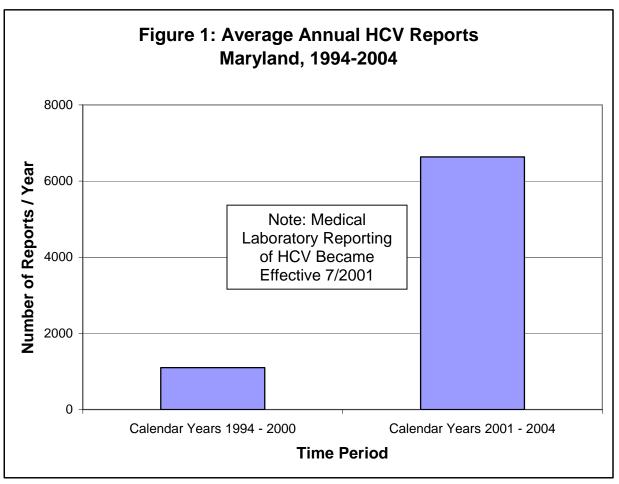
Dr. Rudman's efforts to identify support for a model HCV clinic to be based in a family practice residency program which would allow for provision of needed services while enhancing the development of physician HCV knowledge and skills

Other meetings:

Additional meetings were held as requested by the Chair with selected members of the SACHC staff.

Appendix 3. Summary of HCV Surveillance Findings, Maryland, 1994 - 2004 Summary:

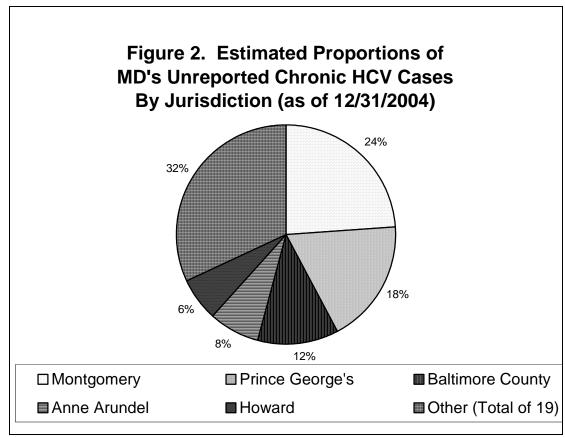
 Annual numbers of reports received by public health agencies about HCV infections in Maryland residents increased markedly during the 4-year period from 2001 through 2004 in comparison to the prior 7-year period from 1994 through 2000.



Source: Maryland Electronic Reporting and Surveillance System (MERSS)

2. If the estimate¹ for prevalence of chronic HCV infections (1.8%) in the US population is applied to each of Maryland's jurisdictions, and then those figures are compared with numbers of HCV reports to public health in those jurisdictions through 2004, an estimate can be made of the numbers of Maryland residents (approximately 65,000 statewide) with chronic hepatitis C infection who have not been reported to public health.

Of these 65,000 unreported chronic HCV cases, nearly two-thirds reside in five jurisdictions (Figure 2). Many of these persons may not know that they have a serious chronic infection. Note: such estimates are approximate and may not reflect jurisdiction-specific variations in HCV disease.



Sources: DHMH Office of Epidemiology and Disease Control Programs; MERSS

3. Analysis of Maryland HCV cases reported during 2001-2004 shows that their demographic characteristics and associated risk factors are similar to those found in national studies (explained in Section C). However, a limitation on assessing Maryland disease cases in the State's communicable disease database is the high proportion (88%; see Figure 4) of cases of HCV with incomplete information.

- 4. Challenges to future efforts to assess HCV infection in Maryland include:
 - a. Difficulty in recognizing clinical presentation;
 - b. Lack of access to health care by certain groups at high-risk for hepatitis C infection (for example, those who inject illicit drugs; incarcerated persons);
 - Nonspecific laboratory findings and lack of resources for HCV confirmation:
 - d. Insufficient staff in local health departments for investigation and case follow-up; and
 - e. Variations among local health departments in procedures for collecting and entering HCV reports and case investigation findings.

A. Background

HCV infection is the most common blood-borne pathogen in the United States affecting some four million individuals. More than half of those are suffering from chronic infection (1). This population is at risk for chronic liver disease and primary hepatocellular carcinoma. Deaths attributed to HCV-related chronic liver disease affect 1-5% of the infected population per year (1).

Based upon national prevalence studies, approximately 99,000 Marylanders are estimated as being chronically infected with HCV. However, the cumulative total of HCV reports in Maryland's surveillance database is about 35% of that figure, suggesting that many persons in Maryland who have chronic HCV infection may not be aware of it.

B. Surveillance for Hepatitis C in Maryland

Data about HCV infection is collected in Maryland in order to better prevent and control the spread of hepatitis C infection and its consequences. More specifically, case reporting and the subsequent public health follow-up serve to:

- Identify newly infected individuals to determine possible sources of infection, and to ensure that they are educated on the need for medical evaluation and the value of early intervention, how to reduce disease progression, and to provide referrals to medical or support services;
- Identify clusters or outbreaks of infection and break the chain of infection;
- Provide information to all HCV-infected persons on how to prevent exposing others; and
- Determine the occurrence of HCV in specific populations and geographic locations to better inform HCV prevention and service activities.

In order to accomplish these goals,

- Maryland law and regulation mandate that both medical laboratories and healthcare providers report HCV cases to public health. HCV became reportable by healthcare providers in 1980, first as "Hepatitis, Type Non-A, Non-B," and then specifically as "Hepatitis C" in 2003. Medical laboratories were first required to report laboratory evidence of HCV infection beginning in 2001.
- Maryland's local health departments investigate laboratory reports of positive tests for HCV, and morbidity reports from healthcare providers.
 - Guidelines for case investigation by local health departments are disseminated by DHMH. The initial focus of the investigation is to verify the diagnosis and then to classify cases as either acute (newly acquired) or chronic.
 - Cases are classified based on Centers for Disease Control and Prevention ("CDC") and Maryland case definitions (see below, p. 68). The criteria for classification are fairly strict, contributing to a failure to categorize the majority of reports (Table 1). Unclassified reports result when the information needed for classification is unavailable (e.g., a critical test was not performed) or simply because the report was not fully investigated. Furthermore, using the CDC criteria, cases classified as "acute" are limited to cases of symptomatic disease. Such cases are only a subset of all newly acquired infections since a majority of cases are known to be asymptomatic.
 - For cases that have been classified as acute, information about risk factors for infection is collected using a standard questionnaire developed by the CDC.
- Case information is entered into a DHMH communicable disease database, the Maryland Electronic Reporting and Surveillance System ("MERSS").

Local health departments' capacities to investigate the many reports of HCV are limited for a number of reasons:

- Difficulty in contacting cases for follow-up;
- Lack of staff to conduct case investigations; and
- Receipt, over time, of multiple reports on the same individual, without a personal identifier clearly linking those reports to one person.

Several local health departments, particularly in the larger jurisdictions that receive the overwhelming majority of reports, indicate that they do not have the capacity to conduct case investigations and data entry. In many instances, the entry of the case report (without follow-up information) into the surveillance database is all that can be accomplished. Without thorough case investigation, the information available from the database is largely incomplete and may misrepresent the population as a whole. Furthermore, there is a danger that clusters of acute infection could go undetected.

C. Epidemiological Profile: Acute and Chronic Hepatitis C Cases, & Unclassified Reports in Maryland, 2001-2004

Despite its limitations, MERSS data shows approximately 26,000 reports were received between 2001 through 2004 for all categories of HCV infection (Table 2). Several characteristics of these reports include:

- The majority (88%) of the approximately 26,000 reports of HCV infections are unclassified, and most of these probably represent chronically infected individuals.
- 63% are male.
- Among those with a reported race, 54% are White and 44% are African-American. However, race is unknown for 54% of all reports (Table 2).
- The age distribution is similar to national statistics (Figure 1).
- Approximately 7,500 of HCV reports represent residents of Baltimore City.
 Among other jurisdictions, Baltimore County has the highest number of residents (approximately 4,600) reported with HCV infection.
- The majority of the cases classified as acute and chronic are reported from outside of Baltimore City. In contrast, the majority of the unclassified reports are reported by Baltimore City (Figure 2). Baltimore City represents 11% of the population, but constitutes 36% of the unclassified reports of HCV (Table 3). Figure 2 shows that the state's four largest jurisdictions, which accounted for 61% of all HCV reports, each left 91-99% of MERSS HCV reports unclassified. The best performance in this area occurred in several of the state's smaller jurisdictions, with about 45% of reports unclassified. However, due to the influence of the larger jurisdictions, the statewide average for unclassified reports was 88%.

During the most recent 4-year period (2001-2004), 50 cases of acute HCV were reported (Table 4). The average number of acute HCV cases per year was 12. Based upon information derived from the overall case investigation and the reported risk factors for disease, the local health department determines the suspected source of infection.

- Please note: in 2004, 16 of 18 (88%) cases of acute hepatitis C were associated. with the only outbreak identified during the past 4 years. This common-source outbreak resulted from contamination of a radiolabeled injectable product used in a cardiac imaging procedure.
- Among the other 34 (non-outbreak) cases, 31% reported using needles to inject drugs, 9% had contact with a case, and 6% reported being dialysis patients. One case was a medical employee who suffered a needle stick (Table 5).

D. Challenges

Determining the burden of HCV disease in Maryland using current public health surveillance techniques continues to be challenging. A number of issues hinder current surveillance efforts, especially recognition of HCV disease or exposure risk and follow-up investigation of reports received by local health departments:

- Clinical recognition of acute HCV is not easily determined: Acute HCV is
 classified based on both clinical findings and diagnostic test results, however
 80% of individuals have no easily recognized signs or symptoms. In chronic HCV
 disease, lab findings may be identical to those of acute hepatitis C. There is no
 single laboratory test that determines whether a reported lab finding of HCV
 represents an acute or a chronic case.
- Reliability of Laboratory Testing: The screening test to detect infection is an
 antibody test, which can suffer from a high rate of false positives. In other words,
 even when a screening test result is positive, it may not be an accurate predictor
 of the presence of HCV infection. Confirmatory testing is also not specific
 enough to determine acute or chronic infection.
- Inconsistent or incomplete investigation of HCV reports: Local health
 departments in Maryland vary in their capacities and procedures related to how
 much staff time will be spent investigating whether a lab test showing HCV
 infection indicates an acute or a chronic infection; or whether the lab result may
 be a false positive. The number of HCV reports of all types entered into MERSS
 each year has increased since HCV was added to the list of reportable diseases
 for laboratories (Figure 1).

E. Conclusions and Recommendations:

- Making hepatitis C infection reportable by medical laboratories and by healthcare providers has increased our ability to assess the burden of this disease in Maryland; however, two-thirds of Maryland's hepatitis C cases are estimated to be unreported.
- 2. Resources are not well matched to the demand created by reports sent to local health departments, especially in some of the more populous jurisdictions.

Table 1. Number of Reported Cases and Reporting Rates (per 100,000 persons) HCV Infection in Maryland by Category and Year (*Source: MERSS*)

	2001	2002	2003	2004
	# (Rate)	# (Rate)	# (Rate)	# (Rate)
Hepatitis C acute	9 (0.17)	14 (0.26)	9 (0.16)	18 (0.37)
Hepatitis C chronic	593	793	904	773
Hepatitis C unclassified	6,245	4,413	3,558	9,207

Table 2. Number of Reports, 2001-2004, HCV Infection (All Categories) [With Breakdown by Residence, Gender, & Race/Ethnicity]

	Number	(%)	Number per 100,000 pop.*
Residence			
Baltimore City	7,547	28	294
Counties	18,988	72	98
Total	26,536	100	121
Gender			
Male	16,622	63	157
Female	9,860	37	87
Unknown	54	<1	N/A
Total	26,536	100	N/A
Race			
White	6,580	25	N/A
African American	5,426	21	N/A
Asian	104	<1	N/A
American Indian	25	<1	N/A
Multi-racial	2	<1	N/A
Other	125	<1	N/A
Unknown	14,274	54	N/A
Total	26,536	100	N/A
Ethnicity			
Hispanic	123	<1	N/A
Non-Hispanic	4,256	16	N/A
Unknown	22,157	84	N/A
Total	26,536	100	N/A

^{* -} Note: Number of HCV reports of any type during 2001-2004 divided by projected population (person-years) of that subgroup during period. N/A - not applicable. Source: MERSS.

Table 3. Combined HCV Reports Of All Types (Acute, Chronic, And Unclassified) By Jurisdiction And Year (Source: MERSS)

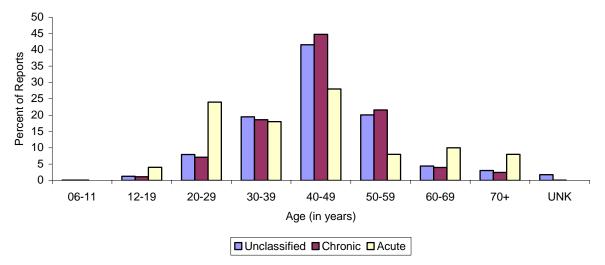
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County	2001	2002	2003	2004	Total
Baltimore City	2,180	485	458	4,424	7,547
Anne Arundel	751	846	657	824	3,078
Allegany	99	93	80	64	336
Baltimore	1,174	1,052	832	1,546	4,604
Calvert	28	41	25	32	126
Caroline	30	41	38	34	143
Carroll	97	226	189	221	733
Cecil	21	55	101	122	299
Charles	48	44	39	35	166
Dorchester	3	4	6	6	19
Frederick	176	291	154	230	851
Garrett	12	21	11	24	68
Harford	251	256	247	276	1,030
Howard	171	94	86	130	481
Kent	20	21	13	13	67
Montgomery	86	336	264	426	1,112
Prince George's	898	631	593	757	2,879
Queen Anne's	58	54	46	42	200
Somerset	73	73	112	177	435
St Mary's	76	30	25	36	167
Talbot	43	53	46	47	189
Washington	328	309	311	358	1,306
Wicomico	127	112	78	115	432
Worcester	97	52	60	59	268
Total	6,847	5,220	4,471	9,998	26,536

Table 4. Reported Acute HCV Cases and Rates (per 100,000 persons) by Residence, Gender, Race & Ethnicity
Maryland, 2001-2004

	#	(%)	Rates (per 100,000)
Residence			
Baltimore City	1	2	0.04
Counties	49	98	0.26
Total	50	100	0.20
Gender			
Male	19	38	0.18
Female	31	62	0.27
Unknown	0	0	N/A
Total	50	100	N/A
Race			
White	38	76	N/A
African America	9	18	N/A
Asian	1	2	N/A
American Indian	0	0	N/A
Multi-racial	0	0	N/A
Other	0	0	N/A
Unknown	2	4	N/A
Total	50	100	N/A
Ethnicity			
Hispanic	2	4	N/A
Non-Hispanic	38	76	N/A
Unknown	10	20	N/A
Total	50	100	N/A

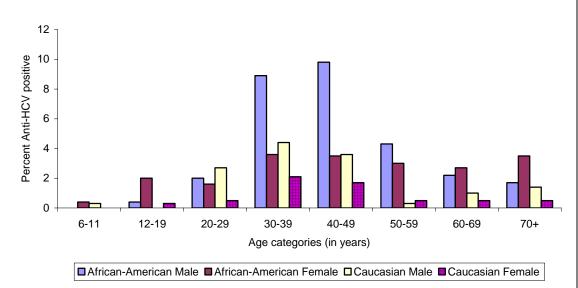
Source: MERSS

Figure 3. Age Distribution of Acute and Chronic Cases & Unclassified Reports of HCV in Maryland, 2001-2004



Source: Maryland Electronic Reporting and Surveillance System (MERSS)

Prevelance of HCV infection by Age, Race, and Gender in United States, 1988-1994



Source: Centers for Disease Control and Prevention, National Health and Nutrition Examination Survey (NHANES) III

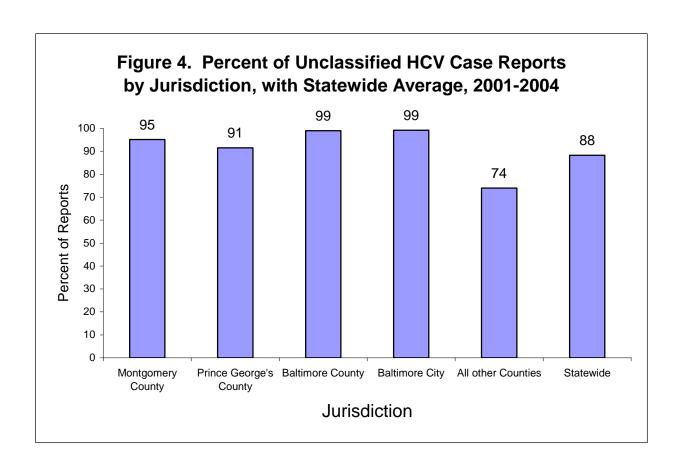


Table 5. Frequency of Reported Risk Factors Among Non-Outbreak-Associated Acute HCV Cases Maryland 2001-2004 *				
Intravenous Drug Use	31%			
Multiple Sexual Partners (>=2)	16%			
Contact with Hepatitis B or non-A/non-B case	9%			
Dialysis Patient	6%			
Dental work or surgery	6%			
Other surgery	6%			
Tattooing	6%			
Medical Employee with needlestick	3%			

^{*} Note: 0, 1 or multiple risk factors may be reported (n=34). Source: MERSS

Explanation of Categories

<u>Acute HCV Infection:</u> Cases are classified using the national case definition for surveillance (http://www.cdc.gov/epo/dphsi/casedef/hepatitiscurrent.htm). Note that this surveillance case definition includes only symptomatic cases.

<u>Chronic HCV Infection:</u> Chronic hepatitis C virus (HCV) infection as indicated by either an elevation in liver function tests or the presence of HCV RNA over a 6-month or greater period.

<u>Unclassified HCV Reports:</u> These reports are not classified as "acute" or "chronic" because not enough information is available from the reporting source or from case investigation to determine the appropriate classification or because the report was not investigated. Additionally, some are further lab reports on cases that have already been classified.

Reference:

1. CDC. MMWR Recommendations and Reports. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease (October, 1998). Available at http://www.cdc.gov/mmwr/PDF/rr/rr4719.pdf. Accessed June 7, 2005.

Appendix 4: Maryland Hepatitis C Control and Prevention Plan

Source: downloaded as .pdf file from www.edcp.org on December 14, 2005

Maryland Department of Health and Mental Hygiene

Maryland Hepatitis C Prevention and Control Plan

September 2002



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. "

<u>Background:</u> 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.

<u>Sources of HCV Infection:</u> 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%).

<u>Consequences of HCV infection:</u> 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 highrisk 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 atrisk 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	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 highrisk 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 highrisk 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			<u> </u>	
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.