Am. J. Trop. Med. Hyg., 101(1), 2019, pp. 214–219
doi:10.4269/ajtmh.19-0117

Prevalence of Chronic Hepatitis B Virus Infection among Children in Haiti, 2017

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Abstract. In 2016, the World Health Assembly endorsed the Global Health Sector Strategy on Viral Hepatitis, which calls for elimination of hepatitis B virus (HBV) by 2030 (definition: ≤ 0.1% hepatitis B surface antigen [HBsAg] prevalence among children aged 5 years). The burden of chronic HBV infection among children in Haiti is unknown. We conducted a nationally representative cross-sectional serological survey among 5- to 7-year-old children based on a two-stage cluster design with two strata: West (includes metropolitan Port-au-Prince) and non-West (all other departments). We collected demographic, socioeconomic, and vaccination history data and tested for HBsAg using a rapid point-of-care test. We estimated HBsAg prevalence and evaluated the association of HBV infection with vaccination history, demographics, and socioeconomic characteristics. Of the 1,152 children, seven (0.5%, 95% CI: 0.2–1.2) were HBsAg positive. The HBsAg prevalence varied by region (West: 0.1%, 95% CI: 0.01–0.9; non-West: 0.7%, 95% CI: 0.2–1.9) ($P = 0.1$), gender (males: 0.7%, 95% CI: 0.2–2.4; females: 0.2%, 95% CI: 0.05–1.1) ($P = 0.3$), and caregiver's education level (none: 0.8%, 95% CI: 0.2–3.1; some or completed primary: 0.5%, 95% CI: 0.1–1.8; some secondary: 0.4%, 95% CI: 0.1–1.8; secondary and higher: 0.0%, 95% CI: 0–0), although the differences were not statistically significant. None of the HBsAg-positive children had documented vaccination with hepatitis B vaccine (HepB). Haiti's chronic HBV infection prevalence among children is low; however, it is above the elimination target. To reach elimination, Haiti needs to achieve high coverage with the three HepB doses and introduce a HepB birth dose.

INTRODUCTION

Globally, an estimated 257 million people are chronically infected with hepatitis B virus (HBV),[1] which is the leading cause of morbidity and mortality due to liver cancer and cirrhosis. In 2015, an estimated 7 million individuals were living with chronic HBV infection (measured by the hepatitis B surface antigen [HBsAg]) in the WHO Region of the Americas (AMR), which equates to a prevalence of 0.7%.[1] The estimated prevalence of chronic HBV infection among children aged < 5 years was 1.3% (95% CI: 0.9–2.2) globally and 0.2% (95% CI: 0.1–0.5) in the AMR.[1]

In 2016, the World Health Assembly endorsed the Global Health Sector Strategy on Viral Hepatitis, which aims to achieve an HBsAg prevalence of ≤ 1% by 2020 and ≤ 0.1% by 2030 among children aged 5 years to achieve elimination by 2030.[2] In 2015, the Pan American Health Organization (PAHO) member states passed a resolution supporting the elimination of HBV and urging all member states to sustain or expand the HBV vaccination coverage among children and to introduce the hepatitis B birth dose (HepB-BD) vaccination.[3] In 2017, elimination of mother-to-child transmission of HBV was added to PAHO's goal to eliminate mother-to-child transmission of HIV, syphilis, and Chagas disease, and the PAHO member states have committed to reducing the HBsAg prevalence among 4- to 6-year-old children in the Americas to ≤ 0.1% by 2020.[4] The risk of progression to chronic HBV infection is highest among individuals infected at birth or by horizontal transmission during early childhood.[5] To achieve elimination, PAHO recommends that countries achieve ≥ 95% coverage with a timely (≤ 24 hours after birth) HepB-BD and the third HepB (HepB3) dose, test all pregnant women for HBsAg, and provide HBV-specific Ig to neonates of HBsAg-positive mothers.[4] In 2017, the HepB-BD coverage was 69% and HepB3 coverage was 90% in the AMR.[6]

In 2012, Haiti was the last country in the Americas to introduce HepB vaccine into the national routine immunization schedule. The vaccine is recommended at 6, 10, and 14 weeks of age as part of the combined pentavalent vaccine, which protects against diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b disease, and HBV infection. The HepB3 coverage in Haiti has been lower than 80% for several years, ranging from 68% in 2013 to 58% in 2017.[7] Despite the WHO recommendations, HepB-BD is not included in the national vaccination schedule in Haiti.

The burden of chronic HBV infection among children in Haiti is unknown, and data among adult populations are limited and outdated.[8–11] A longitudinal study conducted among blood donors during 2005–2014 reported decreasing HBsAg prevalence from 3.95% in 2005 to 3.42% in 2014.[12] Among pregnant women in Haiti, the HBsAg prevalence was 5% in a study conducted in 2006 and 2.5% (95% CI: 1.7–3.4) in a study conducted in 2012.[13,14] Haiti is the only country in the AMR that is highly endemic for HBV (HBsAg prevalence > 7%).[15] Given the lack of data on the burden of chronic HBV infection among Haitian children, we conducted a nationally representative serological survey to determine the seroprevalence of HBsAg in this population. These results are essential to establish baseline estimates of chronic HBV infection among children and assess whether Haiti is on track to reach regional and global targets for the elimination of HBV.

MATERIALS AND METHODS

Design and sampling. During October–November 2017, we conducted a nationwide, community-based, stratified,

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two-stage cluster survey among 5- to 7-year-old children in Haiti. We stratified Haiti into two regions: 1) the West region, which included the Ouest Department and metropolitan Port-au-Prince and 2) the non-West region, which included the nine remaining departments (Nord, Nord-Est, Nord-Ouest, Artibonite, Centre, Sud-Est, Sud, Nippes, and Grand'Anse). We assumed an HBsAg seroprevalence of 5% with a precision of ± 2%, 15% nonresponse, and a design effect of 1.2, which required enrollment of 455 children in each region or 910 children nationally. We used the 2011 population and household database of the Haitian Institute of Statistics and Information as the sampling frame. Enumeration areas (EAs) were the primary sampling unit. We selected 39 EAs in each region or 78 EAs nationally, using probability proportional to size sampling, where the size measure is the estimated number of households in each EA. To enroll 910 children, we needed to visit 62 households in each EA, for a total of 4,836 households nationally. A household was defined as a group of people who live and eat together. For this purpose, enumerators and cartographers enumerated the total number of households within each selected EA. Subsequently, a sample of 62 households per EA were selected for enrollment by simple random sampling.

Data collection. Survey teams were given maps of each EA and a list of the 62 selected households to interview. Only one child aged 5–7 years was eligible for enrollment per household. In households that had more than one child in that age group, interviewers used a random number table to select one child. Interviewers obtained informed consent from the child's caregiver, who was an adult living in the household responsible for the child, before enrollment into the survey. Data collection included a survey questionnaire and an HBsAg rapid test from the selected children. The interviewers used the survey questionnaire to collect demographic (gender and age of the child and the caregiver) and socioeconomic characteristics (education level of the child and caregiver and job status of the caregiver) and vaccination history of the child by card and recall. For the rapid HBsAg test, approximately 50 μL of blood was collected from each selected child by finger prick and tested using the Alere Determine™ HBsAg point-of-care test strip (reported sensitivity: 94.6–98.4%; reported specificity: 99.9–100%).[16] The test reports a positive, a negative, or an indeterminate result. If the result was indeterminate, the test was considered invalid and a second test was performed after caregiver approval. If the second test was also indeterminate, a third test was not performed.

The National Ethics Committee in Haiti and the Ethics Review Committee at PAHO approved the protocol. The Human Subjects Protection Office at the CDC reviewed the protocol and determined that CDC was not involved in direct data collection and interaction with study participants, so the protocol did not require CDC Institutional Review Board review.

Statistical analysis. We calculated the HepB dose 1–3 coverage based on card documentation, caregiver report, or either source. We determined the HepB dose 1–3 vaccination card coverage by calculating the percentage of children with HepB doses recorded on the card among all children. We used caregiver report to determine the number of HepB doses received among children without a vaccination card available. Last, we combined the number of card-documented doses with the number of doses by caregiver report to calculate the HepB dose 1–3 coverage by either source. We considered children who did not have a card available and for whom the caregiver responded, "I don't know," to the HepB recall as unknown and excluded them from coverage calculations and HepB vaccination comparisons with HBsAg prevalence. We considered receipt of three doses of HepB as complete vaccination.

Data from the paper questionnaires were entered into a Microsoft® Access database and imported into SAS v. 9.4 (The SAS Institute, Cary, NC) for statistical analysis. For the descriptive analysis of the survey population, we used the PROC FREQ and the PROC SURVEYFREQ procedures to determine whether there were any significant differences among participants by demographic and socioeconomic characteristics. We accounted for survey design and sampling weights when estimating coverage with HepB and seroprevalence of HBsAg by using the strata, cluster, and weight statements in the PROC SURVEYFREQ procedure. The survey weights were calculated by taking into account the number of eligible children in the household, the response rate of households per EA, and the probability of selecting the EA. We conducted a descriptive analysis of the demographic and socioeconomic characteristics of the total survey sample and by region. We estimated vaccination card retention and national HepB vaccination coverage among 5- to 7-year-old children and compared these variables in the West and non-West regions for significant differences. The prevalence of HBsAg was estimated nationally and by demographic (region, gender, and age of the caregiver) and socioeconomic characteristics (education level of the caregiver), and HepB vaccination history (complete HepB vaccination by either source). The Rao–Scott χ^2 test was used to compare survey categorical responses. P-values < 0.05 were considered statistically significant.

RESULTS

General characteristics. Among the 78 EAs visited, 1,181 children aged 5–7 years were identified for potential enrollment and caregivers of 1,152 (97.6%) children provided consent. Among 1,152 children aged 5–7 years, 530 (46%) lived in the West region and 622 (54%) lived in the non-West region. The distribution of children by gender and age was similar in the two regions (Table 1). Overall, 62.4% of children attended primary school. Among caregivers, 40.4% were aged 30–39 years, 27.6% were aged < 30 years, and 31.9% were aged ≥ 40 years. Overall, 81% of caregivers had received some level of education: 31.2% in the non-West region and 54.1% in the West region completed some secondary or higher education. When characteristics of the survey sample were extrapolated to the general population, no significant differences between the regions were identified, except that caregivers in the West region were more likely to have finished some secondary or higher education than caregivers in the non-West region ($P = 0.01$) (Table 1).

Hepatitis B surface antigen prevalence. Of 1,152 children tested, seven (0.5%, 95% CI: 0.2–1.2) were positive for HBsAg. Four children had the test repeated because of an indeterminate initial result, and all had a negative result on the second test. When stratified by region, one of 530 (0.1%, 95% CI: 0.01–0.9) children living in the West region and six of 622 (0.7%, 95% CI: 0.2–1.9) children living in the non-West region were HBsAg positive ($P = 0.1$). Males (0.7%, 95% CI: 0.2–2.4) had a higher HBsAg prevalence than females (0.2%, 95% CI: 0.05–1.1), but this difference was not significant ($P = 0.3$) (Table 2). The HBsAg prevalence was not different by the

TABLE 1
Demographic characteristics of survey sample of children aged 5–7 years and caregivers in West and non-West regions—Haiti, 2017

	Total		West region		Non-West region	
	N	%	*N*	%	*N*	%
Total	1,152	–	530	46.0	622	54.0
Gender of the child*						
Male	573	49.8	272	51.4	301	48.4
Female	578	50.2	257	48.6	321	51.6
Age of the child (years)						
5	353	30.6	150	28.3	203	32.6
6	412	35.8	209	39.4	203	32.6
7	387	33.6	171	32.3	216	34.7
Education level of the child*						
None	42	3.7	22	4.2	20	3.2
Kindergarten/preschool	391	34.0	189	35.8	202	32.5
Primary	717	62.4	317	60.0	400	64.3
Age of the caregiver* (years)						
< 30	318	27.6	137	25.9	181	29.1
30–39	465	40.4	235	44.4	230	37.0
≥ 40	368	31.9	157	29.7	211	33.9
Education level of the caregiver						
None	219	19.0	78	14.7	141	22.7
Some or completed primary	452	39.2	165	31.1	287	46.1
Some secondary	375	32.6	210	39.6	165	26.5
Completed secondary or higher	106	9.2	77	14.5	29	4.7
Caregiver has a job*	857	74.5	382	72.2	475	76.5

* Data missing from some questionnaires.

vaccination status (P = 0.9). Of the seven HBsAg-positive children, four were unvaccinated, one was completely vaccinated by recall only (caregiver did not have the child's vaccination card), and two children had unknown vaccination status. The HBsAg prevalence was highest among children who had caregivers who were aged < 30 years (0.8%) and among children who had caregivers who had no education (0.8%); however, the differences were not statistically significant (Table 2).

Receipt of HepB vaccine. Vaccination cards were available for 555 (49.1%) children (Table 3); the HepB vaccination status was unknown for 249 (21.6%) children. Among children without vaccination cards, most caregivers reported the card was in another location (47.7%) or the card was lost (38.0%). Among 903 children with a vaccination card available or caregiver report, 252 (27.0%) received ≥ 1 HepB dose, 126 (14.2%) received ≥ 2 HepB doses, and 76 (9.0%) received three HepB doses. Among children with vaccination cards, a higher proportion in the non-West region (7.1%) received three HepB doses; however, in the West region, the three-dose HepB coverage was higher when considering vaccination cards and caregiver report (non-West: 8.8% versus West: 9.2%). However, the differences between number of doses received by card documentation only and by either source

TABLE 2
Hepatitis B surface antigen prevalence among 5- to 7-year-old children—Haiti, 2017

	No. of children tested	No. of children HBsAg positive	HBsAg prevalence % (95% CI)	*P*-value
Total	1,152	7	0.5 (0.2–1.2)	–
Region				
West	530	1	0.1 (0.01–0.9)	0.1
Non-West	622	6	0.7 (0.2–1.9)	
Gender of the child*				
Male	573	5	0.7 (0.2–2.4)	0.3
Female	578	2	0.2 (0.05–1.1)	
HepB3 vaccination by using either source†				
Yes	76	1	0.6 (0.05–5.8)	0.9
No	827	4	0.4 (0.1–1.6)	
Age of the caregiver* (years)				
< 30	318	2	0.8 (0.1–4.4)	0.7
30–39	465	2	0.3 (0.1–1.3)	
≥ 40	368	3	0.5 (0.1–1.9)	
Education level of the caregiver				
None	219	3	0.8 (0.2–3.1)	na‡
Some or completed primary	452	2	0.5 (0.1–1.8)	
Some secondary	375	2	0.4 (0.1–1.8)	
Completed secondary or higher	106	0	0 (0–0)	

HBsAg = hepatitis B surface antigen; HepB3 = third hepatitis B vaccine. Percentages account for strata, cluster, and weight. Design effect (DE): national DE = 1.4, West region DE = 0.4, and non-West region DE = 1.5. Estimated intra-class correlation (ICC) = (DE – 1)/(b – 1), where b is the average number of responses per cluster: national ICC = 0.025, West region ICC = –0.045, and non-West region ICC = 0.033.

* Data missing from some questionnaires.

† Two positive children's vaccination status unknown because of no card or recall information for HepB1–HepB3.

‡ P-value not available because of zero cells.

TABLE 3
Hepatitis B vaccination coverage among 5- to 7-year-old children in West and non-West regions—Haiti, 2017

	Total		West region		Non-West region		
	N = 1,152		*N* = 530		*N* = 622		
	N	% (95% CI)	*N*	% (95% CI)	*N*	% (95% CI)	*P*-value
Vaccination card available	555	49.1 (43.8–54.4)	250	47.8 (39.6–56.1)	305	49.9 (43.3–56.5)	0.7
HepB1*							
Vaccination card	133	14.5 (10.8–19.2)	48	11.5 (7.6–17.0)	85	16.0 (11.1–22.5)	0.2
Caregiver report	119	12.5 (10.0–15.6)	52	12.4 (9.2–16.6)	67	12.6 (9.3–16.8)	1.0
Either source	252	27.0 (22.0–32.7)	100	23.9 (18.3–30.7)	152	28.6 (21.9–36.4)	0.3
HepB2*							
Vaccination card	63	7.7 (4.7–12.5)	28	6.8 (3.9–11.6)	35	8.2 (4.3–15.2)	0.7
Caregiver report	63	6.5 (4.7–8.8)	33	8.2 (5.4–12.4)	30	5.6 (3.6–8.6)	0.2
Either source	126	14.2 (10.2–19.5)	61	15.0 (10.1–21.7)	65	13.8 (8.7–21.3)	0.8
HepB3*							
Vaccination card	52	6.6 (3.7–11.5)	24	5.6 (3.2–9.6)	28	7.1 (3.3–14.5)	0.6
Caregiver report	24	2.3 (1.4–3.8)	14	3.6 (2.1–6.0)	10	1.7 (0.8–3.8)	0.1
Either source	76	9.0 (5.8–13.6)	38	9.2 (5.9–14.1)	38	8.8 (4.8–15.7)	0.9

HepB = hepatitis B vaccine. West and non-West percentages account for cluster and weight, whereas total percentages also account for strata.
* Two hundred forty-nine children missing both card and recall information for HepB1–HepB3 (no card, and the caregiver answered "I don't know" to recall questions).

were not statistically different by region (vaccination card: $P = 0.6$; either source: $P = 0.9$).

DISCUSSION

This study is the first to estimate the prevalence of chronic HBV infection among children in Haiti. We found that 0.5% (95% CI: 0.2–1.2) of children aged 5–7 years were HBsAg positive. Although not significant, the prevalence of HBsAg was higher in the non-West region (0.7%) than that in the West region (0.1%), which is consistent with findings from a 2012 study among pregnant women, where the HBsAg prevalence was higher in the non-West region than that in the West region (3.0% versus 2.1%).[14] Haiti has a low HBsAg prevalence among children; however, the higher bound of the 95% CI is above the global target (< 1% among 5-year-old children) for 2020.[2] In addition, because the prevalence estimate of chronic HBV infection in children is above the PAHO regional HBsAg target of ≤ 0.1%,[4] efforts to achieve high hepatitis B vaccination coverage are needed in Haiti to achieve the global and regional goals of HBV elimination.[2,4]

We found variability in HBsAg prevalence by socioeconomic and demographic characteristics, although the results were not statistically significant. The HBsAg prevalence was higher among children born to caregivers with a lower level of education. In the 2012 study among pregnant women in Haiti, women with no education also had a higher burden of HBV infection, and the difference was statistically significant.[14] Vaccination coverage surveys in Haiti and other countries also reported a positive association between higher maternal and caregiver education and vaccination coverage.[17–19] The HBsAg prevalence was also higher among males than females, which could be due to horizontal HBV transmission through rough play. For example, HBV infection has been associated with transmission in day care settings.[20–22] A day care study found that toddler-aged males receive more bites than toddler-aged females,[23] which could mean that males have a higher risk of being infected with blood-borne pathogens, such as HBV, from other children than females.

Given that the chronic HBV prevalence among children is above PAHO regional goals, Haiti should follow two strategies recommended by WHO and PAHO, which are to achieve high HepB3 coverage and introduce HepB-BD as soon as possible after birth to prevent perinatal transmission of HBV.[2,5,15,24,25] In rural Amazon, Colombia, another area of the Americas with a historically high HBsAg prevalence and challenges with access to vaccinations, studies have reported decreasing HBsAg prevalence among children after introduction of HepB3 and HepB-BD.[26,27] Children who received HepB-BD plus three doses of the pentavalent vaccine had 70% less risk of HBV infection compared with children who had not received the recommended vaccinations.[27]

Strengthening routine immunization services is a vital component for achieving high HepB3. Haiti has been heavily dependent on international donors to purchase vaccines, and presently, Gavi, the Vaccine Alliance, supports funding for the pentavalent vaccine.[28] In 2017, the government of Haiti committed to fund vaccines and increase efforts to strengthen the national immunization program, which is an important step to improve routine immunization services.[29] In addition, the country plans to use a community health worker strategy that will enable the Expanded Program on Immunization to reach more children with routine immunizations.[29]

Infants born to mothers who have chronic HBV infection and are hepatitis B e antigen (HBeAg) positive or have high viral load, especially above 200,000 IU/mL, are at the highest risk of perinatal infection and progression to chronic HBV infection.[5,30] In a 2012 serosurvey among pregnant women in Haiti, the HBsAg prevalence was 2.5% and about a quarter had HBV DNA levels > 200,000 IU/mL.[14] These findings indicate a high risk of mother-to-child transmission of HBV infection in Haiti, which supports the need for the introduction of a birth dose of HepB in the routine immunization schedule. The HepB-BD is the only vaccine that needs to be given within 24 hours of birth. The coverage with HepB-BD correlates worldwide with high rates of institutional deliveries and having skilled birth attendants (SBAs) at the time of delivery.[31] In Haiti, only 39.4% of deliveries occur in health-care facilities (HF) and only 41.7% of deliveries have an SBA present; however, over 90% of pregnant women attend at least one antenatal care (ANC) visit.[19] Strategies proven to improve coverage with a timely HepB-BD include training of health-care workers and education of women attending ANC about the importance of HepB-BD administration.[32–34] Special strategies would be needed to provide timely HepB-BD for home births or births

outside HF. The use of pregnancy registers by community health workers has been successful in informing HCWs of infants needing vaccination following a home birth.[35–37] Because monovalent HepB is heat stable and able to withstand exposure to a temperature as high as 37°C for up to 1 month,[5] its use outside of the cold chain has increased timely HepB-BD coverage in countries with high rates of home births,[33,38,39] while maintaining vaccine immunogenicity.[40] In addition, the use of compact prefilled auto-disable injection devices, which can be administered with minimal training, might also be useful in remote areas that lack trained HCWs.[33,35,41]

There were four main limitations of this study. First, in the study design, an HBsAg prevalence of 5% was used to estimate the required sample size, which was based on limited data from older studies. We found a much lower HBsAg prevalence of 0.5%; therefore, the study was underpowered, which limited our ability to detect any statistically significant differences among groups compared. Second, even though we did not expect the age cohort included in this study to have received hepatitis B vaccination, we found that nearly 30% of children received at least one HepB dose, possibly due to the availability of the vaccine in the country before official introduction, or as anecdotally volunteered by some caregivers, vaccines were given by private providers or in other countries. Despite this, the results may not have been impacted significantly because only 9% of children received all three doses of hepatitis B–containing vaccine. Third, we had to rely on caregiver recall of vaccination status for half of the enrolled children who did not have a vaccination card, which might be subject to recall or social desirability bias. Because the children in the survey were aged 5–7 years, it might have been more difficult for their caregivers to recall specific vaccines received during infancy or early childhood or the caregiver may have responded that their child had been vaccinated to appear more favorable. Fourth, the sensitivity (94.6–98.4%) of the rapid HBsAg test used for this study is lower than the specificity (99.9–100%)[16]; therefore, it is possible that some children had a false-negative test result and the actual HBsAg prevalence might be higher than our findings.

In conclusion, Haiti has a low HBsAg prevalence among children; however, we found variability in the HBsAg prevalence by region and by demographic and socioeconomic characteristics, and the HBsAg prevalence is higher than the PAHO regional HBV elimination goal. Therefore, achieving high coverage of HepB3 and introducing HepB-BD are necessary to help decrease perinatal and early childhood transmission of infection and achieve the regional target for HBV elimination by 2020.

Received February 7, 2019. Accepted for publication March 30, 2019.

Published online May 20, 2019.

Acknowledgments: We thank Paule-Andrée Louis-Byron, Maxi Raphael, and Dieula Louissaint of Expanded Program on Immunization; Patrick Dely and Annemarie Desormaux of Directorate of Epidemiology, Laboratory and Research, Haiti; Jacques Boncy and Jocelyne Andre-Alboth of National Public Health Laboratory, Ministry of Public Health and Population, Port-au-Prince, Haiti; Jean Andre of PAHO, Haiti; Alexandre Canez, Michaud Josue, Vilus Haydn Joseph Lutherson, Louis Jean Gerlan, Ardiles David Brignol, Stephania Noel, Myriam Israel, Jean Albertiny Calixte Chery, Moselande Pierre, Benjamin Joseph, Kettia Negaud, Nardine Massillon, Jeannette Georges, Sophia Laurore Bresemy, Edelyne Claude, Geraldine Loubeau, Saraphyna Brunvil, Smith Gustave, Gerardine Gerard, Guersley Chery, Guilene Estesias, Florene Saintelien, James Dodo, Eltha Tanis, Jean Claude St Fleur, Marie Sonide Dorilma, Nathalie Cadet Abraham, Ghislaine Romain, Marie Elisna Eliscat, Jean Patrick Gerard, Sherly Gay, Emie Gabriel, Makenley Moise, Hermine Michel, Johnson Mervil, Nathalie Laguerre, Fabienne Cerelus Mildor, Jean Renand Barreau, Kettie Parfait, Josue Dormelus, Marie Emmanuelle Casimir Philogene, Ashley Desormes, Valex Paul, Oudeline Mele, Josue Pierre, Marie Myrtha Ferjuste, Jean Roberto Target, Nathalie Louis, Wislene Noel, Kesnel Mogelin, Ange Laure Duclaire, Marie Guerda Etienne, Sophia Vales, Clenise Thermitus, Marie Yolande Medor, Jenita Cius, Joanne Joseph, Alence Therone, Jeanise Jean, Mirlene Laurenceau, Igline Dorilas, Jimmy Ezean, Kerline Floritan, Guerna Aldeus, Saul Junior Estesias, Cathelie Menelas, Alexis Felix, Catiana Felix, and Modeline Francois of Institut Haïtien de l'Enfance; and Kathleen Wannemuehler and Amber Dismer of CDC.

Financial support: This survey was supported by a cooperative agreement between the CDC and the Haiti Ministry of Public Health and Population.

Disclosure: Valery Blot works for Institut Haitien de L'Enfance, the institution that was funded through a cooperative agreement between CDC and the Haiti Ministry of Health and Population to implement the survey.

Disclaimer: The findings and conclusions in this study are those of the authors and do not necessarily reflect the official position of the CDC nor the Pan American Health Organization.

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