Testimony presented to the INSTITUTE OF MEDICINE
Prevention and Control of Viral Hepatitis Infections in the U.S

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Today’s Presentation

- About the Hepatitis B Foundation
- Now is the time to implement “Zero Tolerance” against HBV!
- Recommendations as to how we can achieve this ambitious goal
A national nonprofit organization dedicated to finding a cure and improving the quality of life for those affected by hepatitis B worldwide through . . .

Research
Education
Patient Advocacy

www.hepb.org
Research, Education and Patient Advocacy

- Comprehensive Web Site
- Phone and Email Help Lines
- Patient Conference
- Community Education and Screening Programs
- Drug Discovery for HBV and HCV
- Early Detection Biomarkers for Cirrhosis and Liver Cancer
- Research Internships
In the world
350-400 million are chronically infected with HBV
1.4 - 2 million Americans have chronic HBV

1 million individuals die from HBV each year
5,000 Americans die from HBV

30 million new HBV infections each year
80,000 Americans acquire new infections
### Burden of Chronic Hepatitis Exceeds that of HIV

<table>
<thead>
<tr>
<th></th>
<th>HIV</th>
<th>HBV</th>
<th>HCV</th>
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<tbody>
<tr>
<td>Chronic infections in the U.S.</td>
<td>1-1.2 (million)</td>
<td>1.25* (million)</td>
<td>3.2 (million)</td>
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<tr>
<td>New infections / year</td>
<td>40,000</td>
<td>80,000</td>
<td>30,000</td>
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<tr>
<td>Deaths / year</td>
<td>15,000</td>
<td>5,000</td>
<td>8-10,000</td>
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*Underestimation - excludes APIs, immigrants, institutionalized, incarcerated
Multiple recent published revised estimates up to 2 million
A Call To Action!

ţ With a good vaccine . . . we should not tolerate the incidence of new infections

ţ With effective therapies . . . we should not allow any individual to suffer from a lack of awareness or access to care
We Have the Necessary Tools

- Good vaccines, Effective therapies
- National immunization & screening guidelines
- Network of perinatal & adult hepatitis coordinators
- Dedicated nonprofit organizations
- Effective public-private partnerships
- Support from Congress, CDC, NIH, OMH, and professional societies such as AASLD
A Zero Tolerance policy would ensure that no American is left behind.

We need to address:

(1) Access to prevention

(2) Access to care
*Estimated No. of Treated CHB Infections in the U.S.

- **1.4-2MM** CHB infected
- **25%** US born
- **37%** Non-Asian foreign born
- **12%** Asian foreign born

- **Diagnosed**: ~300k
- **Treated**: ~50k

*Slide courtesy of Gilead Sciences (IMS data)*
“Hepatitis B is the deadliest disease that can be prevented through infant vaccination.”
(Dr. John Ward, director of DVH at CDC)

- Approximately 20,000 babies are born to HBV-infected women each year in the U.S.
- Up to 1,500 newborns are chronically infected

Each perinatal infection indicates a missed opportunity for prevention or failure of intervention
Access to Prevention: Taking Care of Moms

Infected pregnant women are currently treated as vessels of disease

They should be treated as portals of entry into their communities for additional prevention and identification of chronic disease.

Testing and vaccinating a woman’s family and social network reduces transmission and ongoing disease.

Lack of care leaves infected moms uneducated and unprotected.
New HBV infection rates are highest among adults between the ages of 19-49 years.

Current adult HBV screening guidelines focus on known at-risk groups.

Targeted strategies miss those who do not admit to being at-risk or don’t understand their risk.

Include screening recommendations as part of routine care, independent of perceived risk.
The risk of developing liver cancer is 60 times greater with HBV than in the general population.

In HBV, liver cancer can occur without cirrhosis, which distinguishes it from hepatitis C.

Of the estimated one million people worldwide who die each year from the complications of HBV, up to 600,000 are due to liver cancer.
Access to Care: Underestimation of Burden

- The CDC estimates 1.4 million Americans have CHB.
- Recent preliminary studies indicate the number is probably closer to 2 million.
- Only 25% of those chronically infected have been diagnosed, and only an estimated 50,000 people are being treated.

**How can we do a better job of identifying the chronically infected and get them into care?**
Approved therapies can reverse fibrosis and cirrhosis, and may prevent end-stage liver disease/liver cancer if started early enough.
Our recommendations will be organized to follow the format of the IOM Statement of Task:

- Strategies for preventing new HBV infections
- Strategies for reducing morbidity and mortality from chronic HBV
- Assessing the type and quality of data needed from state and local viral hepatitis surveillance systems to guide and evaluate prevention services
- Special needs of specific subpopulations
Preventing New Infections

Adopt Zero Tolerance

- Require all birthing hospitals to follow the CDC guidelines for perinatal screening and vaccination
- Provide the resources and funding to state and local health departments to implement the CDC’s recommendations for infected pregnant women
- Ensure family and social networks are tested and vaccinated to achieve prevention and identification of new chronic infections
Awareness of HBV status is a necessary component to initiating access to care.

Of the 1-2 million Americans with CHB, only 25% of people know they are infected.

In HIV, approximately 75% know their status.

Recommendations for screening as part of routine care, independent of perceived risk, will increase earlier identification of disease, just as it has for HIV.
Access to Care: People Need to Know Their Status

1 million HIV
- 250,000 Aware & Not in Care
- 250,000 Unaware & In Care
- 500,000 Awareness & In Care

1.25-1.4 million Chronic HBV
- 990,000 Unaware & Not in Care
- 225,000 Aware & Not in Care

3.1 million Chronic HCV
- 670,000 Aware of infection & on treatment
- 2,330,000 Unaware & Not in Care

50,000 Aware of infection & on treatment

HIV - CDC and Kaiser Family Foundation
HBV - CDC and Gilead estimates (IMS, Synovate)
Strategies for Reducing Morbidity and Mortality

- Strengthen efforts to identify the true burden of HBV in the U.S.
- Encourage all people, especially those at high-risk, to know their status
- Link chronically infected persons to care
- Expand provider education about the importance of early detection and management of HBV
Identify the True Burden of Chronic HBV

Make a concerted effort to identify all those who are chronically infected with HBV:

- To reduce ongoing transmission risks
- To decrease cirrhosis and liver cancer
- To link chronic hepatitis registries with other registries for better management, understanding of outcomes, and co-infections & co-morbidities
The high prevalence of undiagnosed chronic HBV infection is alarming.

Current screening guidelines are still risk-based.

Individuals will be missed who do not want to admit their risk or may not understand their risk.
Link Chronically Infected Individuals to Care

- Reduces cost since the combined burden to individuals and society far exceed the cost of early identification and proactive management.

- Treatment is a secondary form of cancer prevention!

- Provide accessible safety net coverage – expand Medicaid and Medicare to cover the poor who suffer from chronic viral hepatitis.
Focus on missed opportunities in primary care, which is where most people are first diagnosed.

Improve provider knowledge about how to routinely screen and manage HBV in their daily practice.

Dispel the myth of a “Healthy Carrier”

Emphasize the importance of lifelong monitoring.
Chronic disease management is an important cornerstone of our national public health effort.

Need to substantially increase national investment:

- To build the capacity of our federal health agencies to expand and sustain a robust chronic HBV surveillance system
- To support research to improve monitoring of chronic disease and to study additional unanswered questions
We do not have national surveillance data system for CHB, including stage of disease when patients are first diagnosed.

Current surveillance for hepatitis B in the U.S. focuses on acute disease.

Need to expand chronic surveillance to identify the true burden of disease by counting everyone.

Chronic surveillance would provide a good picture of where HBV is occurring, and in what local communities, to help target efforts.
Current monitoring methods are lacking in sensitivity and do not detect disease early enough.

New, non-invasive methods are needed.

The stage of liver disease in a chronically infected individual is decisive in determining when intervention should begin.
Additional Research for Unanswered Questions

*When to treat and should everyone be treated to prevent disease progression?*

*Why is maternal to child transmission still a challenge?*

*Treat pregnant women in the last trimester to reduce vertical transmission?*

*What is the impact of waning vaccine immunity?*

*What is the natural history of HBV in children as it impacts treatment and long-term outcomes?*
In the U.S., APIs report having less health insurance, lower use of most health care services, and less likely to have a source of ongoing care.

It is well documented that APIs have both reduced access and ability to seek health services.

Developing programs to increase access to prevention and care would eliminate disparities.
Additional Comments

- 2008 has been pivotal for HBV in terms of public efforts and public-private partnerships

- A unique convergence of activity around HBV from Congress, CDC, NIH, OMH and IOM

- Great successes, but flat funding continues for chronic viral hepatitis

Dollars Do Equal Concern!
With improved chronic surveillance, screening, and early medical intervention, we can now prevent new infections, reduce serious outcomes, and eliminate disparities.

With a safe vaccine and seven approved drug therapies, we can now achieve Zero Tolerance against HBV and leave no American behind!
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