Consideration of Effective Seroprotection Rate (eSPR) and Cost Per Protected Patient (CPP) as Estimates of Real-World Outcomes in Adult Hepatitis B Virus (HBV) Vaccination

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Background

• HBV vaccination is associated with considerable public health burden due to prevalence, healthcare costs, and lack of cost effective therapies

• The US Advisory Committee on Immunization Practices (ACIP) recommends preventative vaccination for adults at risk of HBV infection

• Currently available HBV vaccines include 2- and 3-dose series

• Legacy, 3-dose HBV vaccines (ENGEX-B®, Hepatitis B Vaccine [Recombinant], GlaxoSmithKline®; ENGERIX-B®, Hepatitis B Vaccine [Recombinant], GlaxoSmithKline®) administered with a 6-week dose interval that allows series completion in a single month

• Effective HBV vaccines in reducing risk of infection is impacted by compliance (ie, series completion according to clinical- and cost-effectiveness parameters)

• Compliance remains suboptimal, particularly for 3-dose series, limited 3-dose series costs (ie, 22% of the general population have been observed in several real-world studies)

• Poor compliance rates may limit the effectiveness of a 3-dose series

• Effective HBV vaccines can also be influenced by patient characteristics: 3RF with a full series of a 3-dose vaccine is reduced in certain risk population (eg, people with diabetes mellitus aged ≥40 years and people with diabetes mellitus aged <40 years at the discretion of the treating clinician and some public health populations), as identified by the 2018 ACP Guidance on HBV vaccination

• The effective eSPR (CPP) is a measure of clinical and cost-effectiveness that accounts for failure with dosing regimen. Combined with vaccine costs, eSPR (CPP) can be used to calculate a cost per protected patient (CPP) measure of cost-effectiveness to determine potential real-world value of a vaccine.

Objective

To determine eSPR and CPP for a 2-dose vs a 3-dose adult HBV vaccine series as measures of real-world clinical- and cost-effectiveness in the general population, a diabetes subpopulation, and a public health subpopulation

Methods

• Adults at risk included the 3-dose vaccine (ENGEX-B®) and the 3-dose vaccine (ENGEX-B®, GlaxoSmithKline®) all adults indicated for administration of HBV vaccination and sites of care where adult HBV vaccination is administered were included. Public health settings included: state and local health departments, federally qualified health centers, correctional facilities, STD clinics, and drug treatment facilities

• The model used to calculate eSPR and CPP is shown in Figure 1

• The model applies direct vaccine costs only; it does not include administrative costs, which the Centers for Medicare & Medicaid Services attribute as an additional $10 per dose

• eSPR calculated using

  1. Headed HBV costs from Phase 3 registration trials of the 3-dose HBV vaccine administered over 3 months and the 3-dose HBV vaccine administered over 6 months

  2. The 3-dose HBV vaccine administered for 2 or 4 doses (ie, 2-dose or 4-dose series)

• CPP was calculated in average cost per dose per patient of patients receiving that dose

• The model applies direct vaccine costs only; it does not include administrative costs, which the Centers for Medicare & Medicaid Services attribute as an additional $10 per dose

Results

• To determine if there were differences between the 2- and 3-dose vaccine in the general population (Table 1), the diabetes subpopulation (Table 1), and the public health subpopulation (Table 1)

• To maintain consistency CPP limited to vaccine cost only, administrative costs were not included in this analysis

• To determine if there were differences between the 2- and 3-dose vaccine in the general population (Table 1), the diabetes subpopulation (Table 1), and the public health subpopulation (Table 1)

• The average cost for the regimen reflects the sum of the weighted cost per dose for the regimen

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• eSPR with series completion with the 3-dose HBV vaccine was approximately 2-fold greater in the general population (30% vs 31%), 3-fold greater in the diabetes subpopulation (31% vs 30%), and 4-fold greater in the public health subpopulation (22% vs 15%)

• Higher eSPR with the 2-dose vaccine is likely attributable to higher rates of series completion and seroprotection compared with the 3-dose vaccine

• CPP with the 2-dose in the 1-dose vaccine was $231.02 less in the general population, $115.75 less in the diabetes subpopulation, and $23.77 less in the public health subpopulation (Figure 2)

• The between-dose variation in CPP was greater in the diabetes subpopulation (31%) compared with the general population (5%) and the public health subpopulation (22%); this was due in part to the higher seroprotection conferred by the 3-dose vaccine to people with diabetes

Conclusions

• eSPR and CPP represent important real-world, value-driven metrics for comparing clinical- and cost-effectiveness of adult HBV vaccines

• In this analysis, a 2-dose HBV vaccine demonstrated higher eSPR and lower CPP compared with a commonly used 3-dose vaccine in both the general population, and in diabetes and public health subpopulations, indicating a potential for greater real-world value and potential cost savings on a CPP basis with the 2-dose series

• This analysis demonstrated that a greater number of patients can be protected from HBV with the 2-dose vaccine than the 3-dose vaccine based on a fixed spend

• Routine evaluation of series completion rates at all care sites that administer adult HBV vaccines is recommended to provide understanding of eSPR and CPP in their institution and to support informed, value-oriented decision-making in vaccine selection

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