



# Association between timely initiation of hepatitis B vaccine and completion of the hepatitis B vaccine and national immunization program vaccine series



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## SUMMARY

**Background:** Little is known about the association between the initiation of hepatitis B vaccine (HB vaccine) at birth and completion of the HB vaccine and the national immunization program vaccine (NIPV) series in Fujian, China.

**Methods:** A provincial survey, including children in the community and newborns in hospital, was conducted to evaluate coverage with a timely first dose of HB vaccine and the completion of three doses of HB vaccine and the NIPV series in 2013. A proportion of the samples was rechecked to investigate the relationship between the administration of a timely first dose of HB vaccine and completion of the HB vaccine series and the NIPV series (three doses of HB vaccine, one dose of Bacillus Calmette–Guérin vaccine, three doses of oral poliomyelitis vaccine, three doses of diphtheria–tetanus–pertussis vaccine, one dose of measles-containing vaccine, one dose of Japanese encephalitis attenuated live vaccine, and two doses of group A meningococcal polysaccharide vaccine).

**Results:** A total of 6589 subjects (including 3785 community children and 2804 hospital newborns) were included in this study; 97.34% of them received a timely first dose of HB vaccine ( $\leq 24$  h after birth) and 99.10% and 88.27% completed the HB vaccine series and the NIPV series, respectively. Among the 1680 children from eight counties who were rechecked, those with a timely first dose of HB vaccine had higher completion rates of the HB vaccine series and the NIPV series than those with a delayed first dose of HB vaccine (99.69% and 88.90% vs. 83.05% and 79.66%, respectively; both  $p < 0.001$ ). Compared to those with a delayed HB vaccine first dose, the odds ratios for completing the HB vaccine series and the NIPV series among children who received a timely first dose of HB vaccine were 65.96 (95% confidence interval (CI) 21.73–200.25) and 3.24 (95% CI 1.81–5.81), respectively.

**Conclusions:** Coverage with a timely first dose of HB vaccine is high in children in the community and newborns in hospital, and timely receipt of the first dose of HB vaccine is associated with an increased likelihood of completing the HB vaccine series and the NIPV series in Fujian, China.

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## 1. Introduction

Infection with the hepatitis B virus (HBV) is highly prevalent in Fujian, China. The prevalence of positivity for hepatitis B surface antigen was estimated to be 10.2% in the population aged 1 to 59 years in 2006.<sup>1</sup> To control HBV infection, hepatitis B vaccine

(HB vaccine) has been recommended for newborns and infants since 1992, and was included in the national immunization program vaccine (NIPV) series in 2002.<sup>2</sup> It is recommended that infants receive three doses of HB vaccine, to be given within 24 h after birth and at 1 month and 6 months of age.<sup>1,2</sup>

Many measures have been taken to improve coverage with a timely first dose of HB vaccine (within 24 h after birth) and completion of the HB vaccine series since 2002, such as the implementation of the free vaccine policy.<sup>1</sup> Correspondingly, the coverage rate for a timely HB vaccine first dose increased from

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40–60% in 1992–2002 to around 90% in 2003–2005 in Fujian.<sup>1,3,4</sup> However, previous studies have always evaluated coverage with a timely HB vaccine first dose in children in the community;<sup>1,3,4</sup> the level of vaccination among newborns in hospitals, and how different the coverage is between children in the community and newborns in hospital, remains unknown.

In addition, previous studies by the present investigators have revealed that infants who receive a timely first dose of HB vaccine are more likely to complete the HB vaccine, diphtheria–tetanus–pertussis (DTP), and measles-containing vaccine (MCV) series.<sup>1,5</sup> In the USA, administration of HB vaccine at birth was found to be associated with the timely receipt of three doses of HB vaccine and the 4:3:1 series (four doses of DTP vaccine, three doses of poliomyelitis vaccine, and one dose of MCV),<sup>6</sup> but not the 4:3:1:3 series (the 4:3:1 series plus three doses of *Haemophilus influenzae* type b vaccine).<sup>7</sup> However, the impact of timely initiation of the HB vaccine first dose on completion of the NIPV series in Fujian, China is still unclear.

Therefore, a provincial NIPV series survey, including community children and hospital infants, was conducted in 2013 to study coverage with a timely first dose of HB vaccine and to verify the association between timely administration of the first dose of HB vaccine and completion of the HB vaccine series and the NIPV series in Fujian, China, a region where HBV infection is highly endemic,<sup>1</sup> the immunization rate is high,<sup>3</sup> and the vaccine series and recommended vaccination schedules differ from those in the USA.<sup>8,9</sup>

## 2. Methods

### 2.1. Survey design and data collection

The survey was conducted in May 2013 to obtain coverage rates for the timely initiation of the HB vaccine first dose and completion of the HB vaccine and NIPV series among children in the community born between January 1, 2010 and December 31, 2011. The target population was selected by stratified random sampling. First, 18 random counties were selected from the nine cities of Fujian (two counties in each city), and 30 villages were identified in each selected county. Second, seven children who had resided in the village for at least 3 months at the time of the survey visit were selected by probability proportional to size sampling (PPS). Finally, a house-to-house investigation was completed by trained staff. Basic information, including date of birth, domicile, and immunization history, was extracted from the child's immunization certificate kept by the parents.

Coverage of timely HB vaccine first dose initiation was also evaluated in hospital newborns. In each of the 18 counties, one county-level hospital and two township hospitals were selected randomly. At least 100 infants born between February 1 and February 28, 2012 in each county hospital, as well as all infants born between January 1 and December 31, 2012 in each of the 36 township hospitals, were investigated to calculate the coverage rate of a timely administration of the first dose of HB vaccine in newborns. Information on the HB vaccine first dose was obtained from the immunization certificate kept by the parents, or the immunization registry records kept by the hospitals. The nine cities (and 18 counties) surveyed were Fuzhou (Minqing, Taijiang), Xiamen (Huli, Haicang), Putian (Chengxiang, Xianyou), Sanming (Shaxian, Mingxi), Quanzhou (Yongchun, Shishi), Zhangzhou (Xiangcheng, Nanjing), Longyan (Xinluo, Yongding), Nanping (Jianyang, Songxi), and Ningde (Fu'an, Zherong).

To further study the relationship between timely initiation of the HB vaccine first dose and completion of the HB vaccine and the NIPV series, the immunization information of 1680 community children from eight counties (Minqing, Huli, Xianyou, Shaxian, Yongchun,

Xiangcheng, Xinluo, and Jianyang) were rechecked with the vaccination records in the immunization surveillance system in immunization clinics, and were summarized by initiation time of the HB vaccine first dose ( $\leq 24$  vs.  $>24$  h after birth) and completion of the three-dose HB vaccine and the NIPV series (yes vs. no).

### 2.2. Outcome definitions

Three outcomes were assessed in this analysis: timely initiation of the first dose of HB vaccine, completion of the HB vaccine series, and completion of the NIPV series. In accordance with the recommended vaccination schedule of the China Center for Disease Control and Prevention,<sup>3</sup> timely initiation of the first dose of HB vaccine was defined as receipt of the first dose of HB vaccine within 24 h after birth. Completion of the HB vaccine series was defined as the receipt of three doses of HB vaccine at the correct/appropriate intervals (i.e.,  $>1$  month between doses 1 and 2,  $>2$  months between doses 2 and 3, and  $>4$  months between doses 1 and 3) by 12 months of age, regardless of the time at receipt of the first HB vaccine dose.

The NIPV series refers to three doses of HB vaccine, one dose of Bacillus Calmette–Guérin vaccine (BCG), three doses of oral poliomyelitis vaccine (OPV), three doses of DTP vaccine, one dose of MCV, one dose of Japanese encephalitis attenuated live vaccine (JEV-L), and two doses of group A meningococcal polysaccharide vaccine (MPSV). Completion of the NIPV series was defined as the receipt of the NIPV series at the correct/appropriate intervals for the different vaccines and/or doses, in which the child should have completed the HB vaccine, BCG, OPV, DTP, MCV, and JEV-L series and the first dose of MPSV by 12 months of age, and have completed the second dose of MPSV by 18 months of age (with an interval of at least 3 months between the first and second dose). Community children aged less than 18 months at the time of the survey were deemed to have completed the NIPV series if they had received all NIPV series vaccines except the second dose of MPSV. Any violation of the requirement was defined as delayed initiation of the HB vaccine first dose, incompleteness of the HB vaccine series, and incompleteness of the NIPV series, respectively.

### 2.3. Statistical analysis

Individual vaccination data were checked and classified according to the definitions. The coverage rate of timely administration of the HB vaccine first dose was counted by city. The Chi-square test or Fisher's exact test was used to compare the rates of timely HB vaccine first dose between local children and floating children, and between community children and hospital infants. Local children were defined as children with a permanent local Hukou, while floating children were defined as those living without residence registration in the survey location.

The percentages of children who had completed the HB vaccine series and the NIPV series were calculated by initiation time of the HB vaccine first dose ( $\leq 24$  h and  $>24$  h after birth). Odds ratios (OR) and 95% confidence intervals (95% CI) were calculated. A subgroup analysis was done by urbanicity (rural area vs. urban area). According to the distance between the area of residence and the central city, and the economic development of the region, three counties were classified as urban areas (Huli, Xiangcheng, and Xinluo) and five counties were classified as rural areas (Minqing, Xianyou, Shaxian, Yongchun, and Jianyang). Given the small sample of the control group, details of the delay in HB vaccine first dose were described, and the proportion of children with a delayed HB vaccine first dose was compared between the two subgroups (rural children vs. urban children; local children vs. floating children).

Pair-wise comparisons of heterogeneity were applied among the ORs for relationships between the timely initiation of HB

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