Impact of Recommendations to Suspend the Birth Dose of Hepatitis B Virus Vaccine

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Context In July 1999, due to concerns about thimerosal content, the American Academy of Pediatrics (AAP) and the Public Health Service (PHS) recommended suspending hepatitis B virus (HBV) vaccination at birth except for mothers who had positive or unknown hepatitis B surface antigen (HBsAg) status. In September 1999, the Centers for Disease Control and Prevention recommended that hospitals resume HBV vaccination at birth with a new thimerosal-free vaccine. Whether the 2 changes in recommendations within 3 months led to less-than-optimal compliance in hospital nurseries is unknown.

Objective To determine hospital HBV vaccination policy before the recommendation for delay of HBV vaccination and 1 year later.

Design, Setting, and Participants Survey of all 46 hospitals with obstetric services and neonatal nurseries in Cook County, Illinois.

Main Outcome Measures Hepatitis B virus immunization practices before July 1999 and in August 2000; hospital factors associated with routine HBV immunization and compliance with AAP and PHS recommendations.

Results Before July 1999, 74% of surveyed hospital nurseries offered HBV vaccine to all neonates; only 39% did so in August 2000. Being located in the Chicago city limits (88% vs 57%; P = .02) and having an academic affiliation (93% vs 66%; P = .05) were positively associated with routine neonatal immunization before July 1999. Both academic affiliation and city location were associated with routine immunization in August 2000 (71% vs 25%; P = .003) and 60% vs 14% (P = .002), respectively) and with compliance with recommendations for suspension (57% vs 25% [P = .03] and 56% vs 10% [P = .001]).

Conclusions We documented a 35% decrease in hospital nurseries that routinely offered HBV immunization 1 year after the AAP and PHS recommendations were made. Special efforts may be required to make at-birth administration of HBV vaccination universal.
Because 2 changes were made in the HBV immunization recommendations within 3 months, compliance required hospital nurseries to change policies rapidly. We hypothesized, therefore, that there might have been confusion about the desirability for administration of the HBV vaccine to newborns. We surveyed hospitals in Cook County, Illinois, to determine how the AAP and PHS recommendations affected HBV vaccination practices in newborn nurseries.

**METHODS**

We designed a survey about HBV vaccination policy that focused on 3 questions: What was the newborn HBV vaccination policy before July 1999? Did HBV immunization policy change during or after the summer of 1999? And what was the HBV immunization policy a year later (August 2000) after thimerosal-free vaccine became available?

The survey was directed to all general-care nurseries in Cook County that provided obstetric services and routine medical care to healthy, full-term infants. We selected hospitals from *The American Hospital Association Guide to the Health-Care Field*. Intensive care nurseries were not included in the sample because HBV vaccine is not recommended for premature infants born to HBsAg-negative mothers until the infants reach a weight of 2000 g. In August and September 2000, we telephoned the medical directors of the newborn nursery for each hospital. If the medical director was not available, we spoke with the nursing director or another physician whose primary role was providing care in the nursery. In addition to HBV immunization policy, we asked about characteristics of the nursery; who sets immunization policy in the hospital, consent procedures, and refusal rates for HBV immunization; and whether information was routinely given to parents about HBV vaccine. For survey purposes, policy referred to either written policy or generally observed practices that determined HBV vaccination of newborns. Using the same guide, we determined suburban or Chicago location and hospital membership in the Council of Teaching Hospitals and Health Systems (COTH), a component of the Association of American Medical Colleges, with membership limited to hospitals affiliated with an accredited medical school that participate in 4 or more approved active residency programs. We linked 2 indexes of hospital characteristics from the Health Care Financing Administration (HCFA) Payment Impact File: case-mix adjustment and disproportionate-share adjustment. Case-mix adjustment is an algorithm that predicts patients’ hospital costs and is used to infer the acuity and complexity of patients. A higher case-mix adjustment indicates sicker patients. Disproportionate-share adjustment uses the proportion of Medicare patient days for which Medicaid is the primary payer to estimate patients’ socioeconomic status, with a higher index referring to patients of lower economic status.

The analysis of survey responses focused on HBV immunization policy before July 1999 and in August 2000. We examined which factors were associated with routine HBV immunization. Using a $\chi^2$ test, we examined whether there was a significant association between routine newborn HBV immunization and hospital location, deliveries per month, and membership in COTH and whether policy was set by individual or committee. We compared mean

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**Table 1. Chronology of Recommendations Regarding Hepatitis B Virus (HBV) Birth-Dose Vaccination, November 1991 to July 2000**

<table>
<thead>
<tr>
<th>Date</th>
<th>Eventaber</th>
<th>Agency</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 1991</td>
<td>Recommendation for universal HBV vaccination (first dose at birth to 2 mo of age)</td>
<td>ACIP AAP Pediatrics</td>
<td>MMWR</td>
</tr>
<tr>
<td>July 7, 1999</td>
<td>Suspension of at-birth dose of HBV vaccine recommendation because of theoretical concern about thimerosal content</td>
<td>AAP/PHS MMWR</td>
<td>MMWR</td>
</tr>
<tr>
<td>July 15, 1999</td>
<td>Notification of suspension sent to each AAP member</td>
<td>AAP AAP Member Alert</td>
<td>Pediatrics</td>
</tr>
<tr>
<td>September 1999</td>
<td>Reiteration of thimerosal concerns and suspension of at-birth dose of HBV</td>
<td>AAP AAP</td>
<td>Pediatrics</td>
</tr>
<tr>
<td>September 10, 1999</td>
<td>Announcement of thimerosal-free HBV vaccine for newborn use and recommendation to resume newborn immunization</td>
<td>CDC MMWR</td>
<td>MMWR</td>
</tr>
<tr>
<td>September 20, 1999</td>
<td>Statement to suburban Cook County birthing hospitals regarding suspension of at-birth dose of HBV vaccine and recommendation to resume routine newborn immunization</td>
<td>CDPH Suburban Cook County mailing</td>
<td>MMWR</td>
</tr>
<tr>
<td>November 5, 1999</td>
<td>Reiteration of availability of thimerosal-free HBV vaccine for newborn use</td>
<td>CDC MMWR</td>
<td>MMWR</td>
</tr>
<tr>
<td>November 15, 1999</td>
<td>Statement to Chicago birthing hospitals regarding thimerosal-free HBV vaccine for newborn use and recommendation to resume newborn immunization</td>
<td>CDPH Chicago mailing</td>
<td>Chicago mailing</td>
</tr>
<tr>
<td>June 2000</td>
<td>Notice regarding thimerosal-free HBV vaccine for newborn use and recommendation to resume newborn immunization</td>
<td>AAP AAP News</td>
<td>AAP News</td>
</tr>
<tr>
<td>July 21, 2000</td>
<td>Announcement of licensure and availability of another HBV vaccine with decreased thimerosal content</td>
<td>CDC MMWR</td>
<td>MMWR</td>
</tr>
</tbody>
</table>

*ACIP indicates Advisory Committee for Immunization Practices; MMWR, Morbidity and Mortality Weekly Report; AAP, American Academy of Pediatrics; PHS, Public Health Service; CDC, Centers for Disease Control and Prevention; CDPH, Cook County Department of Public Health; and CDPH, Chicago Department of Public Health.*
Table 2. Characteristics of 46 Hospitals and Nurseries With Obstetric Services in Cook County, Illinois

<table>
<thead>
<tr>
<th>Hospital location</th>
<th>No. (%)</th>
</tr>
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<tbody>
<tr>
<td>Chicago</td>
<td>25 (54)</td>
</tr>
<tr>
<td>Suburban Cook County</td>
<td>21 (46)</td>
</tr>
<tr>
<td>Membership in Council of Teaching Hospitals</td>
<td>14 (30)</td>
</tr>
<tr>
<td>Average births per month (range)</td>
<td>180 (38-669)</td>
</tr>
<tr>
<td>Average case-mix adjustment index (range) [SD]†</td>
<td>1.45 (1.12-1.99) [0.19]‡</td>
</tr>
<tr>
<td>Average disproportionate share index (range) [SD]§</td>
<td>0.31 (0.03-0.82) [0.24]¶</td>
</tr>
<tr>
<td>Immunization policy determined by</td>
<td></td>
</tr>
<tr>
<td>Single physician</td>
<td>17 (37)</td>
</tr>
<tr>
<td>Committee</td>
<td>28 (61)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

*Data are presented as number (percentage) unless otherwise indicated.
†Predicts patients' hospital costs to infer the acuity and complexity of patients' conditions. A higher case-mix adjustment index indicates sicker patients.
‡Ranges reflect data for hospitals in the study.
§Estimation of patients' socioeconomic status by using the proportion of Medicare patient-days for which Medicaid is the primary payer. A higher index refers to patients of lower socioeconomic status.
¶Disproportionate-share index (range) (SD) indicates sicker patients.

Table 3. Hepatitis B Virus (HBV) Immunization Policies Before July 1999 and in August 2000 Among Hospitals With Obstetric Services in Cook County, Illinois*

<table>
<thead>
<tr>
<th>HBV Immunization Policy for Full-term Newborns</th>
<th>Before July 1999 (n = 46)</th>
<th>During August 2000 (n = 46)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine, independent of maternal HBV status</td>
<td>74</td>
<td>39</td>
</tr>
<tr>
<td>Not routine, only when indicated by maternal HBV status†</td>
<td>11</td>
<td>33</td>
</tr>
<tr>
<td>Not routine, only when indicated by maternal HBV status and otherwise at physician discretion†</td>
<td>13</td>
<td>26</td>
</tr>
<tr>
<td>Not routine, only when indicated by maternal HBV status and otherwise if the patient had private health insurance†</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

*Data are presented as percentages.
†Women who had a positive or unknown hepatitis B surface antigen status.

RESULTS

We identified 46 hospitals with obstetric services and newborn nurseries in Cook County. We achieved a 100% response rate. Hospital and nursery characteristics are summarized in Table 2.

Four HBV immunization policies for newborns were identified: (1) routine immunization of all infants independent of maternal HBV status; (2) immunization only when indicated by maternal HBV status (HBsAg positive or unknown status); (3) immunization only when indicated by maternal HBV status and otherwise at physician’s discretion; and (4) immunization only when indicated by maternal HBV status and otherwise if the patient had private health insurance.

Before July 1999, 74% of hospital nurseries offered routine HBV immunization of all newborns (Table 3). These institutions accounted for about 77% of Cook County births. The other 26% of hospital nurseries determined HBV immunization of newborns by 1 of the selective criteria (Table 3). Policy of offering routine immunization differed according to city or suburban location and by COTHC membership. Among the 32 non-COTHC hospitals, 60% in the city and 18% in the suburbs practiced routine immunization. A policy of routine immunization in August 2000 did not differ according to number of deliveries per month, who set vaccine policy, case-mix adjustment, or disproportionate-share index (Table 4).

In August 2000, only 39% of hospital nurseries were adhering to the practice of offering routine HBV immunization of all newborns (Table 3). These institutions accounted for about 43% of Cook County births. The other 61% of hospital nurseries determined HBV immunization of newborns by 1 of the selective criteria (Table 3). Policy of offering routine immunization differed according to city or suburban location and by COTHC membership. Among the 32 non-COTHC hospitals, 60% in the city and 18% in the suburbs practiced routine immunization. A policy of routine immunization in August 2000 did not differ according to number of deliveries per month, who set vaccine policy, case-mix adjustment, or disproportionate-share index (Table 4).

Following the July 1999 AAP and PHS recommendation, the HBV vaccine birth-dose policy was changed in 40 of the 46 surveyed nurseries (87%). All nurseries that discontinued routine HBV immunization adopted a policy of administering HBV vaccine only when the infant’s mother had a positive or unknown HBsAg status. Of the 13% of nurseries that did not change their HBV vaccination policy in July 1999, 1 nursery continued routine infant immunization and the other 5 nurseries who previously maintained a policy of giving HBV vaccine only when indicated by maternal HBV status continued that policy. Of the 40 nurseries that changed policy after July 1999, 26 (65%) made a second policy change before August 2000. Seventeen (65%) of these nurseries resumed routine vaccination with thimerosal-free vaccine. In 8 (31%) of the 26 nurseries, the decision to vaccinate newborns was left up to individual physicians. One nursery resumed a policy of routine HBV vaccination but only for infants with private medical insurance.

The policy change to suspend was implemented rapidly: 16 of the 17 that suspended routine HBV birth-dosing did...
so in July 1999, and the other suspended this policy in September 1999. In contrast, resumption of the HBV vaccine birth dose after September 1999 was much slower: 3 nurseries resumed birth dose administration in October, 1 in November, 2 in December, 5 in January 2000, 1 in March 2000, 4 in May 2000, and 1 in June 2000. There was no significant relationship between duration of suspension in nurseries in which 1 person determined vaccine policy vs nurseries in which a committee set the policy. None of the 17 nurseries that offered universal HBV vaccination to newborns before July 1999 and had not resumed this practice by August 2000 expressed an intention to do so.

At the time of the survey, all nursery interviewees were aware of the AAP and PHS recommendations to delay the birth dose of HBV vaccine, and all but 1 were aware of the subsequent availability of thimerosal-free HBV vaccine. Thirty-five percent of the nurseries followed all relevant HBV immunization recommendations, ie, offering routine HBV immunization to all newborns before July 1999, suspending the birth dose except for infants born to mothers who had a positive or unknown HBsAg status during the summer of 1999, and resuming routine HBV immunization by August 2000. When we compared the 16 nurseries that had followed the preferred policy with those nurseries that did not, we found membership in COTH and location in Chicago to be significant predictors. Number of deliveries per month, who set vaccine policy, case-mix index, and disproportionate share index were not associated with whether a nursery followed the recommendations (Table 5).

We collected qualitative data about HBV vaccine policy from the 1 nursery that did not suspend routine infant HBV immunization and 8 that suspended but did not resume. The medical director of the nursery that did not suspend routine immunization believed the benefit of giving routine HBV vaccination at birth was greater than the theoretical risk of harmful effects from thimerosal. Eight nurseries that did not resume gave 1 or more of the following reasons: the cost of administering the vaccine in the nursery (n=3), the belief that physicians had begun to prefer initiating the HBV series at age 2 months (n=4), concern that there could be liability associated with giving HBV vaccine to newborns (n=1), and belief that routine HBV vaccination of infants was not necessary (n=1).

Obtaining parental consent for the vaccine was the policy in 93% of nur-
eries. Seventy-seven percent of nurseries obtained written consent and 15% obtained verbal consent. Giving written documentation of the date of HBV vaccine administration was the policy in 90% of nurseries, and 70% had a policy to provide both written documentation of the date of vaccine administration and information about the vaccine. It was the interviewees’ belief that most parents accept HBV vaccination for their newborns when offered. Ninety-six percent of interviewees estimated the refusal rate at 10% or less, and 85% estimated a refusal rate of 1%.

COMMENT
We found that nearly half the hospitals in Cook County that offered routine HBV immunization to newborns prior to July 1999 were not doing so in August 2000. We identified 2 main patterns of immunization policy that the nurseries followed: temporary suspension of universal immunization of newborns after July 1999 with resumption by August 2000 and permanent suspension of universal immunization of newborns after July 1999. Policy changes were attributed to the recommendations made by the AAP and PHS in July 1999 to suspend the newborn dose. This situation is expected to continue because hospitals that were not implementing a birth-dose policy did not anticipate making further changes in immunization policy.

The net decrease in hospitals offering routine vaccinations of newborns has the potential for negative consequences. A policy to discontinue a practice may be easier to implement than one initiating a practice, especially if the recommendation to initiate follows closely and requires purchase of a new vaccine formulation. When universal HBV vaccination was first recommended, incorporation of vaccination into routine care lagged even though practitioners indicated acceptance of the policy.

BIRTH DOSE OF HEPATITIS B VIRUS VACCINE

First, routine vaccination ensures that infants born to mothers who had a positive or unknown HBsAg status. In a widely reported case, a Michigan infant born to an HBsAg-positive mother believed to be hepatitis B negative did not receive an HBV vaccine until age 2.5 months because the birth dose had been discontinued over concerns about thimerosal. The infant died of acute hepatic failure at age 3 months.

There are also secondary benefits of the birth dose that may be lost as a result of the decrease in the proportion of neonates routinely immunized. Delay in the receipt of the first HBV vaccine dose in the nursery has been associated with delay in on-time completion of the HBV vaccine series and 4:3:1 vaccination series. In an inner-city population, on-time completion of vaccinations is particularly desirable because of historically low on-time immunization rates and high risk for HBV infection.

There was a significant difference in HBV policy between city and suburban hospitals. Chicago hospitals were more likely to have practiced routine immunization before July 1999 and also in August 2000. Although the reasons for this difference are unknown, suburban hospitals may perceive that the prevalence of HBV infection and risk factors for HBV infection, such as injection drug use and multiple sex partners, occur less frequently in the suburban setting. Although the 1998 HBV infection incidence rates were lower for suburban residents (1.8 per 100,000) compared with Chicago residents (4.1 per 100,000), HBV infection is present even in a suburban setting. However, although geographic variation in hospitals routinely offering the birth dose has been noted previously, this variation was found to be inconsistently related to HBV prevalence.

A significantly higher proportion of COTH member hospitals practiced routine immunization of newborns in August 2000. This observation confirms data from a survey of pediatricians in North Carolina soon after recommendations for universal HBV vaccination were made that demonstrated an association between pediatricians’ employment in medical schools or health departments and a belief that universal HBV vaccination was warranted. Physicians in academic centers may have greater appreciation of the benefit of infant immunization, a greater awareness of guidelines, or a greater propensity to follow them. One might suppose that COTH member hospitals may serve populations at greater risk of HBV infection or with poorer compliance with childhood immunization recommendations after leaving the hospital. However, the case-mix index and the disproportionate-share index do not provide evidence indicating that recommendation-adherent hospitals served markedly different patient populations than those that were not adherent.

Our data indicate that there was relatively poor compliance with the CDC and AAP recommendations to resume HBV immunization for all newborns despite relatively good compliance with the first recommendation to suspend. When a recommendation is rapidly reversed, intensified efforts may be required to promote adherence. In July 1999, the AAP mailed a PedComm alert to its members and published an interim report in the journal Pediatrics detailing the recommendation to suspend routine newborn HBV vaccination. Similar alerts were not issued regarding the need for resumption with thimerosal-free vaccine. Rather an article in AAP News recommended resumption of HBV immunization at birth in June 2000. Given the high rate of adherence to the recommendation for suspension that we found in Cook County nurseries, the PedComm Alert may have conveyed an urgency that sped dissemination to practitioners whereas the AAP News article months later conveyed a less urgent message.

A policy to discontinue a practice may be easier to implement than one initiating a practice, especially if the recommendation to initiate follows closely and requires purchase of a new vaccine formulation. When universal HBV vaccination was first recommended, incorporation of vaccination into routine care lagged even though practitioners indicated acceptance of the policy.
A concern about liability associated with giving HBV vaccine at birth may be contributing to the decision to discontinue routine vaccination. Data from a nationwide survey have shown that 70% of practitioners that administered vaccines did not believe they were protected from vaccine-related litigation, suggesting that physicians may consider liability when determining their vaccine practices. Sudden concern about thimerosal and the rush to implement new vaccine policy may have heightened anxiety of practitioners and parents about vaccine safety and led to the perception that liability would be associated with vaccine administration.

Economic factors may have led to abandonment of newborn vaccination in some instances. Although reimbursement for vaccination is available from public and private sources, representatives of several nurseries expressed concern about the cost of resuming vaccination. There may be unrecoverable costs associated with vaccination such as practitioner time required for education, consent, and administration of the vaccine. Also, nurseries may consider unrecoverable costs of vaccination to be greater than the benefits so that suspension was a welcomed recommendation but resumption was not.

Three limitations of this study may affect interpretation of the findings. First, we relied on self-reporting and recall for dates of policy implementation and did not independently verify responses. Second, although Cook County has a population of more than 5 million people and encompasses urban and suburban areas, the data may reflect policies and determinants of policies unique to this location. However, a mail survey in February 2000 in Wisconsin similarly found many hospitals had not reinstated routine at-birth administration of HBV vaccine after suspension because of thimerosal concerns.22 Third, the small sample size precludes fully distinguishing the effects of COTH membership and urban or suburban location.

Special efforts may be necessary to make routine at-birth administration of HBV vaccine universal. Community intervention consisting of educational programs and cost compensation for vaccine administration have been effective in improving the rate of HBV vaccine administration to newborns.29 The medical and public health benefits of initiating HBV vaccine in the nursery seem to justify educational efforts aimed at restoring HBV vaccine administration to newborns. It is noteworthy that our survey and others29 indicate almost all parents accept HBV vaccination for their newborn when it is offered, suggesting that efforts to increase newborn HBV vaccination rates should be aimed at health care practitioners. Adoption of universal HBV vaccination for newborns will potentially eliminate a vaccine “missed opportunity” and ensure high immunization rates against HBV and, possibly, other immunizations recommended for routine administration.

Author Contributions: Study concept and design: Oram, Daum, Lauderdale. Acquisition of data: Seal. Analysis and interpretation of data: Oram, Daum, Lauderdale. Drafting of the manuscript: Oram, Seal. Critical revision of the manuscript for important intellectual content: Oram, Daum, Lauderdale. Statistical expertise: Lauderdale. Administrative, technical, or material support: Daum, Seal. Study supervision: Oram, Lauderdale.

Funding/Support: The Pediatric Immunization Program receives support from the Chicago Department of Public Health, Aventis, Wyeth-Ayerst, and the University of Chicago Hospitals.

Acknowledgment: We thank Martha Van Haitsma, PhD, of the Survey Lab at the University of Chicago for assistance with survey design, Katie Merrell, BA, Senior Analyst at the Center for Health Administration Studies at the University of Chicago for assistance with HCFA information, and Lawrence Casalano MD, PhD, for his critical review of the manuscript.

REFERENCES


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