Committee on a National Strategy for the Elimination of Hepatitis B and C

Gillian Buckley
Brian L. Strom, M.D., M.P.H
Chancellor
Rutgers Biomedical & Health Sciences
Rutgers University, The State University of New Jersey

Jon Kim Andrus, M.D.
Executive Vice President and Director
Vaccine Advocacy and Education
Sabin Vaccine Institute

Andrew Aronsohn, M.D.
Assistant Professor of Medicine
Gastroenterology
University of Chicago

Daniel Church, M.P.H.
Epidemiologist and Viral Hepatitis Prevention Coordinator
Massachusetts Department of Public Health

Seymour Cohen, Ph.D.
Instructor Emeritus
Marine Biological Laboratory

Alison Evans, Sc. D.
Associate Professor
Dornsife School of Public Health
Drexel University

Paul Kuehnert, DNP, RN
Assistant Vice President, Program
Robert Wood Johnson Foundation

Vincent Lo Re III, M.D., M.S.C.E.
Assistant Professor of Medicine and Epidemiology
Perelman School of Medicine, University of Pennsylvania

Kathleen Maurer, M.D., M.P.H., M.B.A.
Director, Health and Addiction Services
Connecticut Department of Correction

Randall Mayer, M.P.H.
Interim Director, Division of Behavioral Health
Iowa Department of Public Health

Shruti Mehta, Ph.D., M.P.H.
Professor of Epidemiology
Bloomberg School of Public Health, Johns Hopkins University

Stuart C. Ray, M.D.
Professor of Medicine
Center for Viral Hepatitis Research, Johns Hopkins University

Arthur Reingold, M.D.
Edward Penhoet Distinguished Professor Global Health and Infectious Diseases
School of Public Health, University of California, Berkley

Samuel So, M.B.
Lui Hac Minh Professor
School of Medicine, Stanford University

Neeraj Sood, Ph. D.
Associate Professor and Vice Dean for Research
Sol Price School of Public Policy
University of Southern California

Grace Wang, M.D.
Family Physician
International Community Health Services

Lucy Wilson, M.D., Sc.M.
Chief, Center for Surveillance, Infection Prevention, and Outbreak Response
Maryland Department of Health and Mental Hygiene
Emerging Momentum for Action

- Viral hepatitis causes 1.5 million deaths a year worldwide
- About 20,000 deaths in the United States
- Medicines approved in 2014 can cure chronic HCV infection in most patients, the HBV vaccine conveys 95% immunity.
- Recent WHO resolution on eliminating viral hepatitis as a major public health problem
Phase One Report

• After analyzing the problems of hepatitis B and C in the United States, the committee concluded that control is feasible in the relatively short term. Eliminating the public health problems of hepatitis B and C will take more time, and require considerable public will, resources, and attention to the barriers mentioned in Tables S-1 and S-2.

• For the committee’s purposes, a public health problem was defined as a disease that by virtue of transmission or morbidity or mortality commands attention as a major threat to the health of the community.
Is Eliminating Hepatitis B Feasible?

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<th>Feasibility</th>
<th>Critical Factors</th>
<th>Crosscutting Barriers</th>
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<td>Ending transmission</td>
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</table>
| Perinatal                                 | Highly feasible | • Identifying HBV-infected mothers  
• Consistent birth dosing with HBV vaccine | • Surveillance is sporadic and underfunded.  
• Vaccine tracking across jurisdictions is poor.  
• Stigma keeps people from screening and care.  
• Foreign-born adults can be difficult to reach with screening and treatment programs.  
• Much of the burden for managing chronic hepatitis B falls on overworked primary care providers.  
• There is a need to better understand the virus and the management of chronic hepatitis B. |
| Children                                  | Highly feasible | • Consistent vaccination and attention to catch-up dosing |                                                                                    |
| Adults                                    | Feasible     | • No system for vaccinating adults  
• Undiagnosed, asymptomatic chronic infections a reservoir for infection |                                                                                    |
| Morbidity and mortality attributable to ongoing infection |             |                                                                                  |                                                                                    |
| Slowing progression to cirrhosis          | Feasible     | • Need for physicians trained in the management of chronic HBV infection  
• The threat of reactivation in chronic or resolved infection  
• No available treatment eliminates cccDNA or cures the disease |                                                                                    |
| Reducing deaths                           |             |                                                                                  |                                                                                    |
The Transmission of HBV

• Mother-to-child transmission is rare in the US, but 800-1000 cases a year suggest problems with prenatal screening prophylaxis failure
• Room for improvement in birth dosing with HBV vaccine and catch up vaccination in children
• Support for birth dose coverage in HBV endemic countries of Asia and Africa could help reduce the future domestic burden of HBV as most chronic infections are imported.
• Universal immunization of infants and children would protect future generations from cirrhosis and liver cancer due to HBV.
• Adult immunization more complicated, but might done more efficiently at places already in contact with people at risk for HBV infection.
Complications among the Chronically Infected

- There is no cure for hepatitis B. The goal of therapy is to suppress HBV DNA to undetectable levels. Cure, though not unheard of, is extremely rare.
- Many chronically infected HBV patients eventually require immunosuppressive drugs for cancer, autoimmune disease or organ transplantation. These drugs can reactivate suppressed HBV, a serious complication that can lead to liver failure.
Barriers to Hepatitis B Elimination

• HBV disease surveillance is inconsistent across jurisdictions and not well funded.
• HBV infection carries a social stigma that could undermine elimination efforts. Education and changes to social norms can alleviate stigma. Such change is possible, but takes time.
• Improved screening could help reduce complications and deaths from HBV, it could also help end transmission. Screening people born abroad would identify new infections, but restrictions on access to care could keep many of the newly identified cases from treatment.
• Screening should be accompanied by a method to enroll and retain patients in care.
• Research on reactivation, better vaccines, and a treatment to cure infection would facilitate HBV elimination.
# Is Eliminating Hepatitis C Feasible?

<table>
<thead>
<tr>
<th>Goal</th>
<th>Feasibility</th>
<th>Critical Factors</th>
<th>Crosscutting Barriers</th>
</tr>
</thead>
</table>
| **Ending Transmission** | Feasible | • No vaccine  
• Reaching people who inject drugs with harm reduction programs  
• Comprehensive drug and alcohol addiction programs  
• Treating those transmitting the virus to prevent new infection  
• Reducing the possibility of reinfection | • Surveillance is sporadic and underfunded  
• Only about half of chronically infected people have been diagnosed  
• Most new infection is associated with injection drug use, the group most affected is difficult to screen  
• Poor, marginalized, and hard-to-reach populations are difficult to enroll and retain in care  
• The high cost of direct-acting antiviral drugs makes universal treatment infeasible  
• Hepatitis C is not a public priority  
• Stigma keeps highest risk people away from care  
• The limited capacity of prison health systems to treat HCV-infected inmates |
| **Eliminating Chronic Infection** | Feasible | • Increasing access to treatment  
• The threat of antiviral resistance  
• Understanding the role of treatment adherence |  |
| **Reducing Morbidity and Mortality Attributable to Ongoing Infection** | Slowing progression to cirrhosis  
Reducing deaths | Feasible | • Problems assessing and staging fibrosis  
• Obesity, HIV, alcohol use can aggravate disease progression  
• Eradicating the virus before progression to advanced fibrosis can almost eliminate complications and risk of death  
• Need for reliable models of disease progression |  |
The Transmission of HCV

- Harm reduction services could help reduce transmission of HCV, but the success of such programs depends on the number of injectors reached and the number of syringes exchanged relative to total injections made.
- Most harm reduction models come from cities, but injection drug use is becoming more common in rural areas and small towns. Adapting these programs to less densely populated areas will be challenging.
- Direct-acting antivirals can both prevent hepatitis C deaths and interrupt transmission, but these goals are meet with attention to widely different patient populations.
- It is possible to be reinfected after cure, but since the direct-acting antiviral treatments are new, research on reinfection is limited.
Eliminating Chronic Infection and Complications among the Chronically Infected

• The drugs that cure HCV infection are expensive so many insurers restrict their access, usually asking for evidence of advanced fibrosis or consultation with a specialist, some also require documentation of sobriety.
• State Medicaid programs have widely different restrictions on treatment.
• Curing hepatitis C in patients with decompensated cirrhosis can avoid the need for transplantation entirely or prolong graft survival after transplantation.
• Curing HCV before it progress to cirrhosis is the most efficient way to prevent fibrosis, hepatocellular carcinoma, and death from hepatitis C.
Barriers to Hepatitis C Elimination

• People who inject drugs drive most transmission in US, but are less likely to be tested or included in surveillance.

• Half of all chronically infected people are undiagnosed. The first step to preventing their disease from progressing is diagnosing them and bringing them to care.

• Some insurers and three-quarters of states’ Medicaid programs have responded to the cost of DAAs by restricting access. Only about one in ten people with chronic hepatitis C receives curative treatment.
Barriers to Hepatitis C Elimination

• The introduction of direct-acting antivirals for hepatitis C drove most of the acceleration in prescription drug spending between 2013 and 2014.
• Even at the current prices, these drugs are cost-effective. The benefits of treatment outweigh the costs.
• Eliminating hepatitis C would require near universal access to treatment.
• Though HCV is more than twice as common as HIV and causes more deaths, it is less of a public priority, far fewer resources are allocated to its prevention, testing, treatment, and research.
• Almost a third of the United States’ chronic hepatitis C cases are found in prisons, but managing the infection is not usually within the capacity of a prison health system.
Statement of Task

Phase One Statement of Task

The IOM will conduct a literature review and convene two meetings of the committee, one of which will include a two part workshop, one part focused on HBV and one focused on HCV to determine whether HBV and HCV elimination goals for the United States are feasible and to identify possible critical success factors. A brief report containing the committee’s conclusion regarding the feasibility of setting elimination goals and possible critical success factors shall be prepared.
Statement of Task

Phase Two Statement of Task

The committee will prepare a consensus report containing committee conclusions and recommendations, specifically identifying:

1) the appropriate hepatitis reduction or elimination goal(s) and specifying a plan of action to achieve the goal(s) including, but not necessarily limited to: medical and substance abuse services, community-based services, and correctional health services;

2) barriers to achieving the goal(s) such as access to treatment and related policy issues; public health infrastructure resources for screening, education and outreach; and surveillance;

3) potential solutions to the barriers identified; and

4) specific stakeholders and their responsibilities to achieve the goal.
<table>
<thead>
<tr>
<th>TARGET AREA</th>
<th>BASELINE 2015</th>
<th>2020 TARGETS</th>
<th>2030 TARGETS</th>
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</thead>
<tbody>
<tr>
<td><strong>Impact targets</strong></td>
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<tr>
<td>Incidence: New cases of chronic viral hepatitis B and C infections</td>
<td>Between 6 and 10 million infections are reduced to 0.9 million infections by 2030 (95% decline in hepatitis B virus infections, 80% decline in hepatitis C virus infections)</td>
<td>30% reduction (equivalent to 1% prevalence of HBsAg among children)</td>
<td>90% reduction (equivalent to 0.1% prevalence of HBsAg among children)</td>
</tr>
<tr>
<td>Mortality: Viral hepatitis B and C deaths</td>
<td>1.4 million deaths reduced to less than 500,000 by 2030 (65% for both viral hepatitis B and C)</td>
<td>10% reduction</td>
<td>65% reduction</td>
</tr>
<tr>
<td><strong>Service coverage targets</strong></td>
<td></td>
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<tr>
<td>Hepatitis B virus vaccination: childhood vaccine coverage (third dose coverage)</td>
<td>82%&lt;sup&gt;13&lt;/sup&gt; in infants</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>Prevention of hepatitis B virus mother-to-child transmission: hepatitis B virus birth-dose vaccination coverage or other approach to prevent mother-to-child transmission</td>
<td>38%</td>
<td>50%</td>
<td>90%</td>
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<tr>
<td>Blood safety</td>
<td>39 countries do not routinely test all blood donations for transfusion-transmissible infections 89% of donations screened in a quality-assured manner&lt;sup&gt;12&lt;/sup&gt;</td>
<td>95% of donations screened in a quality-assured manner</td>
<td>100% of donations are screened in a quality-assured manner</td>
</tr>
<tr>
<td>Safe injections: percentage of injections administered with safety-engineered devices in and out of health facilities</td>
<td>5%</td>
<td>50%</td>
<td>90%</td>
</tr>
<tr>
<td>Harm reduction: number of sterile needles and syringes provided per person who injects drugs per year</td>
<td>20</td>
<td>200</td>
<td>300</td>
</tr>
<tr>
<td>Viral hepatitis B and C diagnosis</td>
<td>&lt;5% of chronic hepatitis infections diagnosed</td>
<td>30%</td>
<td>90%</td>
</tr>
<tr>
<td>Viral hepatitis B and C treatment</td>
<td>&lt;1% receiving treatment</td>
<td>5 million people will be receiving hepatitis B virus treatment 3 million people have received hepatitis C virus treatment (Both targets are cumulative by 2020)</td>
<td>80% of eligible persons with chronic hepatitis B virus infection treated 80% of eligible persons with chronic hepatitis C virus infection treated</td>
</tr>
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