AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

VIRAL HEPATITIS: THE SECRET EPIDEMIC

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

JUNE 17, 2010

Serial No. 111–93

Printed for the use of the Committee on Oversight and Government Reform

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

62–946 PDF WASHINGTON : 2011

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

EDOLPHUS TOWNS, New York, *Chairman*

PAUL E. KANJORSKI, Pennsylvania
CAROLYN B. MALONEY, New York
ELIJAH E. CUMMINGS, Maryland
DENNIS J. KUCINICH, Ohio
JOHN F. TIERNEY, Massachusetts
WM. LACY CLAY, Missouri
DIANE E. WATSON, California
STEPHEN F. LYNCH, Massachusetts
JIM COOPER, Tennessee
GERALD E. CONNOLLY, Virginia
MIKE QUIGLEY, Illinois
MARCY KAPTUR, Ohio
ELEANOR HOLMES NORTON, District of Columbia
PATRICK J. KENNEDY, Rhode Island
DANNY K. DAVIS, Illinois
CHRIS VAN HOLLEN, Maryland
HENRY CUELLAR, Texas
PAUL W. HODES, New Hampshire
CHRISTOPHER S. MURPHY, Connecticut
PETER WELCH, Vermont
BILL FOSTER, Illinois
JACKIE SPEIER, California
STEVE DRIEHAUS, Ohio
JUDY CHU, California

DARRELL E. ISSA, California
DAN BURTON, Indiana
JOHN L. MICA, Florida
JOHN J. DUNCAN, JR., Tennessee
MICHAEL R. TURNER, Ohio
LYNN A. WESTMORELAND, Georgia
PATRICK T. McHENRY, North Carolina
BRIAN P. BILBRAY, California
JIM JORDAN, Ohio
JEFF FLAKE, Arizona
JEFF FORTENBERRY, Nebraska
JASON CHAFFETZ, Utah
AARON SCHOCK, Illinois
BLAINE LUETKEMEYER, Missouri
ANH "JOSEPH" CAO, Louisiana
BILL SHUSTER, Pennsylvania

RON STROMAN, *Staff Director*
MICHAEL MCCARTHY, *Deputy Staff Director*
CARLA HULTBERG, *Chief Clerk*
LARRY BRADY, *Minority Staff Director*

CONTENTS

	Page
Hearing held on June 17, 2010	1
Statement of:	
Johnson, Hon. Henry C. "Hank", a Representative in Congress from the State of Georgia; Hon. Bill Cassidy, a Representative in Congress from the State of Louisiana; and Hon. Mike Honda, a Representative in Congress from the State of California	13
Cassidy, Hon. Bill	15
Honda, Hon. Mike	23
Johnson, Hon. Henry C. "Hank"	13
Koh, Howard K., M.D., M.P.H., Assistant Secretary of Health, U.S. Department of Health and Human Services, accompanied by John W. Ward, M.D., Director, Viral Hepatitis Program, Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention	30
Mayer, Randy, chief, Bureau of HIV, STD, and Hepatitis, Iowa Department of Public Health, appearing on behalf of the Institute of Medicine; Michael Ninburg, executive director, Hepatitis Education Project; Jeffrey Levi, executive director, Trust for America's Health; and Rolf Joachim Benirschke, former NFL place kicker, San Diego Chargers, and spokesman for Hepatitis C awareness	69
Benirschke, Rolf Joachim	90
Levi, Jeffrey	83
Mayer, Randy	69
Ninburg, Michael	76
Letters, statements, etc., submitted for the record by:	
Benirschke, Rolf Joachim, former NFL place kicker, San Diego Chargers, and spokesman for Hepatitis C awareness, prepared statement of	92
Cao, Hon. Anh "Joseph", a Representative in Congress from the State of Louisiana, prepared statement of	105
Cassidy, Hon. Bill, a Representative in Congress from the State of Louisiana, prepared statement of	19
Connolly, Hon. Gerald E., a Representative in Congress from the State of Virginia, prepared statement of	12
Honda, Hon. Mike, a Representative in Congress from the State of California, prepared statement of	25
Issa, Hon. Darrell E., a Representative in Congress from the State of California, prepared statement of	7
Koh, Howard K., M.D., M.P.H., Assistant Secretary of Health, U.S. Department of Health and Human Services, prepared statement of	34
Levi, Jeffrey, executive director, Trust for America's Health, prepared statement of	85
Mayer, Randy, chief, Bureau of HIV, STD, and Hepatitis, Iowa Department of Public Health, appearing on behalf of the Institute of Medicine, prepared statement of	71
Ninburg, Michael, executive director, Hepatitis Education Project, prepared statement of	78
Speier, Hon. Jackie, a Representative in Congress from the State of CAlifornia, prepared statement of	103
Towns, Chairman Edolphus, a Representative in Congress from the State of New York, prepared statement of	3

VIRAL HEPATITIS: THE SECRET EPIDEMIC

THURSDAY, JUNE 17, 2010

HOUSE OF REPRESENTATIVES,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The committee met, pursuant to notice, at 10:09 a.m., in room 2154, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the committee) presiding.

Present: Representatives Towns, Kucinich, Clay, Watson, Connolly, Quigley, Speier, Chu, Issa, Bilbray, Jordan, Chaffetz, Luetkemeyer, and Cao.

Staff present: Kwane Drabo, investigator; Adam Hodge, deputy press secretary; Carla Hultberg, chief clerk; Marc Johnson and Ophelia Rivas, assistant clerks; Emily Khoury, professional staff member; Kwame Canty and Gerri Willis, special assistants; Julie Rones, counsel; Ron Stroman, staff director; Lawrence Brady, minority staff director; John Cuaderes, minority deputy staff director; Rob Borden, minority general counsel; Jennifer Safavian, minority chief counsel for oversight and investigations; Frederick Hill, minority director of communications; Adam Fromm, minority chief clerk and Member liaison; Kurt Bardella, minority press secretary; Seamus Kraft, minority deputy press secretary; Justin LoFranco, minority press assistant and clerk; Ashley Callen, Sery Kim, and Jonathan Skladany, minority counsels; Mark Marin, Molly Boyl, and Meredith Liberty, minority professional staff members; and Sharon Casey, minority executive assistant.

Chairman TOWNS. The committee will come to order.

Today's hearing entitled, "Viral Hepatitis: The Secret Epidemic," will examine the concerns about Hepatitis B and Hepatitis C as raised by the Institute of Medicine in a recently released report. That report, entitled, "Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C," indicates that the United States is experiencing a hepatitis crisis. Many call hepatitis the silent epidemic because the attention it has received has not been in proportion to the vast number of Americans it affects.

Hepatitis B and C are among the leading causes of preventable deaths worldwide and are the most common blood-borne infections in the United States.

The Institute of Medicine found that the current Federal approach to battling these diseases is simply not working. The IOM Report suggests a greater need for a federally coordinated response to these diseases, better surveillance, knowledge and awareness, immunization and viral hepatitis services. Today's hearing will re-

view that report and will explore how to implement its recommendations.

Today I would like to welcome my colleagues who are helping to focus much needed attention on these diseases: Congressman Hank Johnson from the State of Georgia, Congressman Bill Cassidy from the State of Louisiana, and Congressman Mike Honda from the State of California. I would like to thank all of you for being here today.

We are also joined today by Dr. Howard Koh, Assistant Secretary for Health at the Department of Health and Human Services. He is accompanied by Dr. John Ward, Director of the Viral Hepatitis Program at the Centers for Disease Control and Prevention.

I thank all of our witnesses for being here today and look forward to hearing about progress on this issue, as well as how Congress can play a more pivotal role in making sure evidence-based recommendations are implemented. I want to thank all of you for being here.

At this time, I yield to Congressman Chaffetz from the great State of Utah for his opening statement.

[The prepared statement of Chairman Edolphus Towns follows:]

Opening Statement
of
Chairman Edolphus Towns

Committee on Oversight and Government Reform

Viral Hepatitis: The Secret Epidemic

June 17, 2010

Today's hearing will examine the secret epidemic of hepatitis, and what can be done to prevent and treat this disease. I call hepatitis the secret epidemic because the attention it receives has not been in proportion to the vast number of Americans it affects.

Hepatitis B and C are among the leading causes of preventable deaths worldwide and are the most common blood-borne infections in the United States. Up to 5.3 million people in the United States are living with chronic hepatitis B or C. But because of the asymptomatic nature of the disease, most people who are infected are unaware until they have developed liver cancer or liver disease many years later. While effective use of the HBV vaccine has greatly reduced new occurrences of the virus, about 43,000 people still develop acute hepatitis each year.

Recently, the hepatitis epidemic has gained new attention due to a study issued by the Institute of Medicine, which found that the current federal approach to battling these diseases is simply not working. The IOM Report suggests a greater need for a federally coordinated response to these diseases, better surveillance, knowledge and awareness, immunization and viral hepatitis services. Today's hearing will review that report, and will explore how to implement its recommendations.

Viral hepatitis affects roughly 2 percent of the entire United States population. If left unchecked, it can cause cirrhosis, liver cancer and liver failure. Several sub-populations are at greater risk of current and new infections, as chronic viral hepatitis disproportionately affects certain minority communities. Chronic hepatitis B is a leading cause of death in Asian Americans, with as many as 1 in 10 living with chronic Hepatitis B.

Hepatitis B is a blood borne disease that is primarily transmitted from mother to child. There is a vaccination for hepatitis B, which if administered early enough, can properly stop the spread of the virus from mother to child. Unfortunately the surveillance and screening measures that are in place now are insufficient, especially in terms of the mother's exposure and need for treatment. Thus, there's a critical need to address this gap.

Hepatitis C is also a blood borne disease. It is primarily transmitted through injection drug use or through unsafe sexual contact. However, others may have been exposed when our blood supply was not filtered for disease prior to 1992. Thus, some people may have been infected by blood

transfusions prior to 1992, or possibly during surgery where the facilities may have been contaminated.

African Americans and Hispanics have the highest rate of hepatitis C infections. Hepatitis C also affects a large segment of baby boomers, a number of whom may have served in the military. Baby boomers account for two out of every three cases of chronic hepatitis C infections in the United States.

What is more alarming is that 75% of people born between 1946 and 1964 are unaware of their status. These statistics trouble me deeply. Too many people in this country are unaware of the serious health effects of hepatitis, as well as the costly nature of going without treatment.

The stigma that is associated with these diseases may play a role in whether or not people come forward to seek help.

The overarching challenge is that many of those infected with both hepatitis B and C are asymptomatic. Nor are they aware that it may be communicated to others in their households. That is why we need to bring greater attention to these diseases – to improve prevention for those not yet infected, and to make sure those who are infected have access to early and consistent treatment that can stop their progression.

I look forward to hearing from all parties involved about their progress on this issue as well as how Congress can play a more pivotal role in making sure their recommendations are implemented.

Mr. CHAFFETZ. Thank you, Mr. Chairman, and thank you for calling this hearing. This is an important, vital issue. I am proud that this committee would actually bring this to our attention and to hold this hearing. I want to thank the Members, the bipartisan group of Members who are concerned about this issue. I would like to associate myself with the comments that you made.

This is a huge issue; it affects Americans from coast to coast, it affects the world, really, and it is something that we need to pay a lot more attention to.

I would like to ask unanimous consent to enter into the record the comments from the ranking member, Darryl Issa, as he had some comments on this.

Chairman TOWNS. Without objection, so ordered.

[The prepared statement of Hon. Darrell E. Issa follows:]

EDOLPHUS TOWNS, NEW YORK
CHAIRMAN

DARRELL E. ISSA, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143

Majority (202) 225-5051
Minority (202) 225-5074

Statement of Rep. Darrell Issa, Ranking Member

"Viral Hepatitis: The Secret Epidemic"

June 17, 2010

Thank you, Mr. Chairman, for holding today's hearing about the government's efforts to prevent, detect, treat, and hopefully one day find a cure for viral hepatitis. Over the course of the last decade, this committee has monitored the federal government's response to this major public health problem, and I am encouraged that we will continue to do so on a bipartisan basis.

Moreover, it is critical for us to realize that an effective strategy for combating viral hepatitis will require a robust partnership between the public and private sector to increase awareness about prevention and treatment.

The question before us today is simple: What must be done to stop the spread of viral hepatitis, which already affects nearly six million Americans and kills more than 15,000 Americans every year?

Following this question, we must ask whether the government is doing all that it can raise awareness, decrease the infection rate, and provide adequate treatment to those who depend on government-provided health care – particularly our active duty military and veterans.

Ten years ago, we were shocked to learn from a GAO study that the Department of Veterans Affairs was not properly screening for viral hepatitis, thus increasing the infection rate and exposing untold numbers of our men and women to this silent killer. Furthermore, it has been sixteen years since the Department of Health and Human Services has updated the Strategic National Vaccine Plan, raising questions about whether or not the government has been either unable or unwilling to keep pace with the virus.

Mr. Chairman, I am also concerned, as you are, about the rate at which minority populations are increasingly suffering from the effects of this silent epidemic. The cultural factors in poor, urban areas and among immigrant populations that might account for this trend cannot escape our careful consideration. Moreover, since many Americans depend on programs like Medicaid and Medicare, we have an obligation to consider whether these programs might be failing the poor and elderly through inefficient use of federal resources or bureaucratic inertia in the face of this threat.

Whatever the case, it will not suffice for us to simply spend more money to fund programs that have yet to demonstrate success, and we must reinvigorate our response at a local, community-based level if we are going to begin to see the trend reversed and infection rates decrease.

Finally, we cannot fail to address the fact that in a great many instances, viral hepatitis is spread behaviorally. We must continue to enforce tough laws designed to combat the illegal drug trade, and we must continue to educate the public about dangers posed by irresponsible life choices.

Again, thank you, Mr. Chairman for holding today's hearing, and I look forward to hearing from our witnesses – particularly from our colleagues who have demonstrated a strong commitment to this important cause.

Mr. CHAFFETZ. And I would much rather hear from the panel than hear from me, so, with that, I yield back the balance of our time.

Chairman TOWNS. Thank you very much. I thank the gentleman.

The gentlewoman from California.

Ms. WATSON. Thank you so much, Mr. Chairman, for this exceedingly important subject-matter hearing on the secret epidemic of viral hepatitis, affecting millions of Americans and their families each year.

This hearing comes at a critical time: 1 in 12 people around the world are affected by chronic and viral hepatitis, and it is one of the most leading causes of preventable death worldwide.

In the United States, about 1,500 people die each year from liver cancer or liver disease as a result of a hepatitis infection. But, if we increase the amount of resources and awareness devoted to this disease, many of those lives could be saved. Treatment does exist, and it is more effective if the disease is caught early. But because this disease is asymptomatic, as many as 75 percent of those infected do not know it until they have already developed liver cancer or liver disease.

In response to this serious public health problem, the Institute of Medicine was asked to provide insight into what opportunities were being missed in relation to prevention and control of Hepatitis B and Hepatitis C, and the IOM's committee found that there is a staggering lack of knowledge about chronic viral hepatitis among health care and social service providers, at-risk populations, members of the public, and policymakers. And without proper knowledge, health care providers cannot sufficiently screen and treat their patients, and Americans who may have the virus will not understand the dire need to get tested.

As a representative of California's 33rd District in the city of Los Angeles, I understand the impact these viruses have on individuals and society, and also the disproportionate effect they have on certain minority communities. Chronic Hepatitis B is a leading cause of death in the Asian and Pacific Islander community. African Americans have the highest rate of acute Hepatitis B infections, while Hepatitis C affects both African Americans and Hispanics at the highest rate.

While I am pleased that the Obama administration has taken the initiative to appoint Dr. Howard Koh as the Assistant Secretary of Health at the Department of Health and Human Services with the specific task of developing a national strategy for hepatitis, our communities and the Federal Government cannot delay in ensuring that they have sufficient culturally and linguistically sensitive access to prevention and treatment responses.

So I am looking forward, Mr. Chairman, to today's witnesses and to learn more about how we can start impacting and controlling these vicious diseases. Thank you. I yield back.

Chairman TOWNS. I thank the gentlewoman from California for her statement.

I now yield 5 minutes to Congressman Bilbray of California.

Mr. BILBRAY. Thank you, Mr. Chairman. Mr. Chairman, between 1985 and 1995, I had the privilege of supervising a county of 3 million, specifically part of the supervisor's responsibilities in Califor-

nia's public health, and this was the period when the hepatitis epidemic seemed to spread very quickly. The awareness, whatever we can say on that. And with all the discussion that we had with HIV and AIDS and all that other argument, the dirty little secret was the huge impact on the general population, specifically the working class population of the hepatitis problem.

And I just want to say clearly, as somebody who was able to be briefed in that period, I think one of the untold stories in this country is that a whole lot of a certain segment of our community, and it crossed racial lines, I think what happens is it is so much easier to identify people based on the color of their skin, but not look at their social economic group. That group, which includes a very large percentage of the minority community, has been disproportionately impacted.

But there is a generational issue here. So I think with these challenges we need to recognize that there are opportunities, and I hope, as we address this issue, that we are not blinded by color because it is easier to do that. We look at the fact that there is a social economic group that truly is a rainbow coalition in the negative sense, but that it is also a generational challenge.

With these two challenges, we have opportunities. We have opportunities to focus resources, focus attention, and go directly, like someone said, the laser beam toward a much more cost-effective and much more humane approach to this issue.

I think the one thing that hasn't been talked about in the last year, when we talk about health care, is that hepatitis is the iceberg that is under the water that no one realizes that our health care system is running full steam for. There is going to be an impact here that we are totally ignoring and is going to have a major impact not just to the private sector, but to the public sector and the community at large, and we ought to be addressing that.

There are opportunities coming down the line, in my opinion, to be able to address this issue, address it with good science, good medicine, and hopefully good politics, something we don't see very often in this town. But hopefully we can work together. This is a bipartisan effort waiting to be done, and I hope that we join together to do it, Mr. Chairman.

Chairman TOWNS. I thank the gentleman from California for his statement.

[Applause.]

Chairman TOWNS. Thank you very much.

Any other Members seeking recognition? Yes, the gentleman from Virginia.

Mr. CONNOLLY. Thank you, Chairman Towns, and thank you for holding this very important public health hearing. It is valuable because it increases awareness of the dangers of hepatitis while addressing some common misperceptions and related stigmas about the strains of the virus.

5.3 million Americans are living with Hepatitis B or C, and an estimated 75 percent of those are unaware of the fact they carry the virus. Public education is essential. Between 15 and 40 percent of individuals with hepatitis will delvelop liver cirrhosis if not treated properly, making hepatitis the leading cause of liver transplantation in the United States. Viral hepatitis causes 12,000 to

15,000 deaths annually, and approximately 20,000 people are newly infected each year with Hepatitis C.

Responding to this immense public health threat requires a comprehensive approach that reduces the unconscious transmission of hepatitis from mothers to children, while reducing the transfer of Hepatitis C through needles associated with drug use.

Because hepatitis can go undetected for decades, many mothers have no idea they are passing the virus on to their children. Asian Americans are disproportionately affected by Hepatitis B. Approximately 1 in 12 carry the virus. My district is home to a diverse Asian-American population. In fact, it is the largest single ethnic group in my district. We need to ensure that our education efforts are multilingual and address not just illegal drug or sexual transmission of this virus, but also the unconscious transmission from mother to child, particularly for that more vulnerable population.

I look forward to learning more from the CDC at this hearing about our efforts to arrest the spread of Hepatitis B among especially Asian Americans. Since there is an expected vaccine for Hepatitis B, we can make progress in reducing transmission rates.

Some individuals with Hepatitis C were infected over 30 years ago, prior to proper sterilization methods of needles in medical settings. Others received the disease through illicit drug use. Today we need to focus on drug suppression efforts and effective needle-exchange programs that can and will reduce the incidence of Hepatitis C.

It is clear that the primary obstacle of reducing the spread of Hepatitis B and C is a lack of Federal resources. In America's five largest cities, we provide only $90,000 annually for viral hepatitis prevention. $90,000. We need to do much more to prevent the spread of hepatitis, particularly because increasing the awareness of the disease and increasing the use of the vaccine could and would dramatically reduce rates of Hepatitis B and save lives in America.

And, with that, I yield back.

[The prepared statement of Hon. Gerald E. Connolly follows:]

Opening Statement of Congressman Gerald E. Connolly

Committee on Oversight and Government Reform

"Viral Hepatitis: The Secret Epidemic"

June 17th, 2010

Thank you, Chairman Towns for holding this important public health hearing. It is valuable because it increases awareness of the dangers of hepatitis while addressing some common misconceptions and related stigmas about the strains of this virus. With up to 5.3 million Americans living with hepatitis B or C and an estimated 75% of those unaware they carry the virus, public education is an essential part of the effort to contain these viruses. Between 15-40% of individuals with hepatitis will develop liver cirrhosis if not treated properly, making hepatitis the leading cause of liver transplantation. Viral hepatitis causes 12,000-15,000 deaths annually in the United States, and approximately 20,000 people are newly infected each year with hepatitis C alone. Responding to this immense public health threat requires a comprehensive approach that reduces the unconscious transmission of hepatitis from mothers to children while reducing the transfer of hepatitis C through needles associated with drug use.

Hepatitis B is frequently transmitted by sexual activity or infected needles, but can also be passed from mothers to their children, generally when mothers are not aware they are infected. Because hepatitis can go undetected for decades, many mothers have no idea they are passing the virus to their children. Asian Americans are disproportionately affected by hepatitis B; approximately one in twelve carry the virus. My district is home to a diverse Asian American population. We need to ensure that our education efforts are multilingual and address not just illegal drug or sexual transmission of this virus but also the unconscious transmission from mother to child, particularly for Asian Americans. I look forward to learning more from the Centers for Disease Control at this hearing about our efforts to arrest the spread of hepatitis B among Asian Americans. Since there is an effective vaccine for hepatitis B, we can make progress in reducing transmission rates.

Hepatitis C is transmitted through blood contact, such as infected needles. Some individuals with hepatitis C were infected over thirty years ago, prior to proper sterilization methods for needles in medical settings. Others received the disease through illicit drug use. Today, we need to focus on drug suppression efforts and effective needle exchange programs that can reduce the incidence of hepatitis C.

It is clear that the primary obstacle to reducing the spread of hepatitis B and C is a lack of federal resources. For example, America's five largest cities receive a mere $90,000 annually for viral hepatitis prevention. We need to do much more to prevent the spread of hepatitis, particularly because increasing the awareness of the disease and increasing use of the vaccine could dramatically reduce transmission rates for hepatitis B.

Chairman TOWNS. Thank you very much. I thank the gentleman for his statement.

Any other Members seeking recognition?

If not, we will move to our witnesses. We will now turn to our first panel of witnesses. Congressman Hank Johnson from Georgia has been a leading advocate in this Congress in pushing for more attention to be paid to the serious health risk that hepatitis poses to our Nation. It has become a personal battle for Congressman Johnson and I am thankful he is willing to share his story with us here today. Welcome, Mr. Johnson.

We also have with us today, Congressman Bill Cassidy from Louisiana. Mr. Cassidy has served his community for more than 20 years, helping to provide medical services for people in need. His efforts in his community include setting up school-based health programs to vaccinate children against the spread of Hepatitis B. Welcome, welcome to the committee.

We also recognize Congressman Mike Honda, who has also been very active in lending his voice to this issue by sponsoring legislation to help combat this critical health issue that affects so many Americans. H.R. 3974, the Viral Hepatitis and Liver Cancer Control and Prevention Act of 2009, if passed, will support the comprehensive prevention measures that are called for in the IOM Report, as well as reduce the disease burden associated with viral hepatitis.

I thank you all for being here today and I look forward to working with you. It is committee policy that all witnesses are sworn in, so, Mr. Johnson, Mr. Cassidy, and Mr. Honda, if you would stand and raise your right hands.

[Witnesses sworn.]

Chairman TOWNS. Thank you very much.

Let the record reflect that they all answered in the affirmative.

Why don't we start with you, Mr. Johnson. You know the rules; you know the clock. But we are not even going to turn it on; we are going to leave you with it, because you know the rules. OK? [Laughter.]

So we are going to come right down the line, Representative Johnson, then Representative Cassidy, and then Representative Honda. Thank you.

Representative Johnson.

STATEMENTS OF HON. HENRY C. "HANK" JOHNSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA; HON. BILL CASSIDY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF LOUISIANA; AND HON. MIKE HONDA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

STATEMENT OF HON. HENRY C. "HANK" JOHNSON

Mr. JOHNSON. Thank you, Chairman Towns and Ranking Member Issa, for holding this hearing today. I applaud the committee for showing leadership on preventing and controlling hepatitis infections by holding this hearing on the Federal Government's response to the viral hepatitis epidemic in this country.

As many of you may know, last year, I announced that I was on a robust course of treatment for Hepatitis C. Today I am back. I am alive, I am feeling great, feeling strong and, in the words of James Brown, I feel good. [Laughter and applause.]

I stand here today bolstered by the love and prayers that I have received from family, constituents, and colleagues. I hope that my disclosure last year will provide others suffering from hepatitis with confidence to speak out and educate the community about this illness. I am testifying today because I know from firsthand experience just how devastating these hepatitis viruses can be on Americans. I am one of the lucky ones who found out I was infected, had insurance, and was able to receive treatment.

A few important facts that I want the committee to be aware of. First, two-thirds of Americans infected with hepatitis are unaware of their infection, leaving them unable to take action to protect their health and the health of others. Second, the only dedicated Federal funding for hepatitis is $19.3 million per year for the CDC. This is not enough and pales in comparison to funding for other infectious diseases. Considering these two facts, it is clear that the Federal Government has failed in its response to hepatitis, and I am hopeful that this hearing can bring about a period where this trend is reversed.

Unlike the majority of people living with infection, I actually do know my status. The vast majority, with estimates as high as 75 percent, do not know that they are infected with hepatitis, the leading cause of liver cancer in America.

A recent Institute of Medicine report on liver cancer and hepatitis found that health providers neither screen nor test for hepatitis, even for patients at risk. I am grateful to have the support of my family and friends, my colleagues and my staff. However, those who test positive often feel stigmatized, making it difficult to encourage people to know their status and get treatment.

As with other infectious diseases, a proper and effective government response will lessen the stigma associated with the illness. It is important to note that even with the passage of health care reform, I am concerned that Hepatitis B and C will and can still impact those who have limited access to health care, such as injection drug users, the homeless, certain racial and ethnic minorities, legal immigrants living in poverty, and undocumented immigrants.

As a member of the Congressional Black Caucus, I want the committee to know that rates of Hepatitis C are twice the national average among African Americans. In fact, 1 in 10 African Americans between the ages of 40 and 60 are estimated to have Hepatitis C. I want to say that once again. In fact, 1 in 10 African Americans between the ages of 40 and 60 are estimated to have Hepatitis C.

As we all know, African Americans are less likely to have access to adequate health care and would be positively impacted by an improved government response to viral hepatitis. Further, the baby-boomer population is estimated to account for two out of every three cases of chronic Hepatitis C. As these Americans continue to age, they are likely to develop complications from Hepatitis C and cost Medicare billions in treatment, transplantation, and palliative costs. We can and should do something about this epidemic.

I can tell you, Representative Bilbray, that the persons who I enumerated as being at risk are not, as you say, as you pointed out, they are not limited to minorities. There are substantial numbers of Caucasians who are afflicted with this chronic ailment, and some I have been working with diligently in the private arena to bring attention to this very serious disease.

We can do better for all Americans at risk for and affected by viral hepatitis. With scant Federal resources, lack of program coordination, and the absence of political will, Americans have continued to develop liver cancer and associated lethal complications of viral hepatitis because of our inaction with regards to these preventable infections.

There have been some positive steps, however. Representative Mike Honda has introduced legislation, which I support, to authorize a comprehensive prevention, education, research, and medical management referral program to reduce the disease burden associated with these costly and lethal infections. This bill, the "Viral Hepatitis and Liver Cancer Control and Prevention Act," H.R. 3974, is also supported by Chairman Towns, and I want to thank the chairman for his support for this important bill.

In addition to these efforts, we need to increase funding for viral hepatitis prevention. Despite dealing with an epidemic that the CDC estimates afflicts 5 million people, the division of viral hepatitis is the smallest funded infectious disease division under the National Center for HIV, Viral Hepatitis, STD, and TB Prevention. At $19.3 million, viral hepatitis receives only 2 percent of the Center's total annual budget. Funding must be increased to the division of viral hepatitis so that the division can mount an effective prevention response and begin funding preventative services.

We must ensure that other funding streams support this work, especially as health reform authorizes new moneys for prevention. I am excited about the prospects of Dr. Howard Koh's interagency working group on hepatitis and the development of an HHS national plan on hepatitis. I hope that this workgroup will receive adequate resources and that, through this workgroup, real and effective work can be done to forge a national strategy to combat hepatitis.

Thank you for holding this very important hearing today and for allowing me to address this committee. I look forward to a very productive and robust hearing on investigating the Federal response to viral hepatitis, and I yield the balance of my time.

Chairman TOWNS. I thank the gentleman from Georgia for his statement.

I now yield time to Representative Cassidy. You are on Appropriations, aren't you?

Mr. CASSIDY. I wish. [Laughter.]

But, no.

Chairman TOWNS. Representative Cassidy.

STATEMENT OF HON. BILL CASSIDY

Mr. CASSIDY. Thank you Chairman Towns and Ranking Member Issa, and other members of the Committee on Oversight and Government Reform for calling this hearing. For the last 20 years, I have been a doctor. I am a hepatologist. A hepatologist is a doctor

who treats liver disease. So it is kind of a confluence of my career to be here in a political life to discuss this. I still treat patients in a public hospital back home, and I can, from my personal experience, verify this affects a cross-section of people; from folks who are homeless to folks who are nuns, folks who are bankers and teachers, folks who are somewhere at a more humbler economic station. And yet they all have a common need, and that is to be treated or comforted.

Now, among my clinical activities, as you mentioned, Mr. Chairman, was founding the Greater Baton Rouge Community Hepatitis B Vaccination Program. For over 6 years, we vaccinated 36,000 kids to prevent Hepatitis B over a 10-parish area. Now, what caused me to do that program was an 18-year-old who came to the Intensive Care Unit. They called me in the middle of the night. She was dying from Hepatitis B.

In the middle of the night, we helicoptered her out to a transplant center in Shreveport, LA, and there to receive a transplant that would cost $200,000 to $400,000 and, if successful, it would cost $30,000 every year thereafter to care for her with the medication and treatment. And I thought to myself, we are going to spend $1 million over the course of her lifetime, when a $50 vaccine would have prevented this. For the amount that we are going to spend for this young lady, I could have vaccinated everybody in my community. So that is what we attempted to do.

Now, let's give credit where credit is due. The way we were able to do that in this public-private partnership is that President Clinton proposed the Vaccines for Children's Program, and Congress, in its wisdom, funded it. So, thereby, the biggest cost item, if you will, which is vaccine, we were able to get from the Federal Government and then, through a public-private partnership, vaccinate 36,000 children.

Now, I am a teacher, so let me pause for a second. I assume everybody has my knowledge, but I have been studying this for 20 years. "Hep" comes from the Greek word for liver; "itis" means inflammation. And viral hepatitis is just inflammation of the liver caused by a virus, Hepatitis B and C being those causing chronic hepatitis most commonly. And, folks, asked the difference between Hepatitis B and C, I say it is like the difference between a dog and a cat: they look alike, superficially they are the same, but in reality they are two different animals. Hepatitis B and C are two different animals, so to speak.

And they have different ways of being transmitted. Hepatitis B, I like to say to my students, so they remember, is spread by blood, birth, and body fluids. So it is spread when a momma gives birth to her baby. If the momma is infected, the virus passes as the child goes through the birth canal; the child is infected from the momma's body fluids. It can also be spread sexually, spouse to a spouse, if you will, and also by blood. So B, B, and B.

Hepatitis C is spread by blood, primarily. Now, there is a medical word for blood cells called corpuscles, so if you are one of my students, I would say C stands for corpuscle. You can remember it is spread by blood.

Now, in the case of B, commonly, it is spread mother to baby. But also it can be spread from ages 15 on because that is, one,

when kids or adults become sexually active and marry, but it is also when they engage in other high-risk activities. For the Hepatitis C, it is typically spread when someone gets, in times past, a blood transfusion. So momma gives birth to a baby; a Vietnam soldier gets shot and gets transfused; they get infected.

And it doesn't necessarily cause a problem right away. What hepatitis does, the "itis," the inflammation is almost like a pimple inside the liver. A little pimple that goes away. But if you have lots of little pimples, you have little tiny bits of scar tissue that build-up. Now, over the course of a year that is not going to be enough, but over the course of 15 to 30 years those little pimples are all over the place in the liver, which go away but leave a little bit of scar tissue, cause so much scar tissue that the liver no longer functions.

I like to point out I have a scar on my wrist. That scar on my wrist does everything I want. I wish I could slam dunk a basketball, but, if I wanted to, it could do that. But we have all seen someone whose arm has been burned, covered with scars, so their arm doesn't work like ours does; it works more like a club, it loses function. Similarly, as the liver is progressively scarred, a little bit of scar doesn't make a difference; progressive scarring inhibits the liver's ability, just like it does an arm, to function as it should.

Now, I go through that to first say that, as Representative Johnson said, most people who have Hepatitis C look like us, men who are in their fifties, maybe early sixties. Now, as it turns out, we have a graph from the table here in our handout, most folks were born between 1950 and 1959, the 1960 through 1969. Now, remember, these little bit of inflammation leading to a little bit of scar tissue slowly accumulating over decades, and folks pick it up when they are 20 to 25, typically, as it slowly builds up, it means the crest of the wave is about to hit.

As Congressman Bilbray spoke, we have this iceberg that is about to impact. So everybody has been picking up this little bit of scar tissue, don't know about it and, boom, if you look on this page of our graph, you will see that as these areas get bigger, we can look at the cost that is going to increase because folks who are not so fortunate as to be treated and cured are now 55 years old, being diagnosed with Hep C, coming to the hospital to be treated by someone like me. That hospitalization costs $30,000 to $100,000 per hospital stay; they get referred for a transplant, and that is $200,000 to $400,000. Sounds a lot like that 18-year-old I saw in the ICU.

Now, to put a kind of more statistical point on it, the Milliman report says that health care costs for these patients will more than double over the coming years; the per patient cost of treating patients with Hep C will increase 3½ times over 20 years, because, again, we have had it for a while; we are starting to have more complications. In 10 years, the commercial and Medicare cost for treating hepatitis patients will more than double, and in 20 years our Medicare cost for treating patients with Hepatitis C, this is the iceberg hitting, will go up fivefold.

What is that cost? Well, if we treat somebody proactively with a vaccine for Hepatitis B, it is $50 for the vaccine. If you are going to treat somebody who has chronic Hepatitis B, it is $2,000 to

$16,000 per year; for Hepatitis C it is $15,000 to $25,000 a year. But the medical costs of Hep C, as we mentioned earlier, are expected to increase from $30 billion to $85 billion between now and 2024, principally because those infected in the sixties are now suffering the consequences of that infection.

So what should be done? That will be elaborated on later on, but I can tell you from my experience: education, education, education. You educate doctors to screen; you educate patients to get checked; you educate spouses of patients as to what this means for their family.

Vaccination. For Hepatitis B there is a vaccine; for Hep C not. We have done a very good job with children. We need to do a better job with adults, because there are folks at high risk who are not getting vaccinated for Hepatitis B. In terms of Hep C, ideally, a partnership of academia, industry, and government could come up with a Hep C vaccine. We need to think better how to integrate these services into the care we already provide.

We went to schools because we knew that the rate limiting step for getting the child vaccinated was the fact that the momma was working full-time and couldn't get off of work to take her baby in to get vaccinated three times. So we brought the program to the schools so the momma didn't have to miss work and, thereby, we were able to vaccinate all these children.

So let me finish by saying, again, thank you for inviting me today. Now, today I praised the Vaccines for Children Program which this Congress, in its wisdom, passed way back when. It is my hope that in 20 years there will be another hepatologist, she will be sitting here and she will be praising the wisdom of this Congress because we put in a bill that, just as the Vaccines for Children Program enabled me and our team to save lives, so what we do in this bill will enable her, as she practices over the next 20 years, to similarly save lives or to make them healthier.

Again, thank you.

[Applause.]

[The prepared statement of Mr. Cassidy follows:]

Testimony of
The Honorable Doctor Bill Cassidy
Member, US House of Representatives
June 17, 2010

Chairman Towns, Ranking Member Issa and other Members of the Committee of Oversight and Government Reform, thank you for calling this hearing on the national strategy to prevent and address infections with Hepatitis B (HBV) and Hepatitis C (HCV). I am a Hepatologists, which is to say a Doctor who specializes in treating liver disease. I still treat hepatitis patients as I continue to teach in a public hospital for the uninsured. I know how effective patient education, immunization and surveillance can be in preventing the spread of hepatitis and relieving the fear of those who are infected.

Among my clinical activities was founding the Greater Baton Rouge Hepatitis B Vaccination Program. In this public-private partnership, over a 6 year period, we vaccinated 36,000 public, private and parochial school children in 10 parishes. The impetus for the program was when an 18 year old girl came to the ICU with liver failure due to Hepatitis B. As she was airlifted to a liver transplant unit with an 80% chance of surviving, the thought occurred to me that we would spend $200,000 to $400,000 for her to have a liver transplant and up to $30,000 a year for the rest of her life for medications and follow-up. Yet, for $50 we could have vaccinated her against Hepatitis B and prevented the disease. In a sense, the cost of treating her because she was not vaccinated was greater than the cost of preventing the disease in her and every other young person in our metropolitan area. We were penny wise and pound foolish.

To give credit where credit is due, because President Clinton and Congress in its wisdom passed the Vaccines for Children's Program, vaccine was made available for efforts such as ours. Statistically, we know because of this program and efforts such as ours, there are those who live today and are in better health.

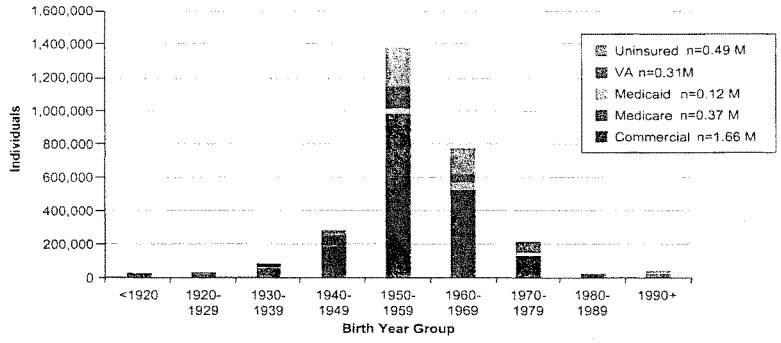
First, to explain hepatitis. "*Hep*" comes from the Greek word for liver and "*itis*" means inflammation. Chronic viral hepatitis is liver inflammation caused by a virus, most commonly HBV or HCV. The difference between HBV and HCV is like the difference between a dog and a cat. There are superficial similarities but they are two different species. In chronic viral hepatitis, the inflammation leads to scarring of the liver. Severe inflammation over years leads to cirrhosis. A cirrhotic liver loses function. Patients with cirrhosis are at risk for liver cancer, vomiting blood, confusion, jaundice and developing fluid overload.

HBV is primarily transmitted through exposure to blood or bodily fluids. Incidents of acute HBV infection have declined due to the advent of the Hepatitis B vaccines. However, babies born to infected mothers, spouses of those infected, recent U.S. immigrants and individuals partaking in certain unsafe activities such as IV drug use are still at a high risk of contracting HBV. HCV is spread by blood-to-blood contact.

According to the recent Institute of Medicine (IOM) Report, 3.5 to 5.3 million people are living with chronic HCV or HBV. In the next 10 years, 150,000 people in the United States will die from liver cancer and end-stage liver disease associated with HCV and HBV. Unfortunately, as many as 65%-75% of those infected are unaware that they are infected because they are asymptomatic.

While new HCV infections have declined over the past two decades, there are at least 3 million Americans with chronic HCV. According to the 2009 Milliman Report, *Consequences of Hepatitis C Virus: Cost of a Baby Boomer Epidemic of Liver Disease*, most of our infected population are baby boomers.

The Highest HCV Infection Prevalence Rates Are Among Americans Born in the Early 1950s and Over Half of HCV Infected Patients Are Now Covered by Commercial Insurance



2008 Estimated Numbers of Individuals with Chronic HCV Infection by Birth Decade and Source of Medical Insurance*

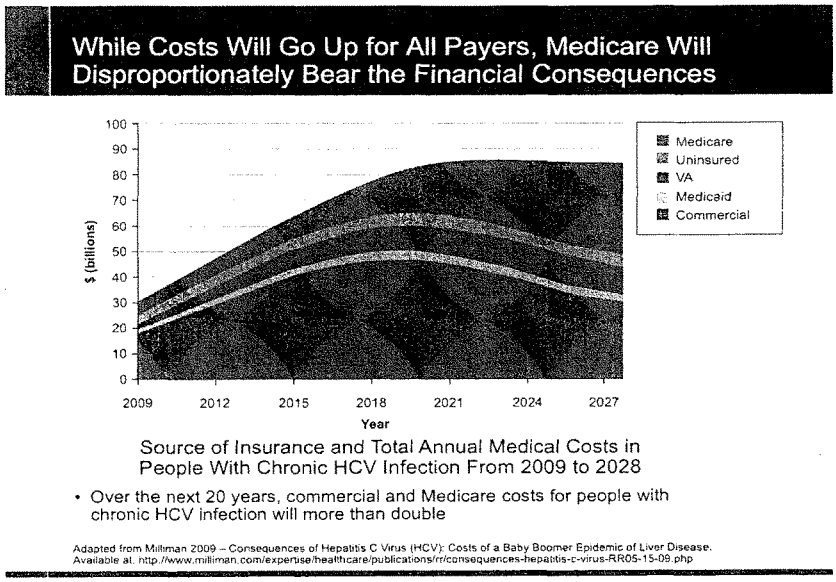
*Estimates for payer populations assume 78% of people have not been diagnosed.
M=million.

Adapted from Milliman 2009 – Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease.
Available at: http://www.milliman.com/expertise/healthcare/publications/rr/consequences-hepatitis-c-virus-RR05-15-09.php

Although most individuals become infected in their twenties, HCV typically takes many years to expand to cirrhosis. Many patients do not develop cirrhosis until they reach their fifties or sixties. This report suggests a growing medical and financial burden to care for the aging HCV patient population. The February 2010 Gastroenterology Journal's article *Aging of Hepatitis C Virus Infected Persons in the United States: A Multiple Cohort Model of HCV Prevalence and Disease Progression* concludes:

> *"Prevalence of Hepatitis C cirrhosis and its complications will continue to increase through the next decade and will mostly affect those older than 60 years of age. Current treatment patterns will have little effect on these complications, but wider application of*

antiviral treatment and better responses with new agents could significantly reduce the impact of this disease in coming years."



The Milliman Report indicates that without changes to the manner in which HCV is diagnosed and treated:

- Overall health care costs will more than double
- The per-patient cost of people with chronic HCV will increase 3.5 times over 20 years
- In 10 years, commercial and Medicare costs will more than double
- In 20 years, Medicare costs will increase 5-fold

The Cost of Inaction

HBV treatment costs $2,000-$16,000 per year[1] and HCV treatment costs $15,000-$25,000[2]. Medical costs of HCV are predicted to increase from $30 billion to over $85 billion in 2024 primarily due to infected Americans aging into Medicare[3]. End stage liver disease costs $30,980-$110,576[4] per hospital admission and an uncomplicated liver transplant cost around $314,000[5]. The cost of inaction is too high.

What Should Be Done?

The IOM report offers some important steps we can take to further combat viral hepatitis. I agree with the report's findings that a major challenge in preventing the spread of HBV and HCV is the lack of knowledge and awareness among health care providers, the public and the at-risk population. Developing educational programs for health care providers and social service providers would help in our efforts to prevent the spread of the disease.

Surveillance, vaccination, education and screening of the diseases should be increased and integrated into clinics that serve high risk populations. The Federal Government should support current HBV vaccination programs, increase the availability of the vaccine for at-risk adults and strengthen procedures so that those who should be vaccinated are done so in a timely manner. In addition, states should be encouraged to implement programs proven to increase immunization rates. Unfortunately, there is no vaccine for HCV. Industry, academia and government can collaborate in the effort to do so.

Thank you again for inviting me to testify today. I trust that just as I testify today about a Vaccines for Children program instituted by Congress, which has saved lives and improved health, someone else in 10 or 20 years will be able to testify that she or he used a bill that we passed to diagnose, prevent and treat viral hepatitis. And this person will be able to say as I can, that because of this, there are those who are alive today and there are those who are healthier because of the wisdom of this Congress.

---

[1] Soemohardjo, S., *New options in the treatment of chronic hepatitis.* Adv Exp Med Biol, 2003.531:p. 191-8

[2] Fried, M.W., et al., *Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection.* N Engl J Med, 2002.347(13): p. 975-82

[3] Pyenson, B., et al., *Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease.* Milliman, Inc., 2009

[4] Wong, L.L., P. McFall, and L.M. Wong, *The cost of dying of end-stage liver disease.* Arch Intern Med, 1997.157(13):p. 1429-32.

[5] American Liver Foundation, 2002-2003. http://www.liverfoundation.org

Chairman TOWNS. Thank you so much for your testimony. Thank you. Thank you very much.

Representative Honda.

STATEMENT OF HON. MIKE HONDA

Mr. HONDA. Thank you, Chairman Towns and members of the committee, for inviting us today to testify on viral hepatitis. As you can tell, we have very passionate testimony here by folks who personally have been involved with it or have worked on it as a professional hepatologist, one who studies. It is good to have a doctor in the crowd.

I just want to acknowledge Congressman Johnson, Dr. Cassidy, Congressman Cassidy, Assistant Secretary Koh and Dr. Ward for joining us here today. In the presence of so many members and leaders within the health community underscores the importance of this issue and we know that is not a new issue, it is one that has been outstanding for a long time. So, Chairman Towns, it is really an opportune time to bring all this together.

I do want to make a shout out for the Tri-Caucus and their effort in the health bill to make sure that the health disparities have been included in the health bill also to address some of the concerns that some Members have had.

As we know, viral hepatitis is highly infectious. For example, Hepatitis B virus is 100 times more infectious than HIV because so many people, as has been said before, are unaware that they have the virus and continue to spread it. An estimated 5.3 million people are infected with either Hep B or C and, tragically, more than half are unaware of their status and, for those reasons, it is 100 times more infectious than HIV. And many more have called this the silent crisis, but, as we can tell today, we are not about to be silent anymore and we are not going to be silent on this issue.

The chronic Hep B and C are expected to cost at least $20 billion over the next 10 years. In fact, the total medical cost for patients with Hep C infections are expected to increase more than 2½ times that, as was said before, from $30 billion to over $85 billion over the next 20 years. And with the bill that we have, H.R. 3974, over the next 5 years we intend to make available $600 million to move forward on this effort to avoid and prevent the spread of Hepatitis B and C. And I am sure with the help of Dr. Koh and his interagency work, the money will be well used and come up with a very comprehensive plan and strategy.

So we need to change the way hepatitis is diagnosed and treated. Our current structure, as we can tell, cannot be sustained if we continue down this path.

So from the Institute of Medicine, they released a report on hep and liver cancer with the crucial recommendation for a national coordinated strategy for prevention and control, and I believe Dr. Koh will speak to that. Their recommendation is calling for CDC to work with State and local health departments to develop a new model for surveillance, and probably the model shouldn't be called new because it has been implemented in various places in this country through folks like Dr. Cassidy and some folks in the State of California have developed kinds of models working with children

and schools. So there are a lot of things out there that can be brought together.

And with the help of the chairman and Congresspersons Cassidy, Johnson, and Dent, we, together, introduced H.R. 3974, and it should mirror all of the recommendations from the Institute of Medicine and it brings together the common concerns of the diverse viral hepatitis community to fight this chronic viral hepatitis by establishing, promoting, and supporting a comprehensive prevention, research, and medical management referral program.

The bill will strengthen the ability of the CDC to support State health departments in prevention, immunization, and surveillance efforts, and through this legislation and with strategic investments in public health and prevention programs billions of dollars can be saved, as has been said before, and tens of thousands of people in States and cities all over this country can improve.

It doesn't stop here, though, Mr. Chairman. It continues to be a global issue also, and I think that we can work with other countries who have made great strides in Hep B and C and other arenas, along with HIV/AIDS. It seems to me that, as we move forward, the synergy of both efforts globally will probably be able to be more efficient and address this problem globally, but we have to start here at home.

So I can tell by the testimony from members of the committee and yourself, Mr. Chairman, and the folks here that we are committed and we are determined to make sure that we address this and conquer this ravaging disease.

One of the things that we could probably look at as Members, different Members across this country, is to host health fairs in our communities. It has been done in San Francisco. I took part in that. I was a little anxious. You really don't want to find out whether you are sick or not, but I was more afraid that I might be sick, so that greater fear drove me to participate in the health fair in San Francisco. Mayor Newsome, Assemblywoman Fiona Ma and myself, we participated in that.

Newsome is fine. I was reported out as negative, so I continue my treatment for the next two immunizations. Three steps, actually. Currently, I guess I am in a safe zone, if you will. But this should be replicated for every citizen and every child in this country. Fiona Ma, we know today, is a carrier, but it is under control. So these are the kinds of things we need to do immediately, that we can do as Members of Congress, to sponsor these health fairs in the neighborhoods that we live and work in.

So I just want to commend you, Mr. Chairman, and the members of the committee for holding this important hearing so that we can move forward with knowledge, determination, and resources. I thank you very much.

[Applause.]

[The prepared statement of Hon. Mike Honda follows:]

Testimony of The Honorable Michael M. Honda

Member, US House of Representatives

June 17, 2010

Chairman Towns, Ranking Member Issa, and Members of the Committee on Oversight and Government Reform, thank you for calling this hearing on a national strategy to prevent and address infections related to Hepatitis B (HBV) and Hepatitis C (HCV).

Few people realize how highly infectious viral hepatitis is. Hepatitis B is 100 times more infectious than HIV. Few realize that, left untreated, it can cause liver disease, liver cancer and premature death decades after infection. Few realize that roughly 2 billion people worldwide have been infected with hepatitis B, more than 170 million people are chronically infected with hepatitis C, and in this nation alone, an estimated 5.3 million people are infected with either hepatitis B or hepatitis C. Tragically, an average of two-thirds of those infected are unaware of their status.

It is no surprise, then, that some are calling this a silent crisis. However, we cannot afford to be silent anymore. In fact, we will not be silent anymore. Why? Because our countrymen and women are dying daily, needlessly, from a disease that is entirely preventable if detected early. Each year, approximately 15,000 people die from liver cancer or liver diseases related to hepatitis B and hepatitis C. That's more than 40 Americans dying every day, with no state or district in our nation exempt from its deadly reach.

Beyond the tragic and preventable loss of human life and its subsequent hit to our country's productivity, the costs to our country are explicitly economic as well. Without effective prevention and vaccination methods in place, chronic hepatitis B and C are expected to cost our country at least $20 billion in treatments alone over the next 10 years. As a result, over the same time frame, commercial and Medicare costs will more than double. Projecting further out, over the next 20 years, total medical costs for patients with hepatitis C infection are expected to increase more than 2.5 times from $30 billion to more than $85 billion.

We must, therefore, change the way hepatitis is diagnosed and treated. The Institute of Medicine released a report on hepatitis and liver cancer with crucial recommendations for a national coordinated strategy for prevention and control

Recommendations include calling for CDC to work with state and local health departments to develop a new model for surveillance.

With the help of Oversight and Government Reform Chairman Edolphus Towns (D-N.Y.) and Reps. Bill Cassidy (R-La.), Hank Johnson (D-Ga.) and Charlie Dent (R-Pa.), I introduced the Viral Hepatitis and Liver Cancer Control and Prevention Act, H.R. 3974, which mirrors man of

the Institute of Medicine's recommendations. In addition, H.R. 3974, provides almost $570 million over the next five years to treat hepatitis.

Our legislation focuses federal efforts on a strategy that saves lives and makes our health system more efficient. We bring together the common concerns of the diverse viral hepatitis community to fight chronic viral hepatitis by establishing, promoting and supporting a comprehensive prevention, research and medical management referral program. And we strengthen the ability of the CDC to support state health departments in the prevention, immunization and surveillance efforts.

Through this legislation, and with strategic investments in public health and prevention programs, billions of dollars can be saved, and so can the lives of tens of thousands of people in states and cities all over America. I urge all of you to join me in supporting activities that promote early detection and education. With your help, we can sound the alarm on this silent crisis.

###

Chairman TOWNS. I thank you. Thank you.

Let me indicate that I look forward to working with you. I think that your coming today and sharing your personal experiences and, of course, doc, your being involved in this over the years and Representative Honda, in terms of your work, I want you to know that I am committed to working with you to try and do much better.

I think that one thing that we need to do, and the reason I asked you, Representative Cassidy, because I am looking for some appropriators. You know, we need some money. That is key to be able to address the problem. I think it is a disgrace to have a problem of this nature and not to focus on it in terms of resources, because we know that if we put enough resources to it, that we will be able to do a whole lot better than what we are doing now.

Mr. Johnson, Congressman Johnson, I am happy to note that you feel good, but we want to make certain that some other folks also feel good, and I think the way to do that is to have the resources to address it.

At this time I would like to yield to——

Mr. HONDA. Mr. Chairman, before you close, just for the record, I am not Daddy Warbucks, but I do sit on Appropriations. So you will find colleagues in support there.

Chairman TOWNS. Right. Thank you very, very much. We appreciate that.

Let me just yield to the ranking member of the full committee, Congressman Issa from California.

Mr. ISSA. Thank you, Mr. Chairman. I thank you all for your indulgence. Obviously, with the conference on financial reform, a lot of us are going back and forth.

What I am concerned about is, if I have two appropriators here, where do I get a budgeteer so that we get this properly in the budget? That may be something for you and for all of us here at the dais. At a minimum, we need to have at least a partial budget that looks at these kinds of items. And I will speak as a Republican for a moment for only one moment: I cannot and will not do earmarks by act of our conference. So we cannot fund these kinds of programs in specificity, no Republican can, unless they are in the budget or in some other way not an earmark.

So I am totally supportive. I believe that to not spend $35 million, we should spend millions in prevention. There is no question that we need to address this informationally in a prevention basis, but I would hope that all of us here, since this is a Members' hearing, realize that even if we can't do a full budget, we need to take the President's budget, we need to work it as to some of these issues, and we need to make sure that we get it passed so that Republicans and Democrats can vote on that portion of the budget.

So, Mr. Chairman, I look forward to working with you on that. It is very clear that this is a problem that should not wait until the next budget cycle.

I yield back.

Mr. HONDA. Mr. Chairman, if I may.

Chairman TOWNS. Yes.

Mr. ISSA. Reclaiming my time. Mr. Honda.

Mr. HONDA. If you would yield. You can help. We probably don't need an earmark, but we do have a bill that you can join us on, H.R. 3974.

Mr. ISSA. That directs the CDC.

Mr. HONDA. It does that and also provides funding for the next 5 years.

Mr. ISSA. That is an earmark. That is one of our problems. Directing specific spending is one of our challenges right now. Look, I have a million pet projects. There is no question at all, we all do. But one of our challenges is to get a budget and work through this. I support the authorization, but authorization that directs specific action crosses the line right now, and the American people agree with us that we need to do it in a formalized fashion. Now, the truth is the President has presented us a budget that we should be acting on, and that is my frustration: the President has done his job; we haven't done ours.

Anyone else?

Mr. HONDA. I didn't know that my bill was an earmark.

Chairman TOWNS. No, I wouldn't say it is an earmark. I think that what we need to do is find an offset, and one way to find it, I think that we might be able to look at the military budget, now that there are some changes there. Maybe we can find the money. An offset is what we really need. So we want to make certain that we get it.

Mr. JOHNSON. Would the gentleman yield?

Chairman TOWNS. I would be delighted to yield to the gentleman, then I will go to the gentleman from Illinois.

Mr. JOHNSON. Thank you. I know that there are many people who are viewing this and they don't really understand the difference between earmarks and items that are lodged in the budget and that are paid for or not paid for. They don't understand all of that, they just know that they are not feeling good, they need help, and they don't want to see others go through what they have had to endure.

So I just want to say that these are issues, Representative Issa, that you have pointed out, and I think that they can all be worked out. We just have to have the will to work them out, and we will find the money to get this done. That is my hope and prayer, that we will be able to make some inroads based on this hearing.

Mr. ISSA. And, Mr. Chairman, I concur with the gentleman. Mr. Johnson is right that we need to find the money; this is a legitimate priority. And I agree with you that if we can find an offset, after all, we are spending a trillion more than we are taking in. There ought to be something in that trillion of excess spending that would allow us to cut here to do a priority, and I look forward to working with the gentleman on it.

Chairman TOWNS. Thank you very much.

I now yield to the gentleman from Illinois.

Mr. QUIGLEY. Thank you, Mr. Chairman. I just had a question for the doctor.

Doctor, you talked about education, but you or I go in to a routine physical and have blood tests. Don't they normally screen for hepatitis?

Mr. CASSIDY. Not necessarily. The way that hepatitis is typically picked up is through a preemployment physical or through an insurance physical. So you and I, kind of middle-class guys, want to up our insurance. As it turns out, with Hepatitis C and Hepatitis B, but particular Hepatitis C, your liver enzymes could be normal, so you don't always have the elevated enzymes that would be the tipoff even if they were to be checked.

So partly you just have to have it on your checklist of questions to ask. Have you ever had a blood transfusion? Have you ever had a tattoo which was not with a sterile needle? In your younger, wilder days, did you ever do anything that you are currently ashamed of, which most people raise their hands if you ask that question delicately. [Laughter.]

Mr. QUIGLEY. Not me.

Mr. ISSA. I don't get it. What good would that do? It is 100 percent.

Mr. CASSIDY. Well, Bilbray is waving both of his hands.

But with that sort of questioning you can then find out that, you know, I did live in Thailand; I got some tattoos when I was in the Army, and we know that Thailand has a lot of hepatitis. So that would screen someone to say, oh, let's check them, sort of thing. So there are ways, specific questions you can ask to get a question to go on to further testing.

Mr. QUIGLEY. How much further testing does it take?

Mr. CASSIDY. Not much. A simple blood test. There is a Hepatitis C antibody which is going to be positive in about 99.9 percent of the people that have it.

Mr. QUIGLEY. But if the normal blood test just picks up the elevation, how much more does it cause, given the extraordinary cost involved with this, with just checking for it in the first place?

Mr. CASSIDY. You could, and the people from Hepatitis C probably have run models on that. If there is a prevalence of about, oh, 2 percent in the population, then you would have to say, OK, we are going to run 100 tests in order to get 2 percent positive. Now, for those 2 percent it can be a game changer, but if you put it in a spreadsheet it may turn out that your cost per detection is too high.

And I will defer to the folks from the CDC because I suspect they run these models. On the other hand, if you want to say we are going to take every guy that was born between 1950 and 1965, then you are getting to the people that have the higher prevalence rate; and I suspect those sorts of recommendations have been considered. So that would be, if you will, a target-rich environment.

Mr. QUIGLEY. Thank you.

Mr. JOHNSON. Would the gentleman yield?

Mr. QUIGLEY. I yield back.

Chairman TOWNS. I will yield for comment, yes.

Mr. JOHNSON. Thank you, Mr. Chairman.

In my own case, back in 1998, my wife noticed that I was just sleeping too much and just really tired, and I noticed it also, but it got to a point where she decided that, hey, you need to go to the doctor and get this checked out. So based on the feeling that I was just worn down and, you know, no matter how much sleep I got, I would still wake up and 5 minutes later I am ready to go back

to bed, and could go back to bed and go to sleep. So my doctor was inquisitive enough to check for Hepatitis C, and that is how we discovered that I had this virus.

And I would point out to people that it is not only those who may have engaged in some kind of high risk activity like intravenous drug use or had a transfusion or got a tattoo. It could have been contracted by someone who went into a dental office or a medical office that, at the time, may have sterilized needles and used them again, or sterilized syringes and used the syringe again, throwing away the needle, and perhaps it could have happened in that way; or in a hospital when you went in and had to get blood drawn or whatever the case might be. Risky procedures back then could have led to the infection.

But I think it is important to note that it is not really important how the disease was contracted; the main thing is do you have it and can you eliminate it so that you can live a long, happy, and prosperous life. So I would like to encourage anyone who feels that they may have been affected or they may be infected to ask your doctor to check for hepatitis in the blood. Also, last but not least, one needle, one syringe on one person is the name or the motto of an organization. I am sure that they are represented today here. But one syringe, one needle, one person. Thank you.

Chairman TOWNS. Let me thank all of you for your time; you have been very generous with it. I want to thank you and indicate again that I look forward to working with you. We can do a whole lot better than what we are doing. Thank you very, very much.

[Applause.]

Chairman TOWNS. I ask the second panel to come forward. That panel includes Dr. Howard K. Koh, Assistant Secretary for Health, U.S. Department of Health and Human Services. He is being accompanied by Dr. John Ward, Director of the Viral Hepatitis Program at the Centers for Disease Control and Prevention in Atlanta.

Let me administer the oath.

[Witnesses sworn.]

Chairman TOWNS. Let the record reflect that both answered in the affirmative.

You may be seated.

Dr. Koh, I will ask you to summarize your testimony in 5 minutes. As you are aware, the committee members may ask questions of both of you who are able to respond based on the fact that both of you have been sworn in. So, Dr. Koh, you may continue.

STATEMENT OF HOWARD K. KOH, M.D., M.P.H., ASSISTANT SECRETARY OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JOHN W. WARD, M.D., DIRECTOR, VIRAL HEPATITIS PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL CENTER FOR HIV/AIDS, VIRAL HEPATITIS, STD, AND TB PREVENTION

Dr. KOH. Good morning, Chairman Towns, Ranking Member Issa, and distinguished members of the committee. I am Dr. Howard Koh, the Assistant Secretary for Health at the Department of Health and Human Services, and I am deeply honored to be here today to discuss the silent epidemic of viral hepatitis and also to

review the coordinated steps of the Department with respect to addressing this major public health challenge.

I am also deeply grateful to our colleague, Dr. John Ward, from the CDC, who is here to my right. Dr. Ward is the Director of the Division of Viral Hepatitis and also an international expert in this area.

You have heard and let me quickly review the key facts of this epidemic, and the burden that weighs heavily on our society. Estimates are that up to 5.3 million Americans have chronic viral hepatitis. Annually, there are an estimated 43,000 new cases of Hepatitis B and an estimated nearly 20,000 cases of Hepatitis C. Viral hepatitis causes up to 15,000 deaths each year, and as a physician who has cared for patients for over several decades, I have seen for myself the impact of this condition on patients and families.

Of great concern is that illness, death, and cost from this disease are all expected to rise substantially in the future, in part because, of those infected, a vast majority, up to 75 percent, are not aware that they have Hepatitis B or Hepatitis C. Moreover, of those who are aware, not enough are in care or receiving appropriate treatment.

As you have heard from the previous panel, Hepatitis B and C infections often persist for years, cause chronic liver inflammation, scarring, cirrhosis, and, most devastatingly, liver cancer. In fact, in contrast to almost all other types of cancer, liver cancer rates have tripled over the last several decades, fueled in large part by chronic hepatitis infection. In the absence of appropriate treatment, up to 40 percent of infected persons will develop liver cirrhosis and, very tragically, viral hepatitis is the leading cause of liver transplantation in the United States.

In the face of this, the CDC has recommended screening to identify persons with viral hepatitis and also recommends prevention and care services. I will be saying more about that in just a second. We are grateful as a country that we have safe and effective vaccines to protect against Hepatitis B. For Hepatitis C, there is no vaccine, but prevention can play a significant role to reduce new cases.

Moreover, prevention and care for viral hepatitis makes great economic sense. Published studies show that the cost for viral hepatitis can run in the billions of dollars per year, so the benefits of a better public health approach are enormous. And, as a physician who is trained in cancer, I am particularly eager to pursue the concept of hepatitis prevention as a new form of cancer prevention, and that is some of the education we would like to do moving forward.

As you have heard, in January 2010, the Institute of Medicine came out with a new report documenting very low levels of awareness and knowledge of viral hepatitis both at community and provider level, and this report documented inadequate investments in prevention and care services and fragmented and poorly developed surveillance systems.

Our Department of Health and Human Services and its agencies are fully committed to the prevention of hepatitis and fully committed to the care of infected individuals, so, in January, as the Institute of Medicine was coming out with its report, the Department

established a new interagency workgroup, which I chair, and this workgroup has broad representation from all the major agencies throughout the Department.

We have started in on the very important work of drafting a comprehensive strategic plan for the Department to improve coordination of prevention, care, and surveillance activities, and we are focused on five major goals: first, to increase community awareness and provider education; second, to strengthen surveillance; third, to improve vaccination for Hepatitis B; fourth, to prevent transmission; and, fifth, to improve clinical preventive care and treatment services.

We have an excellent interagency working group and I am very proud of its members, and we are on a time line to complete an action plan by October 1st of this year. We are motivated by the fact that we have effective public health measures to prevent transmission, and these measures have already helped our Nation achieve remarkable declines in the numbers of new infections from both Hepatitis B and C.

For example, as we have mentioned, now we have safe and effective vaccines for Hepatitis B, and State and local perinatal prevention activities have a proven track record of success and can help eliminate Hepatitis B in newborns in our country. In the past, while cost has been a potential barrier for adult immunization, health reform now provides new opportunities to increase immunizations recommended by the Health and Human Services Advisory Committee on Immunization Practices [ACIP].

With respect to Hepatitis C, we need more research on an effective vaccine, and that is a continued priority for the country. In the meantime, other new prevention tools must be developed and implemented. This includes refining and adapting HIV prevention strategies to also include Hepatitis C; testing and counseling to increase awareness; improving awareness of infection status will also promote safer behavioral practices; we also need better methods to reduce transmission risks in health care settings, and you have heard a lot about that already; and also new and improved therapies. We are encouraged that we have treatments that can result in viral clearance and halt liver damage caused by chronic viral hepatitis.

A key area here is that since millions of Americans are unaware that they have this potentially life-threatening disease, we have as a major goal to raise awareness, to test high-risk persons, increase the number of people who know their status, and link people to preventative and care services. And we are very sensitive about the fact that there are many communities who are experiencing health disparities, and we need culturally appropriate education programs that can increase awareness of this epidemic, increase awareness about the health benefits of vaccination and prevention, and also discuss the need to reserve stigma.

For providers, education can increase understanding of screening and vaccination policies; help with the interpretation of laboratory tests and management of care and treatment; and we also seek to help providers with respect to integrating viral hepatitis services with other appropriate prevention services for HIV, for sexually transmitted disease, and other conditions. We also want to work to

connect clinicians and broader public health surveillance activities so we can advance monitoring and case management.

Our Department's interagency workgroup is also examining ways to enhance that surveillance, and currently the CDC estimates that only about 10 percent of new cases of viral hepatitis are reported each year. Two-thirds of States report cases of chronic Hepatitis C, but those that do have large backlogs of uninvestigated cases, so a clear picture of the nature and scope of chronic Hepatitis C in particular across every State is not readily available.

So we plan to have better integration with respect to monitoring hepatitis and then implementing prevention and care programs. We also want to address the disparities issue, especially how this condition affects Asian-American and Pacific Islanders and African Americans and at-risk populations such as the homeless, immigrants, injection drug users, and incarcerated persons.

So, in summary, Mr. Chairman and distinguished committee members, we are very, very grateful to you for holding this hearing. We all agree on the tremendous burden of this disease on our society. I want to assure you that our Department has taken immediate and coordinated steps to reverse the trends that are before us. We want to work closely together with you and we have a major opportunity with respect to prevention and creating new systems of care.

Again, I want to thank my colleague, Dr. Ward, who has done so much critical work in this area. And I would be very happy to take any questions. Thank you.

[The prepared statement of Dr. Koh follows:]

Testimony
Before the
Committee on Oversight and Government Reform
United States House of Representatives

Statement for hearing entitled, "Viral Hepatitis: The Secret Epidemic"

Statement of
Howard K. Koh, M.D., M.P.H.

Assistant Secretary for Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
Thursday, June 17, 2010

Good morning, Chairman Towns, Ranking Member Issa, and other distinguished Members of the Committee. I am Dr. Howard Koh, the Assistant Secretary for Health in the Department of Health and Human Services (HHS or the Department). I am honored to be here today to discuss the silent epidemic of viral hepatitis in this country, and the coordinated steps the Department is taking to effectively address this significant public health problem through better prevention, care and monitoring efforts.

Viral hepatitis is a collective term describing liver inflammation or hepatitis caused by a group of several different viruses. Three viruses, Hepatitis A virus (HAV), Hepatitis B virus (HBV) and Hepatitis C virus (HCV) cause most viral hepatitis in the United States. Spread in unsanitary conditions, hepatitis A cases have declined significantly in the U.S. in recent years as a result of vaccination programs and food safety efforts. Today, I will focus my remarks on the prevention of HBV and HCV transmission and associated morbidity and mortality. Unlike HAV, HBV and HCV infections are blood-borne and often persist for years, resulting in ongoing (chronic) but usually asymptomatic liver inflammation, and in some cases scarring (cirrhosis) that leads to liver failure and/or and liver cancer. Chronic hepatitis is a major cause of liver cancer and chronic liver disease globally and in the United States.

HBV and HCV Disease Burden

Worldwide, 480 million to 540 million persons are living with chronic viral hepatitis, with 350 million[1,2] to 370[3] million infected with HBV and 130 million to 170 million infected with HCV.[4]

[1] Goldstein ST, Zhou F, Hadler SC, Bell BP, Mast EE, Margolis HS. A mathematical model to estimate global hepatitis B disease burden and vaccination impact. Int J Epidemiol 2005;34:1329--39

All told, chronic viral hepatitis afflicts about 1 in every 12 persons worldwide. About 54,000 persons with chronic hepatitis B infections immigrate to the U.S. annually. Chronic hepatitis causes considerable morbidity. Globally, an estimated 78% of primary liver cancer and 57% of liver cirrhosis are caused by chronic viral hepatitis and about one million deaths from viral hepatitis occur each year.[4] Liver cancer is the fourth -leading cause of death from cancer worldwide, the third -leading cause among men.[5] The most recent liver cancer surveillance data indicate that long-term liver cancer incidence is increasing in the U.S., with an average annual percentage change in incidence between 2001 and 2006 of 3.5% per year.[6]

In the United States, viral hepatitis remains no less of a problem; 3.5 million to 5.3 million Americans have chronic viral hepatitis.[7,8,9] The vast majority, an estimated 65 % and 75% are not aware they are infected with HBV and HCV, respectively.[7] In the absence of appropriate treatment, 15-40% of infected persons will develop liver cirrhosis.[10,11,12] Viral hepatitis is the leading cause of liver transplantation in the United States.[13] Co-factors, including HIV, excessive alcohol use, and fatty liver disease associated with obesity and diabetes, amplify the

---

[2] World Health Organization. Hepatitis B. Geneva, Switzerland: World Health Organization; 2000. Available at http://www.who.int/mediacentre/factsheets/fs204/en/print.html

[3] W.M. Lee, Hepatitis B virus infection, *N Engl J Med* **337** (1997) (24), pp. 1733–1745.
[4] Perz, J.F., The contribution of hepatitis B virus and hepatitis C virus infections to cirrhosis and primary liver cancer worldwide. *Journal of Hepatology* 2006; 45 (4):529-538.
[5] WHO Cancer Fact Sheet No 297 Feb 2009. http://www.who.int/mediacentre/factsheets/fs297/en/print.html
[6] CDC. Hepatocellular carcinoma – United States, 2001-2006. MMWR 2010;59 (17:517-20).
[7] IOM (Institute of Medicine). *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C.* Washington, DC: The National Academies Press. At 21 (2010)
[8] Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. Ann Intern Med 2006;144:705--14
[9] CDC. Surveillance for Acute Viral Hepatitis – United States, 2007. 2009;58 (No. SS-3)
[10] CDC. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. 2008;57 (No. RR-8)
[11] Lok AS, McMahon BJ. Chronic Hepatitis B. *Hepatology*2007; 45:507-539
[12] Seeff LB. Natural History of Chronic Hepatitis C. *Hepatology* 2002; 36:S35-S46.
[13] Brown RS Jr. Hepatitis C and liver transplantation. *Nature* 2005;436:973-978.

effects of viral hepatitis, hastening development of liver disease. Fifteen to thirty percent of all persons infected with HIV have chronic viral hepatitis,[14] and liver disease is now the main non-AIDS cause of death in HIV-infected persons.[15] In contrast to almost all other types of cancer, liver cancer rates have tripled over the last several decades,[16] fueled in large part by the progression of viral hepatitis to end-stage disease among persons infected years ago. In the United States, viral hepatitis causes 12,000 to 15,000 deaths annually,[17,18] and viral hepatitis-related illness, deaths, and costs are all expected to rise substantially in the coming years.

Viral hepatitis poses a major health threat for certain populations. Among persons aged 46 to 64 years (i.e., baby boomers), about 1 in 33 have chronic viral hepatitis.[9] One out of every 7 African American men in their 40s is living with chronic hepatitis C,[9] and approximately 1 in 12 Asian Americans is living with chronic hepatitis B.[19] Similarly, the profiles of persons with liver cancer mirror the demographic characteristics of persons with chronic viral hepatitis; liver cancer incidence is highest among Asians/Pacific Islanders, and is increasing among Hispanics, African Americans, baby boomers, and males.[20]

---

[14] Sherman KE, Rouster SD, Chung RT, Rajicic N. Hepatitis C virus prevalence among patients coinfected with human immunodeficiency virus: a cross-sectional analysis of the U.S. Adult AIDS Clinical Trials Group. *Clin Infect Dis* 2002;34:831-7.
[15] D:A:D Study Group. Factors associated with specific causes of death amongst HIV-positive individuals in the D:A:D study. *AIDS* 2010 [epublication May 6, 2010 ahead of print]
[16] Altekruse SF, McGlynn KA, Reichman ME. Hepatocellular carcinoma incidence, mortality, and survival trends in the United States from 1975 to 2005. J Clin Oncol 2009;27:1485--91.
[17] Vogt T, Wise ME, Shih H, Williams IT. Hepatitis B Mortality in the United States, 1990-2004 [Abstract]. 45th Annual Meeting of Infectious Diseases Society of America, San Diego, CA; October 4-7, 2007
[18] Wise M et al. Changing trends in hepatitis C-related mortality in the United States, 1995–2004. *Hepatology* 2008;47:1–8.
[19] CDC. Screening for Chronic Hepatitis B Among Asian/Pacific Islander Populations – New York City, 2005. MMWR 2006; 55(18):505-509.
[20] CDC. Hepatocellular carcinoma – United States, 2001-2006. MMWR 2010;59(17;517-20.

New HBV and HCV infections add to the burden of chronic viral hepatitis and liver disease. In 2007, there were an estimated 43,000 new cases of HBV infection.[10] HBV is spread from mother to child at the time of birth, among household contacts through incidental blood exposures in the home, through injection drug use, and through sexual contact. Viral hepatitis transmission should never occur as a result of health care delivery, but transmission has been documented in a variety of health care settings when providers have failed to follow basic infection control practices. Rates of HBV infection are highest among adults, reflecting low hepatitis B vaccination coverage among persons with risks such as injection drug use and multiple sexual partners. Prevention of mother-to-child transmission is critical, as 90% of HBV -infected newborns remain infected[21,22,23], and about 1 in 4 die from complications of chronic viral hepatitis in later life.[11] Outbreaks of hepatitis B occur in persons not currently recommended to receive the vaccine, such as persons with diabetes, patients in outpatient settings, and residents of long term care facilities; they also occur in health care settings when providers fail to follow basic infection control.

Surveillance data suggest nearly 20,000[10] persons are newly infected with HCV annually in the United States. HCV is primarily a blood-borne virus spread through injection drug use. Transmission also occurs in health care settings as a result of unacceptable lapses in infection control, primarily related to the misuse of syringes and medication vials. Non-injecting drug users who snort cocaine and other drugs also have elevated risks for HCV, possibly from blood exposure associated with intranasal use. Perhaps typically thought of as an urban disease, HCV

---

[21] Edmunds WJ, Medley GF, Nokes DJ, Hall AJ, Whittle HC. The influence of age on the development of the hepatitis B carrier state. Proc R Soc Lond B Biol Sci 1993;253:197--201

[22] McMahon BJ, Alward WL, Hall DB, et al. Acute hepatitis B virus infection: relation of age to the clinical expression of disease and subsequent development of the carrier state. J Infect Dis 1985;151:599--603.

[23] Hyams KC. Risks of chronicity following acute hepatitis B virus infection: a review. Clin Infect Dis 1995;20:992--1000

transmission has been detected among young drug users in suburban and rural communities. In addition, after reports from Europe for several years, sexual transmission of HCV has been detected among U.S. cohorts of HIV-infected men who have sex with men (MSM). In certain circumstances, HCV can be transmitted sexually and at the time of birth.

Public Health Prevention Measures to Address Viral Hepatitis

Public health measures can prevent transmission. These measures have helped our nation achieve remarkable declines in the number of new infections with both viruses. Safe and effective vaccines are available to provide long term protection from hepatitis B. In 1991, the Centers for Disease Control and Prevention (CDC) and the national Advisory Committee on Immunization Practices (ACIP) set forth an ambitious vaccine-based strategy to eliminate HBV transmission in the United States.[24] This strategy involves vaccinating newborns and older children, as well as vaccinating at-risk adults.

Routine vaccination of infants and catch-up vaccination of older children under federally - supported vaccination programs has successfully driven down rates of HBV transmission and acute cases of disease, with rates falling 82% from 8.5 cases per 100,000 population in 1990 to 1.5 cases per 100,000 population in 2007, the most recent year for which data are available.[10]

[24] CDC. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR 1991;40 (RR-13): 1-19. http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm

Rates have declined most dramatically—98%—among children aged 15 years and younger. Vaccine coverage among children aged 19 months to 35 months is 93%.[25,26]

In the United States, approximately 24,000 HBV-infected women give birth each year[27], most of whom are identified by prenatal screening. Their infants are recommended to receive protective hepatitis B vaccination and other prevention services. State and local prevention programs currently do not have the capacity to manage all of the estimated newborns who are exposed. To assure newborns exposed to HBV are protected, CDC recommends that all infants receive a birth dose of hepatitis B vaccine. In 2008, 55% of newborns received a birth dose in the first three days of life.[30] As not all newborns receive protective interventions, each year hundreds of infants are infected with HBV in the United States.[28]

Hepatitis B vaccine is also recommended for adults with sexual and blood exposure risks. As the result of improvements in infection control and ongoing hepatitis B vaccination, relatively few cases now occur in certain populations such as dialysis patients and healthcare workers that previously were considered to be at high risk. However, while the number of new cases has declined among adults, 95 % of all new cases are among adults. A high proportion of those cases occur among persons with risk behaviors such as injecting drug users, MSM, and persons with multiple sex partners. Rates are particularly high among males aged 25 to 44 years old.[10]

---

[25] Estimated Vaccination Coverage* with Individual Vaccines and Selected Vaccination Series Among Children 19-35 Months of Age by State and Local Area US, National Immunization Survey, Q1/2008-Q4/2008† http://www2a.cdc.gov/nip/coverage/nis/nis_iap2.asp?fmt=v&rpt=tab02_antigen_iap&qtr=Q1/2008-Q4/2008

[26] CDC. National, State, and Local Area Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2008. MMWR 2009;58: 921-926.

[27] CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP) part 1: immunization of infants, children, and adolescents. MMWR 2005;54 (RR-16):1–31.

[28] CDC Unpublished Data

Unlike HBV, there is no vaccine yet developed for HCV. However, since HCV was discovered in the 1980s, the development of prevention interventions has caused a significant decline in new cases. Screening of donated blood and other tissues and organs now protects recipients of these donations. Screening, together with behavioral education, and access to clean syringes and drug treatment have had a role in reducing the number of new cases of HCV related to injection drug use[8]. In addition, the adoption of standard precautions in health care settings has reduced transmission risks for all blood -borne viruses, including HBV and HCV.

The onset of liver cancer and other liver disease can be prevented through screening and care for persons chronically infected with HBV or HCV. Current treatments can halt or even reverse the liver damage caused by viral hepatitis. New treatments on the immediate horizon hold even greater promise for a definitive cure. CDC recommends screening to identify persons with viral hepatitis and prevention and care services to reduce transmission and morbidity.

Prevention and care for viral hepatitis makes economic sense. Published studies estimate that medical costs for viral hepatitis run in the billions of dollars per year.[29,30] Numerous studies reveal the cost-effective benefits of screening and care for populations at risk for viral hepatitis.[31],[32],[33],[34] Hepatitis screening linked to vaccination and care is a cost -effective

---

[29] JB Wong, GM McQuillan, JG McHutchison and T Poynard. *Estimating future hepatitis C morbidity, mortality, and costs in the United States*, American Journal of Public Health, Vol 90, Issue 10 1562-1569.
[30] Milliman Study for Vertex Pharmaceuticals. Consequences of Hepatitis C Virus – Costs of a Baby Boomer Epidemic of Liver Disease. 2009
[31] A Rajendra, JB Wong Economics of chronic hepatitis B and hepatitis C Journal of Hepatology, 2007 Oct: 47 (4):608-17. Epub 2007 Jul 30
[32] Kanwal F, et al., Treatment alternatives for hepatitis B cirrhosis: a cost-effectiveness analysis. The American Journal of *Gastroenterology*, 2006;101(9):2067-2089.
[33] Spackman DE, Veenstra D. A cost-effectiveness analysis of currently approved treatments for HBeAg-positive chronic hepatitis B. *PharmacoEconomics*, 2008;26(11):937-949.

prevention approach to eliminating health disparities for Asian and Pacific Island Americans.[35] Preliminary data from a CDC model show that by identifying and referring for appropriate care all HCV-infected persons in primary care, approximately 87,000 cases of end stage liver disease and 11,000 liver transplants can be prevented, and 840,000 undiscounted life years would be gained, with an estimated cost per discounted quality adjusted life year, or QALY, of $43,000. Similarly, preliminary estimates reveal that expanded HBV screening and care could avert approximately 140,000 cases of end stage liver disease and gain 3.3 million QALYs.

The Institute of Medicine Report

In January 2010, The Institute of Medicine (IOM) issued a report titled, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C.* The report identified multiple barriers that have combined to create a situation in which inadequate public resources are available to support the prevention, care and monitoring needed to fully and effectively address this important public health problem.

The IOM report described deficiencies that have created adverse consequences for the health of our nation:

- Inadequate disease surveillance systems underreport acute and chronic infections, so the full extent of the problem is unknown;
- At-risk people do not know that they are at risk or how to prevent becoming infected;
- At-risk people may not have access to prevention services;

[34] Wong JB, et al., Cost-effectiveness of interferon-alpha 2b treatment for hepatitis B e antigen-positive chronic hepatitis B. *Ann Intern Med*, 1995;122(9):664-675

[35] Hutton DW, Tan D, So SK, et al. Cost-effectiveness of screening and vaccinating Asian and Pacific Islander adults for hepatitis B. *Ann Intern Med*, 2007;147(7):460-469.

- Chronically infected people do not know they are infected;
- Many healthcare providers do not screen people for risk factors or do not know how to manage infected people; and
- Infected people often have inadequate access to testing, social support, and medical management services.

The IOM called for an intensified, coordinated national effort to improve the prevention of viral hepatitis and better protect the health of Americans.

The HHS Response to the IOM Report

HHS and its agencies are fully committed to accelerating progress towards the prevention of viral hepatitis and associated disease in the U.S., and advancing this strategy. In January, HHS established an interagency work group on viral hepatitis, which I chair, that has diverse representation from HHS operating divisions. A work group subcommittee is currently drafting a comprehensive strategic action plan for HHS to improve the coordination of viral hepatitis prevention, care and monitoring activities within the Department. The action plan is grouped by focus areas: Increasing community awareness and provider education; strengthening surveillance for viral hepatitis; preventing viral hepatitis transmission through vaccination; preventing blood-borne transmission; and improving clinical preventive care and treatment services. The current timeline is to complete this action plan by October 1, fall 2010.

There are millions of persons who are unaware they have a potentially life -threatening disease. Major goals of viral hepatitis prevention programs are to screen high-risk persons and to increase the number of infected persons who know their status and are linked to preventive and care services. For communities experiencing health disparities, culturally appropriate education programs can increase awareness of this silent epidemic, and of the health benefits and vaccination and screening, while addressing issues of stigma. Provider education can increase understanding of screening and vaccination policies, interpretation of laboratory tests, and management of viral hepatitis care and treatment. Viral hepatitis services can be integrated with other appropriate prevention services for HIV, STD, and cancer. Public health surveillance and case management can link communities with viral hepatitis prevention and care services. .

HHS also recognizes the important health benefits of eliminating HBV transmission. State and local perinatal prevention have a proven track record of success and can provide the necessary services to eliminate HBV among newborns in this country. Studies have shown that cost is a major barrier to successful implementation of adult immunization strategies. Health reform provides new opportunities to increase uptake of immunizations recommended by the HHS Advisory Committee on Immunization Practices (ACIP).

More interventions are needed to prevent hepatitis C. Efforts to find an effective vaccine for HCV should be a continued priority. In the meantime, other new hepatitis C prevention tools must be developed, tested and translated into action. One avenue to explore is to refine and adapt HIV prevention strategies for hepatitis C prevention. Hepatitis C testing and counseling to increase awareness of infection status will promote safe behavioral practices. Together, these

approaches can substantially reduce transmission among injection drug users. HHS is working to ensure adherence to proper infection control practices are needed to reduce transmission risks in health care settings, including improved oversight and regulatory approaches, development of new technologies, and training for health care professionals. Rapid tests can improve access to screening, and new assays may improve detection of recent hepatitis C infection. Studies of HCV transmission will help form the evidence base for new interventions. Also, studies suggest that, if detected early, many hepatitis C infections can be cleared (i.e., cured)[36]. As new and improved therapies are introduced, research should be conducted to guide how best to use them to preserve the health of those infected and prevent transmission.

The HHS interagency working group will also examine ways to improve viral hepatitis surveillance. Effective prevention requires state and local systems that provide consistent and reliable reporting of new infections, rapid detection of disease outbreaks, and identification and referral of persons with chronic infection for appropriate care and treatment. Currently, CDC estimates that about only 10 percent of new cases of viral hepatitis are reported each year. Two-thirds of states report cases of HCV infection, but those that do have large backlogs of uninvestigated cases.[8] As a result, a clear picture of the nature and scope of chronic HCV infections across every State is not available at this time. HHS is working to improve monitoring of viral hepatitis.

[36] Licata A, DiBona D, Schepis F, Shahied L, Craxi A, Camma C. When and How to Treat Acute Hepatitis C? J Hepatol 2003;39:1056-1062

Viral Hepatitis Prevention Activities within HHS

Multiple agencies within HHS are working hard to maximize the impact of available resources in responding to the viral hepatitis epidemic and respond to the recommendations of the IOM report.

Centers for Disease Control and Prevention (CDC)

At CDC, the primary responsibility for prevention and control activities rests with the Division of Viral Hepatitis. Those activities are broadly grouped under four programmatic priorities:

1) Reduce illness and death by identifying persons with viral hepatitis early and referring them to care;
2) Eliminate hepatitis B transmission;
3) Develop, test and translate into action tools to decrease the incidence of HCV; and
4) Guide and evaluate prevention efforts by improving the monitoring of viral hepatitis.

To address those priorities, CDC currently supports viral hepatitis coordinators in 49 states and the District of Columbia. These coordinators are tasked with integrating viral hepatitis services with other public health efforts to reach populations at risk. While funding does not support direct service provision, the coordinators seek whenever possible to leverage available resources and integrate viral hepatitis education, vaccination, and screening with services provided by federally-supported STD and HIV testing and treatment sites, federally qualified health centers supported by the Health Resources and Services Administration, and other programs.

In addition to supporting coordinators, CDC assists states in responding to disease outbreaks by deploying field investigators and by conducting rapid laboratory serologic and genetic testing to identify sources of infection and direct control strategies. CDC also provides technical support to all states for monitoring acute and chronic infections, including assisting states in adopting surveillance for chronic HBV and HCV infections and investigating cases suggestive of the emergence of rare or new causes of viral hepatitis. Funding for enhanced surveillance activities is provided to 9 state and local health departments.

CDC's surveillance activities also include monitoring liver cancer incidence and prevalence through the National Program of Cancer Registries, in collaboration with the National Cancer Institute's Surveillance, Epidemiology, and End Results Program. Data indicate that liver cancer incidence rates vary widely across states, and persistent racial and ethnic disparities exist[21]. These surveillance efforts articulate the burden of liver cancer and can assist states in targeting prevention and control efforts, including primary prevention efforts targeted to the populations most at risk of contracting HBV and HCV.

To identify and address health disparities, CDC surveys populations at increased risk for viral hepatitis, including racial and ethnic minority communities, MSM, and injection drug users. CDC follows approximately 12,000 patients in care for viral hepatitis to study the implementation of recommended preventive and care services.

CDC also supports state and local perinatal prevention coordinators to prevent mother-to-child transmission of hepatitis B. This effort includes ensuring the screening of pregnant women,

vaccination of infants at birth, follow-up with infants to ensure completion of the vaccine series, and testing of infants to ensure the development of antibodies. Similarly, through immunization funding for its Adult Hepatitis B Vaccination Initiative, CDC has begun to close the gap in vaccination of at risk adults. Since the beginning of the Initiative in FY 2007, CDC has made approximately $42 million in Section 317 funds available for the purchase of hepatitis B vaccine for use in over 2,600 venues.

Healthcare-associated transmission of viral hepatitis is entirely preventable through adherence to basic infection control. In the area of healthcare-associated transmission of hepatitis, CDC monitors the size and scope of the problem and assists state and local health departments with healthcare-associated outbreak investigations. Perhaps most importantly, CDC identifies best practices regarding infection control and educates providers, patients and industry about these practices through evidence-based infection control guidelines, peer-reviewed publications, and educational campaigns.

In addition to CDC's work with the states, CDC conducts prevention research to guide policy and program development. CDC fosters development of new approaches to health education, investigation of new screening tests and strategies, studies of licensed and experimental vaccines, and the emergence and implications of viral mutations for diagnosis, prevention, and therapy.

Finally, CDC works with the World Health Organization and other partners to prevent viral hepatitis globally. As of 2008, a total of 177 countries had incorporated hepatitis B vaccine in their national infant immunization programs, and an estimated 69% of the 2008 birth cohort received hepatitis B vaccine. Worldwide, only about 27% of newborns received the birth dose of

hepatitis B vaccine.[37] The FY 2011 Budget includes an increase of 10 percent over the FY 2010 Omnibus to support these activities.

National Institutes of Health (NIH)

At NIH, the primary responsibility for hepatitis research and prevention activities rests with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases (NIAID). NIDDK and NIAID support many activities in hepatitis B and C research and education including the following:

Hepatitis B Research: NIAID supports basic and translational research on hepatitis B. Efforts include drug discovery and development and vaccine improvements, as well as many efforts related to HBV pathogenesis and the varying human responses to infection. In addition, the Institute supports many resources for outside investigators to screen and develop new HBV-specific therapeutic candidates at no cost. NIAID resources include tissue culture and animal model screens and preclinical drug development services. In addition, NIAID is currently soliciting applications for research on new classes of HBV therapies.

Hepatitis B Research Network: This multi-center research Network, established in 2008, aims to advance understanding of disease processes and natural history, as well as to develop effective approaches to treating and controlling hepatitis B. The Network currently includes 21 clinical sites across the United States, including Hawaii, and a central data coordinating center. The Network's centers are in the final stages of planning multiple clinical trials in both adults and

[37] CDC. Implementation of Newborn Hepatitis B Vaccination – Worldwide, 2006. MMWR 2008;57(46):1249-1252.

children that are responsive to the recommendations of the IOM report regarding pregnant women and at-risk populations.

Clinical Research on Hepatitis C: NIH conducts many clinical trials of available antiviral therapies against hepatitis C, such as the drug interferon. Research to develop a vaccine against hepatitis C is also a major priority for the NIH. Basic and applied studies on hepatitis C virus vaccine development are being funded by NIAID, NIDDK, the National Cancer Institute, and the National Institute on Drug Abuse, including those being conducted by the NIDDK intramural NIDDK Liver Diseases Branch and NIAID's Laboratory of Infectious Diseases.

Basic Research on Hepatitis C Virus Infection: NIAID and the NIDDK Liver Diseases Branch conduct basic research and fund research on how the hepatitis C virus infects human cells. New animal models and cell culture systems developed by NIAID and NIDDK-funded investigators are instrumental to advancing hepatitis C prevention and therapy. For example, high-impact research projects are developing a mouse model of hepatitis C virus infection and pioneering advanced tissue culture systems that mimic human liver biology for studying the viral life cycle testing new antiviral agents, and identifying viral and human host factors that may serve as targets for future therapies.

The NIAID-supported Hepatitis C Cooperative Research Centers seek to improve basic understanding of HCV pathology. This program, renewed in Fiscal Year (FY) 2010, sponsors five centers which will advance understanding of the host immune response to infection and the factors that determine whether HCV infections are cleared or persist chronically. The underlying mission of the Centers is to help define successful immune response to HCV and

identify new targets for drugs, vaccines, and other therapeutic strategies for the prevention or treatment of HCV infection.

NIAID intramural scientists and grantees pursue basic and translational studies on the pathogenesis and molecular biology of HCV, investigate the basic immunology of HCV infection, and partner with industry to further the development of HCV vaccines. NIAID scientists also are collaborating with international researchers to understand why cirrhosis is a fairly stable disease for decades in some patients, while in others it may lead to liver-related death or liver cancer. Investigators are performing genetic analyses and searching for biomarkers for the early detection of liver cancer.

NIAID currently is developing and evaluating new agents to treat HCV/HIV co-infected individuals and is supporting clinical research to define the most effective, long-term treatment strategies for HIV/HCV co-infecton. Currently, NIAID researchers are conducting several clinical studies of patients with chronic viral hepatitis at the NIH Clinical Center. These studies are focused on developing better therapeutics for the management of HCV infection in HIV co-infected individuals.

Trans-NIH and Trans-Agency Viral Hepatitis Research Planning: Strategic research plans, such as the trans-NIH *Action Plan for Liver Disease Research*, and the National Commission on Digestive Diseases' research plan, both developed with trans-NIH and trans-HHS input, highlight important research goals relevant to controlling hepatitis B and C. These plans (available at http://liverplan.niddk.nih.gov and http://NCDD.niddk.nih.gov) are currently being implemented by the NIH and partners in the larger research community.

NIH Consensus Development Conferences and Meetings: The NIDDK has provided leadership, along with other NIH Institutes, Centers, and Offices, and other professional organizations, for convening several consensus development conferences on hepatitis B and C, including Management of Hepatitis C (2002), and Management of Hepatitis B (2008). The NIDDK also helped to organize a meeting on Management of Chronic Hepatitis B in 2006, as well as the International Symposium on Viral Hepatitis and Liver Disease in 2009. Recommendations from these conferences and meetings helped to inform the IOM's report.

Health Resources and Services Administration (HRSA)

Within HRSA, many of the activities related to Hepatitis B and C are overseen by the HIV/AIDS Bureau (HAB) and the Bureau of Primary Health Care (BPHC). HAB and BPHC are collaborating on ways to increase screening and referral to treatment for Federally Qualified Health Center (FQHC) patients who are mono-infected with hepatitis C and those who are dually infected with HIV and hepatitis. Examples of HAB and BPHC hepatitis B and C activities include the following":

- HRSA/BPHC is working with the Association of Asian Pacific Community Health Organizations (AAPCHO) and the White House Initiative on Asian American and Pacific Islanders to develop strategies for improving prevention and treatment of viral hepatitis among Asian and Pacific Islander Americans.
- Hepatitis C Treatment Expansion Initiative - Evaluation and Technical Assistance Center (CFDA: 93.928): Under the Special Projects of National Significance Program of the Ryan White HIV/AIDS program, administered by HRSA's HIV/AIDS Bureau, this initiative will provide funds for up to 2 years to build capacity among Ryan White-funded

organizations through the implementation of demonstration models for enhancing HCV treatment protocols in integrated HIV medical treatment settings in the context of providing HIV primary medical care and treatment to individuals co-infected with HCV. In addition to treatment implementation, awarded organizations will also assist the Evaluation and Technical Assistance Center in assessing the effectiveness, feasibility and costs of these service delivery models.

- HRSA supports FQHC services for viral hepatitis treatment and prevention in the following ways:
    - Requiring that, as a condition of health center funding and the FQHC "Look-Alike" designation, all federally-funded health centers and FQHC Look-Alikes provide diagnostic lab services, screenings for communicable diseases, and immunizations against vaccine-preventable diseases, including HBV.
    - Requiring that federally-funded health centers and FQHC Look-Alikes provide health education to patients and the general community. This includes patient education on diseases that may be prevalent in the community or for which the population may be vulnerable, such as viral hepatitis.
    - HRSA promotes screening and treatment of viral hepatitis through a national cooperative agreement. Activities resulting from this agreement include raising awareness of viral hepatitis among health center providers and patients, and providing technical assistance on strategies to treat and prevent viral hepatitis. For example, HRSA recently met with the National Alliance of State and Territorial AIDS Directors and the Northeast Hepatitis Coordinators' Alliance to strategize on hepatitis prevention and treatment in FQHCs.

- In order to better monitor hepatitis incidence in health center patients, HRSA revised its health center grantee reporting mechanism to track patient hepatitis rates.
- The only successful treatment available for endstage liver disease due to HCV is liver transplantation. HRSA provides oversight for the Organ Procurement and Transplantation Network (OPTN) operated under contract by United Network for Organ Sharing (UNOS). Currently there are 16,072 patients on the nationwide liver transplant waiting list, and 6.320 liver transplants were performed in 2009. Because of the critical shortage of donor organs, 1,461 patients died in 2009 waiting for a liver transplant. About 40% of liver transplants performed in the U.S. have HCV, and experts expect this number to rise significantly during the next decade. Although liver transplantation can successfully treat chronic liver failure due to HCV, a major challenge facing these recipients is recurrence of HCV in the new liver that eventually leads to reduced graft survival.[38]

Food and Drug Administration (FDA)

The FDA has multiple centers working on hepatitis B and C prevention activities:

CDER Activities Relating to Hepatitis B and C: FDA's Center for Drug Evaluation and Research (CDER) has the responsibility of reviewing drug products and certain biological products including therapeutic proteins and monoclonal antibodies for the treatment and/or prevention of viral hepatitis including hepatitis B and C.

[38] TD Schiano and P Martin, Review: Management of HCV infection and liver transplantation, International Journal of Medical Sciences (2006) 3(2):79-83.

Currently, there is a great deal of interest within industry in developing treatments for both hepatitis B and C. FDA has approved five drugs and two interferon products to treat hepatitis B. FDA has approved three distinct types of interferon products from three different sponsors for the treatment of hepatitis C. FDA has also approved multiple versions of ribavirin, a drug approved to increase the effectiveness of intereferons in the treatment of hepatits C.

CDER also regularly meets with numerous issue groups and pharmaceutical companies to discuss drug development plans, protocols and proposals. CDER is currently collaborating with the Forum for HIV Research to plan a workshop on hepatitis C drug development. FDA also held a public meeting in April 2010 to discuss expanded access to direct-acting antiviral agents for the treatment of chronic hepatitis C infection in patients with unmet medical need. CDER is in the process of drafting a guidance to industry on the development of direct-acting antivirals for the treatment of hepatitis C. And lastly, FDA issued a Citizen Petition response which recognized the crisis of hepatitis C among people with bleeding disorders and the need to take definite steps to allow people with bleeding disorders and hepatitis C and other patients with hepatitis C with no treatment options to have access to promising investigational drugs beyond current clinical trials.

CBER Activities Relating to Hepatitis B and C: The FDA's Center for Biologics Evaluation and Research (CBER) regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. CBER protects and promotes the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information

to promote the safe and appropriate use of biological products. CBER regulates an array of diverse and complex biological products, both investigational and licensed, including vaccines, blood and blood products, and human tissues and cellular products. In carrying out its mission to ensure the safety, purity, and potency (effectiveness) of biological products, CBER engages in a number of activities pertinent to HBV and HCV.

Scientists in CBER laboratories are currently working on several research projects pertaining to HCV. One research program, *Hepatitis C Vaccines: Development of in vitro and in vivo Systems for HCV Replication and Evaluation of Vaccine Efficacy*, seeks to evaluate new methods and models for evaluating the immune responses to HCV in systems that may be predictive of outcomes in people. Evaluating immune correlates of protection will be invaluable in the assessment of candidate HCV vaccines and to support development of new HCV vaccines.

Another research program – *Studies of Efficacy, Safety and Potency Assay Development for Prophylactic and Therapeutic Vaccines against Hepatitis Viruses* – is focused on developing scientific tools to understand the immunobiology and pathogenesis of HCV. Studies include the development of a small animal model for HCV infection, identification of efficacy biomarkers (*i.e.*, immunologic correlates of protection), development of neutralization tests for the virus, use of nanotechnology for induction of protective immune responses, and studies on the safety of therapeutic vaccines for this virus. These studies will provide the ability to evaluate new technologies being applied to vaccine development, and will be pivotal in guiding and assessing the safety, efficacy and manufacturing issues associated with HCV vaccines.

CBER also engages in research activities pertaining to the safety and efficacy of plasma-derived products in the context of HBV and HCV. CBER research studies have impacted: (1) the safety of blood and blood products with respect to viral pathogens in transfusion recipients; (2) the establishment of national, international, or global standards that would ensure the safety of blood and potency of plasma-derived products; and (3) the development of cell culture based-assays to test for pathogen inactivation.

CDRH Activities Relating to Hepatitis B and C: FDA's Center for Devices and Radiological Health (CDRH), which is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States, has a dedicated Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) charged with regulating all aspects of in-home and laboratory diagnostic tests (*in vitro* diagnostic devices, or IVDs). OIVD's multidisciplinary group of scientists, medical technologists, policy analysts, engineers, pathologists, and clinicians has a dual charge to foster the rapid transfer of new IVDs into the marketplace while preventing marketing of unsafe or ineffective devices, and is engaged in a number of activities related to hepatitis B and hepatitis C.

In addition, OIVD scientific reviewers and managers participate in several interagency groups associated with viral liver disease. The Hepatitis "Think C" Personalized Medicine Group works to improve the dosage of anti-viral medication at the individual patient level through a combination of appropriate diagnostic test and drug regimes. The Liver Fibrosis Interagency Group meets to discuss the ongoing search for new diagnostic biomarkers for liver fibrosis, which could replace the current practice of diagnosis by liver biopsy.

Indian Health Service (IHS)

IHS works to prevent viral hepatitis in its beneficiary population. IHS has a vaccination program to prevent hepatitis B in the Indian communities it serves. Routine vaccination of all newborns occurs at IHS birthing hospitals, with the first dose of hepatitis B vaccine administered as soon as possible after birth. The hepatitis B vaccine series started at birth is completed as part of normal pediatric vaccine schedule. Catch-up hepatitis B vaccination is offered to children and adolescents who need it. Vaccination of at-risk adults varies by site. Screening for the hepatitis B surface antigen in pregnant IHS patients is generally done as part of the regular health care treatment protocol. Treatment of chronic hepatitis B is provided, most notably in Alaska.

Treatment of hepatitis C occurs at some service units, with four IHS areas providing hepatitis C treatment in at least one service unit. Again, the Alaska Area offers the most developed program. The Seattle Indian Health Board Viral Hepatitis Education and Training (VHET) Project offers education and training of providers in screening of at-risk adults for hepatitis B and hepatitis C, and in hepatitis A and B vaccination. The IHS is also developing electronic health record-based surveillance methods to describe the epidemiology of hepatitis C in the HIS beneficiary population.

HHS Office of Minority Health (OMH)

OMH helped sponsor the IOM report, and is ingworking to elevate viral hepatitis as a priority public health issue. AActivities led by OMH include the following:

Hepatitis B Video, titled "B"/PSA: The OMH was asked by the Association of Asian Pacific Community Health Organizations and the Hepatitis B Foundation to collaborate on the national release of the Hepatitis "B" video/PSA. The PSA was awarded the Grand Prize of the B Real Short Film Competition at the Los Angeles Asian Pacific Film Festival in 2009 and, prior to the partnership with OMH, was played in every major feature at the Asian American International Film Festival in New York. As part of the partnership, the PSA was recently aired on ABC during the Oprah Winfrey Show, CNN's Anderson Cooper, Good Morning America, Today Show, the evening news and various Asian media networks. The PSA will be translated into six different Asian languages.

World Hepatitis Day: The OMH, Association of Asian Pacific Community Health Organizations, National Alliance of State and Territorial AIDS Directors, and National Viral Hepatitis Roundtable recently hosted a World Hepatitis Day event to highlight the importance of global action to eliminate viral hepatitis in Asian American, Native Hawaiian, Pacific Islander, African American, American Indian, Alaska Native, and Hispanic/Latino communities.

Compendium Distribution: Compendium on Local Hepatitis B Activities: The Association of Asian Pacific Community Health Organizations (AAPCHO) received an OMH National Umbrella Cooperative Agreement to enhance hepatitis B activities in communities across the nation. As part of this award, AAPCHO will work with the Hepatitis B Foundation and Asian Pacific Islander American Health Forum to develop and implement a comprehensive strategy to promote and distribute a hepatitis B compendium to catalyze partnerships for local and national action.

The compendium includes case studies on the successes and lessons learned from local coalitions that are part of AAPCHO's hepatitis "B Activated" network. The case studies provide examples and recommendations for enhancing coalition efforts for increasing local awareness, and enhancing screening and vaccination activities. The compendium is intended for communities who are interested in developing or strengthening local hepatitis B awareness and prevention efforts.

Bilingual Bicultural Demonstration Program: Funded by OMH under the Bilingual Bicultural Demonstration Program, the Asian Liver Center at Stanford University's "Building the Community Partnership for San Francisco: Hep B Free Campaign" works to screen, vaccinate and treat all San Francisco Asian and Pacific Islander residents against hepatitis B by providing convenient, free or low-cost testing opportunities at partnering health facilities.

Community Partnership: The Immigrant and Refugee Community Organization (IRCO), an OMH Community Partnership grantee, seeks to decrease the prevalence of hepatitis B and HIV in the Asian and Pacific Islander, African Refugee, and Immigrant communities in Portland, Oregon. Since September 2009, IRCO has reached 210 members of the Asian and African refugee and immigrant community and trained 43 healthcare interpreters on hepatitis B transmission, symptoms, and the importance of early detection.

Closing

Given the substantial and increasing disease and economic burden from viral hepatitis, HHS is taking immediate and coordinated steps to reverse these trends, which represent a health priority for our nation. HHS greatly appreciates the committee's interest in these important issues.

Thank you for the opportunity to share this information with you. I recognize that the problems I have identified are significant ones, but I am confident that working together we can succeed in protecting this nation against the needless disease, pain, suffering, and death caused by viral hepatitis. Thank you. I will be happy to answer any questions.

Chairman TOWNS. Thank you very much for your testimony. We really appreciate your being here.

Based on what you have seen, read, and heard, if we have the resources, can we prevent hepatitis?

Dr. KOH. Mr. Chairman, I think the potential for prevention here is unlimited. We understand risks and we understand the trends if we don't act, so we have a great opportunity right now with your leadership and the work of your committee.

Also, I should stress that with the passage of health reform we have an opportunity to talk about true systems of care and a renewed emphasis on prevention. Prevention involves not just work in a clinic, but also in a community. And in this particular case prevention also focuses on immunization strategies as well. So we have tremendous opportunities right now.

Chairman TOWNS. Dr. Koh, if people don't feel sick and don't know they are sick, how can we go about identifying those who are infected?

Dr. KOH. That is the challenge, Mr. Chairman, of screening asymptomatic people, and that is the challenge of prevention, which we are facing much better as a Nation. We have much more commitment and attention from policymakers like yourself, members of the health community, and the general public to advance prevention, testing high-risk groups, and screening. Again, through health reform that has a great prevention focus. We need more attention to developing guidelines for screening and testing high-risk groups, and then making those guidelines available for people to understand, and then also covering prevention services so that cost is not a barrier.

Chairman TOWNS. How bad is the problem of hepatitis?

Dr. KOH. We have heard the numbers over and over. Up to 5.3 million people infected right now. But the big challenge that up to three quarters of the people who are infected are unaware they even have the virus. So the challenge is catching it early for asymptomatic people, spreading the message that we have good treatments if cases are discovered early, sending the message through policymakers like yourself, and really changing the paradigm here with coordinated activity of all of you and then also within our Department.

Chairman TOWNS. As I understand it, the U.S. Preventive Task Force issues a directive to CMS as to what screening and treatment for hepatitis will be covered by Medicare. How can we make sure that the new treatments that you say are just over the horizon will be covered by Medicare if the Task Force issues its directive just before those treatments are ready?

Dr. KOH. Well, there are several parts to your question, Mr. Chairman. First of all, within Medicare and Medicaid, actually, there are new prevention opportunities afforded by health reform, so that is a very exciting part of this new law. It gives us an opportunity to look at new prevention and screening strategies in a whole host of areas.

The U.S. Preventive Services Task Force is, just to clarify, an independent advisory group of experts, and they are one of a number of groups that make screening guidelines. So we look to them, but also many other groups, to come out with recommendations.

So I am hoping, again, that with this very important timing after health reform, with this hearing, and with the establishment of our Department interagency working group, we can bring all these prevention recommendations together and move forward as a country to tackle this major challenge.

Chairman TOWNS. I just want to clear up one other thing that was made in reference to earmarking by my good friend who I work very closely with, that this would not be an earmark; this would be expanding a program that is in existence that needs additional resources in order to accomplish the goals that we all are seeking.

So I just wanted to make that clear. So what we need to do is just fight to expand the program, which there is no question, anybody and everybody you talk to is saying that we need additional resources.

I now yield to the gentleman from California, Congressman Bilbray, for 5 minutes.

Mr. BILBRAY. Thank you, Mr. Chairman. Let me say, Mr. Chairman, as the Representative of the 50th District, which has had a very checkered past when it comes to earmarks, I think this is one of those issues why we really need to talk about a true reform package, so the boundaries, lines are all drawn and everybody knows where the rules are.

But that aside, I would like to sort of engage the two gentlemen with some observations as a layman. First of all, for the record, I avoided tattoos not because of health problems, but because my father, who was a lifer in the Navy, assured me that he would take care of the tattoo with a rusty razor if I ever came home with one. OK? [Laughter.]

But I do worry about the fact that I see that mentality not being applied to the next generation, and that whole acceptability of certain behavior, some of it now totally acceptable, but does constitute still expanded risk. I would like to see what we can do, rather than just talking about how much money we can throw at the problem, which I think, disproportionately, we are not getting a fair share on this issue, but aside from that is that things like protocols for testing.

I would strongly say that we need to get the word out to physicians that targeted populations should be looked at multidimensionally; not just inquiring about behavior, but looking at the population window. When we have that kind of number, any toxicologist or statistician will tell you, you don't ignore that kind of spike and that kind of opportunity.

So, first of all, let me throw out some ideas as a layman, then I will go into it. If I were still at the county, I would be telling our county physicians that you should not be asking them how have you had risky behavior in the past or whatever, because that automatically sets off defensive mechanisms. And it is astonishing how those of us in our fifties and our sixties forget about our good old days when we lived through the 1960's, which most of us can't remember anyway. [Laughter.]

But if we basically look at their age, use the age as an initial, still you can followup on behavior for the general population, but

as a backup not necessary, because I just think you will get defenses.

And the other issue is right now, and I say this, I had the county physician because of a lot of exposure as a county supervisor. The Mexican border was on my district; I spent a lot of time in Mexico, and you know the horrendous problems with hepatitis south of the border. I was inoculated as much as possible at that time. But the treatment now, that exists now, is an IV treatment that is pretty extensive. It is how many weeks?

Dr. WARD. Up to 48 weeks.

Mr. BILBRAY. OK, 48 weeks. One of the biggest problems I know, especially with a lot of at-risk populations, is that when you talk about that kind of treatment, they may start the treatment, but the problem of finishing the treatment is always a big problem. The same kind of things we run into with antibiotics with certain populations.

My question is when you do your evaluation, update your 2004 protocols, are you looking at the new treatments coming down the pike that are being considered, especially I think there are about three different proposals for oral treatment that is much shorter? And it is a lot different going 7 weeks taking a pill than it is going 7 weeks going into a physician's facility and getting a shot. Are we looking at the fact that the treatment effectiveness is going to jump dramatically if any one of these three becomes effective? And is that going to be considered in our upgrade?

Dr. KOH. Sure, Congressman. First of all, thank you for your commitment to this. We want the broadest possible approach here to advance prevention, education, and treatment all at the same time, so with respect to the prevention part there is new effort and research to look at a so-called age-based model for identifying people at risk. Actually, Dr. Ward at the CDC has led that effort, so I am going to ask him to comment on that in just a second.

Then, also, the treatments have advanced quite a bit, as you have noted, and it does have the potential to decrease the duration of treatment quite substantially for patients. So this is all good news coming down in the very near future, I hope, and we want to coordinate better identification of people at risk, whether it is risk-based assessment or age-based assessment, and we also want to advance better treatments. But I think Dr. Ward wants to say something about this.

Dr. WARD. Good morning. We share your interest in looking at alternatives to our current strategies for screening. We want our screening approaches to be part of the solution, and not part of the problem. And right now we have a fairly large body of evidence that risk-based approaches represent barriers to people getting screened, in contrast to presenting opportunities.

So what we have embarked upon is looking at an age-based approach, given that, to your point, upwards of about three-quarters of persons living with Hepatitis C were born between 1946 and 1964, the so-called baby-boom generation. And among that age group, about 1 out of every 30 people, or about 3 percent of persons in that age group, are Hepatitis C infected. And we have embarked upon a study known as BEST-C, to see if this could be easily implementable by physicians.

As we have already pointed out earlier today, Hepatitis C is a major cause of liver cancer. We have other age-based prevention strategies for other types of cancer: breast cancer, colon cancer. So we would like to see how we could begin to look at how Hepatitis C screening in the context of cancer prevention and begin to say this is another age-based approach to protect someone's health for the future without requiring someone to go way back in the past and say this happened, this happened, so then I am eligible for screening. We would like to make it much more accessible and much more easily implementable by physicians and, in so doing, decrease this large proportion of people who currently don't know their status.

Mr. BILBRAY. I apologize. There is a big——

Chairman TOWNS. The gentleman's time has expired.

Mr. BILBRAY. I appreciate it, Mr. Chairman. I just think that this assessment from the update of 2004 and the fact that it is a very complicated issue, and I hope some time we can talk about it, about the fact of the difference of how expensive treatment is with IV, how there are people that will not complete treatment, as opposed to the new technologies coming down, and how that affects the whole formula.

Chairman TOWNS. I thank the gentleman. Time has expired.

The gentlewoman from California, Ms. Chu.

Ms. CHU. Thank you, Mr. Chair.

First, I want to commend you, Dr. Koh, for taking on this disease so strongly. You are the first person in your position to raise this amount of awareness and activity on combating Hepatitis B and C, so I truly commend you on that.

It is a grave concern to me that in the U.S. hepatitis claims more lives each year than HIV/AIDS and is about 100 times more infectious than HIV, yet only 2 percent of CDC's prevention budget is devoted to Hepatitis B and C.

It is also very disconcerting that Asian Americans are disproportionately impacted by this disease. Although APIs make up about 4½ percent of the population, they account for more than 50 percent of Americans who are living with the disease and, in fact, it remains a top killer of Asian Americans.

Many of these Asian Americans have immigrated from countries in which they lack universal vaccination. They may have come here without knowledge that they were carrying the disease and they may have already developed a liver cancer. Pregnant mothers can easily transmit the virus to their newborns, and that is how it is being spread. And it is so prevalent that in the API population all of us know somebody who is infected and, in fact, recently, in my area, the mayor of our local city died because it did develop into liver cancer.

So my question is what you are doing to address the particular issues in the Asian-American community with this incredible prevalence of this disease.

Dr. KOH. Well, first of all, Congresswoman, thank you for your leadership on not only this issue, but on so many issues for the Asian-American and Pacific Islander community. I have seen your commitment personally and I want to thank you for that.

We understand that this condition of hepatitis disproportionately affects the Asian-American and Pacific Islander population, so we have a lot of challenges ahead of us, but we also have opportunities. One opportunity, as you well know, is the President has established a new White House initiative on Asian Americans and Pacific Islanders.

I took great honor in standing with the President when he signed that Executive order last fall in the White House, and the first meeting of that commission, which is co-chaired by Secretary Locke and Secretary Duncan, is next month, in July. So we are going to put this issue on the agenda there to have the White House commission address this squarely.

Then, we are also very lucky to have many leaders in the community, from the community health center organizations, advocacy groups, outreach efforts spearheaded by committed people from Asian-American and Pacific Islander backgrounds very involved here, and then also tremendous research that is going on. And, Congresswoman, you and I attended a very important event where new health data was being released on Asian-American populations. That was a great event to share in. So there is a lot more attention on documenting health concerns in our population and then in mobilizing people who want to make a difference here.

Dr. WARD. Let me just add on to say I think some of the critical areas of our prevention efforts as they relate to Asian Americans include our perinatal Hepatitis B prevention program. As you pointed out, mother to child transmission is a major mode. It continues to result in transmissions, resulting in hundreds of infants becoming infected with Hepatitis B. Many of those are Asian Americans. The number of women, as noted in our written testimony, has increased to about 24,000 per year who are Hepatitis B infected giving birth, and currently our perinatal programs have the capacity to provide case management services for about 50 percent of those.

We have the prevention tools to dramatically prevent transmission in this population through vaccination, Hepatitis B immunoglobulin, but those services have to be available.

Ms. CHU. And how are we going to assure that the resources go toward this sort of effort?

Dr. KOH. Well, again, we are, I think, mobilizing every resource. Having this hearing is a tremendous statement of commitment from policy leaders across the country. We have new energy from this Department interagency workgroup. We have here at the hearing many people from community level and advocacy level who want to make a difference. Research continues to go forward. And then the health reform passage and implementation I think gives us an opportunity to look at all these issues carefully and build a real system of care.

As you heard from Dr. Ward, we are looking more closely on the screening strategies, and there are also new testing technologies that are being explored, rapid testing for Hepatitis C in particular.

I don't know if Dr. Ward wants to say more.

Dr. WARD. I think the other critical area in general, but particularly as they relate to Asian Americans is, one, community awareness and education. You know, despite the high prevalence that

you mentioned, awareness appears to be low, based on the information we have received.

And we need to correct that so that persons understand the benefits of vaccination and screening and early care, rather than waiting for liver cancer to develop. So we have done inventories to identify community organizations who are delivering prevention services for Hepatitis B around the country. We provided some resources to two areas to actually support screening for Hepatitis B through those community organizations. So that is an important opportunity.

The other critical area is provider education. If they are not going to a provider that knows what needs to be done for hepatitis after you have increased their awareness, you really haven't done a full job. So we have to link our community education with provider training so that, when people go to a physician, that physician knows who should be screened, how to interpret the screening test, which sometimes can be complex, and then knows how to interpret that test result and determine who needs care and treatment for hepatitis.

Chairman TOWNS. Let me indicate to the Members that we have three votes on the floor and, of course, I want to yield to the gentleman from Missouri. So, we will try to finish up with this panel and we will resume at 12:15. We will come back at 12:15.

OK, so I now yield 5 minutes to the gentleman from Missouri.

Mr. CLAY. Thank you, Mr. Chairman, and I will be more judicious with my 5 minutes, unlike my colleagues, seeing that there is a vote.

Dr. Koh, I know that you have been very persistent about developing an interagency strategy to address this health crisis. In your view, what are some of the challenges that an initiative like this may face?

Dr. KOH. Well, we have a big Department that has many responsibilities being put before us. When I arrived at the Department last year, we had H1N1 ahead of us and now, of course, we have health reform implementation. But the opportunity, I believe, is that we have really a unique and unprecedented chance to make a difference with respect to conditions like hepatitis, with respect to prevention, and really building systems of care.

Also, if I can say, we have had tremendous leaders in the Department like Dr. Ward and officials at CDC. We have had work at agencies like NIH and the National Cancer Institute. Also, reimbursement discussions at the Centers for Medicare and Medicaid Services. But not that many chances to bring all those leaders and our Department together to really see how it could work together. If I can say the leaders at SAMHSA, Substance Abuse and Mental Health Services Administration [HRSA], Health Resources Services Administration, we have pockets of activity, but now a real chance to bring everybody together and see how we can coordinate this.

Mr. CLAY. Do you have a working group?

Dr. KOH. Yes. We met since January, Congressman. I chaired those. Dr. Ward has been at every meeting. I should also acknowledge Rosie Henson, our Senior Advisor, who has been instrumental in launching this. We have great commitment now across the Department and we are very proud of that.

Mr. CLAY. And I realize that this administration does quite a bit with interagency strategies. How has that worked in this case?

Dr. KOH. Well, we are going to focus within the Department until October, when we get our internal coordination heightened, and then we are very eager to work across Federal Government and then particularly connect with community partners. Many community partners are here today, Congressman, and they have been working on these issues for a long time, and they have a lot to teach us, so we are looking forward to working and connecting all interested parties because this issue is so important.

Mr. CLAY. Very good.

Dr. Ward, according to the recent IOM Report, African-American adults have the highest rate of acute Hepatitis B infection in the United States, and the highest rate of acute Hepatitis B infection occurs in the south. What does HHS plan on doing to address this population?

Dr. WARD. We have an elimination strategy for Hepatitis B. We have a powerful prevention tool, Hepatitis B vaccination. It is safe. It is effective. The Nation committed itself to eliminating transmission of Hepatitis B virus way back in 1992. We have made progress, as Representative Cassidy said; it was mainly around children.

And over and above the mother to child transmission population that still needs to receive fuller attention, the other big gap in our immunization strategy is adults at risk for Hepatitis B, and those low vaccination coverages are the major reason that African Americans continue to have high rates of Hepatitis B.

Mr. CLAY. OK. And then there are many other disparities that exist within this epidemic, including greater rates of infection for many minority groups and the LGBT community. Are there specific strategies in place to address each of these groups? And, if so, how does it differ?

Dr. WARD. Well, we have put out recommendations from CDC of which populations among adults need to receive Hepatitis B vaccine, such as men who have sex with men, injection drug users, persons with multiple sex partners. We have, over the last several years, put out about $45 million in money to help public settings—STD clinics, local health departments, correctional facilities—to receive Hepatitis B vaccine at little or no cost so that vaccine could be used to vaccinate populations which have been shown repeatedly over years to have low coverage, including the ones I just mentioned. So we would like to continue to advance improvements in vaccine coverage, which would then be followed by declines in Hepatitis B.

The other aspect of this is that African Americans also——

Chairman TOWNS. Dr. Ward, we have to cut you real short here because we only have a minute and a half to vote.

Mr. CLAY. He gives pretty long answers, Mr. Chairman. [Laughter.]

Chairman TOWNS. We have to cut you short.

But, anyway, I want to thank both of you for your testimony. We are going to dismiss you and the committee will be in recess until 12:15, as close to 12:15 as we can. Then we will be back. But thank you so much for your testimony.

Dr. KOH. Thank you, Mr. Chairman.

Dr. WARD. Thank you very much.

Chairman TOWNS. Pleasure.

[Applause.]

[Recess.]

Chairman TOWNS. Let me thank you very much for coming. Mr. Randy Mayer is here on behalf of the Institute of Medicine and serves as the chief of the Bureau of HIV, STD, and Hepatitis for Iowa Department of Public Health; Mr. Jeffrey Levi is the executive director of the trust for America's Health organization; Mr. Michael Ninburg is the executive director of the Hepatitis Education Project in Seattle, WA; and Mr. Rolf Benirschke is spokesman for Hepatitis C Awareness.

Consistent with committee policy, we would like to ask you to please stand and let me swear you in.

[Witnesses sworn.]

Chairman TOWNS. Let the record reflect that all of the witnesses answered in the affirmative.

Let's begin with Mr. Mayer and then come right down the line.

STATEMENTS OF RANDY MAYER, CHIEF, BUREAU OF HIV, STD, AND HEPATITIS, IOWA DEPARTMENT OF PUBLIC HEALTH, APPEARING ON BEHALF OF THE INSTITUTE OF MEDICINE; MICHAEL NINBURG, EXECUTIVE DIRECTOR, HEPATITIS EDUCATION PROJECT; JEFFREY LEVI, EXECUTIVE DIRECTOR, TRUST FOR AMERICA'S HEALTH; AND ROLF JOACHIM BENIRSCHKE, FORMER NFL PLACE KICKER, SAN DIEGO CHARGERS, AND SPOKESMAN FOR HEPATITIS C AWARENESS

STATEMENT OF RANDY MAYER

Mr. MAYER. Good afternoon, Mr. Chairman and members of the committee. My name is Randy Mayer. I am Chief of the Bureau of HIV, STD, and Hepatitis at the Iowa Department of Public Health. I also served as a member of the Institute of Medicine's Committee on the Prevention and Control of Viral Hepatitis Infections.

The Institute of Medicine [IOM], is the health arm of the National Academy of Sciences, an independent nonprofit organization that provides unbiased and authoritative advice to decisionmakers and to the public. The IOM was asked by the Centers of Disease Control and Prevention, the Department of Health and Human Services Office of Minority Health, the Department of Veterans Affairs, and the National Viral Hepatitis Roundtable to review current prevention and control strategies for viral hepatitis and to identify priorities for research policy and action.

The IOM assembled an expert committee, of which I was a member, to address this task. The committee met five times over a 12-month period to gather evidence, deliberate on its findings and recommendations, and write the report. The report was released in January of this year, and more detailed information is included in my longer written statement.

You have heard much of what the report discussed earlier today from our other speakers, but the committee learned that in the next 10 years about 150,000 people in the United States are expected to die from liver cancer and liver disease associated with

chronic viral hepatitis. This condition is three to five times more frequent than HIV in the United States. Between 3½ million and 5.3 million people, or 1 to 2 percent of the population of the United States, are living with Hepatitis B or C. Those numbers are unacceptably high considering that Hepatitis B and C are both preventable and treatable.

Unfortunately, about 65 percent of people with Hepatitis B and 75 percent of people with Hepatitis C do not realize that they have the disease. By comparison, about 21 percent of people who are HIV infected do not realize that they have HIV. This means that the majority of those with viral hepatitis are not seeking treatment or taking steps to prevent transmission of the disease to others.

Hepatitis B and C are transmitted by sexual contact and by exposure to infected blood through the use of contaminated needles or other drug equipment and implements. In addition, approximately 1,000 infants per year are infected with Hepatitis B during birth, and people may have acquired Hepatitis C through blood transfusions and transplants that occurred before 1992.

After reviewing a great deal of evidence, the committee identified several underlying factors that impede current efforts to prevent and control Hepatitis B and C. The primary factor is the lack of awareness about viral hepatitis among the general population and among health care and social service providers. This lack of awareness translates into a lack of public resources that are allocated for Hepatitis B and C. States receive, on average, only $90,000 annually in Federal funds for hepatitis prevention among adults.

Because chronic viral hepatitis has not been a public health priority in the United States, at-risk people do not know they are at risk and, therefore, they do not take steps to prevent infection or to get tested for any infection. Many health care providers, especially primary care providers, also are not familiar with risk factors for Hepatitis B and C. Therefore, they do not screen patients for risk factors to determine if they should be tested. In addition, many health care providers don't know how to manage chronically infected patients.

The committee believes that to address this national epidemic, additional Federal resources and guidance are necessary in four specific areas: disease surveillance, provider and community education, Hepatitis B immunization coverage, and viral hepatitis services. Action is needed at the Federal, State, and local levels to address the problem. In fact, 17 of the IOM committee's 22 recommendations are aimed at Federal and State agencies, including the CDC and the Health Resources and Services Administration.

In conclusion, the IOM committee believes that increased funding and a coordinated national effort would lead to reductions in new cases of Hepatitis B and C, in medical complications, and in deaths associated with these diseases and in total health costs.

Thank you.

[The prepared statement of Mr. Mayer follows:]

Hepatitis and Liver Cancer:
A National Strategy for Prevention and Control of Hepatitis B and C

Written Statement of

Mr. Randall Mayer
Chief, Bureau of HIV, STD, and Hepatitis
Iowa Department of Public Health
Des Moines, Iowa
and
Member, Committee on the Prevention and Control of Viral Hepatitis Infections
Institute of Medicine of The National Academies

Before the
Committee on Oversight and Government Reform
U.S. House of Representative

June 17, 2010

Mr. Chairman and Members of the Committee, I am Randy Mayer, Chief of the Bureau of HIV, STD, and Hepatitis at the Iowa Department of Public Health. I also served as a member of the Institute of Medicine's Committee on the Prevention and Control of Viral Hepatitis Infections. The Institute of Medicine, or IOM, is the health arm of the National Academy of Sciences, an independent, nonprofit organization that provides unbiased and authoritative advice to decision makers and the public. Thank you for the opportunity to submit testimony for the record based on the IOM's report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C.*

Background

Hepatitis B and hepatitis C are contagious liver diseases caused by the hepatitis B virus (HBV) and the hepatitis C virus (HCV), respectively. In the next 10 years, about 150,000 people in the United States will die from liver cancer and end-stage liver disease associated with chronic hepatitis B and hepatitis C. It is estimated that 3.5 to 5.3 million people — 1 to 2% of the US population — are living with chronic HBV or HCV infections. Of those, 800,000 to 1.4 million have chronic HBV infections, and 2.7 to 3.9 million have chronic HCV infections. Chronic viral hepatitis infections are 3 to 5 times more frequent than HIV in the United States. Up to 25% of HIV-positive people in the United States are co-infected with HCV and 10% are co-infected with HBV. The current burden of chronic viral hepatitis compared with HIV/AIDS is presented in Table 1.

TABLE 1 Burden of Selected Serious Chronic Viral Infections in the United States

Virus	Prevalence	Percentage of Population Unaware of Infection Status	Deaths in 2006 Related to Infection	Vaccine-preventable	Transmission Routes	Percentage of CDC NCHHSTP FY 2008 Budget
HBV	0.8–1.4 million	About 65%	3,000	Yes	Birth, blood, sex	2% combined
HCV	2.7–3.9 million	About 75%	12,000	No	Birth, blood, sex	
HIV/AIDS	1.1 million	About 21%	14,016	No	Birth, blood, sex	69% (domestic activities)

Abbreviations: CDC NCHHSTP, Centers for Disease Control and Prevention National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Prevention; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV/AIDS, human immunodeficiency virus/acquired immunodeficiency syndrome.

Because of the asymptomatic nature of chronic hepatitis B and hepatitis C, most people infected with HBV and HCV are not aware that they have been infected until they have symptoms of cirrhosis or a type of liver cancer, hepatocellular carcinoma (HCC), many years later. About 65% and 75% of the infected population are unaware that they are infected with HBV and HCV, respectively.

Although the incidence of acute HBV infection is declining in the United States due to the availability of hepatitis B vaccines, about 43,000 new acute HBV infections still occur each year. Of those new infections, about 1,000 infants acquire the infection during birth from their HBV-positive mothers. HBV is also transmitted by sexual contact with an infected person, sharing injection drug equipment, and needlestick injuries. African-American adults have the highest rate of acute HBV infection in the United States and the highest rates of acute HBV infection occur in the southern region. People from Asia and the Pacific Islands comprise the largest foreign-born population at risk for chronic HBV infection. The number of people in the United States who are living with chronic

HBV infection may be increasing as a result of immigration from endemic countries. On the basis of immigration patterns in the last decade, it is estimated that every year 40,000–45,000 people from HBV-endemic countries enter the United States legally.
There is no vaccine for hepatitis C. HCV is efficiently transmitted by direct percutaneous exposure to infectious blood. Persons likely to have chronic HCV infection include those who received a blood transfusion before 1992 and past or current injection-drug users (IDUs). Most IDUs in the United States have serologic evidence of HCV infection (that is, they have been exposed to HCV at some time). While HCV incidence appears to have declined over the last decade, a large portion of IDUs, who often do not have access to health-care services, are not identified by current surveillance systems, complicating interpretation of that trend. African-Americans and Hispanics have a higher rate of HCV infection than whites.

The Charge to the IOM Committee

Despite federal, state, and local public health efforts to prevent and control hepatitis B and hepatitis C, these diseases remain serious health problems in the United States. Therefore, the Centers for Disease Control and Prevention (CDC), in conjunction with the Department of Health and Human Services Office of Minority Health, the Department of Veterans Affairs, and the National Viral Hepatitis Roundtable, sought guidance from the Institute of Medicine (IOM) in identifying missed opportunities related to the prevention and control of HBV and HCV infections. IOM was asked to focus on hepatitis B and hepatitis C because they are common in the United States and often lead to serious, chronic disease. The charge to the committee follows.

> The IOM will form a committee to determine ways to reduce new HBV and HCV infections and the morbidity and mortality related to chronic viral hepatitis. The committee will assess current prevention and control activities and identify priorities for research, policy, and action. The committee will highlight issues that warrant further investigations and opportunities for collaboration between private and public sectors.

The IOM Committee's Findings

Upon reviewing evidence on the prevention and control of hepatitis B and hepatitis C, the committee identified the underlying factors that impede current efforts to prevent and control these diseases. Three major factors were found:

- There is a lack of knowledge and awareness about chronic viral hepatitis on the part of health-care and social-service providers.
- There is a lack of knowledge and awareness about chronic viral hepatitis among at-risk populations, members of the public, and policy-makers.
- There is insufficient understanding about the extent and seriousness of this public health problem, so inadequate public resources are being allocated to prevention, control, and surveillance programs.

That situation has created several consequences:

- Inadequate disease surveillance systems underreport acute and chronic infections, so the full extent of the problem may not be known.
- At-risk people do not know that they are at risk or how to prevent becoming infected.
- At-risk people may not have access to preventive services.
- Chronically infected people often do not know that they are infected.

- Many health-care providers do not screen people for risk factors or do not know how to manage infected people.
- Infected people often have inadequate access to testing, social support, and medical services.

The IOM Committee's Recommendations

To address the above-mentioned consequences and improve prevention and control efforts for viral hepatitis, the committee made recommendations in four categories: surveillance, knowledge and awareness, immunization, and services for viral hepatitis. The recommendations are summarized in Box 1. Seventeen of the 22 recommendations in the report are aimed at federal agencies, including the Centers for Disease Control and Prevention and the Health Resources and Services Administration, and state health departments. The recommendations make clear that additional federal resources and guidance are necessary to improve viral hepatitis prevention and control programs.

In conclusion, the committee believes that implementation of its recommendations would lead to reductions in new HBV and HCV infections, in medical complications and deaths that result from these viral infections of the liver, and in total health costs in our nation.

Thank you for the opportunity to testify. I would be happy to address any questions the Committee might have.

BOX 1 Recommendations

Chapter 2: Surveillance

- 2-1. The Centers for Disease Control and Prevention should conduct a comprehensive evaluation of the national hepatitis B and hepatitis C public-health surveillance system.
- 2-2. The Centers for Disease Control and Prevention should develop specific cooperative viral-hepatitis agreements with all state and territorial health departments to support core surveillance for acute and chronic hepatitis B and hepatitis C.
- 2-3. The Centers for Disease Control and Prevention should support and conduct targeted active surveillance, including serologic testing, to monitor incidence and prevalence of hepatitis B virus and hepatitis C virus infections in populations not fully captured by core surveillance.

Chapter 3: Knowledge and Awareness about Chronic Hepatitis B and Hepatitis C

- 3-1. The Centers for Disease Control and Prevention should work with key stakeholders (other federal agencies, state and local governments, professional organizations, health-care organizations, and educational institutions) to develop hepatitis B and hepatitis C educational programs for health-care and social-service providers.
- 3-2. The Centers for Disease Control and Prevention should work with key stakeholders to develop, coordinate, and evaluate innovative and effective outreach and education programs to target at-risk populations and to increase awareness in the general population about hepatitis B and hepatitis C.

Chapter 4: Immunization

- 4-1. All infants weighing at least 2,000 grams and born to hepatitis B surface antigen-positive women should receive single-antigen hepatitis B vaccine and hepatitis B immune globulin in the delivery room as soon as they are stable and washed. The recommendations of the Advisory Committee on Immunization Practices should remain in effect for all other infants.
- 4-2. All states should mandate that the hepatitis B vaccine series be completed or in progress as a requirement for school attendance.
- 4-3. Additional federal and state resources should be devoted to increasing hepatitis B vaccination of at-risk adults.

- 4-4. States should be encouraged to expand immunization-information systems to include adolescents and adults.
- 4-5. Private and public insurance coverage for hepatitis B vaccination should be expanded.
- 4-6. The federal government should work to ensure an adequate, accessible, and sustainable hepatitis B vaccine supply.
- 4-7. Studies to develop a vaccine to prevent chronic hepatitis C virus infection should continue.

Chapter 5: Viral Hepatitis Services

- 5-1. Federally funded health-insurance programs—such as Medicare, Medicaid, and the Federal Employees Health Benefits Program—should incorporate guidelines for risk-factor screening for hepatitis B and hepatitis C as a required core component of preventive care so that at-risk people receive serologic testing for hepatitis B virus and hepatitis C virus and chronically-infected patients receive appropriate medical management.
- 5-2. The Centers for Disease Control and Prevention, in conjunction with other federal agencies and state agencies, should provide resources for the expansion of community-based programs that provide hepatitis B screening, testing, and vaccination services that target foreign-born populations.
- 5-3. Federal, state, and local agencies should expand programs to reduce the risk of hepatitis C virus infection through injection-drug use by providing comprehensive hepatitis C virus prevention programs. At a minimum, the programs should include access to sterile needle syringes and drug-preparation equipment because the shared use of these materials has been shown to lead to transmission of hepatitis C virus.
- 5-4. Federal and state governments should expand services to reduce the harm caused by chronic hepatitis B and hepatitis C. The services should include testing to detect infection, counseling to reduce alcohol use and secondary transmission, hepatitis B vaccination, and referral for or provision of medical management.
- 5-5. Innovative, effective, multicomponent hepatitis C virus prevention strategies for injection drug users and non-injection drug users should be developed and evaluated to achieve greater control of hepatitis C virus transmission.
- 5-6. The Centers for Disease Control and Prevention should provide additional resources and guidance to perinatal hepatitis B prevention program coordinators to expand and enhance the capacity to identify chronically infected pregnant women and provide case-management services, including referral for appropriate medical management.
- 5-7. The National Institutes of Health should support a study of the effectiveness and safety of peripartum antiviral therapy to reduce and possibly eliminate perinatal hepatitis B virus transmission from women at high risk for perinatal transmission.
- 5-8. The Centers for Disease Control and Prevention and the Department of Justice should create an initiative to foster partnerships between health departments and corrections systems to ensure the availability of comprehensive viral hepatitis services for incarcerated people.
- 5-9. The Health Resources and Services Administration should provide adequate resources to federally funded community health facilities for provision of comprehensive viral-hepatitis services.
- 5-10. The Health Resources and Services Administration and the Centers for Disease Control and Prevention should provide resources and guidance to integrate comprehensive viral hepatitis services into settings that serve high-risk populations such as STD clinics, sites for HIV services and care, homeless shelters, and mobile health units.

Chairman TOWNS. Thank you for your statement.

Mr. Ninburg.

STATEMENT OF MICHAEL NINBURG

Mr. NINBURG. Thank you, Chairman Towns, committee members, for inviting me to testify here today. My name is Michael Ninburg, and I am the executive director of the Hepatitis Education Project, a nonprofit organization based in Seattle, WA. I also serve on the steering committee of the National Viral Hepatitis Roundtable, a coalition of nonprofit organizations, public health districts, and industry partners representing groups around the country. Until very recently, I was also a hepatitis patient.

As we have heard several times this morning, there are over 5 million Americans currently living with Hepatitis B or Hepatitis C, the overwhelming majority of whom are unaware of their infection. Being unaware, they can unwittingly transmit the viruses to others, and often do things to speed up their own disease progression.

Twelve years ago, in this very same committee, Surgeons General Satcher and C. Everett Koop spoke of Hepatitis C as a serious public health threat. You were here, Chairman Towns. Hepatitis B is also a grave public health threat. We still have an opportunity to address these issues, but that window of opportunity is closing.

For those who are diagnosed early for Hepatitis B and C, the prognosis is usually very good. Hepatitis B and Hepatitis C are both treatable conditions, and Hepatitis C is often curable. For people to be treated, however, they have to be diagnosed. This remains one of our greatest challenges.

I was one of the fortunate who was diagnosed. I am also fortunate that I have access to excellent medical health care. In January 2009, I entered a clinical trial looking at promising experimental new drugs for Hepatitis C. The virus rapidly became undetectable in my system and I completed treatment in December of last year. Just a few weeks ago, I received my final lab results and was told that I am cured. I happily used the past tense now when I say that I was a hepatitis patient. Sadly, still many Americans are unable to say that.

My story is the one I know best, but it is not the one that is most important to me. That would be the story of my wife and my boy, Sasha. I met my wife, Lilly, in graduate school, and shortly after we met I told her that I had Hepatitis C and explained to her what that meant and how it was transmitted. Later I explained that there was another epidemic that was silent and largely unknown to the general public, and that was Hepatitis B. I knew that among the groups at greatest risk were those born in countries where Hepatitis B is endemic. One of those countries is China. That is where my wife, Lilly, was born.

I asked her if she had ever been tested for Hepatitis C, and she said that she didn't know. I suggested that it would be a good idea for her to get tested. Eventually she did, and she learned that she had chronic Hepatitis B. Inactive, she was told, but as she got older she would need to be screened for liver cancer to make sure that, if she did develop liver cancer, it was caught early. If caught early, it is very treatable. Because she was tested, her prognosis is very good.

I would like to end my statement today on a note of optimism. There are gaping holes in this country's response to viral hepatitis. That is why we are here. There are, however, examples of successful lifesaving initiatives that we can look to for inspiration. Since the early 1990's, there has been a recommendation in the United States that all pregnant women get tested for Hepatitis B and all babies born to Hepatitis B positive women be given a series of protective vaccinations within the first 12 hours of birth.

A pregnant woman will transmit Hepatitis B to her newborn 90 percent of the time. However, if that newborn gets the series of shots, he or she will almost always develop immunity and not go on to develop chronic infection. As a result of this initiative, we have seen new Hepatitis B infections in the United States plummet since the early 1990's. Also as a result of this initiative, my little boy was given a lifesaving series of vaccinations that spared him the potential fate of dying from liver cancer.

Ultimately, that is what this is about. It is about a little boy who gets to grow up with both parents. It is about a mother and father who don't have to worry that they might outlive their children. It is about brothers and sisters and cousins and friends who don't have to bury a loved one after watching that person die a long, horrible death for end-stage liver disease or liver cancer.

I look forward to taking your questions.

[The prepared statement of Mr. Ninburg follows:]

Written Statement of

Mr. Michael Ninburg
Executive Director, Hepatitis Education Project
Seattle, Washington
and
Member, Steering Committee
National Viral Hepatitis Roundtable

Before the
Committee on Oversight and Government Reform
U.S. House of Representative

June 17, 2010

As Executive Director of the Hepatitis Education Project and a Steering Committee Member of the National Viral Hepatitis Roundtable, I respectfully submit testimony for the record for the hearing "Viral Hepatitis: The Secret Epidemic" and in response to the Institute of Medicine's recent report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C.*

Since 2001, I have had the privilege of managing the Hepatitis Education Project (HEP), a national nonprofit organization based in Seattle, Washington dedicated to improving the lives of those affected by hepatitis. HEP works with populations most affected by viral hepatitis and often least connected to the health care system. Our partners include local, state and federal agencies as well as other community-based organizations.

In this testimony, I will address the urgency of the hepatitis B and hepatitis C epidemics; the role of community-based organizations in addressing this crisis; and my personal experience.

Two Viruses, One Crisis

The urgency of the public health threat posed by hepatitis B and hepatitis C to our country cannot be overstated. More than 5 million Americans are living with chronic viral hepatitis, or almost 2 percent of the U.S. population.

Most of those living with hepatitis B or hepatitis C are unaware of their infection and often remain asymptomatic for decades. Those who remain undiagnosed can unwittingly transmit the viruses to others and unknowingly do things to exacerbate their own liver damage. Many will be diagnosed only when their liver is failing. Sadly, thirty percent or more will eventually develop cirrhosis of the liver and some of those will die from end-stage liver disease. Others will die from liver cancer.

Much of the disease burden from viral hepatitis is preventable. Hepatitis B is preventable through a simple series of vaccinations. For those who are already living with chronic viral hepatitis, the prognosis is usually very good when diagnosis is made early. Hepatitis B and hepatitis C are treatable conditions; and hepatitis C is often curable. For people to be treated for hepatitis, however, they have to be diagnosed. This remains one of our greatest challenges.

Viral hepatitis in the U.S. must also be viewed through the lens of health disparities. Hepatitis B disproportionately affects Asian Americans and Pacific Islanders (API) at rates more than twenty times that of their non-API counterparts. A staggering 1 in 10 foreign-born APIs has chronic hepatitis B. For new hepatitis B infections, there are racial, behavioral and geographic disparities. African American men and injection drug users have the highest rates of those newly infected with hepatitis B; and southern states have a disproportionate number of those new infections.

Hepatitis C disproportionately affects African Americans and Hispanics. And the majority of new hepatitis C infections occur in injection drug users. The real ticking

time-bomb, though, is the prevalence of chronic hepatitis C among baby boomers, those born between 1946 -1964. It is estimated that 2-3 million boomers are currently living with hepatitis C. Most of these men and women were infected more than 30 years ago; the overwhelming majority remains unaware of their status. For the fortunate minority who get diagnosed, many will already have advanced liver disease that is more difficult to treat and manage and leads to progressively worsening and costly health outcomes such as end-stage liver disease and liver cancer. These outcomes are preventable but not if we maintain the current programs, policies and levels of funding for prevention.

Addressing the Epidemics – the Role of Community-Based Organizations

Community-based organizations like the Hepatitis Education Project do much of the work related to viral hepatitis prevention, testing, education and referral to medical care. Programs at my agency include hepatitis A and B vaccination; hepatitis C antibody testing; a national support hotline; education programs for at-risk youth, prisoners, public health workers and medical providers. HEP also operates one of the few walk-in resource centers for hepatitis patients in the country.

Unlike many other disease states, there is very little federal support for these efforts. In FY2010, for example, the Division of Viral Hepatitis (DVH) at the Centers for Disease Control and Prevention (CDC) received $19.3 million. By way of comparison, the budget for domestic HIV prevention for the same period was more than $600 million.

Of the $19.3 budget CDC allocated in FY 2010, about $5 million went to states and some city health departments, or about $90,000 for each state and each of five cities. This is a woefully inadequate amount to address epidemics that affect more than 5 million people – less than $1 per patient per year.

As a result of this inadequate government response, organizations like the Hepatitis Education Project are vaccinating more people against hepatitis A and B, and testing more people for hepatitis C than any public health district in our state. We are proud of the work we do, but the efforts of community-based organizations like ours should complement, not substitute, the work of governmental and public health agencies.

I am hopeful that this hearing and the IOM report will help to outline and stimulate an appropriate governmental response to these twin epidemics and provide the rationale needed to increase funding for critical programs and services.

Two Viruses, One Family

Until very recently I was a hepatitis patient, an experience that is often fraught with uncertainty. When I was diagnosed with hepatitis C relatively little was known about the virus.

Hepatitis C was only discovered in 1989, and from the early through the late 90's this new epidemic was often compared to HIV except that it attacked the liver, not the

immune system. Through the mid-90's, reports about hepatitis C grew increasingly dire. People with hepatitis C were dying from their disease. Some people were lucky enough to get a liver transplant, but that was thought to just delay the inevitable.

I sought medical care for my hepatitis C in 2000. By then, the medical community had a better understanding of the natural history of the disease, but there was still much that they did not know. In 2002, I had a liver biopsy which showed that I had some liver damage, but not enough to warrant immediate treatment. I had the kind of hepatitis C that responded to treatment about 50% of the time. With newer, more effective treatments thought to be commercially available within 5 years I decided to wait for the next class of drugs and in the meantime monitor the health of my liver. Five years came and went and so did the expected due date for the next class of drugs. Now, I was looking at 2010 at the earliest. I had my second liver biopsy in 2007 and the results were not what I wanted to hear. My liver damage was progressing and if I didn't do something, it was likely that I would progress to cirrhosis relatively soon. Once I had progressed to cirrhosis, there would be other potential complications.

In January, 2009, I was very fortunate to enter a clinical trial looking at a promising experimental new drug to treat hepatitis C. The virus rapidly became undetectable in my body and I completed treatment in December, 2009. Just last month I received my final lab results and learned that I am cured. I happily use the past tense now when I say that I *was* a hepatitis patient.

I talk about my hepatitis story because it the story I know best. It is not, however, the story that is most important to me – that would be the story of my wife, Lily, and our little boy, Sacha. Shortly after I met Lily, I told her that I had hepatitis C and explained to her what that meant and how it was transmitted. Later I explained that there was another epidemic that was equally invisible to the general public – hepatitis B. I knew that among the groups at greatest risk were people born in countries where hepatitis B is endemic. One of those countries is China – where Lily was born. I asked Lily if she had ever been tested for hepatitis B and she said she didn't know. I suggested that it would be a good idea to find out her status. She didn't seem to think it was that important. After some cajoling - and close to another year - Lily was tested for hepatitis B. The results showed that she had chronic hepatitis B, likely contracted at birth from her mother. Fortunately it was inactive, the doctor said, but as she gets older she would need to be monitored regularly and checked for early signs of liver cancer. She took the news almost as stoically as she had when I suggested she get tested in the first place.

Confronting the Crisis – A Time for Leadership

I would like to end this testimony on a note of optimism. There are gaping holes in this country's response to viral hepatitis – that's why we're here. There are, however, examples of successful, life-saving initiatives we can look to for inspiration. Since the early 90's there has been a recommendation in the U.S. that all pregnant women get tested for hepatitis B, and all babies born to hepatitis B positive mothers be given a series of protective vaccinations beginning within 12 hours of birth. A pregnant woman with

hepatitis B will transmit the virus to her newborn about 90% of the time. However, if the newborn gets this series of shots, including the hepatitis B vaccine, the child will almost always develop immunity and not develop chronic hepatitis B. As a result of this initiative, we have seen new hepatitis B infections contracted in the U.S. plummet. Also, as a result of this initiative, my little boy was given life-saving vaccinations that spared him the potential fate of dying young from complications related to chronic hepatitis B.

I am encouraged by recent events that show a growing awareness of this public health crisis. Promising developments include the IOM report on Viral Hepatitis and Liver Cancer, the introduction last year of the Viral Hepatitis and Liver Cancer Control and Prevention Act (HR 3794) and the new Interagency Workgroup on Viral Hepatitis headed by Asst. Secretary of Health Koh.

We have an opportunity and we have a responsibility to use this momentum and act now. It should be a collaborative effort – government, industry, payors, health care providers, advocates and patients – but government needs to lead. We need strong leadership within the U.S. government to coordinate a comprehensive response that uses the information we have now, seeks to collect additional information on best practices and effective interventions and implements nationwide programs that include and build upon the core elements of public health to provide information, services and referral into quality care for everyone at risk for, and infected with, hepatitis B and hepatitis C. If we wait, hundreds of thousands of Americans will die unnecessarily premature deaths. If we act now, we can save many of those lives.

Chairman TOWNS. Thank you very much.

Dr. Levi.

STATEMENT OF JEFFREY LEVI

Dr. LEVI. Thank you, Mr. Chairman and members of the committee. I am Jeff Levi. I am executive director of trust for America's Health. We are a nonprofit, nonpartisan advocacy organization.

As you have heard this morning, hepatitis is, in a sense, a ticking time bomb. Over 5 million people in the United States are infected with Hepatitis B or C and an estimated 65 percent to 75 percent are not aware of their status, putting them at risk for developing chronic hepatitis, liver cancer, cirrhosis, or late stage liver disease.

With promising new treatments on the horizon, that could dramatically improve our chances for effectively treating these individuals. We have a moral obligation to make sure that all who can benefit know their status and have access to the care and the end result that Mr. Ninburg had.

However, this is more than a moral argument. It is also a practical financial issue for our reforming the health care system. The direct annual medical costs associated with HBV and HCV have been estimated at $7.6 billion. If we continue down the present course of late identification of people with viral hepatitis and, therefore, advanced disease upon entering treatment, the cost to the health care system will continue to grow.

Indeed, one study has estimated that annual medical costs for Hepatitis C alone could increase to $85 billion a year in 20 years, with Medicare taking on 39 percent of those costs. If we undertake aggressive actions such as those I am about to outline, we can dramatically change that equation for the better.

The United States needs a comprehensive policy response to this problem, and I am hopeful that the panel chaired by Dr. Koh, when they release their report in October, will include at least some of these elements.

First, we need much better situational awareness and surveillance. We do not have sufficient data regarding the scope of the problem and who is affected. This affects not only our ability to prevent and treat disease, but it also creates a vicious cycle of inadequate evidence to support greater public resources to address the problem.

Second, we need to routinize screening for Hepatitis B and C so hepatitis-positive individuals learn their status and are linked to appropriate care. For HBV, providers and patients need to have better awareness of who is at risk and assure they get screened, including all pregnant women. For Hepatitis C, it is time to move to include nation of birth and age, not just behavioral factors. As we heard earlier this morning, it should not strictly be behavioral factors as the basis for screening, as many adults are unaware that the behaviors of their youth have put them in danger of infection.

Third, we must assure that the reformed health care system provides quality prevention and care for hepatitis, from screening and preventive services mandated for all plans, to HHS putting in place the appropriate policies that guarantee quality care for people with hepatitis. With health reform and near-universal coverage, it really

means that people will have the opportunity to take advantage of these new treatments.

Fourth, we must assure that people stay in care with appropriate support services that will assure adherence to treatment. These services are especially important for marginalized populations such as immigrants, incarcerated individuals, or injection drug users. Although many of the adherence issues are similar, our health care system has been much more effective at assuring adherence for HIV than for Hepatitis C. This is in part due to the additional services supported by the Ryan White Program. Just as with HIV, there is a strong public health rationale for assuring successful completion of hepatitis treatment with these kinds of support services.

Fifth, as we focus on assuring treatment, we must also remember that there are major opportunities for primary prevention of hepatitis. We continue to see pockets of outbreaks of Hepatitis B and Hepatitis C. We must close the gaps in Hepatitis B vaccination coverage and use all educational and structural tools at our disposal to prevent transmission of Hepatitis C. This includes Federal funding of syringe-exchange programs. While we are delighted that Congress has lifted the ban on States and localities opting to use exchange programs as part of their fight against hepatitis and HIV, we are disturbed by the delay in HHS issuing guidance to implement this change in policy.

Sixth, within the area of primary prevention, we have within our reach the capacity to virtually eliminate mother-to-child transmission of Hepatitis B. One thousand newborns in the United States become needlessly infected with Hepatitis B each year. HRSA, CMS, and CDC must all work to incentivize routine HBV screening of all pregnant women and assure appropriate interventions with newborns.

Finally, there needs to be an increased emphasis on research. In addition to research for better treatments, we desperately need to understand the reason for the disparate response to HCV treatments. African Americans have the highest rates of Hepatitis C in the United States, more than twice that of Whites. Yet, treatment is nearly half as effective in African Americans as compared to the general population. We need to require that clinical trial cohorts are diverse enough to assure that we know the safety and efficacy of new treatments for all who are affected by hepatitis.

We are at a critical juncture in our Nation's fight against hepatitis. New treatments offer great promise. Reforming the health care system will improve coverage and access and, in the case of Hepatitis B, we have a vaccine that could effectively eliminate it.

Chairman TOWNS. Doctor, could you summarize?

Dr. LEVI. The question remains whether, as a Nation, we will seize this moment. Thank you.

[The prepared statement of Dr. Levi follows:]

U.S. House Committee on Oversight and Government Reform
Hearing on "Viral Hepatitis: The Secret Epidemic"
Testimony of Jeffrey Levi, Ph.D.
Executive Director, Trust for America's Health
June 17, 2010

Thank you, Mr. Chairman. My name is Dr. Jeffrey Levi and I am the Executive Director of Trust for America's Health a nonprofit, nonpartisan public health advocacy organization. I am grateful for the opportunity to be here today to discuss a major, yet largely silent public health crisis, viral hepatitis.

My testimony today builds on the foundation laid by the recently released Institute of Medicine (IOM) report and the work of other leaders in the field, especially the American Association for the Study of Liver Diseases (AASLD) and the National Viral Hepatitis Roundtable (NVHR). Today's testimony also reflects the tremendous expertise shared with TFAH by an expert panel we convened last month. TFAH's principal funding for its public health work comes from the Robert Wood Johnson Foundation and the Kellogg Foundation. We are particularly grateful to AASLD for their support of our hepatitis prevention initiatives.

Overview

Hepatitis is a ticking time bomb. Millions of people in our country are infected with the virus, yet, unfortunately, are not aware of their status, putting them at risk for developing chronic hepatitis, liver cancer, cirrhosis, or end-stage liver disease. The lack of appropriate and timely attention of the health care and public health systems to adequately prevent, identify, and treat hepatitis threatens the lives of individuals and looms as a great threat to the future fiscal stability of our health care system.

To be more precise: The Centers for Disease Control and Prevention (CDC) estimate that as many as 1.4 million individuals in the U.S. have hepatitis B (HBV), yet 65 percent are unaware of their status.[1] An additional 3.9 million are estimated to be infected with hepatitis C (HCV), yet 75 percent are believed to be unaware of their status.[2] This translates into almost 4 million people infected with a contagious disease who are unaware of their status, could inadvertently transmit the virus, and – even more tragically – are not being monitored and offered the opportunity to take advantage of existing treatment the could prevent or delay the onset of the tragic sequelae of hepatitis infection. With promising new treatments on the horizon that could dramatically improve our

[1] *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, Heather M. Colvin and Abigail E. Mitchell, Editors; Committee on the Prevention and Control of Viral Hepatitis Infections; Institute of Medicine. 2010. p. 1. Available from: http://www.nap.edu/catalog/12793.htmlp. 2
[2] Ibid, p. 1.

chances for effectively treating these individuals, we have a moral obligation to make sure that all who can benefit know their status and have access to them.

However, this is more than a moral argument. It is also a practical financial issue for our reforming health care system. Although difficult to determine, the direct annual medical costs associated with HBV and HCV infections have been estimated at $7.6 billion.[3] If we continue down the present course of late identification of people with viral hepatitis – at the point where they are symptomatic and often suffer from late-stage liver disease – the costs to the health care system will continue to grow. Indeed, one study has estimated that the medical costs of HCV alone could increase to $85 billion in 20 years, if all who are infected are in care, with Medicare's taking on 39 percent of those costs.[4] If we undertake aggressive actions, such as those I outline below, we could dramatically change that equation for the better. One modeling effort showed that if we expanded Medicaid coverage to all low-income people with hepatitis B and assured early and appropriate treatment, we could save money in the long run due to the number of liver transplants and end-stage liver disease treatment that would be prevented.[5]

Recommendations

The following recommendations represent an attempt to offer a comprehensive policy response to the problem and continuous threat of hepatitis. Many come at no additional cost to the federal government by simply working within existing authorities. Others require a modest investment in public spending but would greatly enhance our knowledge and response. And some would require a significant yet much-needed investment of federal dollars. But we have a choice: we can invest in prevention and early treatment now – and avoid new infections and the very costly specter of viral hepatitis left untreated – or we can delay our investment, incur far greater cost, and cause avoidable disease, disability, and suffering for millions of people in our country and their families.

Together, these recommendations address three important public health goals: (1) assuring that our public health and health care delivery systems are ready for the new, more effective treatments for hepatitis that are on the horizon. This will ensure that all individuals in the U.S. with hepatitis can benefit from improved health outcomes; (2) assuring that the current disparities associated with hepatitis are appropriately addressed; and (3) reducing the financial impact of hepatitis on our health care delivery system.

Let me now outline some key areas where federal policy change is critical:

1. We need much better situational awareness and surveillance. We do not have sufficient data regarding the scope of the problem and who is affected. This

---

[3] IOM, 2010, p. 25.

[4] Pyenson, B. et al. "Consequences of Hepatitis C Virus- Costs of a Baby Boomer Epidemic of Liver Disease," May 2009. Milliman, Inc. (Report commissioned by Vertex Pharma. Inc.)

[5] Smith, Vernon. "Medicaid Hepatitis Expansion Project – Overview of Findings," Health Management Associates. Presented at *The Dawn of a New Era: Transforming Our Domestic Response to Hepatitis B&C*, September 10-11, 2009. Washington, DC.

affects not only our ability to prevent and treat disease, but it also creates a vicious cycle of inadequate evidence to support greater public resources to address the problem. For example, although HBV and HCV kill as many or more Americans as HIV every year, the disease receives less than two percent of the budget for the National Center for HIV, Viral Hepatitis, STD, and TB Prevention.[6]

We do not need to create a new surveillance system to track hepatitis. Viral hepatitis can be built into the existing, robust HIV/STD surveillance system. While the diseases are different, many of the risk behaviors and affected populations overlap enough to make this expansion feasible. We also need a functioning sentinel surveillance system, where selected facilities report infection rates, so we can identify new pockets of infection and know where to target new primary prevention efforts.

2. We need to routinize screening for hepatitis B and C. As many as 65-75 percent of people with hepatitis are unaware of their status. We must and can do better to address this problem. We have already done so in the HIV arena, where CDC estimates that only 20 percent of people with HIV infection don't know their status.[7] For HBV, providers and patients need to have better awareness of who is at risk and assure they get screened, including all pregnant women. For HCV, it is time to move from screening only those deemed at risk to include nation of birth and age, as many adults are unaware that the behaviors of their youth may have put them in danger of infection. Health IT would be an excellent mechanism for enabling providers to screen for hepatitis and to remind providers about vaccine history.

3. We must assure that the reformed health care system provides quality prevention and care for hepatitis. HBV and HCV screening should be the standard of care in the reformed health care system, and we must significantly improve HBV vaccination until we reach 100 percent coverage. This should include defining hepatitis screening as an essential benefit under the new health exchanges. Providers must be assured they will be properly reimbursed for preventive services, screening, and referral to appropriate treatment, and there needs to be an expansion of training of the health care workforce to screen, identify, and treat viral hepatitis. HHS should begin now to establish the standards of prevention and treatment that will be required of all public and private plans.

4. We must also assure that people stay in care, with appropriate and culturally and linguistically sensitive support services that will assure adherence. Treatment requires a continuum from the point of screening throughout care, as there is a high risk for falling through the cracks. This is especially relevant when working

---

[6]Centers for Disease Control and Prevention Congressional Budget Justification, FY 2011. http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2011_CDC_CJ_Final.pdf

[7] CDC. HIV prevalence estimates – United States, 2006. MMWR 2008; 57(39):1073-76.

with marginalized populations, such as immigrants, incarcerated individuals, or injection drug users. Although many of the adherence issues are similar, our health care system has been much more effective at assuring adherence for HIV than for HCV. This is in part due to the additional services supported by the Ryan White Care program. Just as with HIV, there is a strong public health rationale for assuring adherence to and successful completion of hepatitis treatment. Expanding the mission of the Ryan White Care program, which currently services people with hepatitis who are co-infected with HIV but not those only infected with hepatitis, may be one approach to assuring access to these critical services. This proposal is not as burdensome as it may seem, because, unlike HIV, the course of treatment and services for HCV is time limited. And it is worth noting that the Ryan White Care program has been successful in reducing disparities in outcomes because of the support it provides.

5. As we focus on assuring treatment, we must also remember that there are major opportunities for primary prevention of hepatitis. We continue to see pockets of outbreaks of hepatitis B and hepatitis C. We must close the gaps in hepatitis B vaccination coverage, and we must use all educational and structural tools at our disposal to prevention transmission of hepatitis C. This includes federal funding of syringe exchange programs (SEPs). While we are delighted that Congress has lifted the ban on states and localities opting to use SEPs as part of their fight against hepatitis and HIV, we are very concerned that the Department of Health and Human Services has not yet issued guidance to their grantees about how they may use their federal funding for SEPs. These should be issued without delay so that jurisdictions can use FY 2010 money for this lifesaving intervention.

6. Within the area of primary prevention, we have within our reach the capacity to virtually eliminate perinatal – or mother to child – transmission of hepatitis B. CDC estimates that 1,000 children born in the U.S. to HBV-positive mothers will develop chronic HBV infection each year.[8] Yet transmission of HBV from mothers to newborns is entirely preventable. HRSA, CMS, and CDC must all work to incentivize routine HBV screening of all pregnant women, pregnancy testing of HBV-positive women, and first HBV vaccination to all newborns within 12 hours of birth and treatment protocols of newborns born to HBV-infected women.

7. Finally, there needs to be an increased emphasis on research. In addition to research for better countermeasures, such as a single-dose HBV vaccine or more effective treatments for HCV, we desperately need to understand the reason for the disparate response to HCV treatments. African-Americans have the highest rates of HCV in the United States, more than twice that of whites,[9] yet treatment is nearly half as effective in African-Americans as compared to the general

---

[8] Ward, J. W. 2008b. "Time for Renewed Commitment to Viral Hepatitis Prevention." *American Journal of Public Health* 98(5):779-781.
[9] IOM, 2010, p. 2.

population (28 percent success rate versus 50 percent).[10] We need to require that clinical trial cohorts are diverse enough to assure that we know the safety and efficacy of new treatments for all who are affected by hepatitis.

Conclusion

We are delighted that the federal government, under the leadership of Assistant Secretary for Health Koh, is developing a national strategy for hepatitis, and we hope it will reflect the comprehensive effort that the problem demands. We are at a critical junction in our nation's fight against hepatitis. New treatments offer great promise; a reforming health care system will improve coverage and access; and, in the case of hepatitis B, we have a vaccine that could effectively eliminate it. The question remains whether as a nation we will seize this moment to prevent and reduce needless suffering for millions of people in our country and their families.

I thank you for the opportunity to discuss this issue with you today, and I look forward to your questions.

[10] *Hepatitis C: The Importance of Screening for this Silent Disease*, Isaac Itman, HHS Office of Minority Health. Available from: http://minorityhealth.hhs.gov/templates/content.aspx?ID=5116

Chairman TOWNS. Thank you.

STATEMENT OF ROLF JOACHIM BENIRSCHKE

Mr. BENIRSCHKE. Mr. Chairman, my name is Rolf Benirschke. committee, thank you so much for having us out here. I am a little tired. I look tired; I apologize for that. I took the Red Eye out this morning from San Diego; arrived, shaved in the airport, changed clothes, and am thrilled to be here. I am thrilled because of what you are doing.

In a former life I was a kicker. For 10 years I was a kicker for the San Diego Chargers; played under Don Coryell, the Dan Fouts' years. As a kicker, my job was usually to come in at the end of the game and sort of try to kick it through the uprights.

Today we have heard three panels of incredibly distinguished, knowledgeable people share with you all of the issues. They are out on the table; we know them. My job today is to share with you from a patient's perspective how this virus actually occurs.

By way of background, I am an immigrant's son. My dad came over, learned the language, ended up going to Harvard, ended up teaching at Harvard, became a world-renown pathologist; left Hartford to go to Dartmouth and moved our family to San Diego, where he teaches at the Medical School at UCSD. I have been around academic medicine my entire life. But I am the black sheep of the family. My older brother is an orthopedic surgeon and I was drafted into the NFL. My dad wondered where he went wrong. [Laughter.]

Things changed, though. In my second season with the Chargers, I came down with an illness, originally diagnosed as having Crohn's Disease; it was later amended to ulcerative colitis. But it would require four major abdominal surgeries, two within 6 days of each other, and my weight dropped from 187 pounds to 120 pounds and I wasn't supposed to live. I needed 80 units of blood to survive. That same blood, I would find out 12 years later, that saved my life put my life in jeopardy.

I was able to return to the game, played seven more seasons, wore an ileostomy bag for four of those years and became very involved in raising awareness for people with inflammatory bowel disease and those facing ostomy surgery. I learned that one person can make a difference.

Fast forward my life to getting married and having children. Twelve years ago, after adopting two children and having one, we had our fourth, and I went in for a routine life insurance exam and was told by one carrier that I had a preferred rating, but the other carrier called me and said your liver enzymes are slightly elevated, we would like you to get retested. Feeling good, in good shape, continuing to work out, I was not worried in the least; went and got reexamined. Was brought into the physician's office and, like a 2 by 4 to my head, I was told I was infected with the Hepatitis C virus.

At that moment, I was scared to death. My previous illness just involved me and my silly career. This illness now affected a wife and four kids who were depending on me, and it became real. I felt like I was handed a death sentence; didn't know anything about the virus, felt unclean. How did I get it? Decided to take my family on a 6-week trip. We rented a motor home and drove around the

west of the United States, Grand Canyon, visited a bunch of scenic places. Built some memories, scared that this might be the last time I had with my family. But at the end of that trip came back and, with my wife, made a commitment to understand as much as I could about this virus and fight it.

Fortunately, I was under good medical care; found a hepatologist who was as passionate about fighting this disease as I was about getting rid of it, and I started on a clinical trial. That was 12 years ago. That clinical trial cleared the virus while I was on the treatment, but a month after going off the treatment the virus came back. That trial involved a daily injection of interferon, coupled with an antiviral pill.

After getting the news that I had had the virus come back, my physician sat with me and said there is another molecule out there, a different interferon molecule. If you are willing, I think you should go on treatment. So 3 months later I went on a second course of treatment; daily injection, maximum dose, antiviral pill, and went through all the side effects for another year. Cleared the virus while I was on the treatment, and then a month after going off the virus came back.

Now twice defeated, but buoyed by the knowledge that my reason for going on treatment was still there, a wife and four children, I waited. Now, fortunately, there are other people that have joined our fight, like the government is joining our fight now. There are pharmaceutical companies out there that are advancing research, and 4 years later there was a new treatment, a pegylated interferon, one that required a weekly injection instead of a daily injection; better understanding of how the virus is fought. I went on that treatment. It was a year-long treatment coupled with an antiviral. The 1-month post test came back clear. The 3-month post test came back clear.

Chairman TOWNS. Mr. Benirschke, I am going to have to ask you to summarize, and the problem is, if I don't, I will have to ask you to wait an hour and 45 minutes before we come back.

Mr. BENIRSCHKE. I don't want to do that, sir.

Chairman TOWNS. OK.

Mr. BENIRSCHKE. I will summarize. [Laughter.]

Chairman TOWNS. I figured that would encourage you.

Mr. BENIRSCHKE. Yes. The 6-month treatment came back virus-free, which means I am free of the virus. I am cured.

I am here to thank you for what you are doing. I am here to support all of the things that have been spoken about, the need to raise awareness. Not just raise awareness; to get screened, raise awareness, and then to do something about it. We have, as Congressman Bilbray suggested, a great opportunity to make a difference. There are treatments out there and I just want to thank you again on behalf of all of us for what you are doing.

[The prepared statement of Mr. Benirschke follows:]

Rolf Benirschke story

Alive & Kicking

When Rolf Benirschke learned that he had become infected with hepatitis C from blood transfusions he had received in 1979, the deadly virus re-awakened the same passion and commitment to fight back as when he fought for his life and his budding NFL football career twenty years earlier. This new challenge was different, though, because he had a lot more at stake—his family.

After Rolf and Mary Benirschke's fourth child, Ryan, arrived in 1998, he did what any prudent father would: he sought the purchase of more life insurance to protect his family . . . just in case the unthinkable happened.

The insurance company set up the normal medical exam and blood test. All routine. But when the insurance carrier came back and said they wanted to do another blood test before they issued the coverage, Rolf inquired why. He was told that his AST and ALT liver enzymes were slightly elevated, probably nothing to be worried about, but they wanted to run another test to be sure.

Rolf was curious about this development but felt fine. He submitted to the follow-up test because he still wanted the extra life insurance. When the results came back, he was told to set up an appointment with his family doctor, who got down to business right

away. The news was not good, he said. "Rolf, it appears you have been infected with the hepatitis C virus."

The doctor's unemotional statement hit Rolf—a former kicker in the National Football league—like a blind-side tackle. His shock quickly turned to fear—not just for himself but also for what this news might mean for his family. He was the father of four children under the age of six—and two were adopted from Russia with special needs. Didn't people die from having hepatitis C? How could Mary cope without him?

Rolf remembered reading something about the virus in the newspaper and the growing number of people suddenly discovering they were infected, but that was as far as his knowledge went.

"What does this mean?" he asked hesitantly, not sure if he was going to like what he was about to hear.

"Hepatitis C is a virus that gets into the bloodstream and attacks the liver," his doctor explained. "It was formally identified in 1989, and a year later the first hep C antibody test was developed. Prior to that, physicians knew something was out there. They were calling it non-A or non-B hepatitis because it attacked the liver and acted like hepatitis. A more specific screen was developed in 1992, and that's when most blood banks and testing facilities began thorough screening. Today, our blood supply is very safe, but before the implementation of that test, many people who received blood unknowingly became infected with the virus."

Rolf buried his face in his hands. He must've been one of those who had become infected with hepatitis C accidentally. Back when he was kicking for the San Diego

Chargers, he had undergone emergency surgery during the 1979 season following a near-fatal battle with ulcerative colitis.

During the course of two major abdominal operations six days apart, Rolf needed 78 units of blood to keep him alive—blood that hadn't been screened for hepatitis C, or HIV for that matter. "The only bright side to this, Rolf, is that you didn't contract AIDS," said his doctor. "Remember, we weren't testing for the HIV virus back in the late 1970s either."

Rolf sat in the doctor's office, stunned at this new diagnosis, unable to fully grasp what he had just been told. He felt like he had just been handed a death sentence. He struggled to understand the significance of what it meant to him and his family. His mind began racing a million miles a minute.

This must be a mistake. I feel fine, work out all of the time, and don't have any symptoms that anything is amiss. In a minute, the doctor's going to tell me they probably messed up the blood test and that I have nothing to worry about.

But that scenario didn't happen. Instead, Rolf's doctor proceeded to tell him that hepatitis C was mostly associated with IV drug use, where infected blood is passed by the sharing of dirty needles. He also explained that emergency responders or military personnel working around blood and open wounds, as well as medical workers stuck by needles during operations, could also become accidentally infected. The other common way to get the disease was through blood transfusions.

"Listen, thank you for your time," Rolf told his doctor, still trying to process the grim news. "I'm going to have to talk with my family about where we go from here."

"I understand. Please let me know how I can help," his doctor responded.

4

Feeling Tired

On the drive home, a wearying sense of dread fell over Rolf—the same dread that had dogged his steps twenty years earlier when he was first told he had ulcerative colitis . . . another disease he knew nothing about. His doctor had asked if he had been unusually fatigued lately, a common symptom sometimes associated with hep C. He had responded, "Of course, Doc. With all the needs of our young kids, I am fatigued, my wife is fatigued, but so are most of our friends trying to balance being good parents and working. That certainly isn't a symptom that I would've noticed."

When he got home and told Mary the difficult news, she was just as shocked and concerned as he was. Their future was suddenly very uncertain, and they needed some time to process this together. What they first read about the virus was not promising, so they decided the time was right to get away as a family and quickly build some memories with the kids since they weren't certain what the future held.

So Rolf and Mary rented an RV and charted a six-week trip around the Southwestern U.S. They visited the Grand Canyon, Bryce and Zion National Parks, circled back through Utah and the Nevada desert, and motored down through the gold country of California back to San Diego. It was an emotional time, and Rolf and Mary shared a lot of hugs and tears but made a decision that they would take on this new challenge like they every other challenge they had faced before . . . *together*.

As they traveled, they voraciously read about the virus and what a couple should do when one was infected. They learned they should be especially careful *not* to share razors, toothbrushes, or even nail clippers. All three hygiene practices were no-no's since

hepatitis C was passed "blood to blood." Even though sexual contact with a monogamous partner was not considered a high-risk activity, they decided that Mary should get tested. When they returned home, Mary was tested and found to be free of the virus, greatly relieving the couple.

Rolf set a meeting up with a highly recommended hepatologist, Dr. Tarek Hassanein at the University of California at San Diego, to get educated, evaluate his options, and figure out what to do next. Dr. Hassanein recommended that Rolf should go on a new clinical trial that was being initiated with an interferon molecule that was the treatment of choice at the time.

The trial called for daily maximum dose injections of interferon that Rolf would self-administer for one year, as well as taking a daily antiviral pill. He was warned that the side effects could be quite difficult, so much so that he was strongly urged to go on an anti-depressant drug as well. There were studies indicating that some patients had such a hard time dealing with everything that they contemplated suicide.

The difficult side effects were as awful as advertised. Rolf experienced severe fever with violent shaking chills during the first week of treatment. This was followed by red skin rashes, his hair thinning out, eye sensitivity, nasal infections, and extreme fatigue and irritability over the next twelve months. But he was determined to see this through and not miss an injection while continuing to work.

Those brutal days left him exhausted. He'd often come home from work and fall into bed, telling Mary that he was sorry that he couldn't help her with dinner or the kid's homework.

Somehow, they endured and were encouraged when Rolf's viral loads kept coming back negative. But a year's worth of treatments left him physically and mentally worn out and 20 pounds lighter. When his blood was checked one month after finishing the treatment, however, Rolf and Mary received devastating news: the hepatitis C virus had returned.

Instead of being out of the woods, Rolf was deeper in the weeds.

The Silent Killer

The Benirschkes were not going to give up. Dr. Hassanein encouraged Rolf to go back on treatment three months later with another interferon molecule that had also shown promise.

The second treatment was much like the first: the same physical side effects and the same emotional year-long roller coaster, but at least Rolf and Mary knew what to expect. Knowing how important it was to stay as active as possible and gain some weight, several close friends supported Rolf by meeting three mornings a week from 6-7 a.m. to work out with him and build up his conditioning and morale.

Unfortunately, another year's worth of treatment, though initially promising, netted the same result: the hepatitis C virus returned after going off the drugs.

The only bright side of two years of failed treatments was that Rolf at least knew where he stood . . . that he was infected and needed to be cautious about infecting anyone else. He knew that he could not even take a sip of alcohol or anything else that might further damage his liver.

7

Rolf learned that there were an estimated four million Americans and 170 million people worldwide infected with this serious form of liver disease. Most in the U.S. were Baby Boomers, and as many as 80 percent of them didn't know they had hepatitis C. Since many were fooled by the lack of symptoms, hepatitis C earned the label of the "silent killer."

Worn out from two rounds and two years of energy-sapping treatment protocols, Rolf needed to take a break. Four years later, a new form of interferon called pegylated interferon appeared on the horizon. This latest form of interferon was slower to break down in the body, thus keeping the treatment dose higher in the patient's blood. According to trials, the success rate for achieving a negative sustained viral rate (SVR) jumped from around 20 percent to mid-to-high 40 percent. Injections were needed weekly, not daily.

Even though four years had passed since Rolf's last treatment had failed, his need for a cure hadn't lessened. He still had a wife and four kids depending on him, and he still wanted to avoid the unpleasant prospect of reaching end-stage liver disease and needing a liver transplant to save his life.

The decision was made to again go on treatment for a year. Many of the unwanted side effects returned, but Rolf was familiar with ways to manage them. With optimism created by the knowledge of other patients who had become viral-free, a stronger body from four years of early morning workouts, and a supportive physician, Rolf stayed the course for another long year.

One month after finishing treatment, his blood test came back negative for hepatitis C, which was encouraging—but not a final resolution. When Rolf returned for

the all-important six-month test, he kept his expectations low, just in case. When the doctor's assistant called and explained that the lab had lost his results and that he had to be re-tested, his anxiety heightened.

Did they really lose the test, or are they just trying to make sure before they deliver me bad news? he wondered. It was a nerve-wracking time, but all he could do was wait. When the call finally came, Dr. Hassanein was on the line while Rolf was driving home from a meeting.

Rolf's initial thought when he heard his doctor's voice was whether this was a good or bad sign. Good news was usually relayed by his support staff; Dr. Hassanein would only call if there was bad news to explain. So Rolf was caught off guard when he heard his doctor declare, "Rolf, I've got great news. All of your hard work and persistence has paid off. You are virus free!"

The good news overwhelmed him; tears of relief streamed down his face, and he had to steer his car to the side of the road so that he could compose himself. "Thank you, Doctor. Thank you, Doctor," he repeated several times between deep-wrenching sobs.

Then he called Mary, and he broke down again, as she did, both so relieved that the burden they had been carrying for so many years was now lifted.

Addressing Hepatitis C Head-On

Since that event in 2004, Rolf has remained virus-free, and today is committed to helping spread the word about hepatitis C and the need for people to get tested. He believes strongly that the fear of stigmatization or the absence of symptoms shouldn't keep people from addressing the virus head-on.

To help others who are infected with hepatitis C, Rolf has created a national patient-support and awareness program called "Kick Hep C." The program is designed to reach high-risk groups where hepatitis C may be present and provide information, inspiration, and motivation to get tested and seek treatment if necessary. For more information on Kick Hep C, please visit www.KickHepC.org.

"I'm so thankful that there are companies out there who are joining the fight against hepatitis C and spending time and research on finding new treatment options," Rolf said. "There is too much at stake for us to just bury our heads and pretend the problem doesn't exist. The cost to human life and to our health care system is going to be dramatic if we don't come together to do something about this silent killer."

"I can't tell you what it means to me and my family to have a clean bill of health, and that's something I want everyone with hepatitis C to experience."

sidebar

Rolf Benirschke

Age: 55

Hometown: Del Mar, California

Family situation: He and his wife, Mary, are the parents of Erik, Kari, Tim, and Ryan.

Former occupation: ten-year placekicker for the San Diego Chargers from 1977-86, where he was an NFL Pro Bowl player, winner of the NFL's "Man of the Year" award and NFL Comeback Player of the Year, as well as being elected to the San Diego Chargers Hall of Fame.

Present work: nationally recognized author, speaker, and founder of Legacy Health Strategies, a company dedicated to creating patient support and awareness programs for pharmaceutical and medical device companies.

Contact information: TK

Chairman TOWNS. I want to thank all of you for your testimony.

Let me say to the Members we have a business meeting, and if we can start right now, we can actually do it and it would be over, and then go and vote. That way we won't have to come back in an hour and 45 minutes or 2 hours. So, if that is OK, we will move forward.

Let me thank you again for your testimony. We will probably ask questions for the record, but we are going to have to break at this time because of our voting schedule. So thank you very much, Dr. Mayer, Mr. Ninburg and Dr. Levi.

Ms. WATSON. Mr. Chairman.

Chairman TOWNS. Yes.

Ms. WATSON. May I make one comment? Because the next bill is mine.

Chairman TOWNS. Yes.

Ms. WATSON. I just want to say the major research on interferon has been done down at the medical school and hospital in Cuba, and that is what is sustaining the life of Fidel Castro who had stomach cancer and was expected to die. So had he been able to come to the international research forums and been invited, we would have had interferon in use in clinical trials and other places in our country. So thank you so much.

Chairman TOWNS. Thank you, gentlelady from California.

This panel is actually dismissed. Thank you for coming and your testimony. We do not want to hold you an hour and 45 minutes, so we are going to let you go now. OK? Thank you. You can be excused.

The hearing is now adjourned.

[Whereupon, at 12:47 p.m., the committee was adjourned.]

[The prepared statements of Hon. Jackie Speier and Hon. Anh "Joseph" Cao and additional information submitted for the hearing record follow:]

Opening Statement by Congresswoman Jackie Speier

Committee on Oversight and Government Reform

June 17, 2010 Hearing: "Viral Hepatitis: The Secret Epidemic"

Mr. Chairman and Members,

Today, we have a huge opportunity to address two silent but devastating epidemics in our country- the spread of hepatitis B and C. These two viruses kill more than 15,000 people in our country every year, now surpassing the deaths of those with HIV/AIDS. Their impact in terms of lives and costs to the healthcare system will continue to grow unless we increase awareness of Hep B and C and take strong and decisive action to address this growing healthcare crisis. It is my hope that this hearing will be a first step in committing the same determination to this public health crisis as we did the HIV/AIDS crisis more than two decades ago.

Each and every year, more than 50,000 people with chronic hepatitis B infections immigrate to the United States- a disease that causes nearly 80% of primary liver cancer and nearly 60% of liver cirrhosis deaths worldwide. Tragically, because the disease is largely asymptomatic and more than 65% of those infected have not been tested, tens of thousands of Americans are not adjusting their lifestyles or receiving the treatments that could add years to their lives. As many as 1 in 10 Asian Americans are infected with hepatitis B and the infection rate in San Francisco, a portion of which is in my district, is an astounding fifty percent higher than the national average.

The implications of these diseases are not isolated to those infected and their loved ones, but also to the financial future of our country. Two-thirds of those infected with Hep B and C in the U.S. today are baby-boomers who will soon be eligible for Medicare. Since each liver transplant costs $150,000-$400,000, the costs to our country will be absolutely crushing if we do not increase the levels of the diagnosed and their levels of treatment.

The magnitude of the Hepatitis B and C viruses dwarfs the resources we are currently devoting to prevention and treatment. While the CDC funds Adult Viral Hepatitis Prevention Coordinator positions in forty-five jurisdictions, each

jurisdiction receives an embarrassing $90,000 per year- barely enough money to cover one full time position. It is unacceptable that while the prevalence rate for Hepatitis B and C are five times higher than for HIV/AIDS, only two percent of the National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis prevention budget is devoted to these diseases, while 69 percent of the same budget is allocated to HIV/AIDS programs.

Through prenatal screening we know that nearly 25,000 Hepatitis B infected women give birth in our country each and every year. Yet, because state and local prevention programs do not have the capacity to ensure that all exposed newborns receive a dose of hepatitis B vaccine within their first three days of life, more than 1,000 children become infected annually. We must do more.

I commend the Chairman for calling this hearing. Today is the day we can and must turn the corner on Hepatitis B and C and make sure they become public health priorities.

COMMITTEE ON
TRANSPORTATION AND
INFRASTRUCTURE

COMMITTEE ON
HOMELAND SECURITY
DEPUTY RANKING MEMBER

COMMITTEE ON
OVERSIGHT AND
GOVERNMENT REFORM

Congress of the United States
House of Representatives
Washington, DC 20515-1802

ANH "JOSEPH" CAO
2ND DISTRICT, LOUISIANA

WASHINGTON OFFICE
2113 RAYBURN HOUSE OFFICE BUILDING
Washington, D.C 20515
(202) 225-6636
DISTRICT OFFICE
4640 SOUTH CARROLLTON AVENUE, SUITE 120
NEW ORLEANS, LA 70119
(504) 483-2325

WEBSITE: josephcao.house.gov

Opening Remarks
Rep. Anh "Joseph" Cao

House Oversight and Government Reform Committee

Hearing entitled: "Viral Hepatitis: The Secret Epidemic."

June 17, 2010

First of all, I would like to thank Chairman Towns, for your leadership on viral hepatitis issues, and both you and Ranking Member Issa for commissioning this hearing today. I appreciate your commitment to addressing preventative health issues plaguing our communities. I would like to acknowledge the Oversight and Government Reform Committee Staff for their rapid response and organization in planning this hearing, and I would like to thank them for including my staff and viral hepatitis stakeholders in planning this hearing.

Mr. Chairman and Mr. Ranking Member, when I requested this hearing on April 14, I did so with the bipartisan coalition of Members, with whom I have worked on viral hepatitis issues since arriving in Congress, in mind. This includes three who will be testifying today: Congressman Hank Johnson who will discuss his personal battle with hepatitis C; Congressman Bill Cassidy, a leading hepatologist from my home state of Louisiana; and Congressman Mike Honda who has brought much-needed attention to the disease's disproportionate impact on Asian-Americans. I would also like to acknowledge all the stakeholders testifying at today's hearing, because it is this kind of coordinated effort between the federal government, community health advocates, health providers, private industries, and

state and local government leaders which will bring about meaningful, robust, and effective change.

I am proud to have requested this hearing today, because I believe it is important to examine what the federal government is doing to tackle the issues related to viral hepatitis and liver cancer. Addressing the silent epidemic of viral hepatitis in today's hearing is important in raising awareness and in proving how preventative care yields significant cost savings and saving of human lives. We should use this hearing and the findings in the Institute of Medicine (IOM) report to highlight both the challenges and recommendations for forging an improved and coordinated federal response.

The IOM report highlights the federal governments' failure in responding to this chronic viral hepatitis crisis, especially in securing adequate resources for preventing, diagnosing, and treating chronic viral hepatitis, especially among the 3.5 to 5.3 million Americans affected. This is a grave public health crisis and human tragedy, especially given the asymptomatic nature of the diseases, as 65 to 75 percent of individuals living with viral hepatitis are unaware they are infected until they develop symptoms of liver disease or cancer years later.

The majority of our affected constituents will go on to develop severe liver disease or cancer, at a great cost to their health and our health systems. Hepatitis B and C are the leading causes of liver cancer, which is one of the fastest growing and deadliest forms of cancer. Liver cancer is extremely expensive to treat but preventable if Americans get the hepatitis B vaccine or if chronic viral hepatitis is identified and treated early. In fact, the hepatitis B vaccine is the first anti-cancer vaccination.

As an Asian American and the representative of a district that is roughly 60 percent African American in Orleans and Jefferson Parishes, I am particularly alarmed at the disproportionate impacts of hepatitis B on Asian Americans and hepatitis C on African Americans. Approximately one-half of hepatitis B patients are Asian Americans in contrast to only 5 percent of the population overall. Rates of hepatitis C are twice the national average rate in African Americans. Further, the "baby boomer" population accounts for approximately two-thirds of chronic hepatitis C cases, although most inflicted with the disease are unaware until they

develop symptoms of liver disease or cancer. As these Americans continue to age, they are likely to develop complications from hepatitis C, thus costing Medicare billions in treatment, transplantation, and other costs.

According to a report issued by the Louisiana Department of Health and Hospitals in 2007, approximately 4.6 percent of adults in Louisiana are considered to be at a high risk for contracting hepatitis B. Approximately 5-10 percent of those infected with hepatitis B, or 1,000-2,000 people, will develop chronic liver disease during their lifetime. The Centers for Disease Control and Prevention (CDC) reports that approximately 80,000 of people in Louisiana, or 1.8 percent of the population, are infected with hepatitis C. However, the hepatitis register in Louisiana only contains approximately 42,000 of those reported hepatitis C cases, or 53 percent of the estimated 80,000 cases, in Louisiana. Of those 80,000 affected with hepatitis C in Louisiana, approximately 68,000 will develop chronic hepatitis; 13,000 will develop cirrhosis, which accounts for a 25 percent fatality rate; 4,000 will qualify for a liver transplant; and 120 people will die each year. Sadly, Orleans Parish has one of the highest rates of hepatitis C in Louisiana.

The costs of inaction are too high to not address the viral hepatitis epidemic head-on, as chronic hepatitis B and C infections already cost the United States $16 billion each year. Without concerted efforts to respond, Americans will continue to be infected and fail to be identified; therefore, diminishing the quality of life and life expectancy, as well as increasing labor and health costs, especially to Medicaid and Medicare. A recent study estimates that public and private payers' cost of treating chronic viral hepatitis C alone will more than triple by 2024 to $85 billion annually. Medicare and Medicaid will absorb a disproportionate share of these added costs, especially since two-thirds of American "baby boomers" are living with hepatitis C and aging onto Medicare in the next decade. However, a recent analysis of Centers for Medicare & Medicaid Services (CMS) data found that early Medicaid coverage and treatment of individuals infected with chronic hepatitis B may reduce mortality by up to 20 percent and liver transplants by 60 percent, which would contribute to savings in Medicaid in as early as ten years.

We are spending pennies to treat a disease that is costing our health system billions and costing Americans their lives. The cost of inaction is too high. We, in Congress, are long overdue for examining how the federal government is

coordinating with community health leaders to tackle education, prevention and treatment of this disease.

There are limited resources in our states and communities for viral hepatitis awareness, testing, and treatment, because of a lack of dedicated funding and attention to this crisis. Because budget for the CDC Division of Viral Hepatitis is only 2 percent of the agency's budget, states only receive about $90,000 for hepatitis prevention in adults. This leaves little to no resources for funding actual services, and there is no funding for community-based organizations to provide services. When organizing my AAA Health Fairs in my District, I saw firsthand the limited access to and availability of hepatitis resources, and we were unable to provide hepatitis screenings, even though there was a great need for them.

I have been honored to work with Members from both sides of the aisle – including Congressmen Honda, Towns, Cassidy, Dent, and Johnson – and with advocacy groups and health professionals who are truly dedicated to this issue. I am proud that our efforts produced H.R. 3974, the Viral Hepatitis and Liver Cancer Control Act; H.Res. 1302, recognizing May as National Hepatitis Awareness Month and May 19 as World Hepatitis Day; congressional briefings on viral hepatitis and liver cancer; a free hepatitis screening; and an increased attention to and request for additional funding for viral hepatitis at the CDC.

I implore Congress to help spread messages about the need for action, compassion, and understanding about chronic viral hepatitis in our communities. I urge my colleagues to support raising awareness of the risks and consequences of undiagnosed chronic hepatitis B and hepatitis C infections, and to stress the urgency for a robust governmental and public health response to protect the health of our constituents who are at risk for or suffer from viral hepatitis.

Thank you, again, to Chairman Towns for your efforts to address the viral hepatitis crisis in our communities. Again, I thank you and Ranking Member Issa for commissioning this hearing to raise awareness and to address the federal government's response to the viral hepatitis and liver cancer crisis.

QUESTIONS

FOR

THE HEARING RECORD

Questions for Dr. Howard Koh, Assistant Secretary for Health
U.S. Department of Health and Human Services
From Rep. Wm. Lacy Clay
Committee on Oversight and Government Reform
Hearing entitled, "Viral Hepatitis: The Secret Epidemic"

1. I know that you have been very persistent about developing an interagency strategy to address this health crisis. In your view, what are some of the challenges that an initiative like this may face?

2. How do you plan to address these issues to ensure that the strategies are successful?

3. What specific things has the workgroup done to coordinate hepatitis prevention strategies across agencies?

4. What is HHS planning to do to improve care and medical management of those living with hepatitis, since no dedicated national care program exists?

Questions for Dr. John Ward, Director, Viral Hepatitis Program
Centers for Disease Control and Prevention
From Rep. Wm. Lacy Clay
Committee on Oversight and Government Reform
Hearing entitled, "Viral Hepatitis: The Secret Epidemic"

1. According to the recent I.O.M. report, African American adults have the highest rate of acute hepatitis b infection in the United States, and the highest rates of acute hepatitis b infection occur in the south. What does HHS plan on doing to address this population?

2. There are many other disparities that exist within this epidemic, including greater rates of infection for many minority groups and the L.G.B.T. community. Are there specific strategies in place to address each of these groups? If so, how do they differ?

3. Despite dealing with an epidemic that the CDC estimates afflicts over five million people, the division of viral hepatitis is the smallest funded infectious disease division under the national center for HIV, viral hepatitis, STD, and TB prevention, and only receives 2 percent of its total budget. Given the huge number of people infected and the costs of late stage liver disease caused by chronic hepatitis b and c infections, why has CDC not dedicated more funds to the division of viral hepatitis?

Questions for Dr. Randy Mayer, Chief, Bureau of HIV, STD, and Hepatitis
Iowa Department of Public Health (The Institute of Medicine)
From Rep. Wm. Lacy Clay
Committee on Oversight and Government Reform
Hearing entitled, "Viral Hepatitis: The Secret Epidemic"

1. In your experience, do you believe that local, state, and federal level governments provide enough funding for hepatitis education and care?

2. Can you speak to the importance of community organizations, as well as government ones, in the fight to curb the hepatitis epidemic?

Questions for Mr. Michael Ninburg, Executive Director
Hepatitis Education Project
From Rep. Wm. Lacy Clay
Committee on Oversight and Government Reform
Hearing entitled, "Viral Hepatitis: The Secret Epidemic"

1. How long have you been working on behalf of hepatitis education?

2. Considering your years of experience, what do you believe is the greatest obstacle to this crisis? Is it education and awareness, funding, or something different?

BRIAN P. BILBRAY
50TH DISTRICT, CALIFORNIA

2348 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-0508
FAX (202) 225-2558

DISTRICT OFFICE:
462 STEVENS AVE., #107
SOLANA BEACH, CA 92075
(858) 350-1150
FAX (858) 350-0750

Congress of the United States
House of Representatives
Washington, DC 20515–0550

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

COMMITTEE ON SCIENCE AND TECHNOLOGY

COMMITTEE ON VETERANS' AFFAIRS

HOUSE REPUBLICAN POLICY COMMITTEE

IMMIGRATION REFORM CAUCUS, CHAIRMAN

June 24, 2010

The Honorable Edolphus Towns
Chairman
Committee on Oversight and Government Reform
U.S. House of Representatives
Washington, DC 20515

In connection with the Oversight and Government Reform Committee's hearing on June 17, 2010, "Viral Hepatitis, the Secret Epidemic," I ask that you submit to the witnesses Dr. Howard Koh, M.P.H., and Dr. John Ward the following questions for the hearing record:

1. "I understand that the CDC is currently developing the evidence base it needs to update its 1998 HCV screening recommendations. This two-year study, known as "BEST-C," will implement and evaluate the effectiveness of a one-time, opt-out HCV screening of all persons born from 1945 through 1964 who receive care in managed care settings. I think this approach makes sense, given that 2/3 of those with chronic HCV infection were born between 1945 and 1964. I've also been made aware that the United States Preventive Services Task Force (USPSTF) is undertaking a review of its 2004 recommendations on screening for HCV.

   With the therapeutic advances for the treatment of hepatitis C potentially less than a year away, screening guidelines that do not take this information into consideration have little public utility and can cause confusion. If the USPSTF updates its 2004 recommendations now without this information, the resulting guidelines may be outdated just as they are released. Since USPSTF's guidelines are currently the only guidelines explicitly tied to coverage decisions per MIPPA and the PPACA, how do we ensure that their recommendations are not an barrier to providing coverage for effective screening programs?

   Additionally what can you do to help ensure that these two sets of guidelines (CDC and USPSTF) are aligned as part of a comprehensive national strategy for the prevention and control of hepatitis C?"

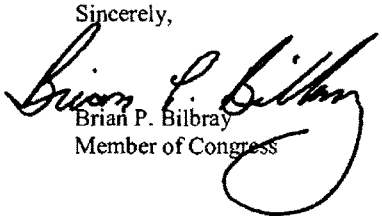
2. "I notice that screening and diagnosis of the millions of patients with hepatitis C isn't included as part of the 5 focus areas for the administration as part of the HHS response to the IOM report (page 9 of testimony). I think spending too much time on preventing transmission, when there are 17,000 new infections per year, versus preventing a huge wave of advanced liver disease, including liver cancer, by

PRINTED ON RECYCLED PAPER

identifying the 2-3 million undiagnosed patients, is a misallocation of resources. How will you make screening the undiagnosed in order to prevent costly, preventable liver disease, a priority and do you think it should be elevated?"

Mr. Chairman, I appreciate your leadership of the Oversight and Government Reform Committee. If you or your staff has any questions regarding the aforementioned questions, please contact Gary Kline of my staff at 5-2575.

Sincerely,



Brian P. Bilbray
Member of Congress

CC: The Honorable Darrell Issa

JASON CHAFFETZ
3D DISTRICT, UTAH

COMMITTEE ON
NATURAL RESOURCES

COMMITTEE ON
THE JUDICIARY

COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM

Congress of the United States
House of Representatives
Washington, DC 20515–4403

1032 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-7751

DISTRICT OFFICES:
PROVO
51 S. UNIVERSITY AVENUE
SUITE 318
PROVO, UT 84601
PHONE: (801) 851-2600
FAX: (801) 851-2609

WEST JORDAN
3895 W. 7800 S.
SUITE 201
WEST JORDAN, UT 84088
PHONE: (801) 282-5502

www.chaffetz.house.gov

June 25, 2010

The Honorable Edolphus Towns
Chairman
Committee on Oversight and Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Towns:

In connection with the Oversight and Government Reform Committee's hearing on June 17, 2010, "Viral Hepatitis: The Secret Epidemic." I ask that you submit to Dr. Howard Koh at the Department of Health and Human Services the following question for the record:

> It seems that awareness, both among the general public and at the provider level, is going to be key if we want to increase the number of patients who know their status. What will you be doing specifically to increase provider awareness, especially at the primary care level?

If you or your staff has any questions regarding this question, please contact Mike Jerman on my staff at 6-7714.

Sincerely,

Jason Chaffetz
Member of Congress

PRINTED ON RECYCLED PAPER

LYNN A. WESTMORELAND
3RD DISTRICT, GEORGIA

WASHINGTON OFFICE:
1213 LONGWORTH HOUSE OFFICE BUILDING
(202) 225-5901

DISTRICT OFFICE:
1601 EAST HIGHWAY 34
SUITE B
NEWNAN, GA 30265
(770) 683-2033

Congress of the United States
House of Representatives
Washington, DC 20515–1008

COMMITTEES:

TRANSPORTATION AND INFRASTRUCTURE

OVERSIGHT AND GOVERNMENT REFORM

SMALL BUSINESS

REPUBLICAN POLICY COMMITTEE

CHAIRMAN, 2010 DECENNIAL CENSUS TASK FORCE

DEPUTY WHIP

June 24, 2010

The Honorable Edolphus Towns
Chairman
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Darrell E. Issa
Ranking Member
Committee on Oversight and Government Reform
B-350A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Towns and Ranking Member Issa,

I am submitting the following question for the record of the June 17, 2010 hearing entitled "Viral Hepatitis: The Secret Epidemic." I request that the following question be posed to Dr. Howard K. Koh, Assistant Secretary for Health, U. S. Department of Health and Human Services.

1) Will you please explain the difference in disease burden caused by the chronically infected vs. burden caused by new infections? It seems that the cost burden caused by thousands of new cases of preventable liver disease far outweighs the cost burden caused by 17,000 new infections per year.

I respectfully ask that the witness respond in writing to my request within 30 days.

Sincerely,

Lynn A. Westmoreland
Member of Congress

PRINTED ON RECYCLED PAPER

COMMITTEE ON
TRANSPORTATION AND
INFRASTRUCTURE

COMMITTEE ON
HOMELAND SECURITY
DEPUTY RANKING MEMBER

COMMITTEE ON
OVERSIGHT AND
GOVERNMENT REFORM

Congress of the United States
House of Representatives
Washington, DC 20515-1802

ANH "JOSEPH" CAO
2ND DISTRICT, LOUISIANA

WASHINGTON OFFICE
2113 RAYBURN HOUSE OFFICE BUILDING
Washington, D.C 20515
(202) 225-6636
DISTRICT OFFICE
4640 SOUTH CARROLLTON AVENUE, SUITE 120
NEW ORLEANS, LA 70119
(504) 483-2325

WEBSITE: josephcao.house.gov

June 25, 2010

The Honorable Edolphus Towns
Chairman
Oversight and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Towns:

In connection with the Oversight and Government Reform Committee's hearing on June 17, 2010, "Viral Hepatitis: The Secret Epidemic," I respectfully request you to submit the attached questions for the record to witness, Dr. Howard Koh, the Assistant Secretary for Health of the Department of Health and Human Services (HHS).

I appreciate your leadership on this issue and your bringing this to the Oversight and Government Reform Committee's attention. If you have any questions regarding the attached, please contact my staff, Cassie Alsfeld, at 5-6636.

Sincerely,

Anh "Joseph" Cao
Member of Congress

Attachment

ATTACHMENT

Questions for the record for Dr. Howard Koh, the Assistant Secretary for Health of the Department of Health and Human Services (HHS).

1. Through FY2010 Appropriations report language, Congress requested a professional judgment (PJ) budget from the CDC Division of Viral Hepatitis.

    a. Please provide the PJ budget for submission into the hearing record to enable a better understanding of what the CDC believes is necessary to mount an effective response to prevent viral hepatitis infections and to increase awareness by the number of people who are unaware of their infection.

    b. Given the significant number of those infected and the costs of late-stage liver disease caused by chronic hepatitis B and C infections, why has the CDC not dedicated more funds to the Division of Viral Hepatitis?

    c. Congress requested a program justification budget for FY2011 from the CDC Division of Viral Hepatitis. What amount is required for a robust and effective response from the Division of Viral Hepatitis, where would this funding go, and what are the obstacles to securing this funding?

    d. Despite dealing with an epidemic that the CDC estimates afflicts over 5 million people, the Division of Viral Hepatitis is the smallest-funded infectious disease division under the National Center for HIV, Viral Hepatitis, STD and TB Prevention and receives only 2 percent of its total budget. The Division has been underfunded and defunded from a record high of $25 million in FY2001 compared to $700 million for HIV and $150 million for STD and TB overall. Why has the Division not been prioritized financially, given this is one of the largest disease burdens in America?

2. Please provide an update on HHS's activity on developing a national strategy to respond to the viral hepatitis epidemics that includes implementation of the IOM Report's recommendations and resource allocations supporting a national strategy.

    a. How will HHS implement the IOM report recommendations? How will HHS fund the implementation and ensure adequate and consistent resources for implementation?

    b. How will HHS ensure that any response or progress at attempting to address the IOM report findings (such as the lack of public awareness, especially for those at-risk, and the lack of awareness among healthcare providers, in addition to the lack of preventative services such as testing and screening, the lack of medical management and care, and the lack of a national surveillance system to know the true disease burden in this country) are accounted for?

3. Reports indicate that between 65 and 75 percent of individuals infected with viral hepatitis are unaware that they have contracted the disease.

    a. What new approaches and / or technologies would be helpful in addressing the large percentage of individuals who are currently undiagnosed?

    b. How is your department preparing to evaluate and address these new technologies to mitigate these situations?

4. Regarding the Interagency Workgroup you have established to prioritize and coordinate hepatitis activity and develop a national plan:

    a. What do you see as key challenges to ensuring the Workgroup's activity is meaningful, robust, and effective?

    b. How will you work with Members of Congress, President Obama, Secretary Sebelius, and Surgeon General Benjamin to elevate hepatitis issues?

    c. How is the Workgroup coordinating activity across agencies?

    d. Where will resources come from to implement the Workgroup's action items?

5. Reports indicate that minorities are disproportionately affected by viral hepatitis. Specifically, reports indicate that Asian Americans are disproportionately affected by chronic hepatitis B with roughly 1 in 10 estimated to be affected by hepatitis B and liver cancer remaining a top killer of Asian Americans.

    a. How is HHS working with its Office of Minority Health and other HHS agencies, the US Bureau of Citizenship and Immigration Services, and healthcare providers to ensure Asian Americans at high-risk for hepatitis B are being screened, vaccinated, tested, and referred into care if they are living with chronic hepatitis B in addition to ensuring all household contacts are screened?

    b. According to the IOM report, African American adults have the highest rate of acute hepatitis B infection in the United States and the highest rates of acute hepatitis B infection occur in the South. How will HHS address this population?

    c. Given the number of health disparities associated with these epidemics among African-Americans, Asian Americans, Pacific Islanders, Latinos, Native Americans and Alaskan Natives, in addition to gay and bisexual men, transgender persons and persons who inject drugs, what will HHS do to address these health disparities?

6. Reports indicate the African-American community is disproportionately affected by hepatitis C. One study found that prevalence rates for African-American men ages 40-50 is as high as almost 14 percent. However, the majority of those infected with hepatitis C are undiagnosed. Mortality rates related to hepatitis C among African-Americans is almost double that among white patients, and African-American patients are less likely to be tested for HCV in the presence of a known risk factor and less likely to be referred for subspecialty care and treatment.

    a. Is attacking this health disparity a priority for your Workgroup and for HHS?

RESPONSES TO THE

QUESTIONS FOR

THE HEARING RECORD

QUESTIONS SUBMITTED FOR THE RECORD
HEARING ENTITLED,
"VIRAL HEPATITIS: THE SECRET EPIDEMIC"
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES
JUNE 17, 2010

Questions for Howard K. Koh, M.D., M.P.H.
Assistant Secretary for Health
Department of Health and Human Services

From Rep. William Lacy Clay

1. **I know that you have been very persistent about developing an interagency strategy to address this health crisis. In your view, what are some of the challenges that an initiative like this may face?**

   Viral hepatitis is a complex health problem. Addressing it effectively requires the coordinated involvement of multiple parts of the Department of Health and Human Services (HHS), as well as the involvement of the community and private sectors. HHS agencies are engaged and committed to tackling this problem.

2. **How do you plan to address these issues to ensure that the strategies are successful?**

   Special care has been taken to include representation from most of the agencies of the Department with responsibility for viral hepatitis research, prevention, and treatment. The plan will be the basis for directing action and tracking implementation over time by those agencies and will provide the framework for their collaboration with non-governmental agencies and the private sector to address the need for viral hepatitis vaccination, screening, diagnosis, care, and treatment.

3. **What specific things has the workgroup done to coordinate hepatitis prevention strategies across agencies?**

   The workgroup has formed panels of Department experts to work on the five components of the strategic plan. The goal is to have a finished document by fall of this year. The action plan will then be used to guide, coordinate, and monitor the efforts of agencies to implement key HHS initiatives for viral hepatitis prevention.

4. **What is HHS planning to do to improve care and medical management of those living with hepatitis, since no dedicated national care program exists?**

   HHS is committed to improving care and treatment to those infected with chronic viral hepatitis. HHS is considering ways to address this in the development of the HHS hepatitis strategic plan. In FY 2010, the Health Resources and Services Administration (HRSA) is funding demonstration grants that integrate hepatitis C care into HIV primary

care and developing technical assistance documents to support clinicians in managing hepatitis C in primary care. If the demonstration grants are successful, they will provide a framework and supporting tools to expand hepatitis C treatment into primary care.

Care and medical management is currently available through the Ryan White Care Act for persons who are co-infected with HIV and chronic hepatitis B or C. However, you correctly note that no similar program exists for persons who are mono-infected with chronic hepatitis B or C. The workgroup's expert panel on improving clinical preventive care and treatment services will be looking at that and other issues in connection with the development of the Department's viral hepatitis action plan. The Centers for Disease Control and Prevention (CDC) is conducting prevention research to identify strategies to increase the number of persons who know their status and will be provided care. CDC has also launched an observational study to monitor receipt of recommended clinical services by persons in care for viral hepatitis.

Medicare covers a comprehensive range of diagnostic and treatment services that are medically necessary for a beneficiary, including services for those living with hepatitis. Such services may include, for example, diagnostic laboratory tests and procedures, doctors' visits, inpatient and outpatient hospital services, care in skilled nursing facilities, and home health care. In addition, Medicare's preventive benefits include coverage of hepatitis B vaccinations for beneficiaries at risk for the disease. Beginning January 1, 2011, CMS has proposed waiving beneficiary cost-sharing for hepatitis B vaccinations.

From Rep. Lynn A. Westmoreland

1. **Will you please explain the difference in disease burden caused by the chronically infected vs. burden caused by new infections? It seems that the cost burden caused by thousands of new cases of preventable liver disease far outweighs the cost burden caused by 17,000 new infections per year.**

   In 2007, there were nearly 50,000 new cases of hepatitis B and 17,000 new infections of hepatitis C. Approximately 3.5 million to 5.3 million Americans have chronic viral hepatitis. As your question suggests, the potential cost of millions of cases of end-stage liver disease is considerable. Identifying persons who are chronically infected and getting them into care is therefore a primary goal of HHS and its agencies. It is also important to prevent new cases of hepatitis B and C, however, because those cases can develop into chronic infections.

From Rep. Brian P. Bilbray

1. **I understand that the CDC is currently developing the evidence base it needs to update its 1998 HCV screening recommendations. This two-year study, known as "BEST-C," will implement and evaluate the effectiveness of a one-time, opt-out HCV screening of all persons born from 1945 through 1964 who receive care in managed care settings. I think this approach makes sense, given that 2/3 of those**

with chronic HCV infection were born between 1945 and 1964. I've also been made aware that the United States Preventive Services Task Force (USPSTF) is undertaking a review of its 2004 recommendations on screening for HCV. With the therapeutic advances for the treatment of hepatitis C potentially less than a year away, screening guidelines that do not take this information into consideration have little public utility and can cause confusion. If the USPSTF updates its 2004 recommendations now without this information, the resulting guidelines may be outdated just as they are released. Since USPSTF's guidelines are currently the only guidelines explicitly tied to coverage decisions per MIPPA and the PPACA, how do we ensure that their recommendations are not a barrier to providing coverage for effective screening programs? Additionally what can you do to help ensure that these two sets of guidelines (CDC and USPSTF) are aligned as part of a comprehensive national strategy for the prevention and control of hepatitis C?

Under provisions in MIPPA and the ACA, recommendations of the USPSTF may be used by HHS in making coverage decisions related to Medicare, Medicaid, and private insurance plans. While a positive recommendation from the USPSTF can lead to expanded coverage and removal of co-payments, an indeterminate recommendation is not a barrier. If Congress, state policy makers, or private insurers determine that a specific service is beneficial, they may expand coverage or reduce co-payments at any time. Thus the evidence-based recommendations of the USPSTF form part of the floor and not a ceiling for clinical preventive services.

As you point out, the CDC is in the process of updating its hepatitis C virus (HCV) screening and treatment recommendations, and the USPSTF is beginning the process of updating its 2004 screening recommendation. The CDC and the staff of the Agency for Healthcare Research and Quality (AHRQ), which support the USPSTF, are coordinating closely on this issue. Given its public health approach, the CDC has launched studies to assess the utility of various HCV screening strategies, including a clinical evaluation of an age based approach to screening. AHRQ staff members were consulted by the CDC in the planning stages of these studies regarding clinical outcomes that would be most useful to the USPSTF recommendation making process. By beginning its evidence review in the coming months, the USPSTF is positioning itself to incorporate the results of multiple studies expected to be released in the next 18 months. CDC staff will be engaged in developing the scope and key questions of the upcoming USPSTF evidence review. If the USPSTF were to wait for the study to be published before beginning its review, it would likely not issue a recommendation until 2014. Given the ever-expanding and on-going nature of research, the USPSTF is continually faced with the challenge of when to begin and end evidence reviews. Recognizing that, no matter how good the planning, occasionally an important study will be released soon after the publication of a recommendation. The USPSTF has in place policies and procedures to allow rapid reconsideration of a topic when significant new evidence becomes available.

CDC currently recommends a risk based approach to offering persons screening for HCV infection. Although this approach is appropriate in some settings, studies have shown that requirements for providers to ask about behavioral risks and for clients to reveal this information represent major barriers to health screening. To eliminate these

barriers and expand access to HCV testing, CDC has launched studies to assess the utility of other HCV screening strategies, including a clinical evaluation of an age-based approach to HCV screening. Physicians are familiar with other age-based screening, such as recommendations to detect risks for cancer, and HCV is a major cause of liver cancer in the United States. Results from the evaluation of this age based approach are expected in 2012. The data will inform CDC and the USPSTF guidelines for the delivery of HCV screening.

2. **I notice that screening and diagnosis of the millions of patients with hepatitis C isn't included as part of the 5 focus areas for the administration as part of the HHS response to the IOM report (page 9 of testimony). I think spending too much time on preventing transmission, when there are 17,000 new infections per year, versus preventing a huge wave of advanced liver disease, including liver cancer, by identifying the 2-3 million undiagnosed patients, is a misallocation of resources. How will you make screening the undiagnosed in order to prevent costly, preventable liver disease, a priority and do you think it should be elevated?"**

Increasing screening and diagnosis is a priority for HHS. Hepatitis C disproportionately affects populations served by HRSA-funded health centers, and screening and diagnosis are important initial steps to preventing and managing the disease. HRSA will begin monitoring hepatitis prevalence and treatment in HRSA-funded health centers in order to plan technical assistance through HRSA funded national cooperative agreements as well as working with the CDC funded State Hepatitis Coordinators. CDC supports Adult Viral Hepatitis Prevention Coordinators in 49 states and several large cities, who provide leadership in the integration of viral hepatitis prevention services such as screening and counseling into existing public health programs. CDC is also developing professional education tools to help primary care provider understand who should be screened and vaccinated.

Several CDC professional educational tools explain the complicated serology surrounding HBV and HCV. CDC is funding two universities, the University of Alabama at Birmingham (UAB) and the University of Washington-Seattle (UW), for public health and professional web-based training. UAB is focusing on the public health workforce and integrating viral hepatitis into existing clinical services for populations at risk, while UW is focusing primarily on clinicians and is educating them about prevention, management and treatment of viral hepatitis. CDC also is working to improve screening and referral for treatment by evaluating new approaches to testing. To address the limitations of a risk-based approach to HCV testing, CDC is conducting an evaluation of an age-based approach to HCV testing. Physicians are familiar with other age-based screening recommendations to detect risks for cancer, and HCV is a major cause of liver cancer in the United States. Results from the evaluation of this age based approach are expected in 2012. Finally, CDC is working with industry to expand access to testing by supporting development of new testing technologies and strategies, such as point of care tests for HCV. CDC recently completed laboratory evaluation for specificity and sensitivity of three rapid HCV tests. CDC is currently field testing those rapid tests to evaluate their use in multiple settings (e.g., HIV testing sites and drug treatment sites).

From Rep. Jason Chaffetz

1. **It seems that awareness, both among the general public and at the provider level, is going to be key if we want to increase the number of patients who know their status. What will you be doing specifically to increase provider awareness, especially at the primary care level?**

   Hepatitis C disproportionately affects populations served by HRSA-funded health centers, and screening and diagnosis are important initial steps to preventing and managing the disease. HRSA will begin monitoring hepatitis prevalence and treatment in HRSA-funded health centers in order to plan technical assistance through HRSA-funded national cooperative agreements as well as working with the CDC funded State Hepatitis Coordinators.

   Patient education and provider training will be part of the HHS Hepatitis strategy. CDC currently provides several professional educational tools that explain the complicated serology surrounding HBV and HCV. CDC is also developing professional education tools to help primary care providers understand who should be screened and vaccinated. Finally, CDC is funding two universities, the University of Alabama at Birmingham (UAB) and the University of Washington-Seattle (UW), for public health and professional web-based training. UAB is focusing on the public health workforce and integrating viral hepatitis into existing clinical services for populations at risk, while UW is focusing primarily on clinicians and is educating them about prevention, management and treatment of viral hepatitis.

From Rep. Anh "Joseph" Cao

1. **Through FY2010 Appropriations report language, Congress requested a professional judgment (PJ) budget from the CDC Division of Viral Hepatitis.**

   a. **Please provide the PJ budget for submission into the hearing record to enable a better understanding of what the CDC believes is necessary to mount an effective response to prevent viral hepatitis infections and to increase awareness by the number of people who are unaware of their infection.**

   The professional judgment budget submitted to the Senate Appropriations committee is attached.

   b. **Given the significant number of those infected and the costs of late-stage liver disease caused by chronic hepatitis B and C infections, why has the CDC not dedicated more funds to the Division of Viral Hepatitis?**

   CDC's budget for viral hepatitis remained steady and has increased slightly in recent years. Funding in FY 2009 for viral hepatitis was approximately $18 million; in FY 2010, the funding for viral hepatitis was $19 million; and the FY 2011 President's

Budget requested $21 million for viral hepatitis. Furthermore, CDC's budget for viral hepatitis does not reflect the entire agency budget for this disease. In addition to amounts specifically in its viral hepatitis budget, CDC supports hepatitis A and B vaccination for both infants and at-risk adults out of its immunization program. CDC prioritizes activities funded out of the viral hepatitis budget in order to achieve the most significant impact.

c. Congress requested a program justification budget for FY2011 from the CDC Division of Viral Hepatitis. What amount is required for a robust and effective response from the Division of Viral Hepatitis, where would this funding go, and what are the obstacles to securing this funding?

The professional judgment budget requested by the Senate Appropriations Committee is attached. It outlines four domestic viral hepatitis programmatic priority areas. These are, in order of precedence: identify persons with viral hepatitis early and refer them to care; improve monitoring of viral hepatitis; commit the nation to eliminate HBV transmission; and develop, test, and translate into action new HCV prevention tools. Any additional funds would be used to advance CDC's work in those areas. While this budget represents CDC's professional judgment regarding what is needed, this professional judgment budget is provided without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed.

d. Despite dealing with an epidemic that the CDC estimates afflicts over 5 million people, the Division of Viral Hepatitis is the smallest-funded infectious disease division under the National Center for HIV, Viral Hepatitis, STD and TB Prevention and receives only 2 percent of its total budget. The Division has been underfunded and defunded from a record high of $25 million in FY2001 compared to $700 million for HIV and $150 million for STD and TB overall. Why has the Division not been prioritized financially, given this is one of the largest disease burdens in America?

We certainly agree that there are tremendous unmet needs in combating hepatitis-- as unfortunately there still are for HIV as well-- as prevention and treatment needs for both diseases continue to outpace emerging challenges.

While CDC has not received resources for viral hepatitis commensurate with HIV, CDC has worked to maximize available resources for both diseases. CDC is continuing to look for ways to leverage its existing prevention infrastructure to build in services for hepatitis. For example

- CDC has incorporated vaccination for hepatitis B into its childhood immunization efforts. While this does not address the current needs of at-risk adults and those who are chronically infected, it can help prevent perinatal transmission and help the agency deal effectively with new generations of at risk persons.

- CDC is working to develop recommendations to ensure that lifesaving clinical preventive services, such as hepatitis C screening for at risk persons, are provided.
- CDC is also working to ensure synergies between HIV and viral hepatitis programs:
  - Recognizing the need to improve hepatitis B vaccination of at risk adults, in 2007, CDC began an initiative to provide hepatitis B vaccination to adults at risk in venues such as drug treatment programs, HIV and STD clinics, correctional facilities, primary care clinics and local health departments.
  - CDC is incorporating messages regarding hepatitis prevention in its HIV prevention programs for drug users.
  - CDC has incorporated questions important to hepatitis prevention in its HIV surveys, as appropriate.

There are certainly lessons to be learned from HIV, and we will be examining how to ensure that communication, surveillance, and program models that have been successful for HIV prevention are applied as effectively as possible to viral hepatitis with available resources.

2. **Please provide an update on HHS's activity on developing a national strategy to respond to the viral hepatitis epidemics that includes implementation of the IOM Report's recommendations and resource allocations supporting a national strategy.**

   a. **How will HHS implement the IOM report recommendations? How will HHS fund the implementation and ensure adequate and consistent resources for implementation?**

In January, I convened a viral hepatitis interagency workgroup, comprised of representatives from virtually all of the operating divisions of HHS. The workgroup has formed panels of Department experts to work on the five components of that action plan. The goal is to have a completed strategic action plan by this fall, which can then be used to guide, coordinate, and monitor initiatives and ongoing efforts to address the viral hepatitis epidemic across the Department.

   b. **How will HHS ensure that any response or progress at attempting to address the IOM report findings (such as the lack of public awareness, especially for those at-risk, and the lack of awareness among healthcare providers, in addition to the lack of preventative services such as testing and screening, the lack of medical management and care, and the lack of a national surveillance system to know the true disease burden in this country) are accounted for?**

All of the topics that you mention are being specifically considered by panels of agency experts, who will be developing components of an HHS action plan for viral hepatitis. The goal is to have a completed strategic action plan by this fall, which can then be used to guide, coordinate, and monitor initiatives and ongoing efforts to address the viral hepatitis epidemic across the department.

3. **Reports indicate that between 65 and 75 percent of individuals infected with viral hepatitis are unaware that they have contracted the disease.**

   a. **What new approaches and / or technologies would be helpful in addressing the large percentage of individuals who are currently undiagnosed?**

Work is needed on multiple fronts to increase the proportion of those infected with hepatitis who are aware of their viral hepatitis and are in care. The Affordable Care Act presents new opportunities to identify individuals infected with viral hepatitis and bring them into care, since expanded insurance coverage can open access to HBV immunizations as well as HCV screening, care, and treatment.

New tools, such as those now being developed by CDC, also need to be disseminated to improve provider knowledge of viral hepatitis and how to prevent it and the diseases it causes. CDC is developing professional education tools to help primary care providers understand who should be screened and vaccinated. CDC is also providing several professional educational tools that explain the complicated serology surrounding HBV and HCV. For example, a pilot education and prevention program funded by CDC targets underserved and at-risk Asian Pacific islanders in Chicago and the surrounding suburban area, and can provide a "best practices" model for programs in other parts of the country. Targeted educational campaigns need to be developed for other disparately affected populations.

Improving state and local surveillance for chronic viral hepatitis, as that currently supported by CDC in nine sites, can help guide delivery of screening and care. CDC is also working to expand access to testing by supporting development of new testing technologies and strategies, such as point of care tests for HCV. Finally, CDC is working to improve screening and referral for treatment by evaluating new approaches to testing. For example, to address the limitations of a risk-based approach to HCV testing, CDC is conducting an evaluation of an age based approach to HCV testing. This approach is similar to other age-based screening recommendations to detect other risks for cancer. (HCV is a major cause of liver cancer in the United States.) Results from the evaluation of this age based approach are expected in 2012.

   b. **How is your department preparing to evaluate and address these new technologies to mitigate these situations?**

CDC is working with industry to evaluate new point of care tests for HCV. CDC recently completed laboratory evaluation for specificity and sensitivity of three rapid HCV tests. CDC is currently field testing those rapid tests to evaluate their use in multiple settings (e.g., HIV testing sites, drug treatment sites). CDC is also working to identify reliable and inexpensive markers of acute HCV infection.

4. **Regarding the Interagency Workgroup you have established to prioritize and coordinate hepatitis activity and develop a national plan:**

a. What do you see as key challenges to ensuring the Workgroup's activity is meaningful, robust, and effective?

Viral hepatitis is a complex health problem. Addressing it effectively requires the coordinated involvement of multiple agencies across HHS, as well as the involvement of the community and private sectors. HHS agencies are engaged and committed to tackling this problem. Special care has been taken to include representation from all the agencies of the Department with responsibility for viral hepatitis prevention and care. The plan will be the basis for directing action and tracking implementation over time.

b. How will you work with Members of Congress, President Obama, Secretary Sebelius, and Surgeon General Benjamin to elevate hepatitis issues?

The Secretary's recently released, "Strategic Initiatives & Key Inter-Agency Collaborations" plan outlines several priorities that reflect new investments we need to meet our public health challenges as well as reforming and refocusing existing programs to help Americans lead healthier lives.

HHS is supporting studies to increase the evidence base for viral hepatitis screening; these can support recommendations for viral hepatitis preventive services. In addition to emphasizing primary care, prevention and wellness, we are improving health care quality and patient safety through delivery system reforms that encourage care coordination and improved patient outcomes. We are also working to ensure access to quality, culturally competent care for vulnerable populations experiencing health disparities. For example, HHS will institute policies that encourage care management for patients eligible for both Medicare and Medicaid and patients with chronic illnesses; reduce disparities associated with patients' race, ethnicity, and socioeconomic status; implement mental health parity in health insurance; improve early detection of mental health and substance use disorders; and promote coordinated, evidence-based care for individuals with behavioral health issues.

c. How is the Workgroup coordinating activity across agencies?

Special care has been taken to include representation from all the agencies of the Department that are involved in viral hepatitis research, prevention, and treatment. The workgroup has assembled an inventory of viral hepatitis activities by the various agencies. The goal is to have a completed strategic action plan by the fall of 2010, which can then be used to guide, coordinate, and monitor initiatives and ongoing efforts to address the viral hepatitis epidemic across the department. Meanwhile, there are already collaborations that have occurred or are occurring across agencies. To name just a few:

- CDC and the Substance Abuse and Mental Health Services Administration collaborated on a one-year pilot to provide free hepatitis A and hepatitis B vaccination in substance abuse treatment settings. The program recruited substance abuse treatment sites that serve minority populations, and 40 programs at approximately 75 sites in 20 states were enrolled. The collaboration purchased and

. distributed 43,950 doses of combined hepatitis A and B vaccine to at-risk persons at those sites.

- CDC and HRSA collaborated on a pilot project addressing HCV and TB in 11 community health centers serving primarily African-American clients in three states (South Carolina, Maryland, and New Jersey). Preliminary data from one community health center shows a HCV positive testing rate of 31.5 percent.
- CDC and the National Institutes of Health have collaborated on a joint study of the burden of viral hepatitis associated liver disease in the United States.

d. Where will resources come from to implement the Workgroup's action items?

The viral hepatitis action plan will identify ways to better coordinate existing activities as well as new initiatives. Resources and needs are among the issues to be considered by the Workgroup.

5. Reports indicate that minorities are disproportionately affected by viral hepatitis. Specifically, reports indicate that Asian Americans are disproportionately affected by chronic hepatitis B with roughly 1 in 10 estimated to be affected by hepatitis B and liver cancer remaining a top killer of Asian Americans.

a. How is HHS working with its Office of Minority Health and other HHS agencies, the US Bureau of Citizenship and Immigration Services, and healthcare providers to ensure Asian Americans at high-risk for hepatitis B are being screened, vaccinated, tested, and referred into care if they are living with chronic hepatitis B in addition to ensuring all household contacts are screened?

Hepatitis B vaccination is the most effective measure to prevent HBV infection and its consequences. Recommendations from CDC and the Advisory Committee on Immunization Practices (ACIP) provide a comprehensive plan to assure that all infants, particularly those whose mothers are HBV positive, receive the hepatitis B vaccine series as part of the recommended childhood immunization schedule, with the first dose of vaccine administered at birth. CDC's perinatal HBV program works to identify pregnant women who are HBV positive, to insure that their infants receive the care that they need to prevent transmission from mother to infant, and that other family members receive hepatitis B screening and vaccination. CDC and ACIP also recommend catch-up hepatitis B vaccination for all children and adolescents, and encourage states to adopt regulations or laws that require hepatitis B vaccination before entry into middle school and, where feasible, before high school and college entry. Finally, CDC and ACIP recommend hepatitis B vaccination for all unvaccinated adults at risk for HBV infection. In addition, HHS and CDC encourage global hepatitis B immunization efforts.

Unfortunately, vaccination is not effective for persons who are already infected with HBV. CDC therefore recommends that HBV testing should be offered as part of routine care for, among others, all immigrants from intermediate or high burden HBV countries (i.e. greater than 2% prevalence) and be accompanied by appropriate counseling and

referral for recommended clinical evaluation and care. A pilot education and prevention program funded by CDC targets underserved and at-risk Asian Pacific islanders in Chicago and the surrounding suburban area and may provide a "best practices" model for similar programs in other parts of the country.

Finally, *Goals and Strategies to Address Chronic Hepatitis B in Asian American Native Hawaiian and Other Pacific Islander Populations* presents the recommendations of the National Task Force on Hepatitis B Expert Panel, convened by the HHS Office of Minority Health and CDC. This document, built upon the proceedings of the hepatitis B track at the Asian American and Pacific Islander Health Summit in September 2006, lays out a national action agenda to eliminate hepatitis B in the Asian American and Native Hawaiian and other Pacific Islander communities with broad goals and strategies that permit focus on specific sub-strategies. The components of this agenda are understood to follow as much as possible the recommended National Standards for Culturally and Linguistically Appropriate Services in Health Care.

b. According to the IOM report, African American adults have the highest rate of acute hepatitis B infection in the United States and the highest rates of acute hepatitis B infection occur in the South. How will HHS address this population?

CDC is conducting formative research with consumers to better understand the barriers to vaccination, screening and other prevention services in communities disproportionately affected by viral hepatitis. CDC conducts surveys of viral hepatitis knowledge and receipt of viral hepatitis vaccination and screening among minority communities including African Americans. CDC is also following about 12,000 persons in clinical care for chronic viral hepatitis to assess access and response to recommended prevention and care services; approximately 20% of patients followed in this study are African American. CDC also supports development of educational programs directed at predominately African American risk populations. Finally, for the past three years, CDC has made Section 317 immunization funds available to states for the purchase of hepatitis B vaccine for administration in public health settings that serve individuals at risk for infection with the hepatitis B virus. To date, approximately $42 million in Section 317 funding has been used by states to purchase vaccine for this initiative.

c. Given the number of health disparities associated with these epidemics among African-Americans, Asian Americans, Pacific Islanders, Latinos, Native Americans and Alaskan Natives, in addition to gay and bisexual men, transgender persons and persons who inject drugs, what will HHS do to address these health disparities?

CDC is conducting formative research with the public to better understand the barriers to vaccination, screening and other prevention services in communities disproportionately affected by viral hepatitis. CDC conducts surveys of viral hepatitis knowledge and receipt of viral hepatitis vaccination and screening among minority communities including African Americans, Asian Pacific Islanders, injection drug users,

and gay and bisexual men. CDC is also following about 12,000 persons in clinical care for chronic viral hepatitis to assess access and response to recommended prevention and care services; approximately 20% of patients followed in this study are African American. CDC also supports development of educational programs directed at disparately affected populations.

CDC supports Adult Viral Hepatitis Prevention Coordinators in 49 states and several large cities, who provide leadership in the integration of viral hepatitis prevention services such as screening and counseling into existing public health programs. Finally, for the past three years, CDC has made Section 317 immunization funds available to states for the purchase of hepatitis B vaccine for administration in public health settings that serve individuals at risk for infection with the hepatitis B virus. To date, approximately $42 million in Section 317 funding has been used by states to purchase vaccine for this initiative.

6. **Reports indicate the African-American community is disproportionately affected by hepatitis C. One study found that prevalence rates for African-American men ages 40-50 is as high as almost 14 percent. However, the majority of those infected with hepatitis C are undiagnosed. Mortality rates related to hepatitis C among African-Americans is almost double that among white patients, and African-American patients are less likely to be tested for HCV in the presence of a known risk factor and less likely to be referred for subspecialty care and treatment.**
   a. **Is attacking this health disparity a priority for your Workgroup and for HHS?**

Yes, it is a priority. CDC is conducting formative research with the public to better understand the barriers to screening and other prevention services in communities disproportionately affected by viral hepatitis. CDC conducts surveys of viral hepatitis knowledge and receipt of viral hepatitis vaccination and screening among minority communities including African Americans. CDC is also following about 12,000 persons in clinical care for chronic viral hepatitis to assess access and response to recommended prevention and care services; approximately 20% of patients followed in this study are African American. CDC also supports development of educational programs directed at predominately African American risk populations. HHS supports studies to assess genetic factors that impact the response to therapy. The findings of recent studies have identified genetic factors associated with the lower response to current HCV therapy observed for African Americans compared with whites. Finally, CDC supports Adult Viral Hepatitis Prevention Coordinators in 49 states and several large cities, who provide leadership in the integration of viral hepatitis prevention services such as screening and counseling into existing public health programs.

Questions for Dr. John Ward
Director, Viral Hepatitis Program
Centers for Disease Control and Prevention
Department of Health and Human Services
(who accompanied Dr. Koh at the hearing)

From Rep. Wm. Lacy Clay

1. **According to the recent I.O.M. report, African American adults have the highest rate of acute hepatitis B infection in the United States, and the highest rates of acute hepatitis B infection occur in the south. What does HHS plan on doing to address this population?**

   The Centers for Disease Control and Prevention (CDC) is conducting formative research with the public to better understand the barriers to vaccination, screening, and other prevention services in communities disproportionately affected by viral hepatitis. CDC conducts surveys of knowledge about viral hepatitis and of receipt of viral hepatitis vaccination and screening among minority communities including African Americans. CDC is also following about 12,000 persons in clinical care for chronic viral hepatitis to assess access and response to recommended prevention and care services; approximately 20% of patients followed in this study are African American. CDC also supports development of educational programs directed at predominately African American risk populations.

   CDC supports Adult Viral Hepatitis Prevention Coordinators in 49 states and several large cities, who provide leadership in the integration of viral hepatitis prevention services such as screening and counseling into existing public health programs. Finally, for the past three years, CDC has made Section 317 immunization funds available to states for the purchase of hepatitis B vaccine for administration in public health settings that serve individuals at risk for infection with the hepatitis B virus. To date, approximately $42 million in Section 317 funding has been used by states to purchase vaccine for this initiative.

2. **There are many other disparities that exist within this epidemic, including greater rates of infection for many minority groups and the L.G.B.T. community. Are there specific strategies in place to address each of these groups? If so, how do they differ?**

   CDC is conducting formative research with the public to better understand the barriers to vaccination, screening, and other prevention services in communities disproportionately affected by viral hepatitis. CDC also conducts surveys of viral hepatitis knowledge and receipt of viral hepatitis vaccination and screening among minority communities including African Americans, Asian Pacific Islanders, injection drug users, and gay and bisexual men. Finally, CDC funds programs to develop materials and strategies to reach marginalized populations. All of these efforts help to inform strategies to address viral hepatitis health disparities in affected communities.

3. **Despite dealing with an epidemic that the CDC estimates afflicts over five million people, the division of viral hepatitis is the smallest funded infectious disease division under the national center for HIV, viral hepatitis, STD, and TB prevention, and only receives 2 percent of its total budget. Given the huge number of people infected and the costs of late stage liver disease caused by chronic hepatitis b and c infections, why has CDC not dedicated more funds to the division of viral hepatitis?**

CDC's budget for viral hepatitis remained steady and has increased slightly in recent years. Funding in FY 2009 for viral hepatitis was approximately $18 million; in FY 2010, the funding for viral hepatitis was $19 million; and the FY 2011 President's Budget requested $21 million for viral hepatitis. Furthermore, CDC's budget for viral hepatitis does not reflect the entire agency budget for this disease. In addition to amounts specifically in its viral hepatitis budget, CDC supports hepatitis A and B vaccination for both infants and at risk adults out of its immunization program. CDC prioritizes activities funded out of the viral hepatitis budget in order to achieve the most significant impact.

Department of Health and Human Services

Centers for Disease Control and Prevention

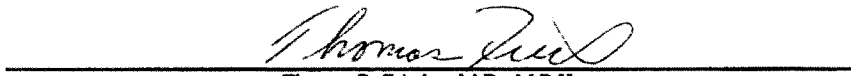
Professional Judgment Budget

for

Comprehensive Viral Hepatitis Prevention and Control in the United States

as

Requested by the U.S. Senate Appropriations Committee



Thomas R. Frieden, M.D., M.P.H.

Introduction

Viral hepatitis is a collective term used to describe liver inflammation or hepatitis that can be caused by a group of several different viruses. Three viruses, Hepatitis A virus (HAV), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) cause the most viral hepatitis in the United States. All can cause disease acutely at the time of infection. However, HBV and HCV infections can persist for years, resulting in ongoing (chronic), but mostly asymptomatic, liver inflammation. Chronic viral hepatitis caused by infections with HBV and HCV is a major cause of liver cancer, chronic liver disease, and death in the United States. In 2010, the Institute of Medicine (IOM) called for an intensified, coordinated national effort to improve prevention of viral hepatitis and better protect the health of Americans. Their report, entitled *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, recommended evidence-based prevention strategies to significantly reduce viral hepatitis transmission and, most importantly, limit or reduce the adverse health impact and economic costs of viral hepatitis associated illness and death.

In Senate Report 111-66 on the fiscal year (FY) 2010 budget for the Department of Health and Human Services, the Senate Committee on Appropriations stated: "The Committee expects the CDC to put forward a professional judgment budget for viral hepatitis no later than August 15, 2010." This report responds to this Congressional request about the cost to develop a comprehensive national program to prevent viral hepatitis transmission and associated liver disease and cancer. It addresses IOM recommendations and is provided without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to Congress are developed. It takes into account current public health investments in viral hepatitis, including perinatal and adult hepatitis B immunization efforts.

Viral Hepatitis Is an Underappreciated Health Risk for Many Americans

Viral hepatitis is a silent epidemic in this country. The damage that viral hepatitis does to the liver is usually asymptomatic until the advanced stages of disease, when it is often too late to treat successfully. An estimated 3.5 to 5.3 million Americans have chronic viral hepatitis, the vast majority (an estimated 70 percent) of whom are unaware of their infection. They are likewise unaware of the need to seek care for their infection, both to reduce the risk of exposing family members and other close contacts, and to minimize the adverse impact of the infection on their own health. In the absence of treatment and care, 15-20% of infected persons will progress to liver cirrhosis. Viral hepatitis is the leading cause of liver transplantation in the U.S. Moreover, in contrast to almost all other forms of cancer, liver cancer rates have tripled over the last several decades, fueled in large part by the population of persons with viral hepatitis who have progressed to end stage disease.

Approximately 12,000-15,000 Americans die of viral hepatitis each year, making it the fourth leading infectious cause of death. Coinfection with HIV and HCV is common, and end stage liver disease secondary to HCV is a leading cause of death for those with HIV. Deaths from viral hepatitis are projected to rise substantially in the coming years. Despite the impact of this disease, healthcare providers, the general public, at-risk populations, and policy makers are mostly unaware of the significant risk it poses to the nation's health.

Babyboomers, African Americans, and Asian Americans have far higher rates of viral hepatitis than the overall population. More than 1 in 33 "baby boomers," aged 46 to 64 years, are infected with viral hepatitis. Rates are even higher among racial and ethnic minorities, representing significant health disparities in this country. For example, one in seven African-American men in their 40s is living with HCV. Approximately one in 12 Asian Americans are living with HBV, and more than 50 percent of the people in the United States with HBV are Asian Americans. Liver cancer is twice as common among African Americans as among whites.

New HBV and HCV infections have declined in recent years, reflecting in part the impact of successful prevention strategies. However, transmission of these viruses is ongoing and adds to the burden of chronic viral hepatitis and liver disease. In 2007 there were an estimated 50,000 new cases of hepatitis B. HBV is spread from mother to child at the time of birth, among household contact through incidental blood exposures in the home, through injection drug use, through healthcare associated infections from exposure to blood, and through sexual contact. Rates are highest among adults with risks such as injection drug use and multiple sexual partners, reflecting low hepatitis B vaccination coverage in this age group. Foreign-born Americans are at risk due to high levels of hepatitis B transmission in many other countries. Outbreaks of hepatitis B also occur via healthcare acquired infection, to persons not currently recommended to receive vaccine, including diabetics, persons in outpatient settings, and residents of eldercare facilities.

Surveillance data suggest that about 20,000 persons are infected with HCV annually in the U.S. Sources of HCV transmission include sexual contact, injection drug use, and poor infection control in healthcare settings. There is no vaccine to prevent HCV.

Current treatments can halt or even reverse the liver damage caused by viral hepatitis. In addition, new treatments on the immediate horizon hold even greater promise for a definitive cure. All persons diagnosed with viral hepatitis should be referred to care to assess stage of disease, identify and manage co-factors (such as alcohol use, diabetes and obesity) that accelerate disease progression, and initiate treatment for those patients who can benefit from antiviral treatment. Of persons with hepatitis C who receive standard therapy, about 40 percent will respond, resulting in virologic cure of their infection. HCV treatment may be less effective for certain populations; however, the first HCV-specific therapies, expected to be licensed in the next several years, might eliminate these disparities in treatment. Despite these advances, most people with viral hepatitis are not aware they are infected until they develop symptoms of severe liver disease or cancer, at which time it is often too late to control the damage caused by their infection. Moreover, of those who are aware of their infection, few receive treatment or care.

Because of the high costs of end stage disease treatments (*e.g.*, liver transplants), the lifetime health care costs for a person with viral hepatitis can easily total hundreds of thousands of dollars. Published studies estimate that the medical costs related to viral hepatitis run in the billions of dollars per year.[1,2] Numerous studies reveal the cost-effectiveness of screening and

---

[1] JB Wong, GM McQuillan, JG McHutchison and T Poynard Department of Medicine, New England Medical Center, Tupper Research Institute, Tufts University School of Medicine, Boston, Mass., USA. *Estimating future hepatitis C morbidity, mortality, and costs in the United States*, American Journal of Public Health, Vol 90, Issue 10 1562-1569.

[2] Milliman Study for Vertex Pharmaceuticals. Consequences of Hepatitis C Virus – Costs of a Baby Boomer Epidemic of Liver Disease. 2009

care for populations at risk for viral hepatitis.[3,4,5,6] Computer models indicate that the cases of life threatening liver disease due to viral hepatitis infections will increase as infected persons age and their disease progresses. As a result, more people in this country will die from liver cancer or end stage liver disease associated with HBV and HCV, raising medical expenditures and reducing productivity.

Health Impact

The human and economic costs of viral hepatitis are projected to accelerate as chronically infected persons develop liver cancer and chronic liver disease. To prevent this from occurring, the Centers for Disease Control and Prevention (CDC) could undertake a phased plan to implement specific actions. These actions are broadly grouped under four programmatic priorities which are, in order of precedence (see table 1):

1) Identify Persons With Viral Hepatitis Early and Refer Them to Care;
2) Improve Monitoring of Viral Hepatitis;
3) Eliminate HBV Transmission; and
4) Develop, Test, and Translate into Action New HCV Prevention Tools

The actions are detailed in the appendix. Phase one describes the activities that could be accomplished in the next 3 years. Phase two activities could be accomplished in years 4–7, and phase three activities could be accomplished in years 8–10.

With full implementation of such a plan, by 2020 the nation could—

- Increase the number of individuals who know their hepatitis B status from 33% to 75%;
- Increase the number of individuals who know their hepatitis C status from 45% to 80%;
- Eliminate the transmission of HBV in the United States; and
- Reduce the number of new cases of hepatitis C by 50%.

---

[3] A Rajendra, JB Wong Economics of chronic hepatitis B and hepatitis C Journal of Hepatology, 2007 Oct; 47 (4):608-17. Epub 2007 Jul 30

[4] Kanwal F, et al., Treatment alternatives for hepatitis B cirrhosis: a cost-effectiveness analysis. The American Journal of *Gastroenterology*, 2006;101(9):2067-2089.

[5] Spackman DE, Veenstra D. A cost-effectiveness analysis of currently approved treatments for HBeAg-positive chronic hepatitis B. *PharmacoEconomics*, 2008;26(11):937-949.

[6] Wong JB, et al., Cost-effectiveness of interferon-alpha 2b treatment for hepatitis B e antigen-positive chronic hepatitis B. *Ann Intern Med*, 1995;122(9):664-675

Table: Funding by Priority and Phase

PRIORITY	Base* Funding	Annual Cost Phase 1 (Years 1–3)		Annual Cost Phase 2 (Years 4–7)		Annual Cost Phase 3 (Years 8–10)	
		Total	Change from Base	Total	Change from Phase 1	Total	Change from Phase 2
1) Identify persons with viral hepatitis early and refer them to care	$7.7M	$32.7M	+$25M	$57.7 M	+ $25M	$107.7 M	+ $50M
2) Improve the monitoring of viral hepatitis	$9.8M	$24.8M	+ $15M	$44.8M	+ $20M	$74.8M	+ $30M
3) Commit the nation to eliminate HBV transmission**	$4.7M	$22.7M	+ $18M	$48.7M	+ $26M	$94.7M	+ $46M
4) Develop, test, and translate into action new HCV prevention tools	$3.6M	$10.6M	+ $7M	$19.1M	+ $8.5M	$29.1M	+ $10M
TOTAL	**$25.8M**	**$90.8M**	**$65M**	**$170.3M**	**$79.5**	**$306.3M**	**$136M**

*Base funding is the amount estimated under the FY 2010 budget. Base funding for viral hepatitis comes from CDC's viral hepatitis, emerging infections, and vaccines for children and food safety budget lines. This funding is projected to increase by $1.8 million under the President's FY 2011 budget request. The increase will be spent across the priority areas including education for screening and vaccination, surveillance and adaptation of HIV prevention interventions for prevention of HCV.

** In addition to funds portrayed in the table above, CDC provides vaccine, mainly through the childhood vaccination programs, through Public Health Services Act Section 317 and the Vaccines for Children program. Amounts spent specifically on hepatitis vaccines for children are not tracked. Approximately $16 million in Section 317 funding was made available in 2010 for states to purchase vaccine for use only in venues serving adults at risk for hepatitis B. However, these funds do not support the infrastructure for vaccine delivery. In addition, approximately $300,000 in American Recover and Reinvestment Act funds were allocated to the evaluation of that vaccine purchase program. States support perinatal HBV coordinators with their Section 317 funds; however, amounts spent on perinatal HBV coordinators are not tracked by CDC.

Appendix: Overview of Priorities and Funding

Priority 1: Identify Persons with Viral Hepatitis Early and Refer Them to Care

> *Health services related to viral hepatitis prevention, screening, and medical management are both limited and fragmented among entities at the federal, state and local levels....Because there is no coordinated federal strategy for HBV and HCV prevention and control, those efforts are uneven in their application and funding.*
>
> —IOM, 2010

Goal: Identify and treat persons with viral hepatitis infections
Key Strategies: (1) Wide access to testing; (2) screening and referral to care for persons living with viral hepatitis; (3) increased education and awareness; (4) case management for infected persons
Base Funding: $7.7 million
Costs: $25 million per year for phase one; final cost $100 million per year (over base) (*See Table for a comprehensive picture of needed resources by year.*)
Impact: Reduce the public health and economic burdens of chronic liver disease

Because the vast majority of persons with viral hepatitis are unaware of their infection and because effective treatments and care can delay or halt disease progression, identifying those who are infected and referring them to appropriate care can greatly reduce the public health and economic consequences of viral hepatitis. For this reason, screening and referral are the highest priority actions for reducing illness and death related to viral hepatitis.

However, aside from support for vaccine purchase provided in the immunization program, current CDC support for adult viral hepatitis prevention is limited to the personnel cost of an adult prevention coordinator for 49 states and a few large cities. These coordinators are tasked with integrating viral hepatitis services with other public health efforts to reach populations at-risk. However, funding for this program is limited and does not support direct service provision (e.g., counseling, testing and referral to care). Additional resources are needed to provide prevention services to reach infected and at-risk persons.

With such resources, CDC and state and local health departments could implement a national program which, in collaboration with other programs and community partners, deliver viral hepatitis prevention, detection, outreach, education, vaccination, screening, and referral for care services to persons at risk for viral hepatitis. This program could actively seek and bring high-risk persons in for screening and care, and increase public awareness and education to reduce ignorance, stigma and other barriers to accessing viral hepatitis services. It could also provide case management to ensure that persons with viral hepatitis receive services to protect their health as well as that of others. These services include referral to care for the early detection of liver cancer and for care and treatment of chronic HCV infection. Finally, professional education activities would ensure that clinicians are trained to effectively deliver screening and care services.

At the state and local level, this comprehensive national program to prevent viral hepatitis and associated liver disease and cancer could be integrated with other community and public health

programs serving populations at risk for viral hepatitis. These include settings already supported by CDC, such as STD and HIV prevention programs, and the federally qualified health centers supported by the Health Resources and Services Administration. Similar integration opportunities could be extended to American Indians/Alaska Natives who are eligible for health services provided by the Indian Health Service or by a tribal organization. CDC could conduct prevention effectiveness research to guide prevention policy development for the agency and other Department of Health and Human Services operating divisions, including the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services.

Specific Actions

CDC, working through state and local health departments, would provide direction and technical and financial assistance to comprehensive ***Viral Hepatitis Intervention Programs (VHIPs)***. VHIP services must be planned using state and local epidemiologic profiles that assemble case tracking, vital statistics, and health care utilization data to document health disparities caused by viral hepatitis and subsequent liver disease and cancer to inform prevention planning. Key ***VHIP*** services include the following:

- Culturally competent public education about the risks of viral hepatitis, opportunities and benefits of testing, and barriers to testing (*e.g.*, stigma);
- Outreach, recruitment, and public awareness activities to inform at-risk communities of the need for screening and bring at-risk persons into screening and evaluation programs;
- Screening of persons through public health and clinical care delivery systems;
- Case management of persons screened to ensure they receive timely services to stop transmission, and appropriate care and referrals to stop progression of disease; and
- Professional education to ensure the use of science-based, clinically appropriate, and high-quality counseling, screening, and follow-up.

FY 2010 spending: $7.7 million
Total increase needed (over base): $100 million per year

- **Phase 1** Increased need: $25 million/year
  10 states: Provide funding to implement a VHIP utilizing a comprehensive public health approach for the delivery of viral hepatitis public health services
- **Phase 2** Increased need over phase 1: $25 million/year
  25 states: Provide funding to implement a VHIP utilizing a comprehensive public health approach for the delivery of viral hepatitis public health services
- **Phase 3** Increased need over phase 2: $50 million/year
  50 states, the District of Columbia, and Puerto Rico: Provide funding to implement a VHIP utilizing a comprehensive public health approach for the delivery of viral hepatitis public health services

Health Impact

- Given no change in current practice, approximately 20 percent of HCV-infected persons would learn their status before developing end stage liver disease or death. Preliminary data from a CDC-developed Markov-type model reveal that by identifying and referring for appropriate care (using current infrastructure), all HCV-infected persons who have at least one primary care visit per year, approximately 87,000 cases of end-stage liver disease and

11,000 liver transplants could be prevented; 840,000 undiscounted life years would be gained with an estimated cost per discounted QALY of $43,000.[7]

- Similarly, these preliminary estimates reveal that expanded HBV screening and care could avert approximately 140,000 cases of end stage liver disease and gain 3.3 million QALYs, or 3.3 million years of potential life gained.[8]
- While funding has not been available to extend the model to estimate cost per discounted QALY for HBV, published literature provides information on the cost-effectiveness of hepatitis B screening. One study estimated $40,000 per incremental QALY gained (2009 dollars) by systematically screening and treating Asian Americans with HBsAg as compared to no screening.[9] For HCV treatment only, three U.S. studies found a range of $8,000 to $67,000 per QALY gained depending on antiviral medications administered and the presence of HBeAg and elevated ALTs.[10,11,12]

[7] CDC preliminary estimates from an ongoing study.
[8] Ibid.
[9] Hutton DW, Tan D, So SK, et al. Cost-effectiveness of screening and vaccinating Asian and Pacific Islander adults for hepatitis B. *Ann Intern Med*, 2007;147 (7):460-469.
[10] Kanwal F, et al., Treatment alternatives for hepatitis B cirrhosis: a cost-effectiveness analysis. *The American Journal of Gastroenterology*, 2006;101 (9):2067-2089.
[11] Spackman DE, Veenstra D. A cost-effectiveness analysis of currently approved treatments for HBeAg-positive chronic hepatitis B. *PharmacoEconomics*, 2008;26(11):937-949.
[12] Wong JB, et al., Cost-effectiveness of interferon-alpha 2b treatment for hepatitis B e antigen-positive chronic hepatitis B. *Ann Intern Med*, 1995;122 (9):664-675.

Priority 2: Improve the Monitoring of Viral Hepatitis

> *Public health surveillance is an essential tool in the prevention and control of infectious and chronic diseases and the medical management of people who have the diseases. The viral hepatitis surveillance system in the United States is highly fragmented and poorly developed. The federal government has provided few resources to local and state health departments to perform surveillance for viral hepatitis.* —IOM, 2010

Goal: Monitor viral hepatitis at the national, state, and local levels
Key Strategies: (1) Report all new infections; (2) detect disease outbreaks; and (3) refer chronically infected persons for care and treatment
Base Funding: $9.8 million
Costs: $15 million per year for phase one; final cost $65 million per year (over base)
(*See Table for a comprehensive picture of needed resources by year.*)
Impact: Provide the information needed to guide and evaluate prevention efforts

> *During fiscal year 2009 alone, the CDC responded 25 times to state requests about outbreaks of HBV or HCV infection in healthcare and other settings. A recent, highly publicized outbreak of viral hepatitis associated with poor infection control practices was detected through surveillance for acute cases of HCV. Detection of the outbreak allowed the state and CDC to investigate and confirm the source of transmission, notify thousands of persons served by the clinic of their risk of exposure, and intervene to stop the poor infection control practices that led to the transmission. This outbreak would not have been detected absent an effective surveillance system in that state.*

Effective prevention would entail a national network of state and local systems that provides consistent and reliable reporting of new infections, rapid detection of disease outbreaks, and the identification and referral of persons with chronic infection for appropriate care and treatment. Such a system is critical to identify and address health disparities affecting racial/ethnic minorities (*e.g.*, Asian/Pacific Islanders, African Americans), and marginalized populations (*e.g.*, homeless, immigrants, injection drug users, incarcerated persons) at risk for chronic viral hepatitis and to plan education, outreach, screening and referral to care.

However, current systems to monitor viral hepatitis at the national, state, and local levels are inadequate to guide and support prevention and control activities. Cases of acute HBV and HCV infection, as well as cases of hepatitis A, are reported in all states and are published annually by CDC. In addition, some states have policies in place to support surveillance of chronic hepatitis B and hepatitis C infection. However, such surveillance is under-resourced, and both acute and chronic infections are vastly under-reported. Although CDC does provide funding for viral hepatitis surveillance to a limited number of jurisdictions, CDC estimates that only 10 percent of new cases of viral hepatitis are reported through that system each year. Further, only two-thirds of states report cases of chronic HCV, and those that do have such large backlogs of cases that it is not possible to articulate a clear picture of chronic HCV infection.

To provide a more accurate national estimate of those living with chronic hepatitis infection, CDC relies on surveys, particularly the National Health and Nutrition Examination Survey (NHANES). However, national surveys under-represent key risk populations and do not provide

data needed for state and local planning. Support for state and local systems is needed to reliably identify modes of transmission and detect disease outbreaks, and inform planning and execution for outbreak investigations and prevention programs.

Specific Actions

Additional resources are needed to monitor the occurrence of viral hepatitis to—

- Guide and evaluate prevention programs providing outreach, education, vaccination, screening and referral to care;
- Assess health disparities related to viral hepatitis for racial/ethnic minorities (*e.g.*, Asian/Pacific Islanders, African Americans, American Indians and Alaska Natives) and marginalized populations (*e.g.*, homeless, immigrants, persons who inject drugs, incarcerated persons); and
- Identify new or previously unrecognized forms of viral hepatitis, and the emergence of viral mutations that compromise vaccination, diagnosis, and therapy.

Key components of such a system include the following:

- Expanding state/local epidemiologic and laboratory capacity to improve detection and investigation of viral transmission and outbreaks of viral hepatitis;
- Eliminating the state backlog of chronic viral hepatitis cases awaiting data entry for transmission to CDC;
- Implementing data standards for uniform reporting to the national viral hepatitis system;
- Identifying mutant viruses resistant to vaccination, diagnosis, or therapy, and rare or new forms of viral hepatitis;
- Linking data to monitor HIV/HCV and HIV/HBV co-infection and other co-factors that increase the risk of end stage liver disease and cancer for persons with chronic viral hepatitis;
- Meeting the information needs of state and local prevention programs;
- Developing disease registries to support referrals of infected persons to care and treatment;
- Conducting surveys of viral hepatitis among underrepresented racial/ethnic minorities and at-risk marginalized populations including the homeless, refugee, and immigrant populations who are affected disproportionately by viral hepatitis; and
- Monitoring persons in care to evaluate receipt of recommended prevention and treatment.

FY 2010 spending: $9.8 million
Total increased need (over base): $65 million per year

- **Phase 1** Increased need over base: $15 million per year
  Support data collection for acute and chronic viral hepatitis in 10 states
- **Phase 2** Increased need over phase 1: $20 million per year
  Support data collection for acute and chronic viral hepatitis in 25 states
- **Phase 3** Increased need over phase 2: $30 million per year
  Support data collection for acute and chronic viral hepatitis in 50 states, the District of Columbia, and Puerto Rico

Health Impact
Ultimately, improved monitoring of viral hepatitis will better inform planning and execution of prevention and care efforts, thereby increasing the proportion of infected persons referred to care and increasing vaccination and harm reduction for at-risk persons. Such as system would:

- Obtain complete and accurate demographic and risk information on 75 percent of new infections in order to target future prevention activities;
- Increase the capacity at state and local levels to detect outbreaks so that new infections are averted by the outbreak response; and
- Achieve early detection of mutant viruses that threaten prevention efforts.

Priority 3: Commit the Nation to Eliminate HBV Transmission

> *Hepatitis B is a vaccine preventable disease for which a safe and effective vaccine has been available for nearly three decades. The longstanding availability of effective hepatitis B vaccine makes the elimination of new HBV infections possible.* — IOM, 2010

Goal: Eliminate HBV transmission in the United States
Key Strategies: (1) Case management for HBV-infected pregnant women and their families; and (2) immunize adults at public health and health care venues serving those at-risk for infection
Base Funding: $4.7 million
Costs: $18 million for phase one; final cost $90 million per year (over base) (*See Table for a comprehensive picture of needed resources by year.*)
Impact: Prevent disease and death resulting from HBV infections

Vaccination is the most effective method of preventing HBV infection and is the basis for the national strategy to eliminate HBV transmission. In 1992, CDC and the Advisory committee for Immunization Practices (ACIP) established a vaccine-based strategy for the elimination of HBV transmission in the U.S. Two expert panels, most recently the IOM, both found that elimination of HBV transmission in the United States is feasible. The ACIP strategy involves vaccinating children beginning at birth adolescents, and at-risk adults. While hepatitis B incidence has declined significantly, particularly among children, new infections continue to occur. Barriers to vaccination include cost and the acceptability of a three dose vaccine series. Missed opportunities to vaccinate allow continued disease transmission. In addition, transmission of HBV has emerged in new populations.

While vaccine purchase is supported through other programs in the public and private sector, a successful strategy involves not only provision of vaccine itself, but services and programs that reach at-risk persons to encourage them to be immunized. These include case management programs to provide preventions services to HBV-exposed newborns, refer mothers for appropriate care for chronic HBV infection, and provide household members with hepatitis B vaccination and screening. This effort would build upon CDC's existing network of perinatal hepatitis coordinators. CDC would also expand efforts to immunize other at-risk adults using a venue based approach.

Prevention and Control for HBV-Infected Mothers, Their Infants, and Their Family Contacts
Vaccination of infants has successfully driven down rates of HBV transmission and acute cases of disease. However, much more should be done. In the United States, 24,000 HBV-infected women give birth each year. These women are at risk of transmitting HBV to their infants and to other household members, as HBV is readily transmitted in household settings. Of infants infected at birth, 90 percent will remain infected and one in four will die prematurely of HBV-related liver disease or cancer.

Since the early 1990s, CDC has supported state/local efforts to prevent mother-child transmission of HBV as part of its childhood immunization efforts. This effort included ensuring screening of pregnant women, vaccination at birth, follow-up with infants to ensure completion of the three dose series, and testing of infants to ensure the development of antibodies. However, the number of HBV-infected women giving birth has greatly increased since that time and current prevention program resources are inadequate to care for all HBV infected mothers, infants and household contacts. States currently do not have the capacity to manage all of the newborns estimated to be exposed to HBV, resulting in avoidable perinatal transmission and new, chronic HBV infections.

CDC also recommends that HBV-infected women identified at the time of pregnancy be referred for medical management of their infection, because they are at risk for chronic liver disease and liver cancer later in life. However, few states have resources to provide such referrals. Family contacts of HBV infected persons are at high risk for HBV infection. Many such contacts are members of racial/ethnic minorities. Although hepatitis B vaccination of such persons has been recommended since 1982, few states have the capacity to provide culturally appropriate hepatitis B screening and vaccination services.

Comprehensive case management program can refer HBV-infected pregnant women to care, prevent infection among their infants through vaccination and monitoring from birth through 18 months of age, and prevent HBV infection and its sequelae among other household members through screening, vaccination, and referral to care. Studies have shown that such an approach is cost-effective. One dollar spent on perinatal hepatitis B vaccine saves about three dollars in medical and work-loss costs and vaccinating 15 infants of HBsAg-positive mothers prevents one death. Studies also have established the cost-effectiveness of screening and immunization for household contacts of persons infected with HBV [13]

Hepatitis B Prevention Among at-risk Adults
Although childhood hepatitis B vaccination coverage has remained above the national goals of 90% for the past 10 years, it has remained low among high risk adults. As a result, most new HBV infections occur among persons engaged in risky sex and injection drug-related behaviors. Hepatitis B immunization is routinely recommended for men who have sex with men, persons with multiple sex partners, and injection drug users (IDUs). Emerging populations of concern include persons with diabetes and others at risk for exposures associated with health care or in residential care facilities, persons vaccinated as infants who may require a booster dose, and persons born in other countries where HBV is prevalent, who represent an ongoing source of

[13] Hutton DW, Tan D, So SK, et al. Cost-effectiveness of screening and vaccinating Asian and Pacific Islander adults for hepatitis B. *Ann Intern Med*. 2007;147(7):460-469.

transmission. All of these groups need access to and attention services from an HBV elimination program.

Multiple studies have established the cost-effectiveness of immunizing against hepatitis B at STD/HIV testing/counseling sites, correctional institutions, and drug-abuse treatment centers.[14,15,16,17] However, the lack of resources for adult vaccination programs has limited vaccination for these persons, allowing continued disease transmission. For example, although CDC has recommended that persons with STDs receive hepatitis B vaccination, 30 percent of people diagnosed with acute hepatitis B had previously been treated for an STD. A similar proportion had been imprisoned. Sexual health clinics and correctional facilities are important settings for education, testing, and vaccination. In fact, an adult hepatitis B vaccination program based on routine immunization at these and other public health clinics serving adults at increased risk of infection would eliminate HBV transmission among adults in the United States by 2020.

Through its Adult Hepatitis B Vaccination Initiative, CDC has begun to close the gap in vaccination of at-risk adults. Since the beginning of the Initiative in FY 2007, CDC has made approximately $42 million in Section 317 funds available for the purchase of hepatitis B vaccine for use in more than 2600 venues. However, funding of this initiative in future years is not assured.

But much work remains to be done. An estimated 6 million persons are eligible for vaccination through this program, which has barely scratched the surface in addressing their needs. Furthermore, an effective vaccination program requires much more than just vaccine itself. Increased capacity is needed at the federal, state, and local levels to establish and implement vaccination plans and procedures, to educate patients at risk for infection, to train providers, and to monitor both the efficiency and efficacy of efforts to insure that vaccine gets to the venues where it is needed and is administered to individuals at risk for infection. The IOM estimated that it would cost $80 million per year for vaccine purchase alone to reach 75 percent of at-risk persons seen in STD/HIV testing/treatment sites and drug treatment centers.

Specific Actions

A comprehensive approach to the elimination of transmission of HBV will—

- Facilitate identification of HBV-infected pregnant women by developing methods to assure positive HBsAg test results are reported directly to local and state health departments;
- Facilitate accurate assessment of hepatitis B infection status of women in labor and for management of their infants;
- Improve access to laboratory testing for HBV infection among cases managed exposed infants and household contacts;

---

[14] Miriti MK, Billah K, Weinbaum C, et al. Economic benefits of hepatitis B vaccination at sexually transmitted disease clinics in the U.S. *Public Health Rep*, 2008;123(4):504-13

[15] Hu Y, Grau LE, Scott G, et al. Economic evaluation of delivering hepatitis B vaccine to injection drug users. *Am J Prev Med*, 2008;35(1):25-32.

[16] Pisu M, Meltzer MI, Lyerla R. Cost-effectiveness of hepatitis B vaccination of prison inmates. *Vaccine*. 2002;21(3-4):312-21

[17] Kim SY, Billah K, Lieu TA, et al. Cost effectiveness of hepatitis B vaccination at HIV counseling and testing sites. *Am J Prev Med*. 2006;30(6):498-506.

- Assure that women infected with HBV, their infants, and their household contacts receive services that they need to prevent transmission and prevent or delay disease progression;
- Test and validate a system to monitor the effectiveness of prevention programs for pregnant women with chronic HBV infection;
- Develop culturally-sensitive educational materials about perinatal HBV and chronic HBV for care providers and families;
- Evaluate the efficacy of hepatitis B vaccine and the need for a booster dose in adolescents;
- Collaborate with WHO and others to support HBV prevention programs in countries where HBV is endemic;
- Assure capacity to administer hepatitis B vaccines in public health settings caring for adults at risk for infection; support sufficient headquarters staff to provide technical assistance and oversight;
- Develop and disseminate community education and provider training to improve acceptance of hepatitis B vaccination; and
- Integrate HBV screening and vaccination in correctional, HIV, and STD treatment settings.

FY 2010 spending: $4.7 million
Total increased need (all phases): $90 million per year

- **Phase 1** Increased need: $18 million per year.
  Support comprehensive case management for mothers and families ($6 million), as well as programs for at-risk adults ($12 million) in 10 states.
- **Phase 2** Increased need over phase 1: $26 million per year.
  Support comprehensive case management for mothers and families (increase of $6 million), as well as programs for at-risk adults (increase of $20 million), in 25 states.
- **Phase 3** Increased need over phase 2: $46 million per year.

Health Impact

- Provide prevention services to 25,000 families, including HBV-infected pregnant women, newborns, and other household members.
- Increase hepatitis B vaccination coverage in high-risk adult populations to 75 percent by 2020.

Priority 4: Develop, Test, and Translate into Action New HCV Prevention Tools

> *Hepatitis C became a global epidemic in the 20th century as blood transfusions, hemodialysis, and the use of injection needles to administer licit and illicit drugs increased throughout the world. Because HCV prevention is a function of multiple factors- safe injection, education, testing, and drug treatment, an integrated programs that includes all these essential elements is more likely to be effective in preventing hepatitis C.* — IOM, 2010

Goal: Prevent new HCV infections
Key Strategies: Develop, test, and utilize new tools to prevent transmission
Base Funding: $3.6 million

Costs: $7 million for phase one; final cost $25.5 million per year (over base) (*See Table for a comprehensive picture of needed resources by year.*)
Impact: Prevent disease and death resulting from HCV infection

The identification of the hepatitis C virus and the development of screening tests have led to a significant decline in HCV transmission. However, surveillance data suggest that about 20,000 persons are infected annually. HCV is efficiently transmitted via direct percutaneous exposure to infected blood. Injecting drug use is the cause of most new HCV infections, and incidence remains high in most U.S. cohorts. However, numerous outbreaks of HCV infection also continue to occur in health care settings, linked to inadequate infection control practices. Other populations have emerged as priorities for viral hepatitis prevention. For example, while often considered an urban phenomenon, HCV transmission among injecting drug users recently has been detected among youth in suburban communities and small towns. A trend seen in Europe for several years is now evident in the United States with sexual transmission of HCV being detected among U.S. cohorts of HIV-infected MSM.

CDC currently conducts surveillance of HCV infection and has initiated a pilot cohort study of chronic HBV and HCV. CDC has responded to numerous suspected outbreaks of HCV transmission and is currently developing guidelines for HCV screening. The agency also provides assistance to efforts to prevent HIV among injecting drug users and aims to release guidance later this year regarding the use of syringe services programs.

Although there is not yet a vaccine to protect against hepatitis C, HCV can be prevented by avoiding factors that lead to its transmission. Effective HCV prevention among IDUs is a function of multiple factors—drug treatment, safe-injection intervention strategies, education, and testing. Drug treatment can help to reduce injection frequency and help injectors to quit. Safe-injection interventions have been shown to reduce HIV transmission, but have not been systematically studied or adapted for use in preventing HCV infection.

Studies of strategies tailored to prevent HCV can promote the development of integrated programs equally effective in preventing HIV and HCV. Prevention programs also need to have the tools to prevent the at-risk individual's transition from non-injection drug user who snorts heroin, cocaine, and other drugs to injecting drug user. Critical to HCV prevention is the development of evidence-based education strategies that focus not only on the messages about how behavior change can or should be made, but also on the context in which those messages are delivered.

Similarly, changes in policies and technologies, along with training of personnel, can reduce transmission in healthcare settings; rapid assays can improve access to screening, and new assays may improve detection of recent HCV infection; studies of sexual transmission will form the evidence basis for new interventions. Lastly, studies suggest that, if detected early, many HCV infections could be cured. As new and improved therapies are introduced, research should be conducted to guide how best to use them to preserve the health of those infected and prevent transmission among networks of IDUs.

Specific Actions

1. Develop novel laboratory tests to improve screening for acute or recent HCV infection;
2. Test new technology and model laws and policies to reduce infections among drug users and improve infection control in outpatient and congregant living facilities (e.g., nursing homes, assisted living facilities, residential care settings);
3. Conduct epidemiologic and laboratory research to assess provider behavior, equipment design, and viral factors associated with transmission of HCV in health care settings;
4. Study social networks of young drug users and tailor new interventions to identify emerging trends of HCV transmission in suburban and rural communities;
5. Develop and test innovative strategies to achieve declines in HCV transmission among IDUs comparable to the reductions attained for HIV infection;
6. Monitor and assess the emergence of sexual transmission of HCV among persons with HIV infection in the United States;
7. Evaluate and implement science-based educational tools and strategies to increase knowledge of HCV among healthcare staff and staff of drug treatment and correctional facilities; and
8. Evaluate and disseminate science-based education and counseling messages that lead to drug cessation or safer injection practices.

FY 2010 spending: $3.6 million
Increased need (all phases): $25.5 million

- **Phase 1** Increased need over base: $7 million per year
  Develop and implement actions one, two, and three
- **Phase 2** Increased need over phase 1: $8.5 million per year
  Develop and implement actions one through six
- **Phase 3** Increased need over phase 2: $10 million
  Develop and implement actions one through eight

Health Impact

Reduce the number of new cases of hepatitis C by 50 percent by 2020.

HEPATITIS EDUCATION PROJECT

Making a difference for hepatitis patients

July 9, 2010

Honorable Wm. Lacy Clay
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Representative Clay,

First, I would like to thank you for your interest in this important public health issue and your support of HR 3974, the Viral Hepatitis and Liver Cancer Control and Prevention Act of 2009.

In response to your first question, I have been working in the field of hepatitis education and advocacy for almost 10 years. During that entire time I have served as the Executive Director of the Hepatitis Education Project.

In response to your second question, I believe that effective screening and testing remains the greatest obstacle in addressing the twin epidemics of hepatitis C and hepatitis B. Most people living with hepatitis C or hepatitis B remain unaware of their infection. An estimated 75% of the 4 million Americans living with hepatitis C are undiagnosed – about 3 million people. And an estimated 66% of the two million Americans living with hepatitis B also remains undiagnosed – an additional 1.3 million people. We cannot mount an effective response to this public health crisis until these people are screened, tested, diagnosed and connected to medical management.

One major obstacle with respect to screening for hepatitis C is the United States Preventive Services Task Force (USPSTF) screening guidelines from 2004. The USPSTF correctly, in my opinion, recommended against screening in asymptomatic adults who are not at increased risk for infection (i.e., general population). However, in adults at high risk for infection, the Task Force found insufficient evidence to recommend for or against routine screening ("I" recommendation). This finding contradicts both NIH and CDC recommendations to screen and test high risk adults. And since USPSTF recommendations are often used as guidelines for providers and payors, the result is that we are missing many people who should be screened and tested.

The Agency for Healthcare Research and Quality (AHRQ) is currently in the process of reviewing the original recommendations from 2004. This is problematic because one of the reasons that the USPSTF originally gave an "I" recommendation for screening in high risk populations was a so-called lack of evidence that treatment regimens then available

Hepatitis Education Project • 911 Western Ave Ste 302 • Seattle, WA 98104 • 206-732-0311
HepInfo@hepeducation.org • http://www.hepeducation.org

for HCV infection, such as pegylated interferon plus ribavirin, improve long-term health outcomes. Whether or not the Task Force was correct in this assessment, we are at a revolutionary turning point in treatment options for hepatitis C patients – new shorter, more effective treatments are expected to be available next year that will increase the cure rate for hepatitis C patients from 45% to 75%. The Task Force will be doing the community a disservice if it moves forward with its potential revision of the 2004 recommendations before these new treatment regimens are reviewed by the FDA. My hope is that they will take these promising new regimens into consideration when revising the screening recommendations for high risk populations.

I should also add that CDC is currently looking at revising their recommendations for hepatitis C screening. CDC *does* currently recommend screening adults at high risk for hepatitis C and is conducting research into the effectiveness of adding an age age-based cohort to their screening recommendations. Two-thirds of Americans living with hepatitis C are baby boomers (born between 1946 and 1964) and the overwhelming majority of these individuals remain undiagnosed. I am confident that this approach will prove effective and when implemented will help diagnose many of these people before they progress to serious liver disease or death.

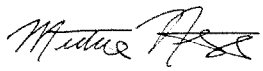
Finally, you mention several potential obstacles in your question: education, awareness and funding. These all are critically important to adequately address this crisis.

In the end, though, none of this will happen without funding. Hepatitis C is the most common blood borne infection in the U.S. And hepatitis B affects more Americans than HIV. And yet, the Division of Viral Hepatitis at CDC is woefully underfunded with a total annual budget of less than $20 million. The budget for HIV prevention alone in FY09 was approximately $750 million. This discrepancy is disgraceful. And people are dying needlessly as a result.

The fight against hepatitis C and hepatitis B in this country is a winnable battle, to use the words of CDC Director Tom Frieden. Our window of opportunity in this battle is closing, though. If we do not act now, much of the disease burden related to hepatitis C and hepatitis B will occur within the next ten years. Now is the time to commit the necessary resources to the critical programs and services that can save these lives and make viral hepatitis history.

Thank you again for this opportunity and your support.

Sincerely,



Michael Ninburg
Executive Director
Hepatitis Education Project

Hepatitis Education Project • 911 Western Ave Ste 302 • Seattle, WA 98104 • 206-732-0311
HepInfo@hepeducation.org • http://www.hepeducation.org

Iowa Department of Public Health
Promoting and Protecting the Health of Iowans

Thomas Newton, MPP, REHS
Director

Chester J. Culver
Governor

Patty Judge
Lt. Governor

July 8, 2010

The Honorable Edolphus Towns
Congress of the United States
House of Representatives
Committee on Oversight and Government Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Representative Towns:

Thank you and Representative Wm. Lacy Clay for your questions on viral hepatitis resulting from my testimony at the hearing entitled, "Viral Hepatitis: The Secret Epidemic" on June 17, 2010. I am pleased to be able to offer my thoughts to you on these questions.

In response to your first question: "In my experience, do I believe that local, state, and federal governments provide enough funding for hepatitis education and care," my thoughts are as follows.

Local, state, and federal funding for hepatitis prevention, education, and care is clearly insufficient to address the scale of these epidemics. States receive, on average, $90,000 in a cooperative agreement with the Centers for Disease Control and Prevention (CDC) to support an Adult Viral Hepatitis Prevention Coordinator, whose job is to integrate hepatitis prevention messages into existing prevention services, such as HIV and STD counseling and testing services. The Coordinators are given no funds for programmatic expenses or core public health services, such as counseling and testing, educational materials, or training of health providers. In addition, there are no federal funds for public health surveillance activities, which critically limits the ability of health departments to measure the magnitude of the epidemics, to respond to outbreaks, and to evaluate prevention and control measures. Finally, states receive no federal funding to support hepatitis care and treatment, or important support services that help infected people adhere to long-term medical management and treatment therapies. These services include treatment of substance abuse and other mental health issues, access to affordable housing, and access to ancillary health services.

Some states are fortunate to have limited funding through their legislatures for prevention and control activities. Currently, 12 states dedicate state revenue to hepatitis prevention and/or care services. The funding ranges from $40,000 to $1,026,000. However, this funding is quite vulnerable given the current economic challenges faced by state governments. There have been several states that have lost all state funding for hepatitis services in the past few years.

With the passage of health reform, more Americans will have access to primary care. This will not eliminate the need for state and local public health programs to provide population-based prevention programming and the need for community-based organizations to provide important education and support services. The Institute of Medicine (IOM) report, *Hepatitis and Liver Cancer: A National Strategy for Hepatitis B and C*, recommends providing risk-factor screening and testing of those at risk

for hepatitis B and C. However, the U.S. Preventive Services Task Force (USPSTF) found insufficient evidence to recommend for or against testing of persons at high risk for hepatitis C infection. The USPSTF is silent on testing of persons at risk for hepatitis B infection, with the exception of pregnant women. Because health reform legislation requires the USPSTF to issue a grade of A or B before services will be routinely covered, it is unlikely that health reform alone will help to find the 65% of persons with hepatitis B who are undiagnosed and the 75% of persons with hepatitis C who are currently undiagnosed.

In summary, funding for hepatitis prevention, education, and care is insufficient to mount a proper public response to these two important diseases. As the IOM report indicates, chronic hepatitis B and C are among the leading causes of preventable death worldwide. Each year, approximately 15,000 deaths are attributed to HBV- or HCV-associated liver cancer or end-stage liver disease in the United States. This exceeds the number of deaths from HIV/AIDS. Three to five times more people live with chronic viral hepatitis infections than with HIV. Yet, funding for HBV and HCV accounts for only 2% of the budget of CDC's National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Prevention, compared to 69% for HIV/AIDS. We must do more to address these diseases.

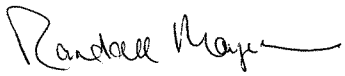
Rep. Clay's second question was, "Can I speak to the importance of community organizations, as well as government ones, in the fight to curb the epidemic?"

Community-based organizations (CBOs) work in conjunction with local and state governments to prevent disease and ensure medical management. State public health departments are central in the coordination of services within a jurisdiction, but CBOs and local health departments are essential in the delivery of front-line services to persons at risk and to those living with hepatitis. State health departments need additional funding to provide grants to local health departments and CBOs to deliver these front-line services.

In the IOM report, we describe several model programs such as the Jade Ribbon Campaign, which targets Asians and Pacific Islanders to reduce the prevalence of chronic HBV infection and HBV-related liver cancer, and the Harm Reduction Coalition, which develops and disseminates hepatitis C information among and for illicit-drug users. State and local health departments can provide funding to these organizations and can help refer at-risk or recently diagnosed persons to them for services. Conversely, CBOs often have access to populations that may not be accessible to local and state health departments and their programs. CBOs have proven that they can be effective in delivering prevention and care services to these populations. As noted in the IOM report, however, there is no coordinated national campaign among governmental and non-governmental agencies, nor is there sufficient funding to allow for a sustained, coordinated response that would address the scale of these epidemics.

Thank you for your consideration of this important issue. Please let me know if I can be of further help in your deliberations.

Sincerely,



Randy Mayer, Chief
Bureau of HIV, STD, and Hepatitis

JOURNAL OF VIRAL HEPATITIS

Journal of Viral Hepatitis, 2010 doi:10.1111/j.1365-2893.2010.01327.x

Hepatitis C testing practices and prevalence in a high-risk urban ambulatory care setting

W. N. Southern,[1,2,3] M.-L. Drainoni,[4,5] B. D. Smith,[6] C. L. Christiansen,[4] D. McKee,[7] A. L. Gifford,[4,8,9] C. M. Weinbaum,[6] D. Thompson,[10] E. Koppelman,[4,5] S. Maher[7] and A. H. Litwin[1,2]

[1]*Department of Medicine, NY, USA;* [2]*Division of General Internal Medicine, NY, USA;* [3]*Section of Hospital Medicine, NY, USA;* [4]*Health and Policy Management Department, School of Public Health, Boston University, NY, USA;* [5]*Center for Health Quality, Outcomes and Economic Research, ENRM Veterans Administration Hospital, NY, USA;* [6]*Division of Viral Hepatitis, Centers for Disease Control and Prevention, National Center for HIV/Viral Hepatitis/STD/TB Prevention, GA, USA;* [7]*Department of Family Medicine: Albert Einstein College of Medicine, Montefiore Medical Center, NY, USA;* [8]*Section of General Internal Medicine, Boston University School of Medicine, NY, USA;* [9]*VA QUERI-HIV/Hepatitis Program, Edith Nourse Rogers Memorial Veterans Hospital, NY, USA; and* [10]*Emerging Health Information Technology, NY, USA*

Received January 2010; accepted for publication March 2010

SUMMARY. Approximately 3.2 million persons are chronically infected with the hepatitis C virus (HCV) in the U.S.: most are not aware of their infection. Our objectives were to examine HCV testing practices to determine which patient characteristics are associated with HCV testing and positivity, and to estimate the prevalence of HCV infection in a high-risk urban population. The study subjects were all patients included in the baseline phase of the Hepatitis C Assessment and Testing Project (HepCAT), a serial cross-sectional study of HCV screening strategies. We examined all patients with a clinic visit to Montefiore Medical Center from 1/1/08 to 2/29/08. Demographic information, laboratory data and ICD-9 diagnostic codes from 3/1/97–2/29/08 were extracted from the electronic medical record. Risk factors for HCV were defined based on birth date, ICD-9 codes and laboratory data. The prevalence of HCV infection was estimated assuming that untested subjects would test positive at the same rate as tested subjects, based on risk-factors. Of 9579 subjects examined, 3803 (39.7%) had been tested for HCV and 438 (11.5%) were positive. The overall prevalence of HCV infection was estimated to be 7.7%. Risk factors associated with being tested and anti-HCV positivity included: born in the high-prevalence birth-cohort (1945–64), substance abuse, HIV infection, alcohol abuse, diagnosis of cirrhosis, end-stage renal disease, and alanine transaminase elevation. In a high-risk urban population, a significant proportion of patients were tested for HCV and the prevalence of HCV infection was high. Physicians appear to use a risk-based screening strategy to identify HCV infection.

Keywords: hepatitis C, prevalence, screening.

INTRODUCTION

An estimated 3.2 million persons are chronically infected with the hepatitis C virus (HCV) in the U.S. [1], roughly three times as many as are infected with HIV [2]. HCV infection is thought to cause approximately 40% of chronic liver disease [3] and the majority of hepato-cellular carcinoma [4] Although the prevalence of anti-HCV is estimated at 1.6% in the U.S. [1], urban populations bear a disproportionate burden of infection and inner city prevalence has been reported as high as 8.3% [5]. Effective treatment for HCV infection is available [6–10], but the majority of those infected are not aware of their status [11–15]. Although testing for patients at high risk is recommended [3,9,10,16,17], optimal testing strategies have not been described [18]. To inform the discussion of testing strategies, we sought to examine the associations between patient characteristics and HCV testing practices among physicians, and estimate the prevalence of HCV infection in a high-risk urban population.

It has been suggested that routine testing for HCV is not efficient [17] or cost-effective [19,20]. Guidelines suggest testing patients with a history of transfusion or organ transplant prior to 1992, persons using injection drugs [3,9,16,17], those with HIV infection [3,9,10], those receiving hemodialysis [3,9,16,17], children of HCV-infected

Abbreviations: ALT, alanine transaminase; EMR, electronic medical record; HCV, hepatitis C virus; MMC, Montefiore Medical Center.

Correspondence: William N. Southern, MD, Department of Medicine, Montefiore Medical Center, 111 East 210th Street, Bronx, NY 10467, USA. E-mail: wsouther@montefiore.org

© 2010 Blackwell Publishing Ltd

mothers, and persons with unexplained elevated alanine transaminase (ALT) levels [3,9,17]. In addition, it has been noted that prevalence of HCV infection is very high in patients with a history of alcohol abuse [21,22], sexually-transmitted diseases (STD) [23–25], and psychiatric disease [26–29]. It has also been noted that the majority of prevalent cases of HCV infection are found in patients born between 1945–1964 [1,30,31], and thus, being born in this high prevalence birth-cohort may be considered a risk factor for HCV infection.

It is unclear which of these potential risk factors physicians consider important when deciding which patients to test for HCV, and which testing strategies yield high rates of positivity. The objectives of this analysis were to examine the testing practices of physicians to determine which patient characteristics are associated with testing for HCV antibody and HCV infection, and to estimate the prevalence of HCV infection in a high-risk urban population. We hypothesized that many patient risk factors would be independently associated with HCV testing, and that the prevalence of HCV infection in this population would be significantly higher than the national prevalence.

METHODS

Study setting

The study was conducted at three community-based primary care (family medicine or internal medicine) clinics affiliated with Montefiore Medical Center (MMC), a university-affiliated teaching hospital. The three participating primary care clinics are large, urban clinics located in the Bronx, New York. Each year, 54 000 adults make over 150 000 primary care visits to the three clinics. The clinic sites are located in economically depressed areas of the Bronx and serve patients with high rates of poverty and substance use. Reported prevalence of HCV infection is higher in New York City [32] than the national estimate and the Bronx has a higher prevalence than NYC as a whole [33].

Study design

This study employed a cross-sectional design with retrospective electronic medical record (EMR) review to examine the associations between patient demographic and clinical characteristics, testing for anti-HCV, and anti-HCV positivity.

Study population

All study subjects were patients included in the baseline testing phase of the Hepatitis C Assessment and Testing Project (HepCAT), a serial cross-sectional intervention study investigating the optimal strategy to improve screening for HCV. A qualifying visit was defined as a primary care visit by patients 18 years and older to one of the three participating clinics between 1/1/08 to 2/29/08.

Data extraction

For research and quality improvement purposes, MMC maintains a data replicate of its computerized Clinical Information System containing patient demographics, outpatient visit records, hospital records, ICD-9 codes, prescriptions, and laboratory test results. From this replicate, we extracted demographic information associated with the qualifying clinic visit for each subject. In addition, we extracted clinical information dating back to March 1997, the year electronic records became available, including inpatient and outpatient ICD-9 diagnosis codes, prescription and inpatient medication records, and laboratory testing results. The Institutional Review Boards of Boston University Medical Center and MMC approved this study. Because the dataset contains only de-identified records, informed consent was not obtained from patients or physicians; instead, a Health Insurance Portability and Acountability Act-approved data use agreement [34,35] was signed by all participating investigators.

Outcome variables

For the current analysis, the primary outcomes were "ever tested" for HCV antibody and HCV antibody positivity. Ever tested for HCV was defined as an anti-hepatitis C virus antibody (anti-HCV) by ELISA performed from March 1997 through May 2008. HCV antibody positivity (indicating past or current HCV infection) was defined as a positive anti-HCV test from March 1997 through May 2008.

Independent variables/definitions

The major independent variables were demographic and clinical patient characteristics shown to be associated with HCV antibody positivity. Although a history of blood transfusion or organ transplant before 1992 is a known risk factor for HCV infection, the EMR had little data on these risks, so the analysis does not include them. In order to create clinically meaningful diagnosis groups, ICD-9 codes were classified using the Healthcare Cost and Utilization Project of the Agency for Healthcare Research and Quality system [36].

Age

For analysis, age was categorized into five distinct groups. In addition, age was dichotomized as within the high prevalence birth cohort (born from 1945 through 1964) defined by the Centers for Disease Control and Prevention (CDC) [1,30] vs not within the cohort.

© 2010 Blackwell Publishing Ltd

Sex
Dichotomized as male and female.

Race/Ethnicity
For analysis, race/ethnicity was collapsed into four categories: non-Hispanic White, non-Hispanic Black or African American, Latino or Hispanic, and other/unknown.

Substance abuse
Substance abuse was coded as present if an ICD-9 code for substance abuse/dependence or a positive urine toxicology for amphetamines, barbiturates, cocaine, or methadone was recorded at any time from March 1997 through the qualifying visit date.

HIV
HIV was coded as present if an ICD-9 code for HIV infection or a positive antibody test confirmed by a Western blot was present at any time from March 1997 through the qualifying visit date.

Sexually transmitted disease
Sexually transmitted disease was coded as present if an ICD-9 code indicating gonorrhea or chlamydia or positive gonorrhea or chlamydia PCR probe was present at any time from March 1997 through the qualifying visit date.

Alcohol abuse
Alcohol abuse was coded as present if an ICD-9 code for alcohol dependence or alcohol-related liver disease, or a serum alcohol level ≥ 80 mg/dL was present at any time from March 1997 through the qualifying visit date.

Cirrhosis
Cirrhosis was coded as present if an ICD-9 code for cirrhosis was present at any time from March 1997 through the qualifying visit date.

End stage renal disease
Coded as present if an ICD-9 code for end-stage renal disease or procedure code for hemodialysis was present at any time from March 1997 through the clinic visit date.

Psychiatric disease
Coded as present if an ICD-9 code for affective disorder, anxiety disorder, schizophrenia, or psychosis was present at any time from March 1997 through the clinic visit date.

Alanine transaminase elevation
The highest ALT value reported from March 1997 through the clinic visit date for each subject was used. ALT was treated as a dichotomous variable: >40 U/L was defined as elevated (40 U/L is a commonly used upper limit of normal [37,38]).

Statistical analysis

Estimating the prevalence of hepatitis C virus infection
Although not all subjects were tested for HCV we estimated floor and ceiling values for the prevalence of HCV infection in our population. The floor estimation assumed that all untested subjects were negative. The ceiling estimation was calculated as follows: a predictive logistic regression model was constructed using the tested population to assign a probability of positivity based on co-morbidities associated with positivity. Assuming that untested subjects would test positive at the same rate as tested subjects based on risk profile, this predictive model was applied to the untested population to assign a probability of positivity in each untested subject. The sum of the untested subjects' probabilities was used to estimate the number of subjects who would have tested positive in the untested population.

Proportion tested/proportion positive
The proportion of patients tested for anti-HCV and the proportion of patients testing positive are reported. The proportions tested and positive were calculated for predefined age categories and demographic characteristics, presence or absence of pre-defined co-morbidities, and the presence or absence of ALT elevation.

To examine the relationship between subject age, and other demographic characteristics, co-morbidities and ALT levels, we calculated the proportion of subjects testing positive in each age category stratified by demographics, co-morbidities, and ALT categories.

To examine factors independently associated with HCV testing, a multivariate logistic regression model was constructed: factors eligible for the model included demographics (age, sex, race/ethnicity), high-risk co-morbidities (substance abuse, alcohol abuse, HIV, STD, cirrhosis, end-stage renal disease, psychiatric disease), and ALT elevation. The model was constructed in a forward stepwise fashion including each factor that maintained an independent association with anti-HCV testing (Wald statistic $P < 0.10$). A similar logistic regression model was constructed to examine factors independently associated with testing positive for anti-HCV.

STATA/IC software, version 10.0, (StataCorp, College Station, TX, USA) was used for all data management and statistical analysis.

RESULTS

Study population

Data on 9579 patients were examined. Demographic and clinical information for the study population are summarized in Table 1. The mean age was 48.6 years (range 18–101). The study population was predominantly female (72.4%) and predominantly Latino (51.3%) or African American

© 2010 Blackwell Publishing Ltd

Table 1 Characteristics of study population

	(n = 9579)
Age	48.6 ± 16.9
Male	2647 (27.6)
Race/Ethnicity	
White	471 (4.9)
Black	3038 (31.7)
Latino	4915 (51.3)
Oth/Unknown	1155 (12.1)
Diagnoses	
Substance Abuse*	558 (5.8)
Alcohol Abuse†	171 (1.8)
HIV‡	429 (4.5)
STD§	271 (2.8)
Cirrhosis¶	97 (1.0)
ESRD**	74 (0.8)
Psychiatric diagnosis††	1550 (16.2)

Continuous variables reported as mean ± standard deviation dichotomous variables reported as No. (%). *ICD-9 or positive urine toxicology. †ICD-9 for Etoh dependence or etoh liver disease or etoh level ≥ 80. ‡ICD-9 or positive antibody test or western blot. §STD. Sexually Transmitted Disease (not HIV): ICD-9 or Positive GC or Chlamydia PCR probe. ¶ICD-9 Code. **ESRD. End-Stage Renal Disease: ICD-9 code or procedure code for hemodialysis. ††ICD-9 for affective, anxiety, schizophrenia, or psychosis.

(31.7%). History of psychiatric disease was reported for 1550 (16.2%) subjects, 558 (5.8%) had a history of substance abuse, and 429 (4.5%) had a history of HIV.

Estimated prevalence

Anti-HCV prevalence among the 3803 (39.7%) persons in this sample tested in our medical systems was 11.5%. The floor estimate of HCV prevalence for the entire study population (assuming all untested subjects are negative) was 4.6%. The ceiling estimate of HCV prevalence (assuming untested subjects would test positive at the same rate as those tested, based on risk profile) was 7.7%.

Hepatitis C testing by age, high risk diagnosis, and alanine transaminase elevation

The proportion of patients tested for anti-HCV and the proportion testing positive stratified by demographics, high-risk co-morbidities, and ALT elevation are reported in Table 2. Several high risk co-morbidities were associated with a large proportion of subjects tested including substance abuse (78.1% tested, 43.8% positive), alcohol abuse (74.3% tested, 33.1% positive), HIV (87.4% tested, 34.4% positive), cirrhosis (89.7% tested, 51.7% positive), and end-stage renal disease (85.1% tested, 9.5% positive). A substantial proportion of subjects aged 18–29 years were tested (30.3%), but a small proportion of those tested positive (0.4%). Of subjects with any risk factor (in the high-prevalence birth cohort, any high-risk co-morbidity, or elevation of ALT), 48.6% were tested and 15.7% of those tested positive. Of subjects without any risk factor noted, 28.8% were tested, and of those, 3.0% were positive.

Multivariate analysis of testing

Bivariate and multivariate associations between factors and HCV testing are reported in Table 3. In multivariate analysis, each of the following factors was significantly independently associated with anti-HCV testing: born in high prevalence birth cohort; male sex; African-American race; Latino ethnicity; substance abuse; alcohol abuse; HIV; STD; cirrhosis; end-stage renal disease; psychiatric disease; and elevation of ALT.

Multivariate analysis of testing positive

Bivariate and multivariate associations between factors and testing positive for anti-HCV are reported in Table 4. In multivariate analysis each of the following factors was significantly independently associated with testing positive for anti-HCV: born in high prevalence birth cohort; male sex; substance abuse; HIV; cirrhosis; and elevation of ALT.

DISCUSSION

Testing practices in the three clinics evaluated in this study show that physicians test patients with known risk factors to identify HCV infection. The majority of patients with substance abuse (78.1%), alcohol abuse (74.3%), HIV (87.4%), cirrhosis (89.7%), end-stage renal disease (85.1%), ALT elevation (67.2%), or STDs (52.8%) were tested. In addition, a substantial proportion of patients with psychiatric diagnosis (49.7%) were tested. Each of these factors was independently associated with testing in multivariate analysis.

The majority of anti-HCV positive patients identified (73.3%) were born in the high prevalence birth-cohort. Being born in these years was also independently associated with HCV testing and anti-HCV positivity in multivariate analysis. Although testing all patients born in the high prevalence birth cohort may be warranted, evidence suggests that birth cohort-based testing alone would be a less than optimal strategy. First, our data suggest that birth cohort-based testing would fail to identify 26.7% of anti-HCV positive persons, which is similar to the unidentified proportions found when testing only in the birth cohort reported by O'Brien (25.4%) [31], Armstrong (34.4%) [1], and Alter (31.3%) [30]. Second, several factors were independently and strongly associated with positivity after

© 2010 Blackwell Publishing Ltd

Table 2 Hepatitis C testing stratified by demographic characteristics, co-morbidities, and ALT elevation (n = 9579)

	Tested No. (%)	Positive No. (%)
Demographics		
Age		
18–29 (n = 1571)	476 (30.3)	2 (0.4)
30–44 (n = 2443)	1006 (41.2)	61 (6.1)
45–54 (n = 2050)	999 (48.7)	173 (17.3)
55–64 (n = 1644)	737 (44.8)	148 (20.1)
≥65(n = 1871)	585 (31.3)	54 (9.2)
Sex		
Male (n = 2647)	1297 (49.0)	239 (18.4)
Female (n = 6932)	2506 (36.2)	199 (7.9)
Race/Ethnicity		
White (n = 471)	198 (42.0)	36 (18.2)
African American (n = 3038)	1244 (40.9)	133 (10.7)
Latino (n = 4915)	1966 (40.0)	242 (12.3)
Oth/Unknown (n = 1155)	395 (34.2)	27 (6.8)
High-risk co-morbidities		
Substance Abuse* (n = 558)	436 (78.1)	191 (43.8)
Etoh Abuse† (n = 171)	127 (74.3)	42 (33.1)
HIV‡ (n = 429)	375 (87.4)	129 (34.4)
STD § (n = 271)	143 (52.8)	12 (8.4)
Cirrhosis¶ (n = 97)	87 (89.7)	45 (51.7)
ESRD** (n = 74)	63 (85.1)	6 (9.5)
Psychiatric diagnosis †† (n = 1550)	771 (49.7)	121 (15.7)
ALT elevation		
AnyALT > 40 U/L (n = 826)	555 (67.2)	169 (30.5)
All ALT ≤ 40 U/L (n = 8753)	3248 (37.1)	269 (8.3)
Combined Factors		
Any risk factor (n = 5262)	2559 (48.6)	401 (15.7)
No risk factor (n = 4317)	1244 (28.8)	37 (3.0)
Total (n = 9579)	3803 (39.7)	438 (11.5)

*ICD-9 or positive urine toxicology. †ICD-9 for Etoh dependence or etoh liver disease or etoh level ≥ 80. ‡ICD-9 or positive antibody test or western blot. §STD, Sexually Transmitted Disease (not HIV): ICD-9 or Positive GC or Chlamydia PCR probe. ¶ICD-9Code. **ESRD, End-Stage Renal Disease: ICD-9 code or procedure code for hemodialysis. ††ICD-9 for affective, anxiety, schizophrenia, or psychosis.

adjustment for birth-cohort status including substance abuse, HIV, cirrhosis, and ALT elevation. Lastly, in our study the risk-based screening strategy yielded high rates of anti-HCV positivity in all categories of risk in patients born outside the high-risk birth-cohort. These data suggest that current risk-based screening methods should be continued, and serious consideration should be given to expanding screening recommendations to include birth in the high-risk cohort. Birth cohort testing alone, however, is not recommended.

In this clinic population of an urban academic medical center, the conservative (floor) estimate of the prevalence of hepatitis C antibodies was 4.6%, almost three times the estimated national prevalence [1]. Our model designed to predict positivity in the untested population estimated a much higher overall prevalence, 7.7%, which is close to the prevalence of 8.3% reported in a similar population by McGinn [5]. Overall, 39.7% of subjects had been tested. Among those with identified risk (either born in the high prevalence birth-cohort, had a high-risk co-morbidity, or an elevated ALT level), 48.6% had been tested.

It is worth noting that the proportion tested was very high (28.8%) among patients with no identified risk (born outside the high prevalence birth-cohort, no high-risk co-morbidity, and no elevation of ALT) and that the rate of positivity in this group was substantial (3.0%), though less than those with identified risks. Whether a substantial proportion of these tested patients had risk factors not identified through the EMR is not clear. It is also possible that some patients without apparent risk were tested because patients or providers were responding to New York Department of Health efforts, begun in 2004, to raise Bronx community and provider awareness of HCV infection [39]. Because of the high underlying prevalence of HCV infection (between 4.6% and

© 2010 Blackwell Publishing Ltd

Table 3 Factors associated with Hepatitis C testing

	Univariate		Multivariate	
	OR_{unadj}	95% CI	OR_{adj}	95% CI
In high-risk birth cohort*	1.64	1.51–1.78	1.39	1.27–1.52
Male	1.70	1.55–1.86	1.35	1.22–1.49
African American	1.08	0.99–1.18	1.22	1.06–1.39
Latino	1.03	0.95–1.11	1.16	1.03–1.32
Substance Abuse†	6.00	4.89–7.37	3.20	2.57–4.00
Alcohol Abuse‡	4.50	3.19–6.36	1.96	1.33–2.90
HIV§	11.59	8.69–15.47	7.75	5.75–10.43
STD¶	1.72	1.35–2.20	1.89	1.46–2.44
Cirrhosis**	13.50	7.01–26.01	4.65	2.30–9.41
ESRD††	8.83	4.65–16.77	8.99	4.68–17.28
Psychiatric Diagnosis‡‡	1.63	1.46–1.82	1.42	1.26–1.60
Any ALT > 40 U/L	3.47	2.98–4.04	2.63	2.24–3.09

*Born 1945–1964. †ICD-9 or positive urine toxicology. ‡ICD-9 for Etoh dependence or etoh liver disease or etoh level ≥ 80. §ICD-9 or positive antibody test or western blot. ¶STD. Sexually Transmitted Disease (not HIV): ICD-9 or Positive GC or Chlamydia PCR probe. **ICD-9 Code. ††ESRD. End-Stage Renal Disease: ICD-9 code or procedure code for hemodialysis. ‡‡ICD-9 for affective, anxiety, schizophrenia, or psychosis.

Table 4 Factors associated with Hepatitis C positivity in those tested

	Univariate		Multivariate	
	OR_{unadj}	95% CI	OR_{adj}	95% CI
In high-risk birth cohort*	3.78	3.03–4.72	2.73	2.14–3.49
Male	2.62	2.14–3.20	1.49	1.18–1.89
African American	0.88	0.71–1.10		–
Latino	1.18	0.96–1.44		–
Substance Abuse†	9.85	7.83–12.39	5.95	4.59–7.72
Alcohol Abuse‡	4.09	2.79–6.01		–
HIV§	5.29	4.15–6.75	3.07	2.30–4.10
STD¶	0.70	0.38–1.27		–
Cirrhosis**	9.06	5.87–13.97	4.24	2.51–7.18
ESRD††	0.81	0.35–1.88		–
Psychiatric Diagnosis‡‡	1.59	1.27–2.00		–
AnyALT > 40 U/L	4.85	3.89–6.04	3.75	2.90–4.84

*Born 1945–1964. †ICD-9 or positive urine toxicology. ‡ICD-9 for Etoh dependence or etoh liver disease or etoh level ≥ 80. §ICD-9 or positive antibody test or western blot. ¶STD. Sexually Transmitted Disease (not HIV): ICD-9 or Positive GC or Chlamydia PCR probe. **ICD-9 Code. ††ESRD. End-Stage Renal Disease: ICD-9 code or procedure code for hemodialysis. ‡‡ICD-9 for affective, anxiety, schizophrenia, or psychosis.

7.7%) in this population, universal testing for high-risk urban populations may be more appropriate than the risk-based screening strategy.

This analysis has several important limitations. First, not all patients were tested for anti-HCV so the prevalence we report is an estimate based on risk profile. Second, we utilized an EMR for data collection so we were unable to capture all risks for HCV infection for each patient. Lastly, we did not take into account the temporal relationship between risk factors and HCV tests. It is possible, for example, that a substance abuse diagnosis might have been coded after a HCV test was ordered, and thus we cannot be sure that the diagnosis of substance abuse was present, or in the physician's mind, at the time of testing. Despite these limitations,

© 2010 Blackwell Publishing Ltd

we were able to uncover a strong relationship between high-risk co-morbidities and physician testing behavior.

In conclusion, we found a very high estimated prevalence of HCV infection in a high-risk urban patient population with a high prevalence of risk factors. We found strong evidence that physicians are using a risk-based screening strategy to identify patients with HCV infection, using known risk factors and other conditions associated with HCV to guide testing. We also found evidence that screening recommendations should be expanded to include the high prevalence birth cohort.

ACKNOWLEDGEMENTS

This project was funded by a Centers for Disease Control and Prevention contract via the Agency Health Care Research and Quality ACTION initiative to Boston University, contract HHSA290200600012 T0#4, the Clinical Investigation Core of the Center for AIDS Research at the Albert Einstein College of Medicine and MMC, funded by the National Institutes of Health (NIH P30 AI51519), and the CTSA Grant UL1 RR025750 and KL2 RR025749 and TL1 RR025748 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH).

CONFLICTS OF INTEREST

Alain H. Litwin has served as a speaker for Roche Pharmaceuticals, and an advisory board member for Vertex Pharmaceuticals. Cindy L. Christiansen is receiving funding from Sanofi Aventis. Mari-Lynn Drainoni has been a consultant on research projects for DiMagi, Inc. Devin Thompson is an employee of Emerging Health Information Technologies. Bryce D. Smith and Cindy M. Weinbaum are employees of the Centers for Disease Control and Prevention.

REFERENCES

1 Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The prevalence of hepatitis C virus infection in the United States, 1999 through 2002. *Ann Intern Med* 2006; 144(10): 705–714.

2 Campsmith ML, Rhodes P, Hall HI, Green T. HIV prevalence estimates – United States, 2006. *MMWR Morb Mortal Wkly Rep* 2008; 57(39): 1073–1076.

3 Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. Centers for Disease Control and Prevention. *MMWR Recomm Rep* 1998; 47(RR-19): 1–39.

4 El-Serag HB, Davila JA, Petersen NJ, McGlynn KA. The continuing increase in the incidence of hepatocellular carcinoma in the United States: an update. *Ann Intern Med* 2003; 139(10): 817–823.

5 McGinn T, O'Connor-Moore N, Allandre D, Gardenier D, Wisnivesky J. Validation of a hepatitis C screening tool in primary care. *Arch Intern Med* 2008; 168(18): 2009–2013.

6 Manns MP, McHutchison JG, Gordon SC *et al.* Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. *Lancet* 2001; 358(9286): 958–965.

7 Fried MW, Shiffman ML, Reddy KR *et al.* Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. *N Engl J Med* 2002; 347(13): 975–982.

8 Hadziyannis SJ, Sette H Jr, Morgan TR *et al.* Peginterferon-alpha2a and ribavirin combination therapy in chronic hepatitis C: a randomized study of treatment duration and ribavirin dose. *Ann Intern Med* 2004; 140(5): 346–355.

9 Strader DB, Wright T, Thomas DL, Seeff LB. Diagnosis, management, and treatment of hepatitis C. *Hepatology* 2004; 39(4): 1147–1171.

10 Ghany MG, Strader DB, Thomas DL, Seeff LB. Diagnosis, management, and treatment of hepatitis C: an update. *Hepatology* 2009; 49(4): 1335–1374.

11 Volk ML, Tocco R, Saini S, Lok AS. Public health impact of antiviral therapy for hepatitis C in the United States. *Hepatology* 2009; 50(6): 1750–1755.

12 Culver DH, Alter MJ, Mullan RJ, Margolis HS. Evaluation of the effectiveness of targeted lookback for HCV infection in the United States-interim results. *Transfusion* 2000; 40(10): 1176–1181.

13 Gordon FD. Cost-effectiveness of screening patients for hepatitis C. *Am J Med* 1999; 107(6B): 36S–40S.

14 Shin A, Cho ER, Kim J *et al.* Factors associated with awareness of infection status among chronic hepatitis B and C carriers in Korea. *Cancer Epidemiol Biomarkers Prev* 2009; 18(6): 1894–1898.

15 Dubois F, Desenclos JC, Mariotte N, Goudeau A. Hepatitis C in a French population-based survey, 1994: seroprevalence, frequency of viremia, genotype distribution, and risk factors. The Collaborative Study Group. *Hepatology* 1997; 25(6): 1490–1496.

16 EASL International Consensus Conference on hepatitis C. Paris, 26–27 February 1999. Consensus statement. *J Hepatol* 1999; 31(Suppl 1): 3–8.

17 Galmiche JP. French consensus conference on hepatitis C: screening and treatment. *Gut* 1998; 42(6): 892–898.

18 Lapane KL, Jakiche AF, Sugano D, Weng CS, Carey WD. Hepatitis C infection risk analysis: who should be screened? Comparison of multiple screening strategies based on the National Hepatitis Surveillance Program. *Am J Gastroenterol* 1998; 93(4): 591–596.

19 Singer ME, Younossi ZM. Cost effectiveness of screening for hepatitis C virus in asymptomatic, average-risk adults. *Am J Med* 2001; 111(8): 614–621.

20 Sroczynski G, Esteban E, Conrads-Frank A *et al.* Long-term effectiveness and cost-effectiveness of screening for hepatitis C virus infection. *Eur J Public Health* 2009; 19(3): 245–253.

21 Degos F. Hepatitis C and alcohol. *J Hepatol* 1999; 31(Suppl 1): 113–118.

22 Caldwell SH, Jeffers LJ, Ditomaso A *et al.* Antibody to hepatitis C is common among patients with alcoholic liver disease with and without risk factors. *Am J Gastroenterol* 1991; 86(9): 1219–1223.

© 2010 Blackwell Publishing Ltd

23 Weinstock HS, Bolan G, Reingold AL, Polish LB. Hepatitis C virus infection among patients attending a clinic for sexually transmitted diseases. *JAMA* 1993; 269(3): 392–394.

24 Thomas DL, Zenilman JM, Alter HJ *et al.* Sexual transmission of hepatitis C virus among patients attending sexually transmitted diseases clinics in Baltimore – an analysis of 309 sex partnerships. *J Infect Dis* 1995; 171(4): 768–775.

25 Gunn RA, Murray PJ, Brennan CH, Callahan DB, Alter MJ, Margolis HS. Evaluation of screening criteria to identify persons with hepatitis C virus infection among sexually transmitted disease clinic clients: results from the San Diego Viral Hepatitis Integration Project. *Sex Transm Dis* 2003; 30(4): 340–344.

26 Kilbourne AM, McCarthy JF, Himelhoch S, Welsh D, Hauser P, Blow FC. Guideline-concordant hepatitis C virus testing and notification among patients with and without mental disorders. *Gen Hosp Psychiatry* 2008; 30(6): 495–500.

27 Himelhoch S, McCarthy JF, Ganoczy D *et al.* Understanding associations between serious mental illness and hepatitis C virus among veterans: a national multivariate analysis. *Psychosomatics* 2009; 50(1): 30–37.

28 Rosenberg SD, Goodman LA, Osher FC *et al.* Prevalence of HIV, hepatitis B, and hepatitis C in people with severe mental illness. *Am J Public Health* 2001; 91(1): 31–37.

29 Dinwiddie SH, Shicker L, Newman T. Prevalence of hepatitis C among psychiatric patients in the public sector. *Am J Psychiatry* 2003; 160(1): 172–174.

30 Alter MJ, Kruszon-Moran D, Nainan OV *et al.* The prevalence of hepatitis C virus infection in the United States, 1988 through 1994. *N Engl J Med* 1999; 341(18): 556–562.

31 O'Brien SF, Fan W, Xi G *et al.* Declining hepatitis C rates in first-time blood donors: insight from surveillance and case-control risk factor studies. *Transfusion* 2008; 48(5): 902–909.

32 Bornschlegel K, Berger M, Garg RK *et al.* Prevalence of Hepatitis C Infection in New York City, 2004. *J Urban Health* 2009; 86(6): 909–917.

33 Hepatitis A, B, and C Surveillance Report. New York City Department Of Health and Mental Hygiene [2005 [cited 2009 Aug. 19]: Available from: URL:http://www.nyc.gov/html/doh/downloads/pdf/cd/cd-hepabc-surveillance-report.pdf

34 Public Welfare: Subtitle A—Department of Health and Human Services. General Administrative Requirements. http://www hhs gov/ocr/hipaa/finalreg html [2002 45 C.F.R. Part 160 Available from: URL:http://www.hhs.gov/ocr/hipaa/finalreg.html

35 Public Welfare: Subtitle A—Department of Health and Human Services. Security and Privacy. http://www hhs gov/ocr/hipaa/finalreg html [2002 (45 C.F.R. Part 164, Subparts A and E) Available from: URL:http://www.hhs.gov/ocr/hipaa/finalreg.html

36 Healthcare Cost and Utilization Project. Agency for Healthcare Research and Quality RMD. Clinical Classifications Software (CCS). 2007.

37 Prati D, Taioli E, Zanella A *et al.* Updated definitions of healthy ranges for serum alanine aminotransferase levels. *Ann Intern Med* 2002; 137(1): 1–10.

38 Pratt DS, Kaplan MM. Evaluation of abnormal liver-enzyme results in asymptomatic patients. *N Engl J Med* 2000; 342(17): 1266–1271.

39 Rude EJ, Weisfuse I. A community experience responding to hepatitis C. *Public Health Rep* 2007; 122(Suppl 2): 89–90.

© 2010 Blackwell Publishing Ltd