
HMA

HEALTH MANAGEMENT ASSOCIATES

*Public and Private Insurance Coverage for
Chronic Hepatitis B Patients:
Health Reform Will Facilitate Early Investments Providing
Long-Term Benefits*

BY

JACK MEYER

GAYLEE MORGAN

VERNON SMITH

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Robert G. Gish, MD
Medical Director, Liver Transplant Program
Chief, Division of Hepatology and Complex GI
California Pacific Medical Center

Ira Jacobson, MD
Chief, Division of Gastroenterology and Hepatology
New York Presbyterian Hospital
Cornell University, Weill Medical College

Emmet B. Keeffe, MD (deceased)
Chair, Department of Gastroenterology and Hepatology
Stanford University Medical Center

W. Ray Kim, MD
Division of Gastroenterology and Hepatology
Department of Internal Medicine
Mayo Clinic

Anna S. Lok, MD
Alice Lohrman Andrews Research Professor
Professor in Internal Medicine
Director of Clinical Hepatology
Associate Chair for Clinical Research
University of Michigan

Henry Pollack, MD
Associate Professor
Department of Pediatrics (Infectious Disease)
New York University Medical Center

Eugene R. Schiff, MD, MACP, FRCP, MACG, AGAF
Leonard Miller Professor of Medicine
Director, Schiff Liver Institute / Center for Liver Diseases
University of Miami Miller School of Medicine

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Executive Summary

The implementation of national health reform in the U.S. provides an important set of opportunities to increase the awareness, routine screening, and treatment of viral hepatitis. An estimated 2.2 million Americans are infected with chronic hepatitis B virus (HBV). Yet, because of the asymptomatic nature of HBV in its early stages, some 65 percent of people who are infected remain unaware of their disease until they have developed liver cancer, cirrhosis, or liver failure many years later.

In many parts of Asia, Africa, and Latin America, HBV is endemic; up to 10 percent of adults in Asia are chronically infected with HBV. An estimated 40,000 to 50,000 people from HBV-endemic countries enter the US legally every year. In the US, the incidence of HBV is declining, but this disease is far from being fully addressed, and it remains a serious public health issue. For example:

- New infections total 43,000 per year in the US.
- When HBV remains undiagnosed, avoidable cases of cirrhosis, liver cancer, and deaths occur, at great human and financial cost. During the 1990s and early 2000s, hospital discharges with an HBV diagnosis increased fourfold, with a corresponding rise in health care costs from \$357 million in 1990 to \$1.3 billion in 2006.
- Approximately 54,000 people infected with HBV immigrate to the US annually, many from countries where this disease is endemic; thus, routine screening and treating immigrant populations from countries with endemic proportions of HBV must be a key part of an effective public policy for this disease.
- HBV is responsible for about 1,815 deaths a year in the US.¹

A growing body of evidence indicates that when HBV is detected in a timely manner and properly treated, these highly adverse outcomes can be delayed or avoided altogether. However, HBV receives only about 1 percent of the funds allocated to the National Center for HIV, Viral Hepatitis, STD, and TB prevention. Enrollment in health coverage is absolutely vital to this early detection and treatment. In fact, our research shows that liver transplants can be reduced by 58 percent and the death rate can be reduced by 20 percent when lower-income people are enrolled in insurance coverage and treated early in the course of their disease.

This study finds projects that over 70,000 people with HBV will newly enroll in Medicaid under the Patient Protection and Affordable Care Act (ACA) and about 75,000 more people with HBV will newly enroll in Health Insurance Exchanges.

Even a modest reduction in costly liver transplants could make an important contribution to the affordability of an HBV screening program. We find that a 5 percent reduction in liver transplants for HBV patients could finance more than 420,000 screenings.

Our research also shows that under certain conditions, screening and related public health investments can yield a long-term payoff in terms of cost avoidance. Experts agree that it is urgent that the US undertake a serious effort to make people with HBV aware of their illness and link them to effective health care.

Policy Recommendations

Advances in HBV treatments coupled with the passage and implementation of national health reform under the ACA present a tremendous opportunity to address the serious threat to public health posed by HBV. Meaningful results, however, will require a comprehensive, three-part policy strategy:

Prevention and Screening

- ⊕ Pursuant to CDC guidelines, “persons who are most likely to be actively infected with HBV should be routinely tested for chronic HBV infection”² and vaccinated. A high percentage of individuals infected with HBV are unaware of their condition. Screening and immunization are the most effective way to produce awareness and stem transmission.
- ⊕ The US should increase outreach to communities of foreign-born persons who are more likely to be actively infected with HBV due to high endemicity in their country of origin (especially countries in Southeast Asia and the Pacific Basin, sub-Saharan Africa, some countries in the Middle East and the central Asian Republics). Outreach should be culturally and linguistically competent in order to ensure that foreign-born persons can clearly understand their risk factors as well as their coverage and treatment options.
- ⊕ The HBV vaccine should be provided immediately to newborns whose mothers are HBV-infected. As noted in the HHS Action Plan, the U.S. needs to expand the capacity of perinatal programs to ensure that all HBV-infected mothers are identified and linked to care, their newborns receive the vaccine, and their household contacts are tested as appropriate, vaccinated, and referred for care.
- ⊕ An aggressive provider education effort is needed to ensure that consistent, effective screening and patient dialogue are integrated into primary care practices.
- ⊕ The Surgeon General of the United States should develop a targeted campaign to educate the public about the importance of testing people for HBV if they are from countries of high HBV prevalence.
- ⊕ HBV screening should be required for children prior to their enrollment in school.

Coverage

- ⊕ As the federal government and the states upgrade and modernize their eligibility and enrollment systems under ACA, an all-out effort should be made to enroll people with one or more chronic illnesses, including HBV, into Medicaid and the Exchanges. States should utilize, modify and expand upon these proven strategies to maximize coverage rates.
- ⊕ Considerable work will be required on the part of states and the federal government to enroll people with HBV into Medicaid and Exchange coverage. A very proactive approach will be needed, using modern techniques to identify individuals who are eligible but not yet enrolled. Such people can be enrolled based primarily on data already available to the government, with appropriate verification, rather than requiring substantial paperwork and other administrative hurdles that might cause some people who are eligible not to apply.
- ⊕ It is also important to *retain* people in coverage. Many individuals are dropped from Medicaid and CHIP even though they remain eligible. By making renewal of coverage more “passive” to the enrollee, through relying on data already available to states based on tax information and enrollment in other means-tested programs, retention of coverage can be increased.

- ⊕ A key piece in enrolling and retaining people with HBV in coverage must include targeted outreach to immigrant populations where patients are less likely to be well informed of their eligibility for public health programs. It is essential that these populations be educated about available coverage and care options in a linguistically and culturally competent manner.
- ⊕ Beginning in 2014, Congress should consider broadening the scope of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act that provides medical care, drugs, and support to people living with HIV. The purpose would be to offer a safety net for individuals with HBV who will remain uninsured after 2014, while continuing to provide services and supports for the HIV population.
- ⊕ States should ensure that ACA's requirements to cover clinical preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP) are enforced and include HBV.
- ⊕ Screening for HBV should be included in the definition of preventive care that would be reimbursed without consumer cost-sharing under ACA. As noted in the HHS Action Plan report, the goal is to "implement routine viral hepatitis testing as part of the standard of care in a reformed health care system."

Care Management

- ⊕ Once people are enrolled in either Medicaid or Exchanges, states should require all participating health plans to make an immediate and comprehensive assessment, or medical work-up, of each new enrollee. This assessment should lead to an individualized, patient-centered care plan customized to the medical and social needs of each patient.
- ⊕ Team-based care and clinical coordination based on evidence-based standards will help serve the complex needs of the HBV population.

All of these goals and strategies will require a health care work force in the US that is trained to prevent and diagnose viral hepatitis and provide care and treatment to infected people, as called for by the HHS Action Plan. New approaches to prevention, screening and treatment of HBV should be mapped into the many non-insurance components of ACA designed to promote public health and improve the delivery system. This includes primary care medical homes, support for community health centers, and new approaches to reward provider teams for achieving better health outcomes and lowering spending.

Introduction

Chronic hepatitis B virus (HBV) is a national and global public health problem. Out of a global population of 7 billion, an estimated 350-370 million are infected with chronic HBV.³ This amounts to about 5 percent of the world's population living with chronic HBV. The prevalence of HBV in the U.S. is estimated at 1.75 million and may be as high as 2.2 million, amounting to 0.5-0.7% of the total U.S. population.⁴

HBV is transmitted by perinatal, percutaneous, and sexual exposure, as well as by close person-to-person contact, especially among children in hyper-endemic areas. The risk of developing chronic HBV infection after acute exposure ranges from 90 percent in newborns of mothers who test positive (referred to as HBeAg-positive), to 25-30 percent in infants and children under 5, and to less than 5 percent in adults.⁵ In addition, immunosuppressed persons are more likely to develop chronic HBV infection after acute infection.⁶

While the incidence of HBV has declined over the past two decades, an estimated 43,000 people per year are newly diagnosed in the U.S.⁷ HBV is endemic in Asia, Africa, and certain parts of Latin America. In fact, some 8-10 percent of adults in Asia are chronically infected with HBV, compared to less than 1 percent of adults in North America and Western Europe.⁸ An estimated 54,000 people infected with HBV immigrate to the US annually.⁹ It is worth noting here that nearly 75% of the HBV-infected individuals in the U.S. are foreign born.¹⁰

Of the foreign born patients who are eligible for public health services, a high number will neglect to access coverage due to lack of familiarity with US public health systems, lack of awareness of their eligibility, fear of consequences for their immigration status, and a variety of linguistic and cultural barriers. Significant attempts at outreach will be necessary in order to direct this population into the appropriate care channels, including informational campaigns and outreach to educate foreign born persons on their eligibility for health services and the delivery of information and services in a linguistically and culturally aware manner. Since routine screening, vaccination and treatment of immigrant populations from countries with endemic proportions of HBV must be a key part of an effective public policy response to the disease, it is essential that any plan designed to address HBV in this country take into account the challenges of providing access to care for these populations.

An additional barrier to treatment is HBV's long latency period. HBV has a long clinically silent phase, during which it causes few or no symptoms. This disease frequently remains undiagnosed until symptoms of late-stage complications develop many years after infection (e.g. primary liver cancer and end-stage liver disease). HBV infection is responsible for 1,815 U.S. deaths each year.¹¹

In addition to the tragic human consequences of undiagnosed and untreated HBV, the cost is very substantial. During the 1990s and early 2000s, hospital discharges with an HBV diagnosis increased fourfold, with a rise in health care costs from \$357 million in 1990 to \$1.3 billion in 2006.¹²

Covering the Uninsured and Retaining Their Coverage

An estimated 27 percent of HBV patients are uninsured and are therefore at higher risk of being unaware of their disease and not receiving proper treatment at an early stage when the illness is discovered.¹³ The prevailing healthcare delivery system in the U.S. is hospital-centric and fragmented. It

frequently neglects and under-funds early detection and screening, instead primarily waiting to provide treatment mainly in specialty care and hospital care when infected individuals present symptoms of late-stage illness and are in dire need of high-tech and very expensive care.

Many lower-income uninsured are adults without dependent children, often referred to as “childless adults.” A substantial proportion of the low-income HBV population is likely to fall into this category. A study by the Kaiser Commission on Medicaid and the Uninsured shows that it will not be easy either to find and enroll this population in Medicaid, or to get them into good care management if they are enrolled. Low-income childless adults frequently have limited English proficiency, lower education levels, and literacy challenges that can make completing the enrollment process difficult.¹⁴ Enrolling eligible immigrants in public health programs has also proven challenging and CMS outreach to immigrant populations is a relatively new development. In 2011, CMS established a partnership with the Cameroon American Council in Washington, D.C. designed to educate community leaders on Medicare, Medicaid and the Children’s Health Insurance Program (CHIP). Cameroon is a country with high HBV prevalence (over 8%) and this type of partnership shows how it is possible to put a mechanism in place to educate patients on their healthcare options, potentially including testing and treatment for HBV.

Beginning in 2014, the new health reform law is projected to provide health coverage to the majority of the uninsured, improve quality of care and patient safety, and slow the rate of growth in health care spending. Nationwide, about half of the newly insured, or roughly 16 million poor and near-poor people would enter Medicaid while another 17 million newly insured people would obtain private health coverage through state-based insurance exchanges (both of these provisions are explained in more detail below). Insurance market reforms aim to make health insurance affordable to people regardless of their age and health status. New demonstration programs and other measures are designed to improve quality of care and lower health spending.¹⁵ Key features of the law include a Medicaid expansion, state-based Health Insurance Exchanges, new funding for community health centers, prevention and wellness initiatives, and several cost control measures.

Quantitative Analysis

To evaluate the long-term impact on health outcomes from coverage and early treatment of uninsured individuals with HBV, we developed a transitional probability model that compares the number of HBV-related deaths and liver transplants under pre-ACA and post-ACA scenarios. The logic behind the model is that, under current law, in the absence of early and effective treatment, only a small portion of uninsured individuals with HBV will become eligible for Medicaid, and then only via the current eligibility pathways, primarily disability, either attributable to their hepatitis or an unrelated condition. A significant portion of the uninsured will not become eligible for Medicaid or will become eligible too late to benefit from treatment. Under the current system, it is difficult to get these individuals into early, effective care that could delay or even avoid the downstream effects of their condition, most notably liver transplants and premature death.

Our quantitative analysis focuses on three key elements of ACA: the Medicaid expansion, the implementation of state-based Health Insurance Exchanges, and the federal mandate that individuals enroll in coverage or face financial penalties. Each of these elements is scheduled to be implemented starting in January 2014.

Medicaid Expansion

Medicaid is the nation's largest health insurance program, covering an estimated 70 million people in FY 2012 (monthly average of 56 million) and costing some \$457 billion in FY 2012.¹⁶ Some 10 million people with disabilities are enrolled in Medicaid, including 20 percent of Americans with severe disabilities and 44 percent of people with HIV/AIDS.¹⁷

Since initial implementation in 1966, Medicaid has featured both mandatory and optional categories of coverage, and large numbers of lower-income people have been excluded. Mandatory coverage is now extended to:

- Poor pregnant women;
- Low-income, uninsured children and some parents of low-income families;
- Low-income elderly, blind and disabled people; and
- Certain low-income Medicare beneficiaries.

In addition, states may cover certain "optional" groups. Poor and near-poor childless adults can only be covered by Medicaid if the state secured a federal waiver, or if the individual fell into a specific eligibility category (e.g., disabled, elderly). Significantly, to expand coverage under a federal waiver, a state must prove that the proposed program expansion would be cost-neutral to the federal government over five years.

In 2014 every legal resident of the U.S. living in a household with family net income under 133 percent of the federal poverty line will be eligible for Medicaid, without regard to family status. This is a very significant change from almost a half century of policy in this program and according to the Congressional Budget Office, is expected to add approximately 17 million additional individuals to Medicaid and CHIP rolls by 2021.

Insurance coverage greatly increases the likelihood that individuals will seek care when it is needed. A large proportion of the new Medicaid enrollees will be adults without dependent children, a group that includes many people with HBV who have never before had access to affordable coverage. Early detection and treatment of HBV will be a significant benefit for many in newly enrolled populations. However, historically, some three-fourths of people who are eligible for Medicaid and CHIP have actually enrolled,¹⁸ so an effective outreach effort will be needed to assure that newly eligible HBV patients actually enroll.

Insurance Exchanges

Many working families and individuals with moderate incomes have been uninsured because they work for an employer that does not offer health coverage, are not eligible for their company plan because they work part-time or just started the job, or cannot afford their share of the premium. These individuals have too much income to qualify for Medicaid, even after the Medicaid expansion is phased in. Unless they have qualifying disabilities, they are not eligible for Medicare if they are under the age of 65. Without access to affordable employer-sponsored coverage, these people are either uninsured, or under-insured and struggling to keep up with the bills for premiums and out-of-pocket health expenses.

Beginning in 2014, individuals and families with incomes between 133 percent of the FPL and 400 percent of the FPL (\$30,657 and \$92,200 for a family of four) will be eligible to obtain health coverage through a state-based health insurance exchange, and receive premium subsidies on a sliding scale relative to their income. Out-of-pocket expenses will also be capped for people in this income range. Many HBV patients stand to benefit from this subsidized private coverage through Exchanges where they will get a wide choice of health plans. Individuals with incomes above 400 percent of the FPL will also be able to purchase coverage through an insurance exchange on an unsubsidized basis.

Insurance Exchanges would operate in the context of an array of new insurance reforms, such as an end to pre-existing condition exclusions and annual and lifetime limits on benefits, as well as not allowing insurers to charge people higher rates because they are in worse health. This will be of considerable benefit to people with HBV, many of whom have been either screened out of health coverage, or priced out.

Estimating the Number of HBV patients newly covered by Medicaid and Exchanges

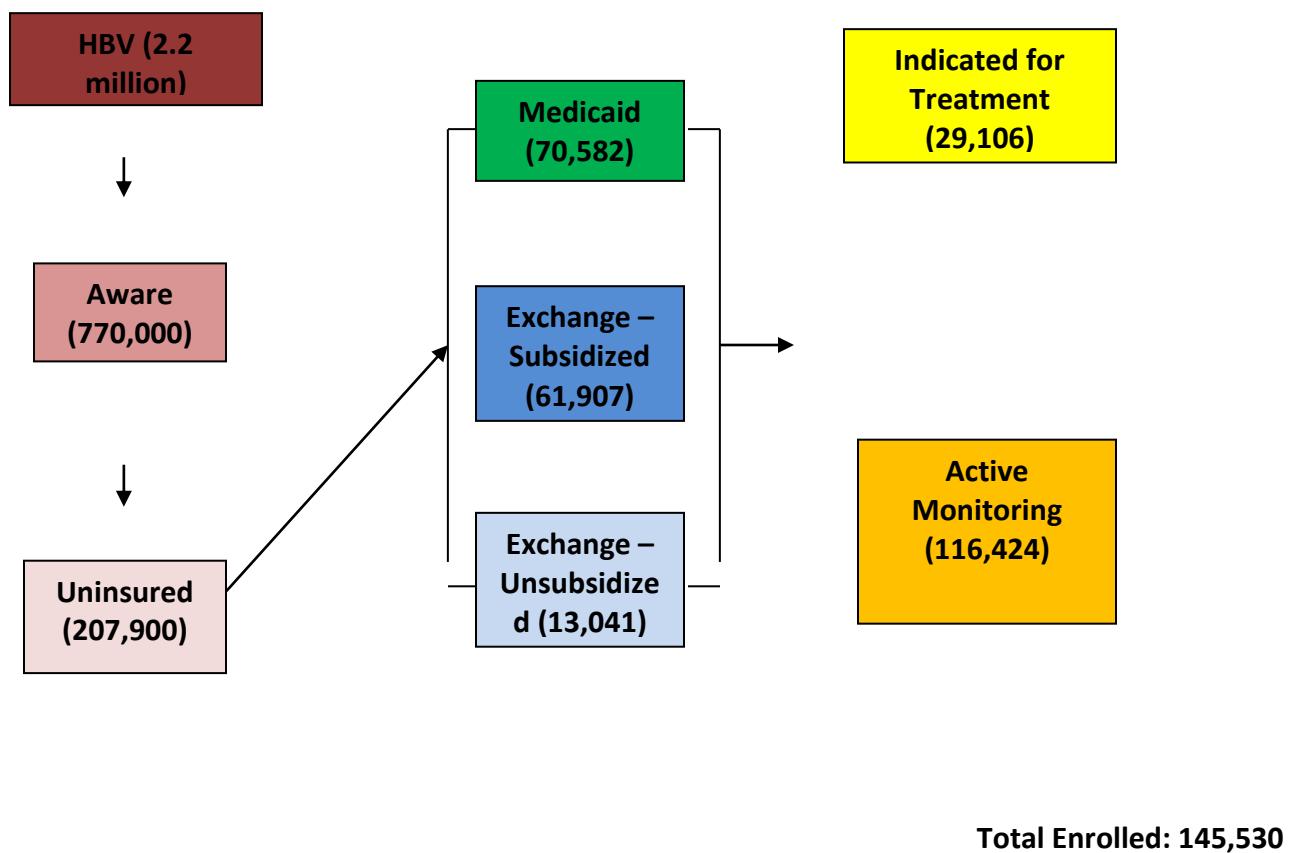
To estimate the number of individuals who would be eligible for and likely enroll in Medicaid or a Health Insurance Exchange, we started with an estimate of the number of people chronically infected in the U.S. Approximately 35 percent of the 2.2 million patients infected with HBV in the U.S. are aware of their status.¹⁹ Of those who are infected and aware of their condition, approximately 27 percent (207,900) are estimated to be uninsured, which is a significantly higher proportion of uninsured than the general population. This figure is based on recent research that looked at insurance status and access to care for both native-born and foreign-born HBV-infected individuals. Tremendous uncertainty exists regarding how the general population will act once the ACA coverage expansions are in place beginning in 2014. There is perhaps even more uncertainty about how specific sub-groups (e.g., immigrants, those who are eligible/not eligible for exchange subsidies) will act. Therefore, we rely on the most commonly cited enrollment estimates -- those published by the Congressional Budget Office (CBO)²⁰ and the Kaiser Commission on Medicaid and the Uninsured²¹ -- as the basis for our own estimates in the model.

Holahan and Headen estimate that approximately 57 percent of those newly eligible for coverage will enroll in Medicaid.²² We adjust this figure to 70 percent (145,530) to account for the fact that this cohort is aware that they have a serious, chronic illness and are, therefore, more likely to enroll than the general population. Based on the CBO projections, approximately 48 percent (70,582) of the uninsured who enroll in coverage will go into the Medicaid program, while 52 percent (74,948) will go into an Exchange. These figures do not account for a relatively small proportion of individuals who are expected to leave their current private coverage in favor of either Medicaid or Exchange-based coverage. Of those who enroll in private coverage through an Exchange, approximately 82.6 percent (61,907) will be subsidized because they have incomes below 400 percent FPL, while 17.4 percent (13,041) will be above that income threshold and, therefore, not subsidized.²³ Figure 1 below summarizes the calculations described above to arrive at the total, previously uninsured HBV-infected population that is projected to enroll in coverage.

We then further adjust this population to incorporate the portion of those eligible and enrolled who would likely be clinically indicated for treatment pursuant to current treatment guidelines.²⁴ Based on

the literature, the model assumes that approximately 20 percent of those meeting the eligibility criteria would be indicated for treatment.^{25,26} Those who are not clinically indicated for treatment would be placed into an “active monitoring” group where they would be tested and monitored regularly by their primary care provider until they become clinically indicated for treatment.

Figure 1: Estimate of Uninsured HBV Population Who Will Enroll in Coverage under ACA



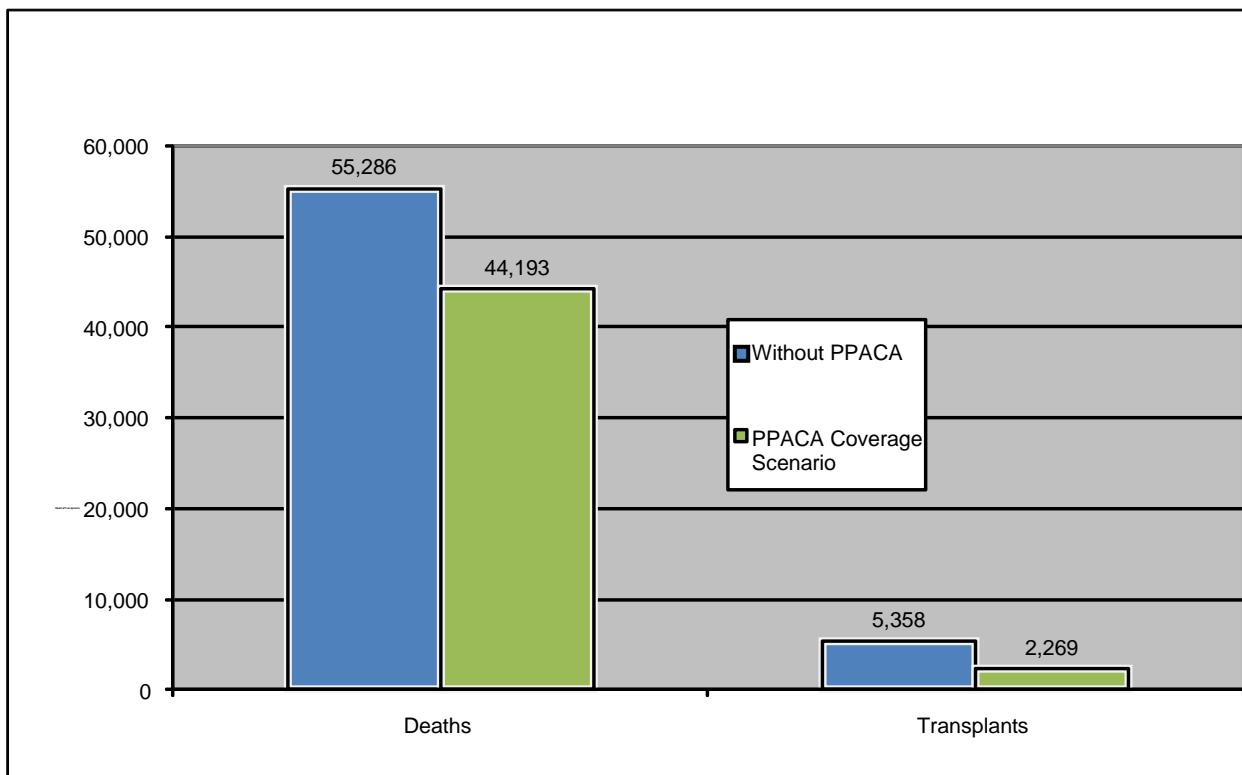
Using a Markov methodology, we follow the cohort through a 20-year time period and compare the clinical outcomes between the pre-coverage expansion and post-coverage expansion scenarios. The model utilizes a set of probabilities from the literature (described in Appendix Table 1), supplemented by input from our panel of expert clinical advisors, to identify the expected annual rates of disease progression without treatment and with treatment. The expansion cohort is assumed to enroll on day one of the demonstration. The expansion cohort moves through a twenty-year period, either advancing to another disease stage, staying in their current disease stage, or, in some cases, regressing to the previous disease stage according to the rates in Appendix Table 1.

Even prior to implementation of the ACA coverage expansions, some portion of the individuals in the cohort is likely to end up on Medicaid during the 20-year window, primarily through disability. The model assumes that 50 percent of individuals in late disease stages, and between one and five percent of individuals in earlier disease stages would come on to the Medicaid rolls through the current eligibility pathways (disease stages are shown in Appendix Table 1) . The model further assumes that uninsured individuals progress through the disease stages at the natural history rate of progression until they are considered Medicaid-eligible, at which point treatment begins. The literature is referenced in Appendix Table 1 and a list of the members of our Expert Working Group can be found under the Acknowledgements section at the front of this document.

Results

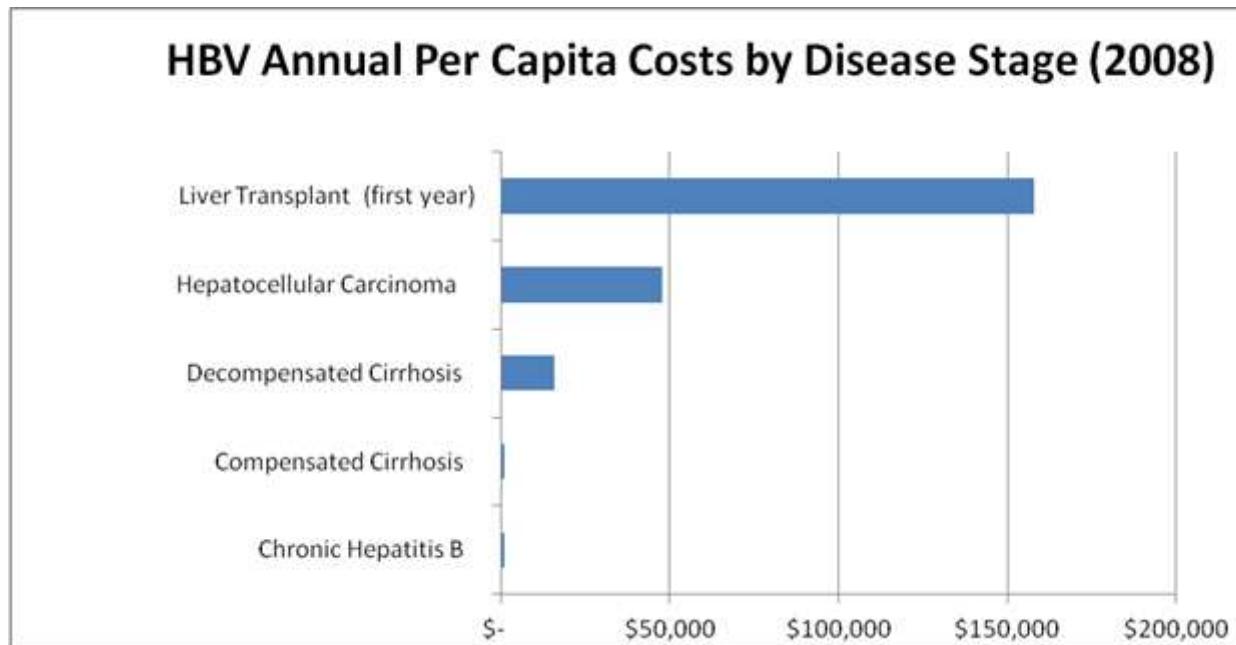
Figure 2 shows the results of the model over 20 years. The model is sensitive to several key parameters, including the initial distribution of the cohort across disease stages and the estimate of what portion of the eligible group *would have enrolled in Medicaid in the absence of the eligibility expansion*. The results make a compelling case for the coverage and early treatment of uninsured individuals who are infected with HBV. Over the 20-year period, new health insurance coverage and early treatment was associated with a reduction in premature deaths of 20 percent, and a reduction in liver transplants by 58 percent, compared to the current state (pre-coverage expansion) scenario.

Figure 2: HBV Clinical Outcomes at 20 Years: With and Without ACA Coverage Expansion



The chart below shows the annual per capita cost by disease stage (2008 dollars). The first year cost of a liver transplant is approximately \$158,000, and this does not include subsequent annual costs for transplant patients, which average close to \$30,000. The cost of screening patients for HBV is approximately \$100. Therefore, every liver transplant avoided could “finance” approximately 1,500 screenings. With the population included in our model, a 5 percent reduction in projected transplants could finance more than 420,000 screenings.²⁷

Figure 3: HBV Annual Per Capita Costs by Disease Stage (2008)



Source: Eckman MH. et al, *The Cost-effectiveness of Screening for Chronic Hepatitis B Infection in the United States*. CID 2011;52.

The model did not look specifically at cost effectiveness under the ACA. However, an earlier version of the model did measure cost effectiveness of HBV coverage and treatment within the context of a pre-health reform world, where a significant expansion in coverage for the HBV population could only be accomplished through a Medicaid waiver. In this context, federal approval is contingent on documenting budget neutrality within five years only for Medicaid, without consideration of savings or benefits accruing to other programs such as Medicare and VA, and without considering the economic and human benefits of a longer, more productive and higher-quality life.²⁸ Within the constraints imposed by federal Medicaid waiver policy, the analysis found that, assuming a low-cost, limited benefits package, coverage costs could achieve “budget neutrality” within seven to 10 years.²⁹ Assuming a slightly more generous benefits package, budget neutrality would be achieved in approximately 12-15 years. In other words, the costs of the new coverage for persons with HBV are offset fully by savings in avoided Medicaid expenditures entirely within these timeframes.

However, under ACA, coverage is offered to all individuals based only on income and legal residence, and without consideration of whether there are cost savings attributable to coverage. Indeed, the CBO estimates the overall cost of coverage for people newly enrolled in Medicaid will total \$627 billion over the ten years from 2012 – 2021.³⁰ Exchanges and related spending would generate gross costs of \$777 billion over this period, with another \$41 billion over ten years for the new small employer tax credits. CBO also accounts for various sources of savings and new tax revenue.

However, there are very likely to be a number of benefits of expanding health coverage that are not fully captured in scoring conducted by CBO and other modeling exercises. Models used to score health reform plans estimate the new costs of covering the uninsured and take account of some of the

offsetting savings, which in ACA takes such forms as reductions in the increase in government payments to providers and health plans and a decline in government payments to safety net providers to compensate them for the uninsured. But these models do not fully capture the savings we can expect as insured people gain greater access to preventive services, acquire a regular source of primary care, obtain counseling about how to use health services more prudently, and get access to affordable medications, specialist physicians, and diagnostic testing.

Moreover, many of the features of ACA beyond the coverage expansion hold the potential to help people access coordinated and integrated health services, along with appropriate social services that support better health. ACA provisions can improve access to care management that will enhance patient compliance with the therapies recommended by physicians and open the door to careful monitoring of chronic conditions, both by medical professionals and by the patients themselves.

The limitations of the CBO analysis with respect to the cost-saving potential of interventions to provide effective care management for patients with chronic illness were summarized by Elbert Huang and colleagues: “For health policy directed at chronic illnesses, a near-term focus is problematic, as the natural history of disease progression often goes well beyond ten years. Thus, the full impact of policies intended to head off unnecessary expenses will not be in full view for policymakers with cost estimates stopping at year ten. The problem cuts both ways. A more complete accounting of the costs of a chronic illness intervention would capture the potential offsetting costs of reductions in care for avoided or postponed complications, but it would also capture the increased spending associated with the chronically ill living longer lives. Further, projection methodologies should have the capacity to capture health and cost effects of alternative policies for chronic illness. Although both the CBO and the CMS track closely the literature relevant to their projection assumptions, to our knowledge neither agency has yet built a forecasting approach for any chronic condition or disease that uses reliable epidemiological data to project expected health and cost effects from alternative policy scenarios.”³¹

Huang et al.’s study of the long-term impact of better diabetes care shows how savings offsets to the cost of care are much larger when a 25-year timeframe is used than under the more traditional ten-year “budget window.” “The cost offsets in the ten-year window are proportionally smaller than those in the 25-year window. For example, in the ten-year window, the cost offset for enrollees ages 41-50 was \$2.1 billion: \$3.6 billion in gross spending minus \$1.5 billion in net spending. This means that 58 percent of program costs were offset by reduced spending on diabetes and its complications. In the 25-year window, the cost offset for the same age group was \$17 billion, which represented an offset of 89 percent of program costs.”³²

Thus, while an official scorecard of the cost of health reform is important, it provides an incomplete picture of the long-range benefits of reforming our health system to cover the uninsured, reduce medical errors, and improve the quality of care. HBV illustrates this point. Attempts to slow, avert, and manage progression of HBV and many other chronic illnesses are not easily captured through a short-term assessment. HBV progresses very slowly and the clinical benefits and cost savings attributable to early treatment are unlikely to be realized until much later, well beyond the five- and ten-year timeframes typically used for budget and policy analysis purposes.

The positive outcomes in terms of avoided transplants and lives saved are significant, as illustrated in Figure 2, though research shows that it will take a substantial number of years before the cost savings will “pay for” the investments needed to achieve these outcomes.

Limitations of this Analysis/Future Study

Our previous quantitative analysis focused primarily on the potential savings to the Medicaid program stemming from early enrollment and treatment of individuals with HBV who could not gain Medicaid coverage - absent a waiver - under current law. This analysis focused on reductions in mortality and liver transplants due to early coverage and treatment under the ACA coverage expansions. In addition, we are now in an era of serious fiscal constraints in both the public and private sectors. This could constrain the ability to make prudent investments even though we can document a long-term "ROI."

Future work should incorporate savings in other government programs (e.g. Medicare, VA) and the private sector, as well as increased productivity, and the potential savings from reducing the spread of HBV. Further, in a time when there are insufficient numbers of livers to meet the demand for transplants, reduced demand for liver transplants due to earlier treatment and slower progression of disease could potentially enable more of these organs to be available for transplantation related to other diseases.

A Multi-Stage Policy Strategy

Advances in HBV treatments coupled with the passage and implementation of the ACA present a tremendous opportunity to address the serious threat to public health posed by HBV. Meaningful results, however, will require a comprehensive, three-part policy strategy:

- ⊕ *Prevention and Screening.* Prevention involves a two-pronged educational outreach effort: (1) to individuals, to help them address behavioral issues and secondary transmission (e.g. perinatal transmission), among other behaviors, that can spread the disease, and (2) to physicians, nurses, and other health care providers to help them counsel patients on prevention.
 - A key component of the screening and prevention strategy is a proactive stance on awareness. HBV cannot be treated if the patient is not aware of the infection. This involves a major national educational effort, which could be led by the Surgeon General.
 - An important thrust in the prevention and screening stage is to target new primary prevention initiatives and serologic testing of groups known to be at high-risk of HBV, pursuant to current treatment guidelines. The CDC now recommends routine HBV testing for all persons currently in the US who were born in regions with high and intermediate HBV endemicity.
- ⊕ *Coverage.* The second stage is an all-out push to get people who are infected and aware enrolled in public or private health coverage so that they will have a source of payment to cover much of the cost of care. This enrollment will require active outreach to vulnerable and hard-to-reach populations.
- ⊕ *Care Management.* The third stage is assuring care management that follows best practices on a continuous basis. When properly monitored, HBV can be effectively treated. A key challenge is to ensure that people identified as having HBV stay in care over the course of their illness and receive culturally and linguistically sensitive support to maintain adherence. It is also important to reach out and provide a solid safety net to help those that remain outside of the coverage system.

Each of these stages is discussed in detail below.

Stage 1: Prevention and Screening

The best public health strategy for HBV, as in other chronic diseases, is prevention. As noted by the CDC:

"Strategies to enhance implementation of the recommendations include 1) establishing standing orders for administration of hepatitis B vaccination beginning at birth; 2) instituting delivery hospital policies and procedures and case management programs to improve identification of and administration of immunoprophylaxis to infants born to mothers who are hepatitis B surface antigen (HBsAg) positive and to mothers with unknown HBsAg status at the time of delivery; and 3) implementing vaccination record reviews for all children aged 11-12 years and children and adolescents aged <19 years who were born in countries with intermediate and high levels of HBV endemicity, adopting hepatitis B vaccine requirements for school entry, and integrating hepatitis B vaccination services into settings that serve adolescents."³³

The CDC has identified the populations that should be screened for HBV infection and immunized if they test negative (referred to as seronegative). Lok and McMahon note that the tests used to screen people

should include HBsAg and hepatitis surface antibody (anti-HBs).³⁴ CDC recommends that the following groups at high risk for HBV infection should be screened:³⁵

- ✓ Persons born in high or intermediate endemic areas: This includes all countries in Asia, Africa, and the South Pacific Islands, and all countries in the Middle East except for Israel and Cyprus (selected other countries are also identified).
- ✓ U.S. born persons not vaccinated as infants whose parents were born in regions with high HBV endemicity (> or =8%)
- ✓ Households and sexual contacts of HBsAg-positive persons
- ✓ Persons with multiple sexual partners or history of sexually transmitted disease
- ✓ Men who have had sex with men
- ✓ Inmates of correctional facilities
- ✓ Individuals with chronically elevated ALT or AST
- ✓ Individuals infected with HCV or HIV
- ✓ Patients undergoing renal dialysis
- ✓ All pregnant women
- ✓ Persons needing immunosuppressive therapy

Making People Aware

Office-based physician practices and community health centers face the challenge of going beyond the traditional medical model to help identify the risk factors for HBV and follow up aggressively and continuously with patients who are at risk. A good place to start is for physicians to work with patients during office or clinic visits to obtain information on their behavior, country of birth, family history or lifestyle factors that could place them in the high-risk categories noted above. This frequently starts at the level of visits to primary care physicians and nurse practitioners, in which the providers obtain information from patients that is of a very sensitive nature. This would include information about patients' consumption of alcohol, whether they use needle-injected drugs (e.g. heroin), and whether they follow unsafe sexual practices. Lok and McMahon state that: "Patients with chronic HBV infection should be counseled regarding lifestyle modification and prevention of transmission and the importance of lifelong monitoring....heavy use of alcohol...may be a risk factor for the development of cirrhosis."³⁶

Thus, the first challenge is for primary care providers (PCPs) to include such a dialogue with their patients in cases where they may have some reason to think that these behavior patterns may be present. The next step is for the PCP to make appropriate referrals for help. This might involve, for example, trying to get the patient into substance abuse treatment and a follow-up plan of care when the program is completed. In addition, the PCP would want to assure that the patient is referred to, and keeps appointments with a specialist who can order the appropriate tests. According to Lok and McMahon: "The initial evaluation of patients with chronic HBV infection should include a thorough history and physical examination, with special emphasis on risk factors for co-infection, alcohol use, and family history of HBV infection and liver cancer. Laboratory tests should include assessment of liver disease, markers of HBV replication, and test for co-infection with HCV, HDV, or HIV in those at risk. Vaccination for hepatitis A should be administered to persons with HBV as per CDC recommendations."³⁷ *Incorporating regular screening and patient dialogue into PCP practice will require a substantial provider education effort.* Effective care will also require better linkages between primary care, mental health and substance abuse treatment as well as a reimbursement system that supports and rewards effective, integrated care. See below for a discussion of some of the ACA provisions that may help support these efforts. Provider education needs to be complemented by

patient education. *The Surgeon General of the United States and the CDC should develop a campaign to educate the public about the importance of being tested if they are in the high-risk groups noted above. The campaign should be focused on geographic regions with high prevalence rates and/or large numbers of individuals who fall into one or more of the groups that CDC has identified as most likely to be actively infected with HBV.*

Vaccinating Children and Adults

A key prevention strategy is ensuring that children and adolescents have received all recommended vaccinations for HBV prior to enrollment in school. The rationale behind this recommendation is that virtually all children attend schools, and using this vehicle becomes an effective way to identify the children who were not vaccinated at birth and who are more vulnerable to HBV. Once identified through this check at school, these children could receive their vaccinations and be protected.

Per CDC guidance, *infants born to HBV positive mothers should receive protective HBV vaccinations (within 24 hours of birth) along with prevention services to reduce perinatal HBV infections.* This type of campaign should be bolstered by the work of community-based organizations that can target outreach and screening to vulnerable populations.

Stage 2: Facilitated Enrollment into Medicaid and Exchanges

ACA holds the potential to improve the detection and treatment of HBV by moving large numbers of HBV patients into public or private health coverage. By enabling more regular check-ups and screening, insurance coverage can help detect HBV. Similarly, by financing a large share of the cost of physician visits, lab tests, diagnostics, and pharmaceuticals, this coverage can help assure that patients are stabilized and properly cared for, which can reduce the likelihood of the need for more expensive care down the road, including liver transplants and cancer treatment.

Still, it is not realistic to think of the Medicaid expansion under health reform in terms of “if we build it, they will come.” Just because individuals are eligible does not mean they will enroll, even though there is no premium and they are entitled to coverage. Many will not enroll unless a concerted approach is taken to facilitate outreach and enrollment. Some strategies that have proven successful to date include the examples below.

We will need a strong effort to enroll people in coverage, complemented by corresponding measures to retain such coverage. “Churning” in and out of Medicaid coverage has been shown to have adverse impacts on both health status and costs.³⁸ States can reduce the likelihood of churning, and reduce the negative impact of churning on continuity of care and performance measurement. To maximize enrollment and reduce the likelihood of churning and its associated costs, States should:

1. Adopt twelve-month continuous eligibility policies, along with establishing categories of program enrollees whose eligibility status is unlikely to change absent a major shift in circumstances.
2. Expand the use of modern tools to promote public program certification and recertification. These tools include using state tax files and earnings data to update information on income.

3. Utilize enrollment data from other means-tested programs such as SNAP (Food Stamps) for a preliminary indication of ongoing eligibility for Medicaid.
4. Develop a system of reminders, both electronic and by telephone.
5. Use pre-populated enrollment and recertification forms.
6. Eliminate or simplify asset tests, face-to-face interviews, and documentation requirements.
7. Dually certify health plans to serve both Medicaid and Exchange members.
8. Require new coverage be retroactive to the date that prior coverage ended.
9. Invest in the requisite information systems infrastructure to promote seamless systems of enrollment and retention.
10. Form public/private partnerships with community-based organizations to reach out and actively find and enroll people, and help them retain coverage.

States should utilize, modify and expand upon these proven strategies to maximize coverage rates.

For individuals eligible to enroll in coverage via Exchanges there will be numerous enrollment challenges. The first will be to identify as many patients with HBV as possible who are eligible for Exchanges and aid them in enrolling and selecting a private plan that will be best suited to their needs. Once enrolled, many patients – especially those who have been uninsured for a lengthy period of time – will need help navigating the health care system. The federal government is working now to establish a nationwide platform that states can plug into to confirm that a patient is a legal resident, and therefore eligible to enter the Exchange, and also to determine the person's household income. That income will establish the size of the premium subsidy that the person is eligible to receive, which will then be automatically and electronically transferred to the health plan the person selects. The enrollees, in turn, will be automatically notified about the amount of the premium for which they are responsible. During this step in the process, as well as in choosing a health plan, there will be a need for consumer assistance as part of the "Navigator" process established under ACA.

A bigger challenge involves addressing changes in a person's household income that would in many cases change the amount of the premium subsidy that this person may receive. For example, consider an HBV patient is working and has an income of \$40,000 a year. This person would be eligible for a sizeable subsidy but still be responsible for a substantial portion of the insurance premium. Then suppose that this person loses a job, or becomes ill and cannot work. Using last year's income, which is what the IRS will rely on, will not reflect the person's real-time circumstances. Thus, states will need to use their own workforce agency databases to update the now out-of-date IRS information on income. Otherwise, this person would be forced to come up with a premium contribution that is more than they can now afford. The updated information from the state could be channeled to the federal database, triggering a larger federal premium subsidy and a smaller personal premium contribution. In some cases, the person's drop in income may be significant enough to move them from the Exchange to Medicaid, at least until such time as their health improves or they regain employment.

This points to an important feature of the HBV population: they are likely to experience substantial churning on and off the Medicaid program. An important challenge is to assure that such people move smoothly between Medicaid and the Exchange as their circumstances change.³⁹ Specific strategies that could be employed include converting from monthly to annual determinations of eligibility, effectively using "12-month continuous eligibility" (this is now used in more than twenty states for children in CHIP but only one state, New York, for adults in Medicaid); offering the same health plans to both Medicaid

and Exchange-eligible individuals, simplifying recertification procedures (e.g. “passive enrollment”), and modernizing MMIS and other IT systems that facilitate enrollment.

While ACA will cover many people who are now uninsured, some patients with HBV will remain uninsured. One approach to ensure that these individuals receive support services would be to seek out opportunities to integrate care for HBV with HIV through the Ryan White program for people living with HIV/AIDS.⁴⁰ It seems possible that the combination of the Medicaid expansion and the Exchanges may create an opportunity to broaden the scope of the Ryan White Care Act, to provide a safety net to assure both screening and treatment for individuals with HBV who will remain uninsured after 2014. The Ryan White CARE Act became law in 1990 and must be periodically reauthorized by Congress, with the next reauthorization coming at the end of fiscal year 2013. As this reauthorization of the CARE Act more or less coincides with the major coverage expansions to be implemented under the Affordable Care Act beginning in 2014, much thought must be given to how the CARE Act should be modified to complement ACA, as tens of thousands of individuals receiving care under the CARE Act make the transition into full insurance coverage either through Medicaid or the health insurance exchanges. While it is clear that the CARE Act will change, it provides an opening to discuss expanding the program to provide care for uninsured patients living with HBV.

Stage 3: Effective Care Management

The third stage in the continuum of addressing the problems of HBV involves improving care management. Once a lower-income person is enrolled in Medicaid, or a moderate-income person in an Exchange, a proactive approach will be needed to get them into care, coordinate care among multiple providers and monitor compliance with treatment plans. Too frequently, the first time such a person hits the medical care system is in the ER. *States should require health plans to arrange for an immediate assessment of each new Medicaid and Insurance Exchange enrollee. This assessment should lead to an individualized care plan customized to the medical and social needs that each patient presents.* The individualized care plans could also incorporate a “contract,” under which the patient also has some responsibilities regarding managing his or her own health and avoiding risky behaviors. All of this could contribute to good care management for people with HBV. This requires building linkages between the health care system and assistance with nutrition, housing needs, and other social services that fall outside of the health care model even though they clearly affect patients’ health.⁴¹ Many HBV patients will have these complex medical and social needs.⁴²

How ACA Could Help

ACA includes several provisions designed to promote effective screening and prevention and to test delivery system redesign and reimbursement strategies that support and reward effective, integrated care.

Prevention and Public Health Fund

ACA calls for the establishment of a Prevention and Public Health Fund, which could be a major new \$15 billion investment through 2019 in public health and prevention. This fund could finance community-based public health initiatives including major programs to address obesity, promote smoking cessation, and improve the built environment. The important work of state and local health departments could be bolstered by this new funding. It is very important that this new fund for community-based prevention activities not be “raided” for use in making up shortfalls in provider payments or other policy measures unrelated to the key mission of this initiative.

Primary and preventive clinical initiatives can also be funded. A portion of these new resources can be devoted to better viral hepatitis screening and prevention activities. HRSA and CDC can provide additional resources to bring comprehensive hepatitis services to sites serving high-risk populations, such as homeless shelters, STD clinics, immigrant service centers, drug treatment facilities, and mobile health vans.

This new fund can assist state and community efforts to prevent disease, detect disease early, and manage conditions before they become severe. HBV should be included in this list since it is a critically important although frequently overlooked chronic disease.

Assistance for Community Health Centers

ACA provided \$11 billion over five years to support, expand and modernize community health centers (CHCs), also known as federally qualified health centers (FQHCs).⁴³ These CHCs serve an estimated 20 million people every year, a number that is expected to double by 2015 as a result of this new federal support. The ACA support will enable CHCs to expand hours of operation, which enhances access opportunities for people who are working, and add provider and non-provider staff; the ACA support will also facilitate the start-up of new centers and permit other centers to expand and modernize their facilities, including moving to electronic medical records.

Approximately 93 percent of CHC patients are low-income and 76 percent are uninsured or on Medicaid.⁴⁴ CHCs are subject to extensive federal requirements mandating that they provide a full array of primary and preventive services, as well as referrals for mental health and substance abuse services and specialty care. CHCs must also provide “enabling services,” including outreach, education and case management. The expansion of the CHC program will expand medical home access for HBV patients and others with chronic illness.

Including Hepatitis Screening and Treatment in Essential Benefits Packages

In December 2011 HHS issued a “Guidance Bulletin” offering preliminary guidance to states and considerable flexibility in designing an essential benefits approach. The new bulletin gives states four

options geared to (1) one of the three largest state employee benefit plans; (2) one of the three largest federal employee benefit plans; (3) the largest HMO in the state; and (4) one of the three largest plans in the small-group market (largest by enrollment). Further, states must ensure that whatever benefit package is selected includes coverage in all of the ten key benefit areas stipulated in the Affordable Care Act (e.g. hospital, physician services, prescription drugs, maternity care, preventive services, etc.).

This new flexibility means that instead of one national set of essential benefits for plans that participate in state-based exchanges, there will be a multitude of state-by-state essential benefit sets, with wide variation in scope. This variation is likely to reflect substantial differences in the extent to which various states have included many or few mandated benefits in their insurance laws. For example, the New Jersey package may be considerably more comprehensive than the Utah package.

Given this new flexibility, a much more complex endeavor may be needed to work toward including screening and appropriate treatment for HBV in states' essential benefit packages. In fact, one aspect of the essential community benefits determination is that in some cases, USPSTF recommendations, while very useful, could fall behind the latest breakthroughs in advanced medical technology to treat HBV and other chronic illnesses. Every effort should be made to include the latest evidence on clinically effective treatments into prevention guidelines.

Requiring Clinical Preventive Services

ACA requires that health plans cover clinical preventive services recommended by the USPSTF and the ACIP. The USPSTF rigorously evaluates clinical research to assess treatments and preventive measures. These include medical screening tests, counseling, immunizations, and preventive medications. Domains include cancer, heart and vascular disease, metabolic, nutritional, and endocrine conditions, and infectious diseases.⁴⁵

ACA requires these recommended preventive services be included in health coverage without patient copayments. The list of covered services for adults includes immunization vaccines for HBV.⁴⁶

Developing an Adequate and Appropriate Work Force

ACA also contains a number of provisions supporting the development and training of an adequate and skilled health care work force. This includes incentives for physicians to train and work in primary care and measures to bolster the nursing labor force. ACA provides support loans and scholarships, primary care training, and additional funding for the National Health Service Corps. There is a need to support training and residency requirements in under-represented fields, and also to address the mal-distribution of health care professionals as well as the total supply. This also includes the importance of cultural and linguistic concordance between the patients and their providers. Tele-health can also be important for people in remote areas.

Instead of the usual approach of starting with the professions and figuring out "how many we need," a process that has yielded constantly changing and sometimes unreliable forecasts of shortages and surplus, a better approach is to start with how we want to deliver care to people with complex medical needs, particularly one or more chronic illnesses, and then let the improved care delivery models determine the work force needs. ACA stresses the importance of patient-centered care and new approaches to payment that reward better health outcomes and lower total spending, such as ACOs and

bundled payments. It will be important to determine the work force needs for HBV using this approach.⁴⁷

Supporting Medical Homes

As states look for ways to improve health care for people with chronic conditions in order to enhance outcomes and contain long-term costs, ACA offers an important opportunity. ACA provides enhanced federal funding for two years for "health homes" serving Medicaid beneficiaries with chronic conditions.

Under Section 2703, states can offer health home services to eligible Medicaid beneficiaries with chronic conditions who select a designated health home provider. The legislation defines chronic conditions to include a mental health condition, a substance use disorder, asthma, diabetes, heart disease, and being overweight (as evidenced by a body mass index over 25). *States may elect to include other chronic conditions such as HIV/AIDS, subject to CMS approval. This creates an opportunity to add HBV to this list of chronic conditions that are part of a health home.* A state's designated health home population must include individuals who have at least two of these chronic conditions, one chronic condition and at risk for another, or one serious and persistent mental health condition.⁴⁸

In addition to the provisions detailed above, ACA includes a number of demonstration programs that could improve access to care and quality of care for people with HBV or other chronic illnesses:

- **Pilot project for community health centers to assess individualized wellness plans:** Directs the Secretary to establish a pilot program to test the impact of providing at-risk populations who utilize community health centers under this section an individualized wellness plan designed to reduce risk factors for preventable conditions identified by a comprehensive risk factor assessment (Section 4206). HBV could be designated as one of these preventable conditions and the definition of "at-risk populations" could include people at high risk for HBV.
- **Establish a Medicaid Quality Measurement Program:** HHS will identify and publish a recommended core set of adult health quality measures for Medicaid-eligible adults. HHS will then establish a quality measurement program and appropriate funds under grants and contracts (Section 2701). Consideration should be given to including the detection and treatment of HBV in this set of adult health quality measures.
- **Medicaid Global Payment System Demonstration Project:** Up to five states will be selected by HHS to participate in a pilot project to shift Medicaid payments to safety net hospital systems from fee-for-service to a global capitated payment model. This means that such hospitals would form the hub of a network of providers, including physicians, who would receive a fixed amount of funding to cover a wide array of services ranging from diagnosis and pre-hospital treatment through the hospital stay and for some period after hospital discharge. Providers would share risks with Medicaid but also be rewarded for lowering the total cost of the episode of care (Section 2705).
- **Medicaid Bundled Payment Demonstration:** Medicaid would offer a set of "bundled payments" for episodes of health care including hospital care and selected physician services that occur before, during, and after the hospital stay. Up to eight states can receive these demonstration project awards for this program that runs from 2012 through 2016 (Section 2704).⁴⁹

- **Grants for workplace wellness:** HHS will be making grants to employers with fewer than 100 workers who provide access to comprehensive workplace wellness programs. This includes health awareness, adopting healthy behaviors, and healthy workplace environments (Section 10408). Screening for HBV could be worked into the health awareness feature of these employer initiatives.
- **Demonstration to provide access to affordable care:** Establishes a three-year demonstration program in up to ten states providing access to comprehensive health care services to the uninsured at reduced fees. Awards up to \$2 million each will be made to nonprofit, public/private partnerships (Section 10504).
- **Integrating quality improvement and patient safety into clinical education:** Medical schools and other health training schools may apply for support in developing and implementing academic curricula to integrate quality and patient safety improvements into the clinical education of health professionals (Section 3508).⁵⁰ Physicians, nurses and other health professionals should learn more about HBV during their clinical training.

Conclusions

HBV has been a hidden chronic disease in America, escaping the attention of both clinicians and policymakers. With some two-thirds of chronically infected patients unaware of their conditions, we have a public health crisis and a health care cost crisis that could be greatly ameliorated with the multi-stage set of interventions outlined in this report.

Our results show that early detection, timely screening and treatment, enrollment in public and private insurance coverage, and effective care management can reduce the need for liver transplants and save lives. These investments will have long timeframe paybacks—there is no “quick fix” to this problem.

The Affordable Care Act provides a number of important opportunities to assist people with HBV. Tens of thousands of HBV patients will be newly insured, opening the door to better primary and specialty health care as well as access to diagnostic tests, medications, and other services. The number of people who actually access coverage will depend on the extent to which active enrollment measures are employed. Other important ACA provisions related to the new prevention and public health fund, support for community health centers, and support for medical homes can facilitate the detection and treatment of HBV. Furthermore, insurance market reforms, most particularly the elimination of lifetime and annual limits on benefits, should prove very important to HBV patients.

Policy Recommendations

In the context of ACA and recent evidence demonstrating the severity of the HBV epidemic, we offer several recommendations for policymakers.

Prevention and Screening

- ⊕ Pursuant to CDC guidelines, “persons who are most likely to be actively infected with HBV should be tested for chronic HBV infection”⁵¹ and vaccinated. A high percentage of individuals infected with HBV are unaware of their condition. Routine screening and immunization are the most effective way to produce awareness and stem transmission.
- ⊕ Increased outreach to communities of foreign-born persons who are more likely to be actively infected with HBV due to high endemicity in their country of origin (especially countries in south-east Asia and the Pacific Basin, sub-Saharan Africa, some countries in the Middle East and the central Asian Republics). Outreach should be culturally and linguistically competent in order to make sure that foreign-born persons can clearly understand their risk factors as well as their coverage and treatment options.
- ⊕ The hepatitis vaccine should be provided immediately to newborns whose mothers are HBV-infected, with the goal of eliminating perinatal transmission of HBV. As noted in the HHS Action Plan, the U.S. needs to expand the capacity of perinatal programs to ensure that all HBV-infected mothers are identified and linked to care, that their newborns receive the vaccine, and that their household contacts are tested as appropriate, vaccinated, and referred for care.
- ⊕ An aggressive provider education effort is needed to ensure that consistent, effective screening and patient dialogue are integrated into primary care practices.
- ⊕ The Surgeon General of the United States and the CDC should develop a targeted campaign to educate the public about the importance of being tested if they are in a high-risk group.

- Parents should be required to assure that their children are screened for HBV prior to enrollment in school.

Coverage

- As the federal government and the states upgrade and modernize their eligibility and enrollment systems under ACA, an all-out effort should be made to enroll people with one or more chronic illnesses, including HBV, into Medicaid and the Exchanges. States should utilize, modify and expand upon these proven strategies to maximize coverage rates and receive federal funding that covers at least 90 percent of the cost.
- Congress should consider broadening the scope of the Ryan White Care Act to provide a safety net for individuals with HBV who will remain uninsured after 2014, while continuing to provide services and wrap-around support for the HIV population.
- States should ensure that ACA's requirements to cover clinical preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP) are enforced and include HBV.
- Screening for HBV should be included in the definition of preventive care that would be reimbursed without consumer cost-sharing under ACA. As noted in the HHS Action Plan report, the goal is to "implement routine viral hepatitis testing as part of the standard of care in a reformed health care system."

Care Management

- Once people are enrolled in either Medicaid or Exchanges, states should require all participating health plans to make an immediate assessment, or medical work-up, of each new enrollee. This assessment should lead to an individualized care plan customized to the medical and social needs that each patient presents. Screening for HBV should be included in these assessments for people at high-risk of having this disease.

All of these goals and strategies will require a health care work force in the U.S. that is trained to prevent and diagnose viral hepatitis and provide care and treatment to infected people, as called for by the HHS Action Plan. New approaches to prevention, screening and treatment of HBV should be mapped into the many non-insurance components of ACA designed to promote public health and improve the delivery system. This includes primary care medical homes, support for community health centers, and new approaches to rewarding provider teams for achieving better health outcomes and lowering spending. As noted in the HHS Action Plan, the goal should be to "develop state and local Viral Hepatitis Centers of Excellence charged with collecting an enhanced set of viral hepatitis surveillance data....and through these centers of excellence, develop models for linking viral hepatitis surveillance systems (e.g. HIV and cancer) to electronic laboratory reports and medical records."

Finally, the US needs a long-term framework for evaluating the impact of investments in public health. We recommend a three-stage approach relating to screening and early detection, insurance coverage, and care management. The Affordable Care Act provides a number of avenues for such investments over time. The US must ensure that individuals with HBV have access to care, both to improve the health status of those infected and to protect those with whom they come in contact. CBO estimates that ACA will leave an estimated 23 million Americans without coverage in 2021,

meaning that the objective of universal coverage remains unattained and that in the interests of all Americans, strategies need to be developed to achieve coverage for those who remain uninsured.

Appendix Table 1

HBV DISEASE STAGE PROGRESSION

Source Stage	Target Stage	Annual Transition Probability - Natural History	Weighted Annual Transition Probability With Treatment*	Natural History Source(s)
Inactive HBV, not indicated for treatment	0	93.0%	NA	
	1	5.0%	NA	Authors' estimate; EWG input
	4	1.0%	NA	Liaw (1988) ⁵²
	7	1.0%	NA	2002 EASL consensus statement
Chronic Hepatitis B Indicated for Treatment	1	94.1%	97.2%	Kanwal (2006) ⁵³ , Fattovich (1988), Villeneuve (1994) ⁵⁴ , Hsu (2002) ⁵⁵ , Dragosics (1987) ⁵⁶ , Liaw (1988), EWG input
	2	3.4%	1.0%	
	3	0.0%	0.0%	
	4	1.5%	0.8%	Enriquez (2007) ⁵⁷
	5	0.0%	0.0%	2002 EASL consensus statement
Compensated Cirrhosis	7	1.0%	1.0%	
	1	8.0%	30.0%	Kanwal (2006)
	2	76.7%	63.6%	Kanwal (2006), de Jongh (1992) ⁵⁸ , Benvegnù (2004) ⁵⁹ , EWG input
	3	5.0%	1.0%	Kanwal (2006), Brunetto (2002) ⁶⁰ , Fattovich (1988), Hsu (2002), Liaw (2004) ⁶¹ , EWG input
	4	3.4%	1.5%	
	5	2.0%	0.0%	EWG input
Decompensated Cirrhosis	7	4.9%	3.9%	Kanwal (2006), Brunetto (2002), de Jongh (1992), Benvegnù (2004)
	2	8.0%	30.0%	Kanwal (2006)
	3	65.6%	54.5%	Kanwal (2006), Brunetto (2002), Fattovich (1988), Hsu
	4	3.4%	1.5%	

HBV DISEASE STAGE PROGRESSION

Source Stage	Target Stage	Annual Transition Probability - Natural History	Weighted Annual Transition Probability With Treatment*	Natural History Source(s)
Hepatocellular Carcinoma	5	4.0%	4.0%	Kanwal (2006), UNOS; EWG input, Bennett (1997) ⁶²
	7	19.0%	10.0%	Kanwal (2006), Brunetto (2002), de Jongh (1992)
	4	52.7%	52.7%	Kanwal (2006), Kim (2002) ⁶³ , EWG input
	5	4.0%	4.0%	Kanwal (2006)
	7	43.3%	43.3%	
	6	90.0%	90.0%	
	7	10.0%	10.0%	Kanwal (2006)
6 Post-Transplant	6	90.0%	90.0%	
	7	10.0%	10.0%	Kanwal (2006)
7 Death				

*Sources: Authors' estimates based on Kanwal (2006) and input from expert working group.⁶⁴

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- ¹⁶ Projection by author Vern Smith based on: Congressional Budget Office, *Medicaid Baseline*, March 2011; and CMS, Office of the Actuary, National Health Statistics Group, 2011.
- ¹⁷ HMA Projections for enrollment for FY 2010, based on CBO, *Budget and Economic Outlook*, January 2010; CBO, *Medicaid Baseline*, 2010 CMS, Office of the Actuary, National Health Statistics Group, 2010; percentages estimated by Kaiser Commission on Medicaid and the Uninsured and Urban Institute.
- ¹⁸ Matthew Buettgens, John Holahan, and Caitlin Carroll. “Health Reform Across the States: Increased Insurance Coverage and Federal Spending on the Exchanges and Medicaid.” Urban Institute. March 2011.
- ¹⁹ Trust for America’s Health. “HBV and HCV: America’s Hidden Epidemics. September 2010.
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- ²² This is the standard take-up rate used by Holahan and Headen. They also use an optimistic scenario with a 75% take-up rate.
- ²³ These figures are adapted from the CBO projections, using the absolute numbers cited in the report in order to form a reasonable percentage split between those patients who will go into Medicaid and those who will go into exchanges.
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²⁶ Internal Gilead estimate based on “Analysis of Foreign-Born CHB Populations, 2008”, a proprietary marketing analysis prepared for Gilead by Plan A, Inc., Mountain View, CA.

²⁷ Eckman MH. et al, *The Cost-effectiveness of Screening for Chronic Hepatitis B Infection in the United States*. CID 2011:52.

²⁸ *Medicaid Chronic Viral Hepatitis Expansion: Healthcare Resource Utilization and Policy Analysis* prepared for Gilead Sciences by Health Management Associates (2008) for a full description of findings and methodologies used for this analysis.

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³⁰ Congressional Budget Office. Statement of Douglas W. Elmendorf. “CBO’s Analysis of the Major Health Care Legislation Enacted in March 2010. Before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives. March 30, 2011.

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³² Huang et al. *supra*.

³³ <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm>

³⁴ Lok and McMahon. *Supra*. p. 2.

³⁵ Weinbaum CN, Williams I, Mast EE, et al. Recommendations for identification and public health management of persons with chronic hepatitis B virus infection. MMWR Recomm Rep 2008;57(RR-8):1-20.

³⁶ Lok and McMahon. *Supra*. p. 3.

³⁷ Lok and McMahon, *Supra*. p. 6.

³⁸ See for example, Andrew B. Bindman, Arpita Chattopadhyay, and Glenna M. Auerback. “Interruptions in Medicaid Coverage and Risk for Hospitalization for Ambulatory Care-Sensitive Conditions.” *Annals of Internal Medicine*. 16 December 2008. Vol 149. No. 12: 854-860.

³⁹ The issue of churn is addressed Benjamin D. Sommers and Sara Rosenbaum. “Issues in Health Reform: How Changes in Eligibility May Move Millions Back and Forth Between Medicaid and Insurance Exchanges. *Health Affairs*. February, 2011:228-236. The article looked at the population under 200% of the poverty line, and found that in the first six months, over 1/3 moved above the 133% level, or dropped below it, and in the first year, half did so.

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⁴⁶ <http://www.healthcare.gov/news/factsheets/2010/07/preventive-services-list.html>

⁴⁷ http://www.futurehealth.ucsf.edu/Content/29/2011_11_California_Healthcare_Workforce_ACA_v2.pdf

⁴⁸ <http://www.commonwealthfund.org/~media/Files/Newsletters/States%20In%20Action/Dec%202010%20Jan%202011%20StatesInAction.pdf>.

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