Published in final edited form as:

Int J Gynaecol Obstet. 2018 April ; 141(1): 126–132. doi:10.1002/ijgo.12434.

A decision analytic model for prevention of hepatitis B virus infection in Sub-Saharan Africa using birth-dose vaccination ★

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Abstract

Objective—To compare prenatal maternal hepatitis B virus (HBV) screening and infant vaccination strategies to inform policy on HBV prevention in Sub-Saharan Africa.

Methods—A decision analytic model was created using previously published data to assess the ability of three intervention strategies to prevent HBV infection by age 10 years. Strategy 1 comprised of universal vaccination with a pentavalent vaccine (HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenzae*) at age 6 weeks. Strategy 2 comprised of universal HBV vaccine at birth plus pentavalent vaccine. Strategy 3 comprised of maternal prenatal HBV screening and targeted HBV vaccine at birth for all exposed infants plus pentavalent vaccine. The reference strategy provided neither maternal screening nor infant vaccination. Rates of HBV infection and costs were compared.

Results—The reference strategy had an HBV infection rate of 2360 per 10 000 children. The HBV infection rate for strategy 1 was 813 per 10 000 children vaccinated (1547 cases prevented). Strategies 2 and 3 prevented an additional 384 cases and 362 cases, respectively. Inclusion of HBV vaccination at birth was the preferred approach at a willingness-to-pay threshold of US\$150.

Conclusion—Including a birth-dose HBV vaccine in the standard schedule was both cost-effective and prevented additional infections.

★Presented at the 37th Annual Meeting of the Society for Maternal Fetal Medicine: The Pregnancy Meeting; January 23–28, 2017; Las Vegas, NV, USA.

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Author contributions

SA, LMH, and JDO contributed to the study design, acquisition and interpretation of the data, and revisions to the manuscript. GHE contributed to acquisition of the data and revisions to the manuscript. ATNT contributed to the study design, interpretation of the data, and revisions to the manuscript. SA wrote the first draft of the paper. All authors approved the final version of manuscript.

Conflicts of interest

The authors have no conflicts of interest.

Keywords

Birth-dose vaccination; Decision analysis; Hepatitis B virus; Infection; Prevention; Sub-Saharan Africa; Vertical transmission

1 INTRODUCTION

More than 360 million people worldwide are chronically infected with hepatitis B virus (HBV), which is a frequent cause of liver disease and hepatocellular carcinoma; infection with HBV is endemic in Sub-Saharan Africa, where the seroprevalence is 10%–15% [1]. Vertical (mother-to-child) transmission of HBV occurs via exposure to infected blood and body fluids during delivery, and is strongly associated with the maternal viral load (measured as the concentration of HBV DNA) and the presence of the HBV e antigen [2]. As the likelihood of chronic HBV infection is inversely related to age at the time of exposure, it is crucial that steps are taken to prevent vertical transmission. Vaccination against HBV is both safe and effective. Most cases of vertical transmission (75%–95%) can be prevented by vaccination alone if a monovalent birth-dose HBV vaccine is followed by completion of at least three-doses of a Hepatitis B vaccine in infancy [3,4].

Universal administration of the HBV monovalent vaccine within 24 hours of delivery has been recommended by WHO [1], irrespective of the maternal infection status. Prophylactic use of anti-HBV immunoglobulin is expensive and often not available in resource-limited settings. Many countries in Sub-Saharan Africa—including South Africa, Zambia, Ghana, Mali, and Niger—do not include the birth-dose HBV vaccine in their national vaccination strategy despite high rates of maternal HBV infection. National policies prioritize the pentavalent vaccine series (comprising HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenzae*) that is given at 6, 10, and 14 weeks of age. Reasons given to support lack of vaccination at birth include cost, low birth rates in health facilities, insufficient data on the relative contribution of vertical versus horizontal transmission to overall prevalence rates for pediatric HBV, and logistic challenges [5]. Nonetheless, in 2012, Cameroon Baptist Convention Health Services (a provider of maternity care for more than 80 years) implemented a program of maternal HBV screening and targeted birth-dose HBV vaccination for exposed infants (T. Welty and E. Welty, telephone communication, December 2015).

Information regarding the cost and efficacy of various HBV prevention strategies is urgently needed to guide national vaccination policies in Sub-Saharan Africa. The aim of the present study was to compare three different intervention strategies in terms of the number of HBV infections prevented and the costs involved.

2 MATERIALS AND METHODS

A decision analytic model was created to assess strategies for HBV prevention in Sub-Saharan Africa, with a focus on Cameroon. Three intervention strategies were compared with a reference strategy. The details of these four strategies are outlined in Figure 1.

Institutional review board approval was not required for the present study owing to the literature-based nature of the design.

The primary outcomes were the number of HBV infections acquired by 10 years of age (capturing both vertical transmission and horizontal transmission during childhood) and the cost per HBV infection prevented.

The model assumed that prenatal care, perinatal care, and testing for the presence of HBV surface antigen were accessible for healthcare facility deliveries. Additional case-finding costs to identify pregnancies or births were not included in the model. Furthermore, the model assumed 100% compliance with birth-dose HBV vaccination and completion of the pentavalent series. Any partial protection provided by an incomplete series was not modeled. The present model also assumed that the pentavalent vaccine series was ineffective for the prevention of vertical transmission because it was not provided until 6 weeks after delivery. Figure 2 shows the branch of the decision analytic model for strategy 2 (no maternal HBV screening; universal birth-dose HBV vaccine plus pentavalent vaccine) as an example.

Base prevalence estimates were derived from published data collected in Cameroon and from ranges that were representative of countries in Sub-Saharan Africa (Table 1). A systematic search of the English-language literature was conducted using the Medline and Embase databases on November 12, 2016. The completed literature search combined the terms “Hepatitis B” and “Cameroon”, “Africa”, or “developing countries” with each of the following words: “vaccination”, “incidence”, “horizontal transmission”, “vertical transmission”, and “efficacy”. The bibliographies of the identified sources were also searched. The probability ranges for the sensitivity analysis were defined as the highest and lowest values available in the literature review. One in every 10 children were assumed to have protective levels of antibodies against the HBV surface antigen following birth-dose vaccination, therefore decreasing the rate of horizontal infection by 10% [15]. Robust data were not available to determine the protective effect against vertical transmission of birth-dose HBV vaccination that is not followed by additional doses. Therefore, if a modeled child only received the birth dose vaccination that was not followed by any additional vaccines, the model included a wide range of protection from vertical transmission of HBV from 5% to 50%.

Cost estimates for HBV vaccines and prenatal screening tests were based on representative information collected by the Cameroon Baptist Convention Health Services HBV vaccination program and included costs for injection supplies, delivery, and storage (Table 1). All costs are reported US dollars at the 2015 exchange rate. The time value of money was not considered because all costs were incurred in the same year in this model. The present analysis used willingness-to-pay (WTP) thresholds to define the maximum cost that a society is willing to pay for each incremental improvement in outcome. The WTP threshold for vaccination among low- and middle-income countries ranges from less than \$100 to greater than \$2000, depending on the country, severity of infection, and transmissibility [21]. The average WTP threshold for HBV prevention is not well-documented in Sub-Saharan Africa; therefore, a range of \$100–\$2000 was used in the present study.

The analysis was performed using TreeAge Pro 2009 (TreeAge Software, Williamstown, MA, USA). Owing to inconsistencies in the baseline assumptions and probability ranges in the literature review, sensitivity analyses were applied. The estimates of probability, and cost were varied across the probability range, alone and in combination. Monte Carlo simulation was also used to simultaneously vary all values at random over multiple iterations. This allowed for estimates of the frequency that the conclusion of the model was concordant with the base case analysis. A total of 10 000 Monte Carlo simulations were performed.

3 RESULTS

The results of the decision analysis model are presented in Table 2. The reference strategy was associated with 2360 cases of HBV infection per 10 000 children. The most effective intervention for preventing HBV infection by age 10 years was strategy 2, which included universal administration of the birth-dose HBV vaccine. Use of strategy 2 would prevent 1930 HBV infections per 10 000 children vaccinated at a cost of \$53.87 per infection prevented. The current national program of administering the pentavalent vaccine series from 6 weeks of age (strategy 1) was also effective at preventing HBV infections (1547 per 10 000 children) and was the least expensive intervention (\$34.90 per infection prevented).

The incremental cost per infection prevented by the addition of a birth-dose of HBV vaccine (universal or targeted) to the prevention program was also assessed (Table 2). Strategy 2 prevented an additional 384 HBV infections when compared with strategy 1, whereas strategy 3 prevented an additional 362 infections. For every additional HBV infection prevented by the addition of birth-dose vaccination, the cost was \$130.41 for universal administration or \$125.35 for targeted vaccination.

In one-way, two-way, and three-way analyses, the preferred strategy when considering cost per infection prevented was sensitive to both the proportion of children who completed the pentavalent vaccine series and the maternal seroprevalence of HBV (Figure 3). Strategy 1 was preferred at a seroprevalence of less than 6%; however, as the seroprevalence increased to greater than 6%, a strategy that included the birth-dose HBV vaccine became the preferred option. Strategy 3 was the preferred option only when the proportion of children who completed the pentavalent series exceeded 80% and the seroprevalence of HBV was less than 13%. In the majority of HBV prevalence rates and vaccine completion rates seen in Sub-Saharan Africa, universal birth dose HBV is the preferred strategy at a WTP threshold of \$150 (Figure 3).

The other major factor determining the optimum intervention was the WTP threshold (Figure 4). As this value increased to \$150, either strategy 2 or strategy 3 became the preferred option. By contrast, strategy 1 was the preferred option at a WTP threshold of less than \$150.

4 DISCUSSION

The present study examined the cost and efficacy of three intervention strategies to prevent HBV infection before age 10 years in a Sub-Saharan setting. The analysis required creation of a decision tree, in which each branch represented a different vaccination schedule. The

benefit of this approach was that it enabled consideration of a range of HBV prevalence and vaccination regimens to ensure that the results obtained were applicable to a large geographic region.

The present study indicated that the addition of a universal birth-dose HBV vaccine to the pentavalent vaccine (strategy 2) prevented the greatest number of additional HBV infections and was the preferred strategy at a WTP threshold of \$150 per infection prevented when the maternal HBV seroprevalence was greater than 6%. The prevalence of HBV infection during pregnancy in Sub-Saharan Africa is 5%–13% [6, 22] and so is often higher than the 6% cutoff value identified in the present study. Targeted birth-dose HBV vaccination (strategy 3) prevented more HBV infections before age 10 years than did strategy 1 (pentavalent vaccine only). Because the current WTP threshold in low-to-middle-income countries is \$100–\$2000 for diseases such as typhoid and HIV infection [21], the present cutoff of \$150 should be considered within the acceptable range for medical interventions in Sub-Saharan Africa.

The present study findings were in agreement with those of Klingler et al. [23]. These investigators conducted a cost-effectiveness study modeled on Mozambique and found that birth-dose HBV vaccination cost slightly more per infection prevented than the pentavalent vaccine yet was still within a range typically considered cost-effective in a low-income country. However, unlike the study of Klingler et al. [23], the present analysis incorporated local data on HBV epidemiology among pregnant women in Cameroon and known vaccination costs (including administrative costs). The present study also included a probabilistic sensitivity analysis to expand the range of estimates and improve the ability to generalize the findings to other countries in Sub-Saharan Africa.

One limitation of the current model was uncertainty about the contribution of horizontal versus vertical transmission to the prevalence of HBV infection among children. Although HBV is endemic in much of Sub-Saharan Africa (defined as an HBV surface antigen positive test result rate of >8%), and most studies show high rates of positive test results for HBV e antigen [7, 8], a few pediatric studies have suggested that, in Africa, there is a higher HBV acquisition risk after—instead of during—the perinatal period [4,17]. Owing to this gap in the literature, the present study estimated rates of vertical and horizontal transmission on the basis of the available data [4,7], and assumed a broad range of horizontal transmission (5%–30%). However, the results obtained were not sensitive to this wide range.

Another limitation was the lack of information regarding the relative efficacy of HBV vaccination initiated at birth versus at 6 weeks. One randomized controlled study conducted in Cote d'Ivoire addressed this question [16]. The findings suggested that birth-dose vaccination was associated with a reduction of up to 50% in infant HBV infection when compared to a vaccination strategy started at 6 weeks [16]. However, this difference was not statistically significant, possibly owing to the small number of participants. A study that assessed the independent impact of a birth-dose HBV vaccination program in China showed that greater than 50% of the reduction in HBV prevalence could be attributed to this intervention [24].

The present study did not account for the cost of identifying HBV-exposed infants who were born outside of a healthcare facility. This discrepancy therefore underestimated the costs of universal administration of the HBV vaccine at birth. The charge to patients in the hospital in Cameroon was at least \$4–\$5. Greater than 60% of all births in Cameroon occur in a healthcare facility and this coverage is increasing [25]. The present study obtained vaccine costs from local hospitals, which incorporated the cold-chain costs. Provision of the birth-dose HBV vaccine to women undergoing home deliveries would therefore add both cold-chain and case-finding costs.

The incremental effects of each dose of the pentavalent vaccine were not modeled in the present study owing to a lack of base data estimates. This discrepancy would have a minimal effect in many Sub-Saharan countries because approximately 90% of all infants successfully complete the pentavalent vaccine series. However, it is a potential issue for countries in which the completion rates are just 13%–30% [12, 13]. For countries with low pentavalent vaccine completion rates, use of the birth-dose HBV vaccine might increase the overall HBV immunogenicity of incomplete vaccine series and offer increased cost effectiveness. The pentavalent vaccine cannot be administered at birth because the non-HBV components lack immunogenicity at this time point. Consequently, the present study assumed that the full pentavalent series should still be given after the birth dose (i.e. four doses of HBV vaccine in total rather than three).

The present study did not consider the long-term healthcare costs associated with chronic HBV infection because country-specific data were lacking. In many Sub-Saharan countries, limited care is available to patients with chronic HBV infection. The present study therefore determined only the cost per HBV infection prevented rather than the cost per quality-adjusted life year. Nonetheless, the birth-dose HBV vaccine was expected to remain cost-effective even when considering the cost per quality-adjusted life year.

In conclusion, the current findings support WHO recommendations for universal birth-dose HBV vaccine administration irrespective of the maternal HBV status [1]. Use of this approach within a healthcare facility is below typical WTP thresholds and so offers a cost-effective intervention strategy for low- and middle-income countries working to reduce rates of HBV infection. Further research is needed to determine the WTP threshold as there is no published data on WTP thresholds for HBV.

Acknowledgments

The authors would like to thank Tom and Edie Welty for their input and information about costs and pricing from Program to reduce perinatal HBV transmission. LMH is funded by National Institutes of Health grant K12HD001258-13, which partly supported the present study.

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Synopsis

Providing a dose of hepatitis B virus vaccine at birth prevented additional infections during childhood and was cost-effective in a Sub-Saharan African setting.

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Figure 1.

Prevention of HBV infection. The three intervention strategies are shown. The pentavalent vaccine comprised HBV, diphtheria, tetanus, pertussis, and haemophilus influenzae. The reference strategy excluded both maternal prenatal HBV screening and vaccination of the offspring. Abbreviation: HBV, hepatitis B virus.

Figure 2.

Decision analysis tree for intervention strategy 2. This approach comprised a universal birth-dose of HBV vaccine plus a pentavalent vaccine (HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenza*) but no maternal prenatal HBV screening. Abbreviation: HBV, hepatitis B virus; HBeAg, HBV e antigen.

Figure 3.

Sensitivity analysis for the three intervention strategies at a willingness to pay threshold of \$150. The pentavalent vaccine comprised HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenzae*. Abbreviation: HBV, hepatitis B virus.

Figure 4.

Cost-effectiveness acceptability curves for the three intervention strategies. The pentavalent vaccine comprised HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenzae*. The reference strategy excluded both maternal prenatal HBV screening and vaccination of the offspring. Abbreviation: HBV, hepatitis B virus.

Table 1

Estimates used in the decision analysis model.

Parameter	Base case	Range	Data sources for base case and range estimates
Prevalence of HBV	0.10	0.05–0.20	[6],[7],[8]
Prevalence of HBeAg	0.25	0.22–0.28	[7],[8]
Probability of vertical transmission of HBV if the mother tested positive for HBeAg	0.90	0.70–0.95	[3],[4]
Probability of vertical transmission of HBV if the mother tested negative for HBeAg	0.30	0.10–0.40	[9]
Probability of horizontal transmission of HBV by age 10 years	0.20	0.05–0.30	[10],[11]
Proportion who complete the pentavalent vaccine series ^a	0.90	0.68–0.99	[12],[13],[14]
Relative risk of vertical transmission following birth-dose of HBV vaccine	0.8	0.7–0.9	[15],[16]
Relative risk of horizontal transmission following birth-dose of HBV vaccine	0.9	0.8–1.0	[15]
Relative risk of horizontal transmission following pentavalent vaccine	0.10	0.05–0.15	[17],[18],[19]
Sensitivity of HBsAg screen	0.990	0.963–0.999	[20]
Specificity of HBsAg screen	0.990	0.952–0.999	[20]
Costs, US\$ ^b			
HBV vaccine	5	NA	NA
Pentavalent vaccine	6	NA	NA
Prenatal HBsAg screen	4	NA	NA

Abbreviation: HBeAg, hepatitis B virus e antigen; HBsAg, hepatitis B virus surface antigen; HBV, hepatitis B virus; NA, not applicable.

^aThe pentavalent vaccine comprised HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenzae*.^bCosts are given at the 2015 exchange rate.

Table 2

Infections and costs associated with the hepatitis B virus prevention strategies.

Strategy	HBV infection per 10 000 children	No. of HBV infections prevented per 10 000 children	Cost per HBV infection prevented, US\$	Cost per HBV infection prevented versus strategy 1, US\$
Reference				
No maternal prenatal HBV screening; no vaccination of the offspring	2360	NA	Reference	NA
Intervention				
1. No maternal prenatal HBV screening; pentavalent vaccine ^a	813	1547	34.90	Reference
2. No maternal prenatal HBV screening; universal HBV vaccination at birth + pentavalent vaccine	430	1930	53.87	130.41
3. Maternal prenatal screening for HBsAg; targeted HBV vaccination at birth + pentavalent vaccine	451	1909	52.06	125.35

Abbreviations: HBsAg, hepatitis B virus surface antigen; HBV, hepatitis B virus; NA, not applicable.

^aThe pentavalent vaccine comprised HBV, diphtheria, tetanus, pertussis, and *Haemophilus influenzae*.