

# Strategies to Optimize Adult Hepatitis B Vaccination

Benefit of a novel 2-dose, 1-month vaccination regimen to  
population health

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Based on the Hepatitis B Managed Markets  
Roundtable, April 12, 2019, San Francisco.

## HIGHLIGHTS

- Availability of a 2-dose, 1-month hepatitis B vaccination for adult populations may offer a solution to provide high rates of protective immunity
- Effective hepatitis B vaccination regimens are a cost-effective tool to manage long-term population outcomes and total cost of care
- In-depth analyses of individual organizations' population hepatitis B vaccination compliance rates can inform the extent of opportunity for improvement

Supplement to

**M A N A G E D**  
**Care**

Volume 28, No. 9  
September 2019

Sponsored by Dynavax Technologies Corporation

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## Strategies to Optimize Adult Hepatitis B Vaccination

### Benefit of a novel 2-dose, 1-month vaccination regimen to population health

- Introduction
- Executive summary
- Clinical overview of hepatitis B vaccination
- Economic considerations of hepatitis B vaccination
- Current management approaches
- Opportunities to optimize adult hepatitis B vaccination

#### About this publication

This MANAGED CARE Special Supplement, “*Strategies to Optimize Adult Hepatitis B Vaccination: Benefit of a 2-dose, 1-month Vaccination Regimen to Population Health*,” was produced with support from Dynavax Technologies Corporation. It is based on information presented at a roundtable meeting held in San Francisco on April 12, 2019, and attended by physicians, pharmacists, health plan medical and pharmacy directors, and pharmacy benefit managers from across the country.

This meeting was moderated by Neil Minkoff, M.D., Chief Medical Officer, ICON Managed Markets, who also served as editor of this publication.

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#### Disclosure of significant relationships

Neil Minkoff, M.D., has no real or apparent conflicts of interest with respect to companies, organizations, or proprietary products mentioned in this supplement.

The material in this special supplement has been independently peer reviewed.

This MANAGED CARE Special Supplement, “*Strategies to Optimize Adult Hepatitis B Vaccination: Benefit of a 2-dose, 1-month Vaccination Regimen to Population Health*,” was produced with support from Dynavax Technologies Corporation.

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## INTRODUCTION

### Hepatitis B vaccination: critical to population health but historically overlooked

Liver disease has become a growing concern stemming from increased care costs due to recent and future potential advances in the treatment of hepatitis C, cirrhosis, non-alcoholic steatohepatitis (NASH), and the cost of the more than 8000 liver transplants done in the United States annually (DHS 2019). Yet the treatment and prevention of hepatitis B has historically received little attention from population health managers at most levels of managed care organizations. This is in part due to the misperception that hepatitis B infection is a short-term, self-limiting illness, and therefore a low priority. Though this may be true of acute infections, chronic infections have a host of long-term consequences, including cirrhosis and hepatocellular carcinoma.

If we are to learn anything from the recent measles outbreaks that have dominated the news headlines, it is the value of vaccines. As the old adage goes, an ounce of prevention is worth a pound of cure. And since there is no *cure* for hepatitis B, the healthcare system must focus its attention on its *prevention*, by optimizing vaccination strategies.

After decades of inertia, an entrant to the adult hepatitis B virus (HBV) vaccine marketplace is a 2-dose, 1-month HBV vaccine that was shown to provide more rapid and improved seroprotection versus a comparator in clinical studies. In a clinical study, protective immunity was achieved in more than 90% of adults, including in traditionally vaccine hyporesponsive adult subpopulations (Jackson 2018). This advancement has changed the market landscape and has created an opportunity for organized care leaders to take a proactive leadership role in improving population health.

There are 3 main opportunities for successfully vaccinating the adult population against hepatitis B.

- 1. Patient identification:** In the absence of a universal vaccination policy, occupational and behavioral risk assessments need to be conducted to identify adults at risk of HBV infection.
- 2. Compliance:** The individual should agree to, and then adhere to, the vaccine dosing schedule of 2 injections over 1 month, or 3 injections over 6 months.
- 3. Protection:** The vaccine should provide high rates of protective immunity even in hyporesponsive populations; e.g., patients with diabetes, smokers, males, overweight, and older populations.

A panel of managed care executives representing medical and pharmacy directors at commercial health

plans, IDNs, and PBMs, collectively representing nearly 31 million lives, convened in San Francisco to provide insights on challenges and opportunities related to optimizing adult HBV vaccination in at-risk adult populations. The meeting was an opportunity to discuss how to optimize resources in preventing this liver disease. The panel presented a range of unique perspectives related to improving adult hepatitis B vaccination rates in their own systems, both in provider and payer arenas. The roundtable panel shared their concerns about HBV and recognized the value of prevention from a population health perspective. Even though hepatitis B vaccination is largely a clinical decision driven by providers, participants recognized that there are a number of steps that managed care administration could take to ensure successful vaccination in the at-risk adult population. Everyone in the healthcare delivery system has a role in shaping effective population health policies.

This supplement presents key insights discussed by the panel.

—Neil Minkoff, MD

### EXECUTIVE SUMMARY

- Historically, managed care executives have not actively engaged in vaccine decision-making; however, advances in hepatitis B vaccination may help optimize vaccination strategies from a population health perspective
- Roundtable participants were encouraged by the clinical performance of a 2-dose, 1-month hepatitis B vaccination in the adult population
- Payer and IDN participants shared easy-to-implement management techniques to encourage utilization of a preferred option in the adult hepatitis B vaccine category:
  - Designating an internal population health champion to promote improved strategies in hepatitis B vaccination
  - Examining internal vaccine compliance data to identify opportunities to maximize the value of vaccination programs
  - Including hepatitis B vaccines on both the medical and pharmacy benefit to allow flexibility in site of care and promote dose series completion
  - Implementing NDC blocks with 1-year advance notice of switch to preferred agent
  - Instituting an age edit whereby vaccine recipients  $\geq 18$  years old would be given a 2-dose vaccine

The managed care executive roundtable session began with an assessment of the managed care decision makers' current perceptions of hepatitis B and their role in operational issues associated with prevention strategies.

## HEPATITIS B: BURDEN OF DISEASE

### Epidemiology

Infection with HBV causes significant morbidity and mortality in the United States and remains an important public health problem. Approximately 21,900 new cases of HBV infection occurred in U.S. adults in 2015 (CDC 2015). In the U.S., 800,000 to 2.2 million individuals are living with chronic HBV infection (Kowdley 2012). Most infected carriers remain asymptomatic and are unaware of their disease status or their risk of transmitting HBV (Hamborsky 2015). An estimated 5500 individuals in the U.S. die from chronic liver disease due to HBV each year (Hamborsky 2015). Hepatitis B is responsible for 15% of liver cirrhosis diagnoses and 50% of hepatocellular carcinoma cases (Starr 2011, Hamborsky 2015).

The incidence of hepatitis B in the U.S. increased more than 11% between 2011 and 2016 (CDC 2016). Some of this increase has been attributed to the misuse of prescription opioids and associated intravenous heroin abuse (CDC 2019).

There is no cure for hepatitis B, so vaccination measures are key to helping to protect high-risk populations (Box 1, Mast 2006). Recombinant HBV vaccines were introduced in the mid-1980s and have proven to be beneficial. The incidence of HBV infection in the U.S. decreased 82% from 1990 to 2007 (Daniels 2009). Contributing to the decrease in disease burden was the 1991 recommendation by the CDC's Advisory Committee on Immunization Practices (ACIP) to include hepatitis B vaccine in universal vaccinations for infants (MMWR 1991). This was bolstered by the subsequent creation of perinatal and childhood HBV vaccination quality measures (NQF 2012, NCQA 2019). Nonetheless, HBV infection and its consequences continue to be an important public health problem, particularly in adults born before the 1990s.

### Economic impact

Total hospitalization charges related to hepatitis B (exclusive of physician charges) in the U.S. were estimated to be nearly \$1.3 billion in 2006 (Kim 2009). The indirect costs of hepatitis B-related morbidity and mortality, such as costs relating to forgone earnings, decreased production, or lost leisure time, are also substantial. In the U.S., indirect costs associated with hepatitis B were estimated at \$253 million in 2004 (Everhart 2008).

#### BOX 1

### Hepatitis B vaccination guidelines

The CDC's Advisory Committee on Immunization Practices (ACIP) recommends HBV vaccination for a variety of adults, including those commonly seen in primary care settings (Mast 2006). These include high-risk groups for whom time to seroprotection could be important, like travelers and healthcare workers who may have occupational exposure to pathogenic bodily fluids (OSHA 2011).

#### CDC recommendations for hepatitis B vaccinations

 Medical Diagnoses	 Sexual Exposure	 Occupational Risk	 Other Risk Factors
<ul style="list-style-type: none"> <li>• Diabetes, aged 19 to 59 years</li> <li>• Chronic liver disease</li> <li>• HIV infection</li> <li>• End-stage renal disease, including predialysis, hemodialysis, and home dialysis patients</li> </ul>	<ul style="list-style-type: none"> <li>• Sexually active patients who are not in a long-term, mutually monogamous relationship</li> <li>• Patients seeking testing or treatment for a sexually transmitted disease</li> <li>• Men who have sex with men</li> <li>• Sexual partners of HBV-positive persons</li> </ul>	<ul style="list-style-type: none"> <li>• Persons who have occupational risk of infection, including healthcare and public safety workers</li> <li>• International travelers</li> <li>• Employers must offer HBV immunization at no cost to healthcare and public safety workers</li> </ul>	<ul style="list-style-type: none"> <li>• Current or recent injection drug users</li> <li>• Household contacts of HBV-positive persons</li> <li>• All patients seeking protection from HBV infection</li> </ul>

Sources: Mast 2006, OSHA 2011

***“The only bargains that exist today in healthcare are immunizations. They really are. Relatively low-cost, and [may offer a] lifetime of protection.”***

—Medical Director, Regional Health Plan

A liver transplant that might be necessitated by hepatocellular carcinoma caused by chronic HBV infection cost an estimated \$813,000 in 2017 (Milliman 2017). Additionally, hepatitis B transmission or reactivation can pose a complication in solid organ transplantation and has historically been associated with worse outcomes, along with higher costs because of the need to manage patients with antiviral therapies (Levitsky 2013).

***“When [patients] get a transplant and get immunosuppressed, if they have hep B, they do really lousy and they become costly.”***

—Medical Director, Regional Health Plan

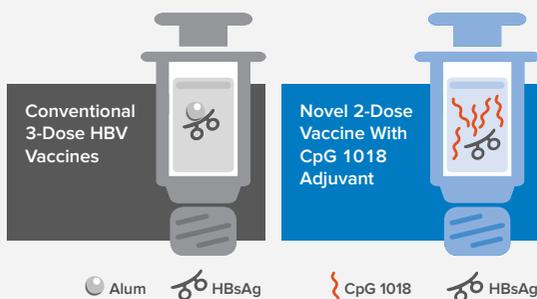
### Limitations of traditional vaccines

Conventional (alum-adjuvanted) 3-dose hepatitis B vaccines leave many adults unprotected and require 3 doses over 6 months to achieve protective immunity. Clinical studies have shown protective immunity is not reached until 7 months after the first dose (Kuan 2013). The potential factors that may limit response to conventional 3-dose HBV vaccines in adults include:

#### BOX 2

#### The 2-dose hepatitis vaccine uses a novel adjuvant

As an alternative to an alum adjuvant, the 2-dose vaccine option uses a potent stimulator of the innate immune system (CpG-1018) which acts through the activation of Toll-like receptor-9. Both vaccine formulations contain 20 mcg of HBsAg per dose.



- Lower rates of protection for hyporesponsive subpopulations; e.g., adults with diabetes, smokers, overweight, age >40 years, male gender (Eng 2013)
  - An important consideration given the aging population and increasing rates of obesity and diabetes
- Poor completion rates/compliance for the full dosing series (Nelson 2009)
- Time to seroprotection—inadequate protection until series completion (Kuan 2013)

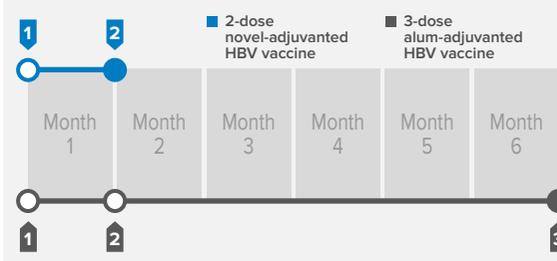
Given these concerns, panel participants were notably excited about a recent new vaccination option that may help address some of limitations of traditional hepatitis B vaccines (Box 2).

### CLINICAL VALUE OF A NOVEL 2-DOSE, 1-MONTH HEPATITIS B VACCINE REGIMEN

Head-to-head clinical trials compared a conventional 3-dose alum-adjuvanted recombinant hepatitis B surface antigen (HBsAg) vaccine delivered over 6 months with a 2-dose HBsAg vaccine delivered over 1 month that uses a novel adjuvant. The 2-dose option was approved by the U.S. Food and Drug Administration (FDA) in November 2017 (FDA 2017). In early 2018, ACIP voted unanimously in favor of including the novel 2-dose vaccine regimen on its list of recommended products for adult hepatitis B vaccination (Schillie 2018). The dosing schedule is shown below (Figure 1).

FIGURE 1

#### Dosing schedule: 2 doses in 1 month vs 3 doses in 6 months

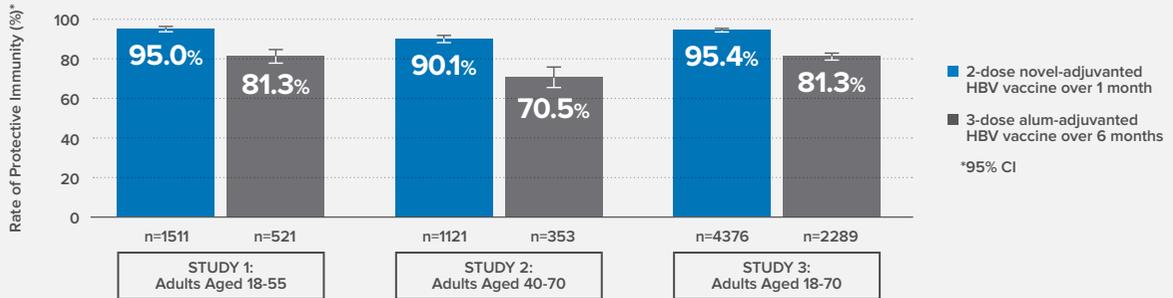


### Significantly higher levels of seroprotection afforded by the 2-dose, 1-month vaccine option

Across 3 pivotal studies, the 2-dose, 1-month regimen demonstrated a higher rate of protection versus 3 doses of a conventional alum-adjuvanted HBV vaccine. The 2-dose regimen protected more than 90% of adults compared with approximately 81% for the 3-dose option (Figure 2, Jackson 2018).

**FIGURE 2**

**In 3 clinical study populations, a 2-dose, 1-month vaccine with a novel adjuvant protected more adults against HBV infection than a conventional 3-dose, 6-month vaccine**



Source: Jackson 2018

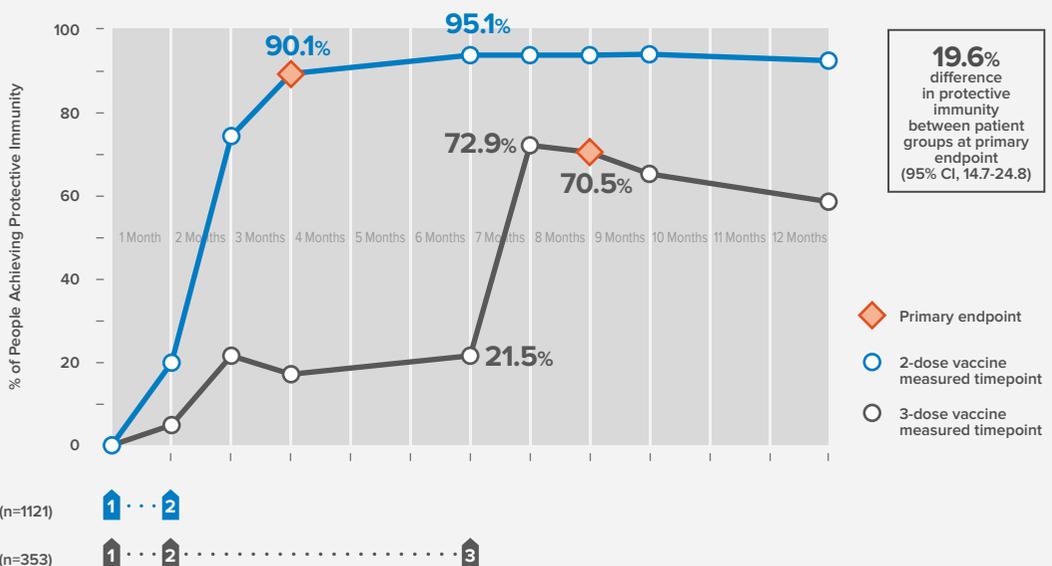
In clinical studies, the threshold of protective immunity was defined as an antibody concentration of  $\geq 10$  mIU/mL (Jackson 2018). An important distinction is that this definition of protective immunity is binary — patients are either seroprotected or not. Therefore, the idea that patients could receive “partial protection” from an insufficient immune response or noncompliant dosing could create a false sense of security.

**“One could argue that the consequences of having a population that’s underprotected both in the short-term and the long-term could be a lot more hepatitis B cases and complications associated with hepatitis B.”**

—Medical Director, Regional Health Plan

**FIGURE 3**

**In a clinical study, 2 doses of an HBV vaccine using a novel adjuvant provided earlier and higher levels of protective immunity than 3 doses of a conventional HBV vaccine in patients aged 40-70**



Source: Heyward 2013

### Relatively slow protective immunity with the 3-dose, 6-month option

Roundtable participants had an immediate and positive reaction to the seroprotection curves from the first clinical trial in patients aged 18 to 55 (NCT00435812) and the second in patients aged 40 to 70 (NCT01005407), as the data demonstrated faster and higher rates with the 2-dose option in terms of peak seroprotection and time to seroprotection. The efficacy curve from the second clinical trial is shown as an example (Figure 3).

The second clinical trial was a randomized, active-controlled, observer-blinded, multicenter phase 3 study in healthy adults aged 40 to 70. This population is known to be less responsive to vaccination (Eng 2013). The 2-dose, 1-month regimen provided higher rates of protection versus the conventional 3-dose, 6-month option at every timepoint measured. The primary analysis compared the rate of protective immunity at Week 12 for the 2-dose regimen with that at Week 32 for the 3-dose option (Heyward 2013).

Roundtable participants recognized the value of the 2-dose, 1-month hepatitis B vaccination regimen in that it rapidly resulted in greater protective immunity than the conventional alternative. They were surprised to see that, in the case of the conventional 3-dose option, the last dose is the most important because it confers the majority of the immunity. The first 2 doses of the conventional alum-adsjuvanted vaccine produced marginal seroprotection. This seemed counterintuitive to their shared belief that the first 2 vaccine doses would confer the majority of the immunity. Roundtable participants also noted that the immune response of the conventional 3-dose vaccine appeared to diminish slightly, resulting in a decrease in the number of seroprotected patients occurring after peak seroprotection at each dose.

***“If it takes seven months to achieve protective immunity [with the 3-dose option], are we misleading people into thinking they’re safe [after 1 or 2 doses]?”***

—Medical Director, Regional Health Plan

### Advantage of rapid seroprotection to special populations

The immunosuppressive anti-CD20 agents used in oncology (and more recently in the treatment of MS) carry the risk of HBV reactivation during treatment. Guidelines recommend that these patients should be screened for hepatitis B infection prior to the initiation of therapy (Hwang 2015). Roundtable participants noted that these patients may face a delay in initiating therapy until they have completed a hepatitis B vaccination regimen. In these instances, the difference between completing a hepatitis B vaccination series in 1 month or 6 months could be important.

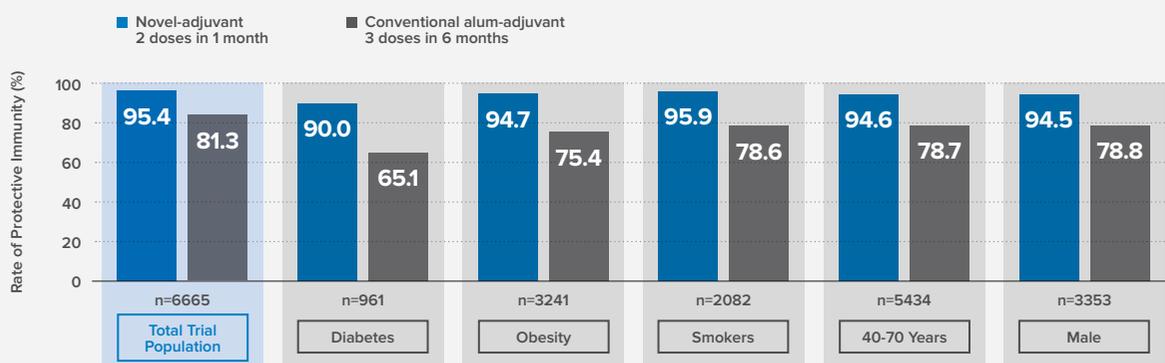
Additionally, providing rapid seroprotection to healthcare workers can help reduce the risk of occupationally acquired hepatitis B infection and can help diminish concerns over liability and workplace safety.

### Higher rates of protective immunity in classically hyporesponsive populations

Data from a third clinical trial (NCT02117934) showed that the 2-dose, 1-month regimen delivered higher rates of protection in known hyporesponsive populations (Figure 4). The 2-dose regimen protected 90.0% to 100% of patients in the groups studied, whereas protection rates with the conventional 3-dose vaccine were 65.1% to 78.8%

**FIGURE 4**

**In a third clinical trial, a novel 2-dose, 1-month hepatitis B vaccine provided significantly higher rates of protective immunity in adults with diabetes and other known hyporesponsive populations**



Source: Jackson 2018

93.9%, depending on patient factors (Jackson 2018). Rates of protective immunity were measured at 6 months for the 2-dose regimen and at 7 months for the 3-dose option.

### **Benefit of a 2-dose, 1-month vaccination option for international travelers**

The CDC recommends hepatitis B vaccination for travelers to foreign destinations where hepatitis B is endemic (Mast 2006). Roundtable participants noted the chronologic challenge presented by the 3-dose, 6-month vaccine option. Very often travelers may not have allowed enough time to complete a 3-dose hepatitis vaccine series before departing on their vacation. If a trip was planned 3 months in advance, they may receive 1 or 2 of the required 3 doses but may also run the risk of forgetting to return for the 3rd dose after their travel. Roundtable participants agreed that in most cases the travel planning process would allow for sufficient time to complete a 2-dose, 1-month vaccine series.

***“There’s no point vaccinating international travelers with the 3-dose option, unless for some reason somebody is going to get their immunization 6 months in advance, which is unlikely.”***

—CMO, Regional Health Plan

Payer and PBM participants were encouraged by the performance of the novel 2-dose, 1-month hepatitis B vaccine regimen in the adult population and recognized the value this innovation could provide.

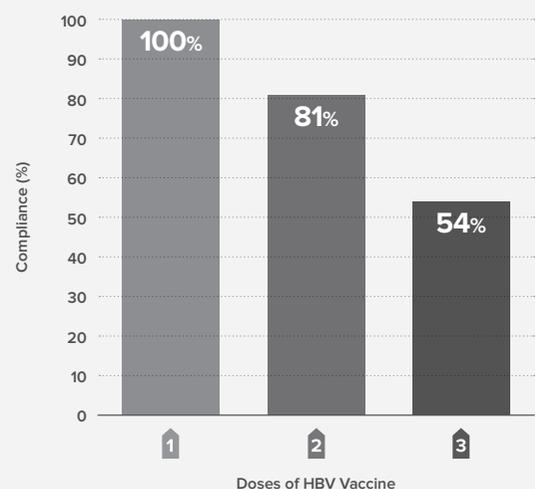
### **Safety studies**

Roundtable participants appreciated the fact that these clinical trials have created the largest safety database of any hepatitis B vaccine. The safety profile of both vaccines was similar in 3 pivotal clinical trials over 10,000 subjects with up to 12 months of follow-up. The percentage of subjects with an unsolicited adverse event was similar in both arms of each study. The most common local reaction was injection site pain, and the most common systemic reactions were fatigue and headache. An extensive post-hoc pooled analysis found that the novel 2-dose vaccine regimen did not increase the risk of autoimmune or cardiovascular events (Hyer 2018).

## **COMPLIANCE CONSIDERATIONS OF ADULT HEPATITIS B VACCINATION**

Compliance is understood to be a critical issue in all adult immunization. A Vaccine Safety Datalink study of more than 88,000 conventional 3-dose adult hepatitis B vaccine recipients showed that 81% received at least 2 doses and only 54% received all 3 doses within 1 year (Figure 5, Nelson 2009). The population in this study were members of managed care plans and several regional Kaiser Permanente plans, which are well known for their successful provider and patient engagement efforts. Real-world at-risk populations may exhibit compliance rates that are considerably lower. This fact is critical considering the third dose of a conventional 3-dose alum-adsorbed hepatitis B vaccine at 6 months generates the majority of the protective immunity (Figure 3). Inspired by the clinical data, roundtable participants were curious to review the compliance statistics for their own member populations, both as a whole, and in at-risk subpopulations.

**FIGURE 5**  
**Compliance with a 3-dose hepatitis B vaccine schedule in a Vaccine Safety Datalink study**



Source: Nelson 2009

Vaccine performance at a population level can be estimated by multiplying the observed seroprotection rate (SPR) seen for that population in the clinical studies (where compliance was 100%) by the dosing compliance observed in the Vaccine Safety Datalink study. The result is the effective seroprotection rate, or ESPR, for that population (Box 3). The ESPR is the SPR adjusted by the size of the compliant patient population at intermediate doses or at the completion of the series. The ESPR also includes patients who achieved seroprotection despite not completing the entire regimen.

### BOX 3

#### The effective seroprotection rate is an estimate of vaccine efficacy in a population

- The effective seroprotection rate (ESPR) is a product of the achieved peak seroprotection rate at a specific dose and the size of the compliant patient population at that dose
- ESPR also includes patients who achieved seroprotection despite not completing the entire regimen

$$\text{Compliance Rate} \times \text{SPR} = \text{ESPR}$$

The estimated ESPR for the conventional 3-dose, 6-month regimen can be calculated by adding the individual ESPR values for each of the 3 doses. The sum of the ESPRs includes those who only received one dose but achieved protective immunity, those who received only 2 doses and were seroprotected, and those who achieved seroprotection by completing all 3 doses. The result, shown in Figure 6 below, is an estimation of the effectiveness of the 3-dose hepatitis B vaccine option at a population level.

Applying a real-world lens to hepatitis B vaccination in this way helps to illustrate an important limitation of the 3-dose regimen. Protective immunity is generated in only about half of those who begin the vaccination series when accounting for vaccination schedule compliance and the immunogenic qualities of the 3-dose vaccine option.

Population health managers in managed care organizations who are curious about the effective seroprotection rate for hepatitis B vaccination among their own plan members could recreate this calculation using compliance values derived from their plan's data.

*"I'm just throwing money down the drain if only 54% of patients get all 3 doses."*

—VP, PBM

#### OPERATIONAL CONSIDERATIONS IN A CHANGING APPROACH TO VACCINE MANAGEMENT

Managed care executives attending the roundtable acknowledged that the driving force for change in adult hepatitis B vaccination is likely to come from providers. Panel members also expressed the belief that the role of managed care executives should be to reduce barriers and reduce limitations on what providers may offer.

#### Motivation to manage hepatitis B vaccines

The panel of managed care executives expressed an expectation of contracted networks to appropriately deliver hepatitis B disease management and HBV vaccination in adults. Roundtable participants admitted that because of a range of competing priorities they have historically devoted little attention to managing vaccines other than those for influenza and pneumococcus. Instead, the decision of whom to vaccinate, and with what, has been left to provider choice.

Clinical insights gathered during the roundtable on the benefits of the 2-dose, 1-month hepatitis B vaccine regimen prompted participants to consider how a managed care organization could encourage an evolution in provider network beliefs and behavior and to explore how this change would be implemented.

#### Operational efficiency of the 2-dose vaccine option

The novel 2-dose hepatitis B vaccination offers adults improved seroprotection over a conventional 3-dose vaccine. It may also provide the added benefit of improving operational efficiency. Completing the 2-dose series requires one fewer office visit than the 3-dose vaccine

**FIGURE 6**

**The estimated effective seroprotection rate (ESPR) of the conventional 3-dose, 6-month regimen illustrates the significance of compliance**

Total number of doses received	Compliance rate at this dose	SPR at this dose*	ESPR
1	19%	4.2%	0.8%
2	27%	24.0%	6.4%
3	54%	79.5%	42.7%
<b>Total ESPR</b>			<b>49.9%</b>

\*SPR using pooled data from the first 2 clinical studies in vaccine recipients aged 18-55 and aged 40-70 (n=3506).

Sources: Halperin 2012, Heyward 2013, Nelson 2009

option. Participants recognized that this could reduce the administrative burden of scheduling, lower cost by decreasing the number of missed appointments, and remove the burden of rescheduling those missed appointments. Moreover, there is a commensurate reduction in the logistical costs of stocking and managing more vaccine product on the refrigerator shelves.

### **Vaccination improves care quality**

Quality of care is a concern shared by payer and provider organizations alike. The value of vaccination is equally well understood. Pharmacy and medical benefit decision makers unanimously acknowledged that if an NCQA HEDIS measure or a CMS Five-Star quality measure for adult hepatitis B vaccination were in place, they would not hesitate to take action to improve their plan's quality performance scores. They would introduce system-wide performance incentives to promote changes in clinical practice and drive hepatitis B vaccination for all appropriate at-risk plan members.

Quality measures were characterized as being far more effective at driving change than guidance from professional associations or governmental bodies. Vaccination against influenza and pneumococcus in the older adult population are backed by several quality measures. The issue of vaccinating against hepatitis B was important enough that a quality measure to vaccinate infants and children was put in place nearly 30 years ago. Yet we still have a large unprotected adult population that remains vulnerable and at risk of infection.

In the absence of national quality guidelines and performance benchmarks, IDNs or Medicare Advantage plans might take more of a long-term population health perspective and be more likely to actively manage hepatitis B vaccination of their at-risk adult population. They would be more likely to realize the potential long-term cost savings of preventing cirrhosis, hepatocellular carcinoma, and liver transplantation in plan members.

### **The role of the internal population health champion**

Roundtable participants recommended that efforts to improve hepatitis B vaccination within a health system could be bolstered by an internal champion, such as a population health expert or an infectious disease specialist. This individual could be the driving force for changing clinical practice within the health system or in contracted provider networks.

An internal champion could prove instrumental in ensuring that health system or plan members are maximizing the value of their current vaccination program. By reviewing compliance data, the population health manager could compare dosing series completion rates in the overall adult vaccine recipient population with

that of at-risk subgroups (e.g., patients with diabetes). Additionally, the completion rates between sites of care (physician's office vs retail pharmacy) could be compared. These efforts could serve as a benchmark for subsequent changes resulting from updated vaccination initiatives.

### **An operational framework for systematic review and change implementation**

After the designated population health manager completes a review of the hepatitis B vaccination compliance data for the plan or health system, efforts can begin to build internal awareness of the opportunity by sharing the data and discussing the potential cost-effectiveness of encouraging the use of the 2-dose, 1-month vaccine option. Once leadership agrees on an appropriate course of action, organizational buy-in can be secured to overcome any operational challenges that may arise. These could include making edits to the EMR system to prompt healthcare providers to discuss the benefits of vaccination with at-risk patient populations.

Executing a switch to the 2-dose option for the adult population could include such optimization strategies as creating a communication plan for the provider network and supporting pharmacies, implementing a range of appropriate management tools, and ensuring cross-team and provider network education.

Hepatitis B vaccination efforts could be integrated with a variety of other complementary population health initiatives. Programs geared toward promoting vaccination may be improved by including hepatitis B as part of a more comprehensive approach. Similarly, liver health initiatives might benefit from expanding their scope beyond hepatitis C to include hepatitis B prevention as well.

As part of a comprehensive implementation plan, vaccine compliance data could be reassessed at a suitable timepoint (e.g., 12 months). Improvements in vaccine compliance would serve as a surrogate for enhanced protective immunity in the population. This would help document the positive change in population health and demonstrate the value of these efforts.

## **BEST PRACTICES AND OPPORTUNITIES TO OPTIMIZE ADULT HBV VACCINATION**

Managed care executives suggested a range of tactics designed to promote the implementation of a strategy favoring the 2-dose, 1-month vaccine regimen once the organizational culture was in place to manage the adult hepatitis B vaccine category.

### **Potential management tools for establishing the 2-dose, 1-month regimen as the preferred option**

#### **1: Verify NDCs have been added to the claims database**

The first step toward changing clinical practice in favor of the 2-dose hepatitis B vaccine option is to ensure

the appropriate NDCs have been correctly listed in the claims systems of the plan's benefit design. Unnecessary billing rejections may result if the system is not accurately updated.

### **2: Institute an NDC block for other products**

Establishing an exclusive reimbursement for the preferred agent could be achieved by implementing an NDC block for the non-covered adult hepatitis B vaccine options. This approach would carry the potential risk of alienating providers who might attempt to bill for administering residual supplies of the other agent. To avoid this possibility, roundtable participants recommended notifying contracted provider groups to explain the switch, describing how sufficient lead time will be allowed before an exclusive reimbursement for the preferred product takes place. This would provide clinicians enough time to exhaust their remaining supply of the 3-dose adult vaccine.

***“We talk about how we’re really concerned about population health, and here is a simple thing to do.”***

—Medical Director, Regional Health Plan

### **3: Ensure coverage under both medical and pharmacy benefit**

Another relatively simple approach proposed by roundtable participants is to change the benefit design to include the 2-dose hepatitis B vaccine option in both the medical and pharmacy benefit. This would allow flexibility in the site-of-care and promote vaccine completion rates. An example of this is where a patient preparing for foreign travel might receive their first dose in the series at a clinician's office and their final dose at a retail pharmacy 30 days later, shortly before they depart.

***“That’s an interesting idea about getting the first dose in the office, the second dose in a pharmacy.”***

—CMO, Regional Health Plan

### **4: Implement an age edit to ensure appropriate patient population**

Another strategy proposed for a network-driven commercial plan is to implement an age edit where reimbursement would be denied if the recipient was not in the right age range. In this approach, the conventional 3-dose vaccine option would continue to be administered in individuals from birth to <18 years old, where it is still the only approved option. Meanwhile, vaccine recipients aged 18 and older would receive the 2-dose option.

***“We already have age edits where we’ll cover it down to 50 years old for [shingles vaccines], because that’s where the data are.”***

—Pharmacy Director, IDN

## **A ROADMAP FOR CHANGE**

Managed care executive participants who attended this roundtable session agreed that the approval of an effective 2-dose HBV vaccine option creates an opportunity to reevaluate current practices. While inertia and barriers may exist and will vary by organization, all executives in charge of population management should reexamine their efforts toward hepatitis B prevention. The first step is to investigate the vaccine compliance of plan members, evaluate current management tools, and identify an appropriate approach for each provider network in order to encourage a shift in clinical behavior toward the 2-dose hepatitis B vaccine regimen for at-risk adults.

## **SUMMARY**

- Managed care decision makers rely on healthcare providers to recognize and act on a changing environment in hepatitis B vaccination
- Roundtable participants were encouraged by the value of the 2-dose, 1-month HBV vaccination in the adult population (net cost and performance)
- Techniques for managing the hepatitis B vaccine category and favoring the 2-dose vaccine option for adults were explored and included:
  - Designate an internal population health champion to drive change
  - Examine internal vaccine compliance data to identify opportunities to maximize the value of vaccination programs
  - Ensure HBV vaccines are on both the medical and pharmacy benefit to allow site-of-care flexibility and promote dose series completion rates
  - Institute an NDC block with advance notice of switch
  - Implement an age edit to ensure vaccine recipients 18 years of age and older are given the 2-dose vaccine option

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