



## Household survey of hepatitis B vaccine coverage among Brazilian children

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### ABSTRACT

We conducted a multi-stage household cluster survey to calculate hepatitis B vaccine coverage among children 18–30 months of age in 27 Brazilian cities. Hepatitis B vaccine is administered at birth, 1 month and 6 months of age by Brazil's national immunization program. Among 17,749 children surveyed, 40.2% received a birth dose within one day of birth, 94.8% received at least one dose of hepatitis B vaccine, and 86.7% completed the three-dose series by 12 months of age. Increased coverage with the birth dose and administration of hepatitis B in combination with diphtheria–tetanus–pertussis–*Haemophilus influenzae* type b antigens could improve protection against hepatitis B.

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### 1. Introduction

Hepatitis caused by hepatitis B virus (HBV) is a major public health problem in Brazil. Several areas within the country have presented high prevalence of chronic hepatitis B infection, among them the western Amazon region and parts of southern Brazil. Seroprevalence surveys in several communities in Brazil have detected a prevalence of antibodies to hepatitis B surface antigen (HBsAg) of

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3.3% in the state of Acre [1], 4.8% in a rural community in the state of Rondonia [2], and 9.7% among native people in the western Amazon region [3]. Hepatitis B vaccination was introduced in Brazil in 1989 in immunization campaigns, and in 1991–1992, was introduced in the public vaccination schedule for infants in these hyperendemic regions. Vaccination against hepatitis B for infants was extended to the whole country in 1996, but due to limited vaccine supplies, hepatitis B vaccine coverage in infants only increased after 1998 [4].

The Brazilian national immunization program recommends three doses of hepatitis B vaccine at birth, 1 month of age and 6 months of age [5]. Monovalent hepatitis B vaccine is produced by Butantan Institute, a public sector Brazilian vaccine manufacturer, for the national immunization program and is provided at no cost in public vaccination clinics. Hepatitis B vaccine may be administered at the same visit as other routine immunizations, including diphtheria–tetanus–whole cell pertussis and *Haemophilus influenzae* type b (DTwP-Hib) vaccine [5]. Annually, approximately 12 million doses of hepatitis B vaccine are administered by the national immunization program. National estimates of coverage with three doses of hepatitis B vaccine are based on the number of doses administered among children less than 12 months of age and the estimated birth cohort. Estimates of the proportion of children who complete the recommended hepatitis B series on-time are important for evaluating and improving upon current hepatitis B prevention efforts.

In 2006, the Brazilian Ministry of Health commissioned a population-based vaccine coverage survey to provide estimates of the proportion of children receiving recommended immunizations. We report here on the results for hepatitis B vaccine coverage among young children in cities throughout Brazil.



Fig. 1. Map of Brazilian states showing the 26 state capitals and federal district included in the vaccination coverage survey.

## 2. Methods

### 2.1. Survey methodology

A household survey was undertaken to assess vaccine coverage of newborns in the 26 capital cities of Brazilian states and Brasília, the Federal Capital (Fig. 1). In total, the estimated population of these 27 cities in 2007 was more than 45 million people, 24.5% of the entire Brazilian population. The survey targeted the 2005 birth cohort including children between the ages of 18–30 months as of July 1, 2007. The WHO thirty-by-seven cluster methodology was chosen to provide 95% confidence for expected vaccine coverage of 80% with desired precision of 7%, 10% refusal and a design effect of 1.5. The total sample size was increased to between 60 and 150 clusters of 7 children each, proportional to the size of the birth cohort in each city. The primary sampling unit was the census tract. To obtain a representative and probabilistic sample of children, census tracts in each capital were ranked according to the percent of households earning more than 20 times the minimum wage, mean household income and percent head of households with 17 or more years of education according to 2000 census data [6]. Socioeconomic quintiles were created according to the sum of census tract rankings, and equal numbers of census tracts were randomly selected from each quintile. To account for decreasing birth rates, contiguous census tracts in the same socioeconomic quintile were combined to include a minimum of 56 children in the target age group (based on census estimates). Each selected cluster of census tracts was divided into quadrants and one quadrant was randomly selected to begin searching at consecutive households until 7 eligible children had been identified in the cluster.

Interviewers enrolled the first seven children identified who had been born in 2005. The child's parent or guardian completed a short structured interview and were asked to show the child's vaccine record. Dates of each dose of vaccine that the child received were transcribed from the vaccine record.

### 2.2. Calculation of vaccination coverage from household survey

Vaccination coverage with three doses of hepatitis B vaccine was calculated based on doses received before the child's first birthday recorded on vaccination cards; children without vaccination cards were treated as unvaccinated. All doses in the first year of life were included. The recorded date of receipt of the first dose of hepatitis B was used to calculate percent of children who received a birth dose within the first 3 days of life. Vaccine coverage and 95% confidence intervals were adjusted for clustered survey design using the complex tables module in EpiInfo for Windows software (Version 3.5.1, Centers for Disease Control and Prevention, Atlanta, GA). Estimates for each city were weighted according to the size of the population in each socioeconomic stratum.

### 2.3. Comparison with estimates from the national immunization program

Hepatitis B vaccination coverage estimates for 2005 among children <1 year of age were obtained for each city from the national immunization program [7]. Administrative coverage estimates were calculated as the number of hepatitis B doses recorded as the third dose administered to children <1 year at public vaccination clinics during 2005 divided by the population <1 year of age in 2005.

### 2.4. Estimating impact of hepatitis B vaccination

To estimate the impact of hepatitis B vaccination at current versus target levels of vaccine coverage, we used a hepatitis B disease burden and vaccination model developed by the Centers for Disease Control and Prevention (Version 1.1, November 2003) [8]. We used estimated prevalence of hepatitis B infection for Brazil from Goldstein et al. [8], including 1.6% HBsAg-seropositivity among women of childbearing age, assuming 15% of HBsAg-positive women were HBeAg-seropositive, 3% anti-HBc seroprevalence among 5-year-old

**Table 1**  
Estimated coverage with three doses of hepatitis B vaccine by 12 months of age in 27 Brazilian cities surveyed, by region, comparing survey estimates<sup>a</sup> and administrative estimates<sup>b</sup>.

Region city	Estimated population <1 year, 2005	Survey estimate	Administrative data
		% coverage (95% CI)	% coverage
<b>South</b>			
Curitiba	27,879	98.4 (97.5–99.3)	97.5
Porto Alegre	22,231	89.9 (87.8–92.0)	84.0
Florianópolis	5,815	93.0 (90.4–95.7)	85.3
<b>Southeast</b>			
Vitória	4,632	90.0 (85.4–94.0)	98.0
São Paulo	184,217	89.1 (85.9–92.2)	93.1
Belo Horizonte	37,667	84.9 (82.1–87.7)	72.1
Rio de Janeiro	92,190	83.4 (80.2–86.6)	93.3
<b>Central-west</b>			
Brasília	46,993	94.4 (92.6–96.1)	85.4
Cuiabá	9,342	92.9 (90.4–95.3)	74.7
Goiânia	19,658	84.4 (81.0–87.9)	88.3
Campo Grande	13,023	73.4 (67.5–79.3)	87.9
<b>Northeast</b>			
Teresina	15,013	94.3 (91.9–96.7)	86.7
Natal	13,961	86.6 (82.8–90.4)	88.2
Aracaju	8,907	89.0 (86.3–91.7)	67.6
Maceió	18,126	85.2 (82.1–88.3)	77.6
Recife	24,886	87.1 (84.5–89.7)	98.7
Fortaleza	44,406	86.1 (83.2–89.0)	79.2
Salvador	45,839	83.6 (80.9–86.3)	77.3
João Pessoa	11,462	83.0 (80.1–86.0)	94.6
São Luís	19,137	82.0 (78.6–85.3)	94.3
<b>North</b>			
Palmas	4,977	86.7 (84.0–89.3)	71.5
Rio Branco	7,104	83.8 (79.7–87.9)	88.5
Belém	26,766	86.5 (83.3–89.7)	88.6
Boa Vista	6,442	81.6 (77.9–85.4)	86.8
Porto Velho	8,479	86.2 (82.2–90.1)	82.3
Manaus	40,111	76.0 (70.8–81.2)	79.1
Macapá	9,539	69.7 (65.8–73.7)	88.5

<sup>a</sup> Survey estimates correspond to documented vaccine doses received in the first year of life by children born in 2005.

<sup>b</sup> Administrative estimates were calculated as the number of hepatitis B doses administered in public vaccination clinics to children <1 year of age and registered as third doses of hepatitis B vaccine during the 2005 calendar year.

children prior to widespread childhood immunization, 30% anti-HBc seroprevalence among persons 30 years and older, 95% birth dose efficacy (if administered within 24 h of birth) for preventing perinatal HBV transmission and 95% efficacy of three doses for early childhood and late HBV infection.

### 2.5. Human subjects

The study protocol was approved by the ethical review board of Santa Casa Medical School. A parent or legal guardian of each child enrolled provided signed informed consent. In each household surveyed the Informed Consent Form was discussed with the parents or legal representatives of the child, and signed by one of them once there was a decision to participate.

### 3. Results

A total 17,749 children were included in the survey out of a target of 20,370 children (87% completion); for 9% of the target sample, interviewers did not identify seven eligible children in selected census tracts, and for 4%, the child's parent or guardian refused to participate or was unavailable for interview. The percentage of completion was highest (97%) in state capitals in the Amazon region and lowest in southeastern Brazil (77%). Among children enrolled, 98% had vaccination cards.

Table 1 presents estimates of coverage with three doses of hepatitis B vaccine in the first year of life for children born in 2005 in the

27 cities surveyed. Overall coverage was 86.7% (95% CI 85.4, 88.0). Coverage with three doses was above the national immunization program target of 95% in one of the 27 capitals, Curitiba (98.4%), and was above 90% in five capitals (Brasília, Teresina, Florianópolis, Cuiabá and Vitória). Coverage was below 80% in three cities: Macapá and Manaus in the north (69.7% and 76.0%, respectively), and Campo Grande in the central-west (73.4%). Although coverage tended to be higher in southern cities compared to northern cities, coverage varied widely within regions and was not related to population size (Table 1). Coverage was below average in two capital cities located in the hyperendemic area for hepatitis B in the western Amazon region, Rio Branco (83.8%) and Porto Velho (86.2%). When analyzed by socioeconomic quintile, estimated coverage with three doses of hepatitis B vaccine tended to be lower (84.2%) among children in the top quintile of census tracts (stratum A) versus 86.4% among children in census tracts in bottom quintile (stratum E) although differences were not statistically significant (Fig. 2).

The proportion of children who received hepatitis B vaccine on the day of birth or 1 day after birth was 40.4% (95% CI 39.7, 41.2) and only increased to 45.1% (95% CI, 44.4, 45.8) including doses received on the second day after birth. Table 2 shows the percent of children in each city with documented hepatitis B vaccination in the first 3 days of life. The percentage of children vaccinated within the first 3 days of life was highest (75.9%) for the three capitals in the south of Brazil and only 19.2% in cities in the central-western region.

In all, 94.8% of children included in the survey received at least one dose of hepatitis B vaccine; 8.5% did not complete the three-

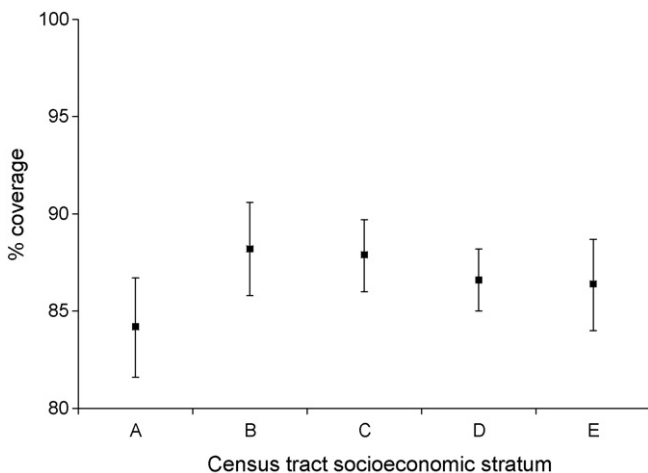
**Table 2**

Percentage of children in survey with documented dose of hepatitis B vaccine in the first 3 days of life, at least one dose by 12 months of age, and percentage of vaccinated children with incomplete hepatitis B vaccine series in 27 Brazilian cities, by region.

Region city	Vaccinated in first 3 days of life	Day of first hepatitis B vaccine dose			First dose by 12 months	Incomplete three-dose series <sup>a</sup>
		Day of birth	Day after birth	2 days after birth		
<b>South</b>						
Curitiba	95.4	90.3	4.8	0.3	99.2	0.8
Porto Alegre	90.5	86.6	3.2	0.7	97.9	8.2
Florianópolis	18.1	12.6	4.0	1.5	96.8	3.9
<b>Southeast</b>						
Vitória	17.9	5.7	6.9	5.3	96.9	7.2
São Paulo	43.7	21.6	16.3	5.8	94.7	6.0
Belo Horizonte	19.7	6.8	7.9	5.0	91.7	7.4
Rio de Janeiro	49.0	41.3	5.6	2.1	94.4	11.6
<b>Central-west</b>						
Brasília	65.9	62.2	3.0	0.3	98.6	4.3
Cuiabá	5.1	2.4	1.3	1.5	97.6	4.9
Goiânia	19.9	8.7	7.5	3.7	89.2	5.4
Campo Grande	39.5	7.5	22.9	9.1	82.0	10.5
<b>Northeast</b>						
Teresina	73.4	29.3	37.8	6.4	98.8	4.5
Natal	46.2	10.4	23.7	12.1	97.5	11.2
Aracaju	87.4	23.0	62.1	2.3	94.0	5.3
Maceió	11.4	4.0	5.5	2.0	96.8	12.0
Recife	52.5	11.5	29.3	11.7	95.0	8.3
Fortaleza	41.3	12.2	22.7	6.4	95.8	10.2
Salvador	17.9	3.5	8.5	5.8	93.0	10.2
João Pessoa	41.3	7.7	21.7	11.9	94.4	12.0
São Luís	29.8	6.2	16.4	7.1	90.2	9.1
<b>North</b>						
Palmas	71.3	33.5	34.2	3.6	92.1	5.9
Rio Branco	79.0	21.2	49.2	8.6	94.5	11.4
Belém	19.0	4.8	12.6	1.6	96.8	10.6
Boa Vista	87.8	34.1	48.2	5.5	95.2	14.3
Porto Velho	61.0	50.2	7.4	3.3	92.9	7.2
Manaus	43.0	14.4	23.7	5.0	94.6	19.6
Macapá	43.4	3.4	27.6	12.4	85.0	18.0

<sup>a</sup> Calculated as the percent of children in survey with documented evidence of at least one dose of hepatitis B vaccine without evidence of three doses by time of survey.

dose schedule. The percentage of children who did not complete the three-dose hepatitis B schedule was inversely correlated with three-dose coverage ( $r = -0.81$ ,  $p < 0.001$ ). Cities with the lowest three-dose coverage had high drop-out rates. In 12 cities, the proportion was above 10%, with the highest proportion in Manaus (19.6%) and Macapá (18.0%) where survey estimates were lowest.



**Fig. 2.** Estimated coverage with three doses of hepatitis B vaccine by 12 months of age, by socioeconomic quintile of census tract of residence (according to percent of households earning more than 20 times the minimum wage, mean household income and percent of households with 17 or more years of education (A = highest, E = lowest). See Section 2) in 27 Brazilian cities surveyed, Brazil, 2005.

Based on administrative data for doses administered in 2005, three cities were above the national immunization program target of 95% (Curitiba, Vitória and Recife; Table 1); only in Curitiba was the survey estimate above 95%. Further, administrative coverage did not correlate with coverage estimates: survey estimates were higher than administrative coverage in 13 cities and lower in 14 cities. The three cities in which the household survey estimated hepatitis B coverage below 80% two showed higher than 85% coverage according to administrative data.

In contrast to hepatitis B vaccine coverage, the survey estimated coverage with three doses of DTwP-Hib (recommended at 2, 4 and 6 months of age) in the first year of life of 94% (data not shown). In all cities, coverage with three doses of hepatitis B vaccine was lower than that for three doses of DTwP-Hib. Only 42% of children received the third dose of hepatitis B and the third dose of DTwP-Hib on the same date, although both are recommended at 6 months of age and can be administered at the same clinic visit. Among children who received both vaccines on the same date, coverage with three doses of hepatitis B was 98.7% (95% CI 98.3, 99.2), versus 77.3% (95% CI 75.2, 79.4) among children who received hepatitis B vaccine and DTwP-Hib on different dates.

In the base-case scenario with no vaccination, the hepatitis B disease burden model predicted 450,000 HBV infections would occur over the lifetime of the 2005 birth cohort, resulting in 8500 HBV-related deaths. With an estimated 87% coverage with three doses of hepatitis B vaccine, and 45% of neonates within 24 h of birth, the model predicted that the vaccination program would prevent 81% of lifetime hepatitis B infections and 6350 HBV-related deaths, a 75% reduction. If hepatitis B vaccine coverage reached the national



**Table 3**  
Number of reported hepatitis B cases and detection rate per 100,000 inhabitants, Brazil, 2000–2007.

Year	Cases reported	Detection rate (per 100,000 population)
2000	7,329	4.32
2001	7,802	4.53
2002	8,369	4.79
2003	12,146	6.87
2004	14,327	8.00
2005	16,185	8.79
2006	15,753	8.43
2007	11,323	5.98

Source: Ministry of Health, 2008.

target of 95% throughout Brazil, with 75% of neonates vaccinated within 24 h of birth, the model predicted an additional 1000 HBV-related deaths could be prevented over the lifetime of the 2005 birth cohort.

#### 4. Discussion

The Brazilian National Immunization Program is widely recognized as one of the most successful public health programs in the country. Vaccination coverage has been increasing since the 1980s. Endemic transmission of polio and measles viruses has been interrupted and the incidence of several vaccine preventable diseases (including rubella, diphtheria, tetanus and *H. influenzae* type b infections) has decreased. Such a trend has not been observed in reported hepatitis B cases (Table 3). However, long incubation and latency periods, misdiagnosis of acute cases, and underreporting of chronic cases complicate interpretation of trends in reported hepatitis B cases. Transmission through blood or blood transfusions has been reduced, if not eliminated, since mandatory screening was introduced in mid 1990s [9]. Importantly, an estimated 25% of the population younger than 20 years of age in Brazil has not been vaccinated against hepatitis B [7] and sexual transmission of HBV remains a concern among unvaccinated adolescents. Educational campaigns promoting safe sex and the use of condoms to reduce HIV transmission also need to promote vaccination against hepatitis B. Questions remain about whether the hepatitis B vaccine strategy has been adequate and whether vaccine coverage is high enough to impact the occurrence of the disease.

The household vaccination survey provided the first individual-level estimates of hepatitis B vaccine coverage to compare with administrative data for major cities and state capitals throughout Brazil. The survey provided information to improve use of hepatitis B vaccine in Brazil, by indicating that birth dose was given late in most cities, drop out rates were surprisingly high and coverage with three doses of hepatitis B vaccine was lower than three doses of diphtheria–tetanus–pertussis–*H. influenzae* type b vaccine. Coverage with the complete three-dose series of hepatitis B vaccine in the first year of life was lower than expected at 86.7% among children born in 2005 in selected cities. Among all vaccines included in the coverage survey, coverage of hepatitis B was lower than for any other routine vaccination. Only one of the state capitals reached the target coverage of 95%. While results of the disease burden model predict that current vaccination coverage prevents 75% of HBV-related deaths over the life of a birth cohort, compared to a scenario without vaccination, higher levels of coverage would have an even greater impact.

Less than half of the children included in the survey had received hepatitis B vaccination in the first day of life, as recommended to prevent mother-to-child transmission. Evidence suggests that early administration of hepatitis B vaccine is most effective, with

little or no protection when the first dose is delayed beyond 48 h [10–14]. Hepatitis B vaccine was available in hospitals in urban areas throughout Brazil during 2005, and the failure to vaccinate children at birth points to operational problems or lack of awareness among health care professionals. Coverage with a birth dose of hepatitis B vaccine in the selected cities varied drastically by region, with high coverage and few delays in the cities in southern Brazil. This difference was not associated with the percentage of hospital or health care facility births in capital cities and the federal district, which was above 98% of live births in all selected cities in 2005 [15]. The timing of the first dose of hepatitis B vaccine in newborns is an indicator of the performance of the vaccination program in these cities and states. Data were not collected on receipt of hepatitis B immune globulin (HBIG), recommended in conjunction with vaccination for infants born to HBsAg-positive mothers. Early administration of first vaccine dose is especially important in endemic settings where HBIG is not available, as is the case in many urban public hospitals in Brazil.

The difference between survey estimates of coverage with three doses of hepatitis B vaccine versus three doses of DTwP-Hib was surprising. One possible explanation is conflicting messages regarding the recommended 0, 1, 6-month infant schedule for hepatitis B, which recommends in a footnote that the second and third doses be administered 30 and 180 days after the first dose, respectively [5]. A combined DTwP-Hib-HepB vaccine from Brazilian manufacturers is currently being evaluated in non-inferiority trials. It is hoped that coverage with three doses of the combination vaccine will reach or surpass those of DTwP-Hib. In the meantime, results of the vaccine coverage survey will be presented to health professionals and immunization program managers to find solutions to minimize missed opportunities.

Results of the household vaccination coverage survey showed that administrative data do not always provide the information needed for program monitoring. The sampling method used in the present survey was based on the thirty-by-seven cluster sample developed by the WHO and has been widely used in similar studies on vaccine coverage [16,17]. A high percentage of the target number of interviews were completed in the selected cities and dates of vaccination were recorded from child health cards, which are kept by nearly all parents or guardians in Brazil. One limitation of the vaccination survey is that it was only conducted in capital cities and is not representative of the entire country. Individual-level estimates of vaccination coverage are needed for rural areas of Brazil. Administrative data differ from survey data and are not directly comparable: children may not reside in the city where they receive vaccination and only a proportion of doses administered in 2005 correspond to doses received by the 2005 birth cohort. While administrative data did not show systematic bias to overestimate or underestimate coverage in selected cities, only one city met the 95% target for hepatitis B vaccine coverage when individual data were collected, versus three cities based on administrative data. Administrative data are summarized from vaccination registers in over 25,000 vaccination clinics throughout Brazil and are subject to transcription errors. One limitation of administrative data is the uncertainty of inter-census estimates of the population <1 year of age used in the denominator. Declining birth rates have resulted in overestimation of the number of newborns in official population estimates of the Brazilian Institute for Geography and Statistics (IBGE). An alternative is the use of registered births in National Information System on Live Births (SINASC) based on birth certificates to calculate vaccine coverage. However, this may overestimate coverage where birth registration is not complete, especially in rural areas in the Amazon and northeastern Brazil where home deliveries are more common. Periodic household coverage surveys are needed to provide individual-level estimates of vaccine coverage.

Suboptimal vaccine coverage and late administration of the first dose of hepatitis B vaccine suggest that current vaccine policy is not preventing as many chronic hepatitis B infections and related deaths as could be prevented in Brazil. The household vaccine coverage survey provided valuable data to improve use of hepatitis B vaccine in Brazil's national immunization program.

### Conflict of interest

The authors declare no conflict of interest.

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