Viral Hepatitis B Sero-prevalence Survey among pregnant mothers and 5-year-old Children in

Sri Lanka – 2022

In collaboration with

World Health Organization

&

The Epidemiology Unit, Ministry of Health, Sri Lanka







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LIST OF ABBREVIATIONS

CHDR – Child Health Development Record

EPI – Expanded Programme of Immunization

HBsAg – Hepatitis B surface antigen

HBeAg – Hepatitis e antigen

ICNO – Infection Control Nursing Officer

RDT – Rapid Diagnostic Tool

MOH – Medical Officer of Health

NBTS – National Blood Transfusion Service

NSACP – National STD/AIDS Control Programme

WHO - World Health Organization

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EXECUTIVE SUMMARY

In line with the global initiative to eliminate viral hepatitis by the year 2030, Sri Lanka needed to demonstrate the achievement of the 2020 hepatitis B control target, defined at \leq 1% hepatitis B surface antigen (HBsAg) in children 5 years old and progress towards the elimination target (\leq 0.1% HBsAg in children 5 years old or less). In addition, it was required to ascertain the prevalence of hepatitis B infection among pregnant mothers, which is a proxy for the prevalence among the general population. Information was also collected about the immunization status with hepatitis B vaccine (HepB).

To achieve the above objectives, a hepatitis B serosurvey was planned according to the WHO protocol of verification of the control status⁹. A country-representative sample of 2538 children of 5 years old and 1266 pregnant mothers was selected using the probability proportional to the population size technique through a multistage cluster sampling method. The children's survey component was school-based while the pregnant mother's component was community-based.

A World Health Organization (WHO) pre-qualified rapid HBsAg diagnostic test kit (RDT; Determine HBsAg 2 from Abbott) was used for the assessment of the hepatitis B status. Positive tests were to be confirmed by a serumbased method in a pre-identified single laboratory. Two sets of questionnaires, information sheets and consent forms were used for children and pregnant mothers. Ethics approval was obtained from the Ethics Committee at the National Hospital, Sri Lanka and the Ethics Review Committee of WHO Headquarters. Additionally, administrative clearances were obtained from both, the Ministry of Health and the Ministry of Education before the commencement of the survey. The survey was carried out in the latter half of 2022.

The Regional Epidemiologists of the selected districts received training on survey methods, including hands-on training on handling and interpreting the RDT. They then trained their district teams. The data was collected by the Medical Officer of Health team and supervision visits were carried out at the district level, supported by the national level as well as WHO regional and country offices.

The response rate for both survey components was over 99%. Among the children sampled, 16 had at least a single blood transfusion and 6 had a history of chronic disease respectively. The coverage for all three pentavalent (HepB-containing) vaccine doses was almost 100%. No children tested positive using the HBsAg RDT, hence no serum-based tests were carried out.

The majority of pregnant mothers included in the survey were between 20-30 years old and in their first pregnancy. None of the mothers had a history of hepatitis B or sexually transmitted illness. No pregnant mothers tested positive using the HBsAg RDT. Therefore, no serum-based confirmation test was carried out.

The findings of the survey restate the low prevalence of hepatitis B infection among the general population in Sri Lanka. Further, the survey provides the value of continuing the highest standards of HepB-containing vaccination practices, 100% screening of blood/products and infection control and prevention activities.

1. INTRODUCTION

1.1 COUNTRY PROFILE

The Democratic Socialist Republic of Sri Lanka, also known as "The Pearl of the Indian Ocean" is an island with a total land area of $65,610 \text{ km}^2$ and a population of 21.8 million as of March 2019, predicted from the last census (2012). The climate in Sri Lanka is tropical and warm, with mean temperatures ranging from 17 °C (62.6 °F) in the central highlands to a maximum of 33 °C (91.4 °F) in other low-altitude areas.

Sri Lanka is a multi-national state with a majority of Sinhalese, followed by Tamils and Moors. The World Bank categorizes Sri Lanka as a lower-middle-income country with a GDP per capita of USD 3852 (2019). Sri Lankans enjoy free health (curative and preventive care services) and free education as they are considered key priorities and responsibilities of the government.

Sri Lanka is administratively divided into 9 provinces and 26 districts.



1.2 HEALTH CARE DELIVERY

Both public and private sectors are involved in health care delivery in Sri Lanka. The public sector is distinctly divided into curative and preventive sectors. Public-curative health care institutes range from large teaching hospitals to district and rural hospitals.

Preventive health care is primarily delivered by the state sector through 365 administrative divisions named as "Medical Officer of Health (MOH) area" covering the entire country and childhood vaccination is one of their key duties. MOH and his/her staff were utilized as the field-level survey team for the selected MOH area.

1.3 EPIDEMIOLOGY - OF HEPATITIS B

1.3.1 GLOBAL

Globally, viral hepatitis is considered a leading cause of death and disability. The annual death toll of viral hepatitis is approximately equal to the deaths due to tuberculosis (TB). Further, the burden of the disease is increasing in a higher phase when compared with HIV, TB and Malaria¹. Death from viral hepatitis is mainly due to B and C types due to cirrhosis and liver cancer. It is estimated that 257 million people are infected with hepatitis B and 71 million with hepatitis C globally per year. Furthermore, hepatitis B and C are reported to cause 900,000 and 400,000 deaths respectively per year.² According to the prevalence of viral hepatitis, countries in the world have been classified as low (<2%), moderate (2-8%) and high (>8%).

1.3.2 LOCAL

Sri Lanka is reportedly a hepatitis B low prevalence country (<2%). Research carried out by Padmasiri et al. in 1995 in Gampaha, which is a densely populated district, reported a prevalence of hepatitis B as 2.5% (95% CI 2%-3%)³. Whereas, Premarathnahas reported the hepatitis B and C prevalence as 0.46% (95% CI 0.14% - 0.77%) and 5.49% (95% CI 4.42% - 6.55%) respectively in Colombo District in 2002⁴. Niriella et al. carried out research among prison inmates in 2015 and reported a hepatitis B and C screening positive rate of 0.25% (DNA positive rate was 0%) and 6.9% (RNA positive rate was only 0.5%) respectively⁵.

Hepatitis B is a notifiable disease in the country and all treating doctors are responsible for notifying the condition to the national system. Disease surveillance data are collected in a timely fashion and shared by the preventive health sector for early interventions to avert the spread of the disease in the community.

1.4 HEPATITIS B – IMMUNIZATION

With the introduction of a safe and effective vaccine in 1982, global immunization against Hepatitis B became the major preventive strategy. In many countries, the prevalence rate of chronic infection among children fell from 8-15% to less than 1% in immunized children².

Hepatitis B vaccination was introduced to the Sri Lankan EPI schedule in 2003. Since then, the country has been immunizing all infants against hepatitis B infection, at 2, 4, and 6 months of age. Data reported to the Epidemiology Unit of the Ministry of Health (focal point for EPI activities in Sri Lanka), as well as immunization coverage surveys conducted at the district level, suggest very high immunization coverage (E.g., coverage with 3 doses of pentavalent vaccine of 99% in 2019)^{6,7,8}. Sri Lanka takes the high-risk group vaccination approach when it comes to adults using monovalent hepatitis B vaccine. Identified high-risk groups are healthcare workers, sex workers (including MSM, transgender), cancer patients, Thalassaemia patients, chronic kidney disease patients on regular haemodialysis, etc.

1.5 HEPATITIS B - TREATMENT

Five state-owned laboratories are available to perform hepatitis B confirmatory tests. They are located in different provinces to provide easy access to draining districts. Further, there are 18 gastroenterology centers around the country with specialized care facilities and there are 103 hospitals with medical specialists who can provide hepatitis B treatments.

1.6 JUSTIFICATION

There is a global initiative to eliminate viral hepatitis by the year 2030^2 . Since Sri Lanka reports a low number of hepatitis B patients annually, has sound infection control and prevention systems in the hospital and public health sector and a strong immunization programme achieving high coverage rates, the country has a high potential to reach the elimination targets ($\leq 0.1\%$ HBsAg in children 5 years old or less) earlier than the stipulated time. The study aimed to show that the 2020 control target ($\leq 1\%$ HBsAg in children 5 years old) has already been achieved.

The sero-epidemiological studies carried out in the country reported that the prevalence of hepatitis B varies between 0.1% and 2.5% ^{12,13}. Routine disease surveillance carried out throughout the country by the Epidemiology Unit of the Ministry of Health also reports a low prevalence of hepatitis B⁸. Additionally, the National Blood Transfusion Service (NBTS) and National STD/AIDS Control Programme (NSACP) of the Ministry of Health also report low hepatitis B patients in their clients ^{13,14}.

However, no national survey had been carried out to identify the exact incidence or the prevalence of hepatitis B. Sri Lanka is not providing the HepB birth dose due to the reported low prevalence of hepatitis B; based on the surveillance systems and targeted studies carried out. However, this strategy can be further justified or refuted with the results of this study. If a high percentage of pregnant mothers was found to be positive for hepatitis B, the HepB birth dose vaccination could be initiated to prevent mother-to-child transmission.

At present there is no regular screening for hepatitis B offered for pregnant mothers in the government health services. This also can be considered with the results of the survey.

Further, the prevalence of Hepatitis B among 5-year-old children is an indicator of the monitoring and evaluation framework of the global viral hepatitis elimination program. Moreover, the seroprevalence of Hepatitis B over the years would give an insight into the impact of the immunization strategy.

The Epidemiology Unit of the Ministry of Health has planned this hepatitis B prevalence survey among pregnant mothers and 5-year-old children according to the guidelines set by the WHO¹⁰.

1.7 OBJECTIVES

General objective

To determine the seroprevalence of viral hepatitis B among pregnant mothers and 5-year-old children in Sri Lanka.

Specific objectives:

- 1. To assess the seroprevalence of viral hepatitis B among pregnant mothers in Sri Lanka by assessing HBsAg
- $2. \ \ \, \text{To assess the seroprevalence of viral hepatitis B among 5-year-old children in Sri Lanka by assessing } \\ \, \, \text{HBsAg}$

2. METHODS

2.1 STUDY DESIGN

A cross-sectional sero-epidemiological survey design was selected as most appropriate to meet the study objectives.

2.2 STUDY SETTING

The study was carried out in selected MOH divisions representing the entire country.

2.3 STUDY POPULATION

There are 2 study populations:

- All pregnant mothers permanently residing in the selected MOH area.
- All children 5 years of age in the selected schools and permanently residing in the selected MOH area.

2.3.1 INCLUSION CRITERIA

Pregnant mothers and children who are residing in the selected MOH area for more than 6 months.

2.3.2 EXCLUSION CRITERIA

Non-consenting pregnant mothers and children whose parents/legal guardians would not consent.

Pregnant mothers and children with bleeding disorders.

2.4 SAMPLE SIZE AND SAMPLING TECHNIQUE

The study sample was selected using a multistage cluster sampling method. Out of the 26 districts, 9 were selected based on the probability proportional to population size. From each selected district, three (3) MOH areas were selected based on the probability proportional to population size at the second stage. Finally, 27 MOH areas were selected for the survey.

The selected 27 MOH areas were varied by their population size. A representative sample of pregnant mothers and 5-year-old children were selected from each MOH area based on the probability proportional to its population size. As all the pregnant mothers in the MOH area are registered in the pregnant mother's register, the required number of pregnant mothers was selected randomly utilizing that register.

Similarly, a school was selected randomly with the list of schools which was available at the MOH office. Then all the grade 1 (5-year-old children) students were recruited to the survey and there were no additional selections within the school. If the number of grade 1 students was insufficient to fulfil the calculated number for that MOH

area, another school was selected randomly from the list. Once a school was selected, all grade 1 students were recruited for the survey. This method was continued until the required sample was achieved.

Standard Formulae¹¹ was used to calculate the required number of pregnant mothers and children for the survey. The final sample size was calculated as 1269 pregnant mothers and 2538 children.

2.5 STUDY INSTRUMENTS

Two separate questionnaires have been used to collect data from pregnant mothers (Annexure 5) and children (Annexure 6). Questions to explore the history of viral hepatitis, other longstanding illnesses, sexually transmitted infections, blood transfusion and hepatitis B vaccination status of both the pregnant mother and her partner were included in the pregnant mother's questionnaire. Birth details such as birth weight, order details of immunization, parental information and hepatitis B vaccination status were included in the child questionnaire.

A WHO pre-qualified HBsAg RDT (Determine HBsAg 2 from Abbott) was used for the assessment of the hepatitis B status. Pre-qualification information for this product is available on the following website:

https://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/200123_pqdx_0451_013_00_determine_hbsag_2_final_pqpr_v2.pdf?ua=1

The test was performed by trained healthcare workers. The test device was labelled with a unique number sticker. The selected finger was cleaned with an alcohol swab and pricked with a disposable lancet. Fifty microliters of blood were obtained from the pricked site and placed on the sample well of the test device with the capillary tube provided with the kit. Thereafter, one drop of the buffer solution which was provided with the test kit was added to the test device as indicated and kept on a flat and steady surface for 15 minutes. The pricked finger site was covered with gauze. At the end of the 15 minutes and before passing 30 minutes, the test results were interpreted.

A pilot was done in an MOH area which was not selected for the survey. This included the pre-testing of the questionnaires as well. After discussing with the field staff and the participants, the necessary changes were made.

2.6 STUDY IMPLEMENTATION

2.6.1. TRAINING OF DATA COLLECTORS

The Regional Epidemiologist of the selected districts (9) for the survey was provided with comprehensive training about the survey. Then s/he was assigned the responsibility of training the survey staff of his/her district. The survey team members of the selected MOH divisions were offered a one-day training. The study methodology and the field execution were discussed in length with hands-on experience of the performance, interpretation, and recording of the results of the HBsAg RDT.

2.6.2. ENROLMENT AND CONSENT

The pregnant mothers selected for the survey were approached by their area midwife and the relevant information about the survey was provided. If the pregnant mother was eligible and agreed to participate, informed written consent was obtained (Annexure 3).

For the recruitment of the grade 1 students, initially, the approvals were obtained from the Ministry of Education at the national level. Then the provincial and zonal education directors were approached. With their concurrence, the principals and the grade 1 class teachers of the selected schools were approached. A parent meeting was organized for the parents of grade 1 students on the school premises. Parents were informed about the survey and they were given time to ask questions and clarify their doubts. Finally, informed written consent was obtained from the parent/legal guardian of the children in the selected schools (Annexure 4).

2.6.3. STUDY PROCEDURES

On the day of the pregnant mothers' survey, firstly they were welcomed by the health staff, and the survey details were briefed. A sticker with the unique number was pasted on the questionnaire, mother's dress as well as on the RDT after confirming her identity.



Secondly, the pregnant mother was sent to the Medical Officer of Health to fill out the questionnaire (Annexure 5). If she was found to be ineligible, she was not subjected to the rest of the survey components. Those who completed the questionnaire components were subjected to the HBsAg RDT testing.





Test results were confidentially informed to the pregnant mother at the same time. If she was found to be negative for hepatitis B infection in the test, it was the end of the survey for her. If she was found to be positive, an additional blood sample (2.5ml) was planned to be taken for the assessment of serum-based HBsAg and hepatitis B 'e' antigen (HBeAg) on the same day. The blood samples were planned to be sent to a nearby pre-identified government hospital laboratory with centrifuge facilities for serum separation. The serum was planned to be sent to a pre-identified single laboratory at the national level for the testing of HBsAg and HBeAg with the unique identifier (sticker) while maintaining 2-8 °C. If a pregnant mother was found to be positive for serum-based tests, it was planned to offer follow-up care in the curative sector according to the Ministry of Health guidelines.

The survey results were treated as highly confidential to protect the privacy of the participants and they were only available to the survey team and the central team. In the study database, the pregnant mothers were identified by the unique number provided. There was no monetary compensation or reimbursement done to the pregnant mothers who participated in the study. However, as a token of appreciation, a sanitary pack was gifted to her by the study team.



Children's surveys were carried out over a single or several days depending on the number to be surveyed and the COVID-19 prevention guidelines in the country (half or one-third of children were attending school on a given day to maintain social distancing). The school administration was consulted and the survey dates/times were fixed in a mutually agreed manner.

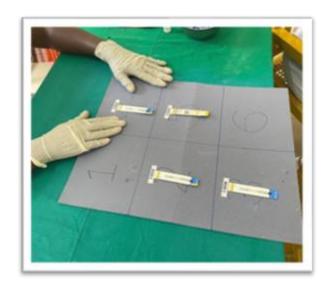
On the day of the school survey, all children in grade 1 were welcomed by the health staff. As the first step of the survey, a sticker with the unique number was pasted on the questionnaire, the child's school uniform as well as on the RDT after confirming the child's identity. Secondly, the child was sent to the Medical Officer of Health, for the filling of the questionnaire (Annexure 6).





The birth, medical, and vaccination details were filled in by the Medical Officer of Health using the "copy" of the Child Health Development Record (CHDR) which was available to him. (It is the Ministry of Health's recommendation to retain a copy of the CHDR of all the children under the care of the MOH office. It is only accessible to the health staff. Consent was taken from the parent/legal guardian to obtain information from this copy) The parents were contacted over the phone only for specific questions and the parent's hepatitis B vaccination status was verified with the card sent along with the child if they had received the vaccine. Except parent's hepatitis B vaccination status, everything else could be obtained from the "Copy" of the CHDR. The children who had completed the questionnaire were subjected to HBsAg testing with the RDT.





If a child tested negative for HBsAg with the RDT, it was the end of the survey for him/her. The whole process took approximately 2 hours. If he/she tested positive for HBsAg with the RDT, an additional blood sample (2.5ml) was planned to be taken for the assessment of serum-based HBsAg by the Public Health Nursing Sister on the same day at the same venue. These blood samples were also planned to follow the same route as respective blood samples taken from the pregnant mothers. The results of the test were informed to the parents/legal guardians in the same methods used for pregnant mothers. Positively identified children were planned to offer follow-up care in the curative sector according to the Ministry of Health guidelines. At the end of the school survey, all the children (those who participated as well as not in the survey) were gifted a valuable study pack as a token of appreciation by the study team.



Both participating pregnant mothers and the parents/legal guardians of the children were well informed about the fact that the positive hepatitis B test results will be mandatorily reported to the public health authorities of the country. This was planned to be done once they reached the curative sector for follow-up care. Since it is important

to avoid duplicate entries to the national surveillance system, the survey team did not plan to notify the positive cases to public health authorities.

As a precautionary measure, all study participants were observed for 10 minutes after the finger prick for any adverse events.

2.6.4.1 PREGNANT MOTHERS

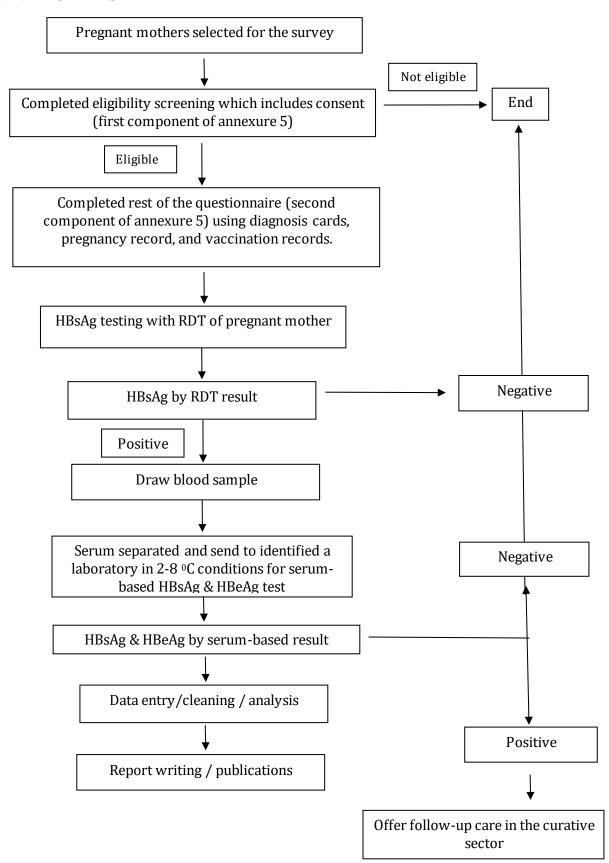


Figure 2.1 2.6.4.2 CHILDREN

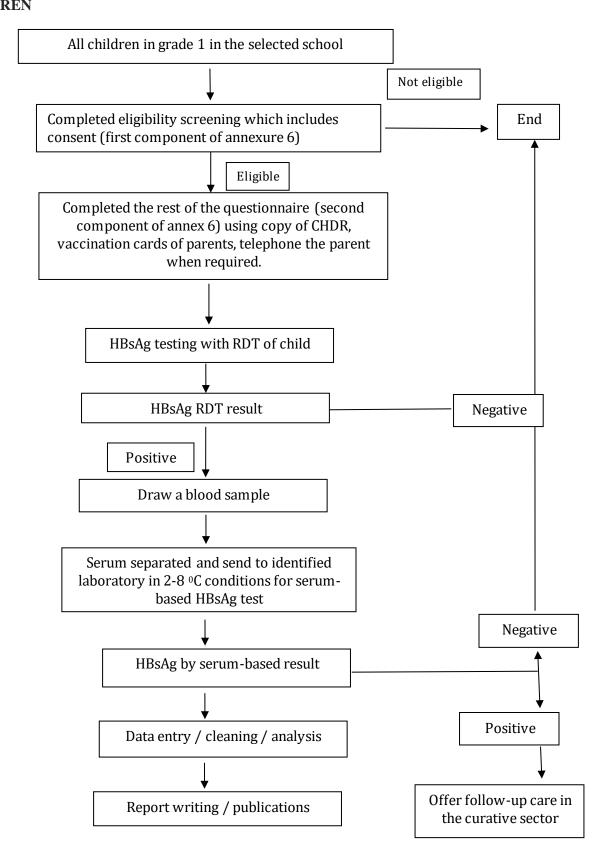


Figure 2.2

2.7. DATA MANAGEMENT AND ANALYSIS:

The questionnaire data were double-entered into an electronic data file. Laboratory data was also planned to be requested in an electronic format (should such a test be performed as per the survey algorithm) and merged later, based on a unique identifier number.

Confidentiality of the recorded data was ensured and they were only handled by the central research team. Both hard copies of the questionnaires and the soft copies of the digitalized data were stored in a restricted area that could be accessed only by the principal investigator. All digitalized data were password protected. All hard copies are kept stored for 5 years for future reference. If any of the participants wanted to withdraw from the study, they were given the liberty to do so until two weeks from the day of their data collection date. After two weeks from the last day of data collection, the database was locked for analysis.

The data were analysed using Microsoft Excel software. The demographic details of the pregnant mothers and their spouses, history of chronic illness, history of vaccination, and the results of the hepatitis B RDT were analysed using frequency distributions.

Similarly, the children's demographic details, birth information, history of illness and vaccination information, and hepatitis B RDT were analysed using frequency distributions.

2.8. ETHICAL CONSIDERATIONS:

Ethics approvals were granted by the Ethics Review Committees at the National Hospital of Sri Lanka and the WHO. Confidentiality of the collected data was strictly maintained. Personal information was accessible only to the principal investigator. Extensive efforts were taken to minimize the selection bias while recruiting the sample.

3. RESULTS:

The survey describes the prevalence of hepatitis B surface antigen among 5-year-old children and pregnant mothers.

Table 1. Selection of the study sample

	District	МОН	Children	Mothers
1	Matale	Yatawatta	34	17
2		Rattota	58	29
3		Galewela	79	40
4	Colombo	Kesbewa	96	48
5		Hanwella	125	63
6		Kaduwela	186	94
7	Gampaha	Negombo	147	78
8		Minuwangoda	195	97
9		Mahara	227	114
10	Kaluthara	Bulathsinghala	71	35
11		Horana	123	62
12		Panadura	182	91
13	Galle	Induruwa	56	28
14		Elpitiya	72	36
15		Galle – MC	96	48
16	Matara	Matara-PS	49	25
17		Akuressa	59	29
18		Weligama	81	40
19	Ampara	Mahaoya	25	12
20		Ampara	52	26
21		Dehiattakandiya	66	36
22	Kurunegala	Kuliyapitiya - East	60	30
23		Polgahawela	72	36
24		Pannala	136	67
25	Anuradhapura	Mihinthale	40	18
26		Galenbidunuwewa	61	27
27		N.P. E	80	40
	Total		2528	1266

While the calculated sample size for children was 2538, a total of 2528 completed the study; resulting in a response rate of 99.6%. Similarly, the calculated sample size for pregnant women was 1269, and 1266 completed the survey, achieving a response rate of 99.8%. (Table 3.1)

3.1 RESULTS OF SURVEY AMONG CHILDREN

TABLE 2. AGE DISTRIBUTION OF CHILDREN

Number	Percentage
392	15.5
2136	84.5
2528	100
	392 2136

Mean age 6.02 years (95% CI 6.182 – 6.222)

All children were in grade 1. However, the majority belonged to the 6–7-year age category as the study was conducted in November of the year (Table 3.2).

TABLE 3. GENDER DISTRIBUTION OF CHILDREN

Sex	Number	Percentage
Male	1244	49.2
Female	1284	50.8
Total	2528	100

A slight majority of students were females (Table 3.3).

TABLE 4. COUNTRY OF BIRTH OF CHILDREN

Country of birth	Number	Percentage
Sri Lanka	2515	99.4
Other	13	0.6
Total	2528	100

The large majority of children were born in Sri Lanka (Table 3.4).

TABLE 5. BIRTH ORDER OF THE FAMILY

1055	
1057	41.8
991	39.2
415	16.4
65	2.6
2528	100
	991 415 65

Most of the children included in the study were either the first or second born in the family (Table 3.5).

TABLE 6. BIRTH WEIGHT OF CHILDREN

Birth weight	Number	Percentage
< 2.5 Kg	359	14.2
2.5 – 3.5 Kg	1878	74.3
> 3.5 Kg	291	11.5
Total	2528	100

Mean weight at birth 2.94 Kg (95% CI 2.926 – 2.965)

There were 14.2% of children born with low birth weight included in the study (Table 3.6).

TABLE 7. HISTORY OF TRANSFUSION OF BLOOD/BLOOD PRODUCTS IN CHILDREN

Transfused blood/blood products	Number	Percentage
Yes	16	0.6
No	2512	99.4
If yes, No. of times transfused		
1	14	87.5
2	2	12.5
>2	0	0.0
Total	2528	100.0

Sixteen children had a history of blood transfusion. Out of them, two had more than one blood transfusion (Table 3.7).

TABLE 8. HISTORY OF CHRONIC DISEASES IN CHILDREN

Chronic disease	Number	Percentage
Yes	6	0.2
No	2522	99.8
If yes,		
Thalassemia	1	16.7
Bronchial Asthma	1	16.7
Heart Disease	1	16.7
Hypertension	1	16.7
Chronic Kidney Disease	1	16.7
Rheumatic fever	1	16.7
Total	2528	100

Six children were suffering from chronic illness (Table 3.8).

TABLE 9. VACCINATION WITH HEP B CONTAINING VACCINES IN CHILDREN

Hep B-containing vaccines (pentavalent)	Number	Percentage
Penta 1 – Yes	2528	100
Penta 1 – No	0	0
Total	2528	100
Penta 2 – Yes	2528	100
Penta 2 - No	0	0
Total	2528	100
Penta 3 – Yes	2527	99.96
Penta 3 - No	1	0.04
Total	2528	100

There was one (1) child who did not receive a pentavalent 3rd dose (Table 3.9).

TABLE 10. OTHER VACCINES GIVEN TO CHILDREN

Other vaccines	Number	Percentage
MMR 1 – Yes	2514	99.4
MMR 1 - No	14	0.6
LJE – Yes	2514	99.4
LJE - No	14	0.6
OPV & DPT – Yes	2514	99.4
OPV & DPT - No	14	0.6
MMR 2 – Yes	2513	99.4
MMR 2 - No	15	0.6
Total	2528	100

MMR = measles mumps rubella vaccine; LJE = live attenuated Japanese Encephalitis vaccine; OPV = oral poliovirus vaccine; DTP = diphtheria tetanus pertussis vaccine

There were 14 and 15 children who missed the 1st and the 2nd dose of the measles vaccine respectively. All children who missed their vaccine doses were vaccinated in the immediate next clinic session (Table 3.10).

TABLE 11. INFORMATION OF PARENTS

Parent's Age	Mot	Mother		Father	
	Number	%	Number	%	
< 20 years	0	0	0	0	
20-30 years	452	17.8	148	5.8	
31-40 years	1616	63.9	1442	57.0	
>41 years	460	18.3	938	37.2	
Total	2528	100	2528	100	
Mean (95% CI)	35.49 (35.28 – 35.	70)	38.91 (38.	.7-39.12)	
Level of education					
No formal education	3	0.1	5	0.1	
Grade 1-5	11	0.4	43	1.7	
Grade 6-11	421	16.6	462	18.4	
Passed O/L	966	38.3	1133	44.8	
Passed A/L	896	35.5	730	28.8	
Passed Diplomas or equivalent	73	2.9	61	2.5	
Passed Degree or above	158	6.2	94	3.7	
Total	2528	100	2528	100	
Occupation					
Full-time - Government	304	12.0	532	21.0	
Full-time - Private	220	8.7	943	37.3	
Self-employed	119	4.7	724	28.6	
Daily paid	26	1.0	245	9.7	
No occupation	1825	72.3	20	0.8	
Government subsidy	24	0.9	7	0.3	
Other	10	0.4	57	2.3	
Fotal	2528	100	2528	100	

Monthly income				
No or not mentioned	2053	81.2	532	21.1
Mentioned				
< Rs 50,000	341	13.5	1243	49.1
Rs 50,000 to 100,000	122	4.8	d651	25.8
> Rs 100,000	12	0.5	102	4.0
Total	2528	100	2528	100
Mean (95% CI)	Rs. 40169 (3628	81 – 44056)	Rs 46401 (447	729 – 48073)
Vaccination against hepatitis B				
Received (95% CI)	31	1.2 (0.78-1.62)	25	0.9 (0.53-1.27)
Not received (95% CI)	2497	98.8 (98.4-99.2)	2503	99.1(98.7-99.4)
Total	2528	100	2528	100

The majority of parents were between 31 to 40 years of age and passed the ordinary-level examination. The majority of mothers did not engage in any job while the majority of the fathers were engaged in full-time private sector occupations. Around 1% of the parents were vaccinated against hepatitis B; this is against the background that HepB for children was introduced in 2003 and adult vaccination is a high-risk approach (Table 3.11).

TABLE 12. RESULTS OF THE HEPATITIS B RDT (CHILDREN)

Result	Number	Percentage
Positive	0	0
Negative	2528	100
Total	2528	100

No child enrolled in the study tested positive for the HBsAg (Table 3.12).

3.2 RESULTS OF PREGNANT MOTHERS

TABLE 13. AGE DISTRIBUTION OF PREGNANT MOTHERS

Age in years	Number	Percentage
<20 years	37	2.9
20-30 years	743	58.7
31-40 years	456	36.0
> 41 years	30	2.4
Total	1266	100

Mean age 29.07 years (95% CI 28.7 – 29.3)

The majority of pregnant mothers were belonging to the 20-30 years of age group (Table 3.13).

TABLE 14. PARITY OF PREGNANT MOTHERS

Parity	Number	Percentage
1	504	39.8
2	426	33.7
3	232	18.3
4	77	6.2
5	22	1.7
6	5	0.3
Total	1266	100

Most of the pregnant mothers were in their first pregnancy (Table 3.14).

TABLE 15. NO. OF LIVING CHILDREN

No. of living children	Number	Percentage
0	556	44.0
1	460	36.3
2	209	16.5
3	38	3.0
4	2	0.1
5	1	0.1
Total	1266	100

The majority of mothers in the study sample were primigravida or had one living child (Table 3.15).

TABLE 16. LEVEL OF EDUCATION AND EMPLOYMENT STATUS OF THE PREGNANT MOTHER AND HER SPOUSE

	Pregnant mother		Spouse	
	Number	Percentage	Number	Percentage
Level of Education				
No formal education	1	0.1	0	0
Grade 1-5	4	0.3	10	0.7
Grade 6-11	237	18.7	231	18.2
Passed O/L	428	33.8	523	41.4
Passed A/L	440	34.7	413	32.7
Passed Diplomas or equivalent	62	4.9	30	2.4
Passed Degree or above	94	7.5	59	4.6
Total	1266	100	1266	100
Occupation				
Full-time - Government	115	9.0	250	19.7
Full-time - Private	118	9.4	524	41.5
Self-employed	28	2.2	314	24.8
Daily paid	7	0.5	138	10.9
No occupation	993	78.5	14	1.1
Government subsidy	1	0.1	3	0.2
Other	4	0.3	23	1.8
Total	1266	100	1266	100
Monthly income				
No or not mentioned	1024	80.9	101	8.0
Mentioned				
< Rs 50,000	184	14.5	729	57.5
Rs 50,000 to 100,000	54	4.3	406	32.1
> Rs 100,000	4	0.3	30	2.4
Total	1266	100	1266	100

While the majority of the pregnant mothers were educated up to the Government Certificate of Education, Advanced Level (GCE A/L), the majority of their spouses were educated up to the Government Certificate of Education, Ordinary Level (GCE O/L). Further, the majority of the spouses were engaged in full-time private-sector employment (Table 3.16).

TABLE 17. PAST MEDICAL HISTORY OF THE PREGNANT MOTHER AND HER SPOUSE

	Pregnant mother		Sp	ouse
	Number	Percentage	Number	Percentage
Past history of Hepatitis				
Hepatitis A	2	0.2	2	0.2
Hepatitis B	0	0	1	0.1
Hepatitis C	0	0	0	0
History like hepatitis	1	0.1	2	0.2
No past history of hepatitis	1263	99.7	1261	99.5
Total	1266	100	1266	100
History of chronic illness of the pregnant mother (Diabetes Mellitus, hypertension, etc.)				
Yes	41	3.2		
No	1225	96.8		
Total	1266	100		
Past history of sexually transmitted Infections				
Yes	0	0	0	0
No	1266	100	1266	100
Total	1266	100	1266	100
Vaccination against hepatitis B				
Received (95% CI)	6	0.4	4	0.3(0.0-0.6)
Not received (95% CI)	1260	99.6	1262	99.7(99.35- 100)
Total	1266	100	1266	100

None of the pregnant mothers had a past history of hepatitis B or C. There were 6 pregnant mothers and 4 of their spouses who had received the hepatitis B vaccination; this is against the background that HepB for children was introduced in 2003 and adult vaccination is a high-risk approach (Table 6.17).

TABLE 18. RESULTS OF THE HEPATITIS B RAPID TEST (PREGNANT MOTHERS)

Result	Number	Percentage
Positive	0	0
Negative	1266	100
Total	1266	100

All pregnant mothers who participated in the survey tested negative for HBsAg. Therefore, it was not necessary to carry out the serum-based hepatitis B surface antigen testing.

4. SUPERVISION:

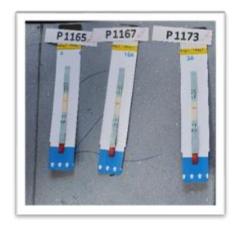
Supervision of data collection was done by the Medical Officer of Health and Public Health Nursing Sister. They visited the study centres and observed all survey steps and required rectifications were made; if any. Additionally, the Provincial and District Consultant Community Physicians and regional Epidemiologists also were involved in the supervision activities and a team of epidemiologists from the national level visited the districts during the study period. They read 10% of the RDT during their field visits. Finally, officers from the WHO/SEARO and WHO/Country Office also visited a few selected sites during the data collection process.

Areas of supervision

1. Correct identification of the individual (either child or pregnant mother) and link to their questionnaire, RDT & recording of results.

The linkage was done using the same number sticker system which is pasted in the participant's dress, questionnaire, RDT and results sheets.





2. RDT reading time

The result of the RDT has to be read after 15 minutes of starting the test and before completion of 30 minutes. The time to read the RDT was entered into a checklist against the child's / pregnant mother's serial number. The process was observed by the supervisors.





3. Supervision of the observation time after the procedure

After the procedure, each participant was observed for 15 minutes for possible side effects. A separate observation area was assigned and a checklist was used to track the entry time and the exit time.





5. DISCUSSION

This is the first survey carried out with a nationally representative sample to assess the hepatitis B status using a WHO-prequalified RDT among 5-year-old children. Further, the survey used the WHO protocol⁹ for verification of the achievement of the hepatitis B control target. Additionally, the survey also looked at pregnant mothers for their hepatitis B status using the same RDT.

The zero prevalence of hepatitis B reported from the survey in both the study groups is most likely due to the following reasons. In children, it is mainly due to high vaccination coverage at national as well as sub-national levels⁶. In pregnant mothers, it is due to the hepatitis B-protected girls are now reaching their reproductive years as the hepatitis B vaccination in the country started in 2003 and the low prevalence reported among the general population by the previous studies⁴. Further, the likelihood of finding hepatitis B-positive pregnant mothers will be reduced in years to come.

Additionally, the sound infection control activities in all healthcare institutes under the supervision of infection control nursing officers (ICNO) help to prevent the cross infection. All the infection control activities are protocolbased and they are being regularly updated by the professional colleges. All the blood and blood products are screened for hepatitis B by the NBTS¹³. The individuals identified as positive for hepatitis B are referred to the curative care services for further evaluation and treatment. All the NSACP clinic attendees are subjected to hepatitis B testing and if found to be positive, they are referred to the curative care services for further management¹⁴. Both NBTS and STI services are available throughout the country under the hospital network of the Ministry of Health and all the services are free for the recipient.

The surveys use the multi-stage cluster sampling technique, usually utilizing the sample weights in the analysis as each individual has an unequal chance to be selected for the sample. However, the survey results turned out to be zero prevalence, so this exercise was not undertaken.

Potential Biases

The children who were absent on the day of the survey were not re-surveyed. However, the number of absentees was minimal in all the survey sites.

Limitations of the study

We could not provide the RDT hands-on training to all the regional epidemiologists in person due to the fuel crisis in the country. Those who reside close to Colombo were invited to the Epidemiology Unit for the hands-on training while the others were joined online. Additionally, a video demonstration prepared by the manufacturer was shared with the participants and the techniques were evaluated during the field visit by the central team.

As the multi-stage cluster sampling was carried out using the probability proportion to the population size at each level as stated in the WHO guideline⁹, the districts with small populations may be excluded.

Further, the migrant groups could be excluded as the survey had a selection criterion of permanent staying in the selected MOH area for at least 6 months.

6. CONCLUSIONS

The survey results showed that there were no children with positive test results leading to the zero prevalence of hepatitis B among 5-year-old children. Further, there were no pregnant mothers found to be positive for hepatitis B, and their prevalence was reported as zero. The findings of the survey reiterate the low prevalence of hepatitis B among the general population in Sri Lanka.

7. RECOMMENDATIONS

The study results suggest continuing the highest standard of control and preventive strategies for hepatitis B in the country. They are high hepatitis B containing vaccination coverage during the routine immunization and adult vaccination program, sound infection control and prevention activities, and the 100% screening of blood and blood products before transfusion and availability of STI services around the country.

The criteria for hepatitis B elimination are the demonstration of < 0.1% of HBsAg among 5-year-old children along with several other indicators. Since the present survey has demonstrated levels less than the required for elimination, by fulfilling other necessities, the country can reach the elimination target before 2030.

A similar type of survey should be carried out at least once in 5 years to provide information to the SDG monitoring committee as hepatitis B prevalence among 5-year-old children is one of their indicators.

REFERENCES:

- 1. Hepatitis B; Fact sheet; July 2019; WHO
- 2. Hepatitis B vaccines; WHO position paper; July 2017; WHO
- 3. Padmasiri E, Rajapaksa L, Jayakuru WS, Withana N. The prevalence of hepatitis B surface antigen in the Gampaha district. Ceylon Med J. 1995 Mar;40(1):10-3. PMID: 7781086.
- 4. Premaratne, EDRG. Sero-epidemiology of hepatitis B and C in Colombo District and an estimate of the contribution of these infections in the aetiology of chronic liver diseases. Thesis in MD in Community Medicine, Post Graduate Institute of Medicine, University of Colombo, Sri Lanka, 2002.
- Niriella, M. A., A. Hapangama, et al. (2015). "Prevalence of hepatitis B and hepatitis C infections and their relationship to injectable drug use in a cohort of Sri Lankan prison inmates." Ceylon Med J 60(1): 18-20
- 6. Sri Lanka: WHO and UNICEF estimates of immunization coverage: 2019 revision, downloaded from, https://www.who.int/immunization/monitoring_surveillance/data/lka.pdf on 30.12.2020
- 7. Epidemiology Unit, Ministry of Health, Sri Lanka; 2014; Unpublished Data
- 8. Epidemiology Unit, Ministry of Health, Sri Lanka; 2019; Unpublished Data
- 9. Guidelines for verification of achievement of hepatitis B control target through immunization in the WHO South-East Asia Region; 2019; WHO
- 10. Documenting the Impact of Hepatitis B Immunization: Best practices for conducting a serosurvey; Immunization, Vaccines and Biologicals; 2011; WHO
- 11. Lwanga and Lemeshow, 1991
- 12. Noordeen F, Pitchai FNN, Rafeek RA, A review of hepatitis B virus infection in Sri Lanka, *Sri Lankan Journal of Infectious Diseases* 2015 Vol.5 (2):42-50
- 13. Annual Statistics Report 2019 National Blood Transfusion Services Sri Lanka, http://www.nbts.health.gov.lk/index.php/publication/2018-01-22-08-43-22
- 14. Annual Report 2021 National STD/AIDS Control Programme Ministry of Health, Sri Lanka http://www.aidscontrol.gov.lk/images/publications/annual_reports/2021/Anual_report_2021_online_version_final.pdf

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The support received from the Ministry of Education, district and zonal educational directors, school principals, and class teachers was commendable.

Finally, we wish to sincerely appreciate the support provided by all the pregnant mothers, children, and their parents by participating in the survey.

ANNEXURE 1

INFORMATION SHEET FOR STUDY PARTICIPANTS – (PREGNANT MOTHERS)

What is Hepatitis B

Hepatitis B is a viral disease that mainly affects the liver and can give rise to long-standing life-threatening complications. It spreads when an infected person's blood or other body fluids enter an uninfected person. The possible modes of entry are sexual contact, mother-to-child transmission at delivery, sharing needles in the case of injectable drug users, or accidental needle prick injuries. However, the disease can be prevented through vaccination. The Hepatitis B vaccine is included in the childhood vaccination regimen as pentavalent and administered at 2,4 and 6 months.

What is the purpose of this study?

Epidemiology Unit, Ministry of Health is surveying to find out Hepatitis B prevalence among pregnant women in the country. This will help the government to make decisions on the schedule of the Hepatitis B vaccine and relevant program-related matters to ensure good protection for the people against Hepatitis B.

You have been selected to participate in the above survey because you have registered your pregnancy with the area public health midwife.

What will happen in this study?

Your consent for the study has to be voluntary. You are requested to inform your willingness/unwillingness in written form in the consent form. No pregnant mother will be recruited to the study without the proper written consent of herself.

On the day of the survey, if you agree to participate, a public health worker will ask you some questions to check your eligibility for the survey. If found to be eligible, the rest of the questionnaire will be completed. This will be happening in your routine antenatal clinic.

Thereafter, a trained public health staff member will prick your finger after cleaning properly to obtain a few drops of blood for the rapid Hepatitis B test. After that, she will make sure that the bleeding is stopped and the pricked site will be covered with gauze and plaster. The results of the test will be informed to you at the same time. If you are found to be positive for the rapid hepatitis B testing, a sample of blood will be drawn for the

confirmatory testing. Your test results will be treated as highly confidential and it will not be available to anyone outside the survey team.

After pricking, you will be observed for 10 minutes for any adverse outcomes. The involvement of you in this study is over by this. If the health care worker finds that you are too sick to participate in the study, then no finger prick will be done.

Benefits to you:

By participating in this study, you will know your Hepatitis B status. Also, you will get advice on further management.

Benefits to the community

This study will help to know about the prevalence of Hepatitis B in pregnant mothers and will help with the decisions on vaccination policies in the country.

Risks for you

There is almost no risk of harm to you by participating in this study. The finger prick may cause little discomfort or pain. It will be done by trained public health staff and sterile materials will be used to avoid infection. The healthcare worker will observe you for 10 minutes after the finger prick to make sure everything is normal.

Data privacy

Your name and identity will be kept confidential by the investigators. Other information without names and identities will be shared among study investigators.

Voluntary consent

Your consent to participate in this study is voluntary. You do not have to take part in this study if you do not wish to do so. You may decline participation now or later. You are allowed to withdraw your consent even until 2 weeks from the day of data collection. In such a case, your already collected data will be deleted from the study.

If you refuse to participate, you will not lose any access to antenatal services, other medical services or any benefits provided by the MOH office or the hospital.

Contact information

You can ask any questions about this study or the consent. If you have any concerns or questions subsequently, please contact the investigators.

Study investigator: Dr Thilanga Ruwanpathirana Contact Number: +94717195023

Epidemiology Unit, Ministry of Health - +94112695112 / +94112681548 / +94112696583

INFORMATION SHEET FOR STUDY PARTICIPANTS (PARENTS / GUARDIANS)

What is Hepatitis B?

Hepatitis B is a viral disease that mainly affects the liver and can give rise to long-standing life-threatening complications. It spreads when an infected person's blood or other body fluids enter an uninfected person. The possible modes of entry are sexual contact, mother-to-child transmission at delivery, sharing needles in the case of injectable drug users or accidental needle prick injuries. However, the disease can be prevented through vaccination. The Hepatitis B vaccine is included in the childhood vaccination regimen as pentavalent and administered at 2,4 and 6 months.

What is the purpose of this study?

Epidemiology Unit, Ministry of Health is surveying to find out Hepatitis B prevalence among 5-year-old children in the country. This will help the government to make decisions on the schedule of the Hepatitis B vaccine and relevant program-related matters to ensure good protection for the people against Hepatitis B.

Your child has been selected to participate in the above survey because your son/daughter is in grade 1 and resides in an area that has been decided to be covered in this survey.

What will happen in this study?

The consent to participate your child in the study has to be voluntary. The consent form will be signed at the end of the parents' meeting or sent to the parents/guardians who were absent on the day of the parents' meeting through your child with a note in the parent-teacher communication book. You are requested to inform your willingness/unwillingness in written form in the consent form. No child will be recruited to the study without the proper written consent of the parents/guardians.

In children, the eligibility will be checked by a public health worker who will obtain some information from the copy of the CHDR of your child which is available in the MOH office. (ex. vaccines your child has received). If found to be eligible, the questionnaire will be completed and if required the public health worker will contact you over the phone. The children's survey will happen in their classroom during school hours.

Thereafter, a trained public health staff member will prick your child's finger after cleaning properly to obtain a few drops of blood for the rapid Hepatitis B test. After that, he/she will make sure that the bleeding is stopped and the pricked site will be covered with gauze and plaster. The results of the children will be informed to the parents/guardians via written form in a neutral sealed envelope through the class teacher. If your child is found to be positive for the rapid hepatitis B testing, a sample of blood will be drawn for the confirmatory testing. The

presence of the parent/s is not required during the day of testing. Your child's test results will be treated as highly confidential and it will not be available to anyone outside the survey team. Especially, the results will not be shared with the class teacher or school authorities.

After pricking, your child will be observed for 10 minutes for any adverse outcomes. The involvement of your child in this study is over by this. If the health care worker finds that your child is too sick to participate in the study, the child refuses or does not cooperate, then no finger prick will be done.

Benefits for your child and the family:

By participating in this study, you will know your child's Hepatitis B status. Also, you will get advice on further management.

Benefits for the community

This study will help to know about the prevalence of Hepatitis B in 5-year-old children and will help with the decisions on vaccination policies.

Risks for your child

There is almost no risk of harm to your child with this study. The finger prick may cause little discomfort or pain. It will be done by trained public health staff and sterile materials will be used to avoid infection. The healthcare worker will observe your child for 10 minutes after the finger prick to make sure everything is normal.

Data privacy

Your child's name and identity will be kept confidential by the investigators. Other information without names and identities will be shared among study investigators.

Voluntary consent

Your consent for your child to participate in this study is voluntary. You do not have to take part with your child in this study if you do not wish to do so. Similarly, you have a right to refuse to obtain information from the "copy" of your CHDR which is available with the MOH office. You may decline the consent to participation now or later. You are allowed to withdraw your consent even until 2 weeks from the day of data collection. In such a case, your child's already collected data will be deleted from the study. If you refuse to participate your child in the study, he/she will not lose any access to vaccination services, other medical services or any benefits provided by the MOH office or the hospital.

Contact information

You can ask any questions about this study or the consent. If you have any concerns or questions subsequently, please contact the investigators.

Study investigator: Dr Thilanga Ruwanpathirana Contact Number: +94717195023

Epidemiology Unit, Ministry of Health - +94112695112 / +94112681548 / +94112696583

Viral Hepatitis B Sero-prevalence Survey among pregnant mothers and 5-year-old children in Sri Lanka – 2022, Epidemiology Unit, Ministry of Health

CERTIFICATE OF CONSENT – PREGNANT MOTHERS

- I have been invited to take part in the Hepatitis B Sero survey.
- I read the foregoing information or it has been read to me.
- I have had the opportunity to ask questions about it, and my questions have been answered to my satisfaction.
- I understand the benefits, discomforts, and risks of the study. If I have concerns, about my participation in the study, I can contact the area MOH, the principal investigator of the study or the Epidemiology Unit at any time.
- I understand that if I am found to be positive for Hepatitis B, my details will be reported to the public health authorities for disease surveillance purposes as it is mandatory in the country.
- I consent voluntarily to be a participant in this study and understand that I have the right to withdraw from the study even until 2 weeks from the data collection, without affecting my medical care.

Name of participant			
Signature of participant			
Date	/	/	(dd/mm/yy)
If not able to sign			
Affix thumb impression of the participant			
Name of Study Investigator		-	
Signature			

Date / (*dd/mm/yy*)

Viral Hepatitis B Sero-prevalence Survey among pregnant mothers and 5-year-old children in Sri Lanka – 2022, Epidemiology Unit, Ministry of Health

CERTIFICATE OF CONSENT - PARENTS / GUARDIANS

- My child has been invited to take part in the Hepatitis B Sero survey.
- I read the foregoing information or it has been read to me.
- I have had the opportunity to ask questions about it, and my questions have been answered to my satisfaction.
- I understand the benefits, discomforts, and risks of the study. If I have concerns, about my child's participation in the study, I can contact the area MOH, the principal investigator of the study or the Epidemiology Unit at any time.
- I understand that if my child is found to be positive for Hepatitis B, details will be reported to the public health authorities for disease surveillance purposes as it is mandatory in the country.
- I consent voluntarily to have my child be a participant in this study and understand that I have the right to withdraw my child from the study even until 2 weeks from the data collection, without affecting his/her medical care.
- I consent the health care workers to obtain the required information from the "copy" of my child's immunization record which is available in the MOH office.

Name of child's parent/guardian				
Name of the child		n the stud	y (strikethrough th	ne irrelevant)
Signature of parent/guardian				
Date	/	/	(dd/mm/yy)	
If not able to sign				
Affix thumb impression of the parent				

Name of Stud	y Inves	tigator			
Signature				-	
Date:	/	/	(dd/mm/yy)		

Viral Hepatitis B Sero-prevalence Survey among pregnant mothers and 5-year-old Children in Sri Lanka – 2022

QUESTIONNAIRE FOR PREGNANT MOTHERS (to be filled by a Health Care Worker by interviewing the pregnant mother once they come to their routine antenatal clinic)

Pr	ovir	nce:	District:			
M	ОН	area:	PHM area:	•••••		
Da	ate:.	••••••	Serial No:	••••		
El	igibi	lity screening – Pregnant Mothers				
-	Do	es the residential address of the pregnant moth	ner fall within the selected MOH are	a Y	es /	No
-	Do	es the mother permanently reside in the MOH ar	rea for > 6 months	Yes /	No	
-	На	s she provided consent to participate?		Yes /	No	
-	An	y known coagulation disorders?		Yes /	No	
-	An	y serious disease that requires hospitalization a	nt present	Yes /	No	
-	An	y evidence of known immunodeficiency diso	rder?	Yes /	No	
-	Ba	sed on these, is the pregnant mother eligible fo	or the survey?	Yes /	No	
Ba	asic i	<u>nformation</u>				
	1.	Name:				
	2.	Age:				
	3.	Parity:, Number of living children				
	4.	Address (Residential):				
	5.	Highest level of education (Tick)				

	Pregna nt mother	Her Husban d
No schooling		
Grade 1-5		
Grade 6-11		
Pass G.C.E. O/L		
Pass G.C.E. A/L		
Diploma/Certificate/Equival ent		
Degree or above		

6. Current employment (Tick) & income

	Pregnant mother	Her Husband
Full-time – public sector		
Full-time – private sector		
Self-employed		
Casual employment		
Unpaid family work		
Unemployed		
Average monthly earnings Rs.		

7	C t t t t	
/	Contact number:	
٠.	donitact namber:	

8. History of, (Pregnant mother)

Hepatitis A: Y	es No	If yes age at	that time	
Hepatitis B: Y	es No	If yes age at	that time	
Hepatitis C: Y	es No	If yes age at	that time	
History and sy	ymptomss	suggestive of	Hepatitis (eg. Jaundice) Yes	No
If yes age at the	nat time			
9. Past history of, (Husband)				
Hepatitis A: Y	es No	If yes age at	that time	
Hepatitis B: Y	es No	If yes age at	that time	
Hepatitis C: Y	es No	If yes age at	that time	
History and sy	ymptoms s	suggestive of	Hepatitis (eg. Jaundice) Yes	No
If yes age at th	nat time			
10. History of any chronic illi	noss of the	progrant me	other: Yes No	
If yes; specify				
11. History of STI of the	No.	0	If yes, specify	
pregnant mother				
12. History of STI of her husband	No.	0	If yes, specify	
13. History of blood	No.	0	If yes,	The number of times:
transfusion of the mother:			reason	
14. History of blood transfusion of her husband:	No.	0	If yes,	The number of times:
transfusion of her husband.			reason	
15. Mother vaccinated for Hepatitis B	No.	0	If yes, the number of doses given	Year vaccinated
перация в			81 v Cil	
16. Her husband vaccinated for Hepatitis B	No.	0	If yes, the number of doses given	Year vaccinated
			g-:	

Rapid test performed:	Yes	No
If yes, the result,	Positive	Negative
If positive, 1) referred for further management:	Yes	No
2) Additional blood sample was taken:	Yes	No
Name of the health worker filling out the ques	stionnaire:	
SignatureDate - DD	-MM-YY	

Viral Hepatitis B Sero-prevalence Survey among pregnant mothers and 5-year-old children in Sri Lanka – 2022-Epidemiology Unit, Ministry of Health

 $QUESTIONNAIREFOR\ CHILDREN\ (to be filled by a Health\ Care\ Worker\ using\ a\ copy\ of\ the\ Child\ Health\ Development\ Record\ which\ is\ available\ in\ the\ MOH\ office\ and\ contact\ the\ parents/guardians\ over\ the\ phone\ where\ relevant\ (contact\ details\ are\ available\ in\ the\ child's\ record))$

Pı	rovince:	District :		
M	ОН area:	PHM area:		
Da	ate:	Serial No:		
El	ligibility screening - Children			
-	Age of the child >5 y - < 6y		Yes / No)
-	Does the residential address of the child fall with	in the selected MOH area	Yes / No)
-	Has the child permanently resided in the MOH ar	rea for > 6 months	Yes / No)
-	Has the parent/guardian provided consent to par	rticipate?	Yes / No)
-	Any known coagulation disorders?		Yes / No)
-	Do any serious diseases require hospitalization a	t present	Yes / No)
-	Any evidence of known immunodeficiency disor	der?	Yes / No)
-	Based on these, is the child eligible for the survey	7?	Yes / No)
	Information about the Child			

Last measur copy	ed, recorded	in the
Weight (Kg)	Height (cm)	Date

1.	Name:
2.	Sex: M F
3.	DOB: D\ M\ Y
4.	Age (At the time of data collection):ys months
5.	Birth WeightKg
6.	Place of Birth: Sri Lanka / Not in Sri Lanka (Specify the country)
7.	Birth order in the family (eg. 1st born child or second etc):
8.	Address (Residential):
9.	Phone numbers of the father/mother/guardian:,
10.	. History of blood/ blood product transfusion: Yes/No, (contact the parent for Q 12 $\&$ 13)
If y	ves, How many times Age at last transfusion MM/YY, Reason:
11.	History of any chronic illness: Yes No If yes specify
Im	amunization History: (filled using the copy of the immunization record which is available in the MOH office)
12.	. Hepatitis B containing vaccine (mark $$ in relevant place if "yes" & circle the type of vaccine):
1st	dose (2m) age: Yes (Penta/Hexa/Mono) No Not Known If Yes, date mm / dd / y
2nd	dose (4m) age: Yes (Penta/Hexa/Mono) No Not Known If Yes, date mm / dd / yy
3rd	dose (6m) age: Yes (Penta/Hexa/Mono) No Not Known If Yes, date mm / dd / yy
If n	not given any of the above: reasons
13.	MMR (first dose) : Yes No
14.	JE : Yes No
15.	OPV & DPT : Yes No

Information	of the	parents	/ Gaudian

17. A	Current age	of Mother	'ys
- /	, darrerr age	OI I-IO CIICI	y S

19. B) Father.....ys

18. A) Highest level of education (Tick)

20. B) Current employment (Tick) & income

	Mother	Father
No schooling		
Grade 1-5		
Grade 6-11		
Pass G.C.E. O/L		
Pass G.C.E. A/L		
Diploma/Certificate/Equivale		
nt		
Degree or above		

	Mother	Father
Full-time – public sector		
Full-time – private sector		
Self-employed		
Daily paid		
Unemployed		
Average monthly earnings Rs.		
Samurdhi //		

21. Parents vaccinated against Hena	atitic	R٧

A) Mother: Yes No If yes, No. of doses, Vaccination card available Yes No

B) Father: Yes No If yes, No. of doses,	Vaccination card availa	ble Yes No	
Rapid test performed:	Yes	No	
If yes, the result,	Positive	Negative	
If positive, referred for further management:	Yes	No	
Name/designation of the health care worker:			
SignatureDate - DD-MM-YY			