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## Vaccination in delivery wards leads to high timely coverage of hepatitis B birth dose vaccine in Islamabad-Pakistan, 2023

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### Abstract

Despite a high burden of hepatitis B in Pakistan, administration of hepatitis B birth dose (HepB-BD) has not been introduced on a national level and timely coverage remains low in selected provinces where the vaccine is available. This project was undertaken to assess the ease of timely (within 24 hours of birth) administration of HepB-BD by delivery nurses. A total of 1,000 HepB-BD doses were provided to delivery units of two public tertiary care hospitals in Islamabad. Out of 2,008 births in three months, 2,000 (99.6%) were vaccinated with HepB-BD. Out of 1,986 new-borns with available time of vaccine administration, all received the vaccine within 24 hours of birth with 98.3% receiving the vaccine within an hour of delivery. Delivery wards are the best setting to provide HepB-BD. Provinces that are already procuring HepB-BD and future nationwide

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introduction of HepB-BD in Pakistan could use lessons from this pilot study to ensure high coverage with timely administration of HepB-BD.

## Keywords

Hepatitis B birth dose; Immunisation; Mother to child transmission; Expanded programme for immunisation

## Introduction

The majority of chronic hepatitis B virus (HBV) infections result from mother-to-child transmission of HBV, which can be prevented by timely (within 24 hours of birth) administration of hepatitis B birth dose (HepB-BD). It is also caused by horizontal transmission in early childhood, which can be prevented by administration of an additional two or three doses of hepatitis B vaccine during the first year of life.<sup>1,2</sup> The full series provides more than 95% protection and is the foundation of the prevention of perinatal and horizontal transmission of HBV.<sup>2</sup>

Pakistan has a substantial burden of chronic HBV infection with an estimated five million people having HBV infection; prevalence of hepatitis B surface antigen (HBsAg) in the general population is 2.5% and 1.3% among children aged <5 years.<sup>3</sup> Pentavalent vaccine, which includes hepatitis B vaccine, was introduced into Pakistan's Extended Programme for Immunisation (EPI) in 2009 and is given at 6, 10, and 14 weeks of age.<sup>4</sup> Coverage with three doses of pentavalent vaccine/hepatitis B vaccine (HepB3) ranged between 80% and 85% during 2019–2023.<sup>5</sup> HepB-BD is not a part of the national schedule, even though Pakistan's National Immunisation Technical Advisory Group (NITAG) had recommended its introduction in 2000. In the past, HepB-BD was procured by three provincial hepatitis programmes (Punjab, Sindh, and Balochistan) and it was handed over to the EPI or Maternal Neonatal and Child Health (MNCH) programmes for administration. In 2022, the coverage of HepB-BD was 70% in Punjab, 15% in Sindh, and 14% in Balochistan (EPI, multiple indicator survey).<sup>6</sup>

The major barriers to the administration of HepB-BD are the unclear roles and responsibilities for procurement of the vaccine by the hepatitis programme and its administration by the EPI or MNCH programmes. Another major barrier to timely vaccination is that the EPI has fixed vaccination sites and requires the mother to bring her infant to the vaccination site. This site is usually situated away from the delivery site and the vaccinator is not available all the time, leaving most infants unvaccinated, especially those born after working hours or on weekends. WHO recommends that the best method to achieve timely vaccination and enhance its coverage is to administer HepB-BD in the delivery units.<sup>7</sup> In Islamabad, 84% of pregnant women deliver in a hospital giving the opportunity for administration of HepB-BD shortly after delivery.<sup>8</sup> A pilot project was carried out in Islamabad to assess the feasibility of using existing health care staff in delivery units to provide timely HepB-BD and to guide the development of a national plan to scale up the introduction of HepB-BD in other hospitals nationwide.

## Methods and Results

Starting from December 2022, the birthing units of two large tertiary care public sector hospitals of Islamabad [Pakistan Institute of Medical Sciences (PIMS) and Federal Government Services Hospital (FGSH)] were selected for the project. The delivery staff was provided additional training on hepatitis B vaccination and the importance of timely administration of HepB-BD for prevention of perinatal transmission of HBV. Nurses were given hands-on training on vaccine administration at the anterolateral side of the thigh, entering vaccination record in the delivery register and the EPI vaccination cards by the EPI and were observed by the EPI workers for a week. To minimise the burden on the delivery staff, only one column (i.e. the date and time of HepB-BD administration) was added to the delivery register. EPI vaccination cards already had a box on HepB-BD vaccination on which the delivery nurse had to enter the date of vaccination after vaccine administration.

A total of 2,000 doses of WHO prequalified monovalent (0.5 mL) hepatitis B vaccine (Serum Institute of India) were procured from the local market and stored at the central vaccine cold chain warehouse. Doses were released to the sites as per their demand along with the vaccination cards, syringes, and sharps containers. The vaccine at each delivery unit was stored in the refrigerator.

After provision of HepB-BD, nurses were trained to inform the parents on the importance of completing the full series of pentavalent vaccine to achieve full protection from HBV infection as well as other vaccine preventable diseases. To address the potential safety concerns, the existing Adverse Events Following Immunisation (AEFI) committee of the Federal Directorate of Immunisation (FDI) was engaged to deal with any issue, if reported. Information about the time of delivery and the time of vaccination was entered in the delivery register and in the child's vaccination card. The empty vaccine vials were collected daily and given to the FDI as evidence of vaccination.

A field supervisor collected the data daily from the delivery registers of each site. Information collected included the basic demographic information about the mother, her hepatitis B and hepatitis C status, time of delivery, and the time of administration of the HepB-BD. The field supervisor entered the data electronically. The project team checked the data daily for completeness and quality. The final data set used for analysis did not contain any personal identifiers.

This project was reviewed and approved by the National Bioethics Committee of Pakistan Ref: No 4-87/NBC-815/22/139. This project was reviewed at CDC and was determined to represent non-research activity.

There were a total of 2,008 deliveries at the two hospitals from December 2022 through March 2023. Most deliveries were undertaken in the labour room but some were delivered via caesarean section in the theatre. All women were routinely tested for HBsAg and anti-HCV prior to admission for delivery. Four women had tests reactive for HBsAg and four others for anti-HCV; none had evidence of co-infection.

Maternal demographic characteristics and new-born HepB-BD vaccination information are shown in Table. Of the 2,008 new-borns, 2,000 (99.6%) were given 0.5 ml of HepB-BD by the delivery nurse in the delivery unit soon after delivery and after undertaking basic care of the baby. The time interval between birth and HepB-BD administration was available for 1,986 new-borns; The time of vaccination was not recorded for two new-borns, and 12 new-borns had incorrectly recorded vaccination time (vaccination time preceded birth time). All 1,986 new-borns with correct recorded time received HepB-BD within 24-hours of birth. Most of these new-borns (1,953 or 98.3%) received HepB-BD within one hour of birth, and nearly all (1,974 or 99.6%) were vaccinated within 12 hours of birth.

Eight new-borns, who were born during the first two days after the start of the project were not vaccinated with HepB-BD because of the misconceptions by the delivery nurses who were not sure if they could give the vaccine to underweight babies (<2,000 grams). Their misconceptions were addressed immediately by the EPI workers with further training.

Most deliveries i.e. 846 (42.1%) took place between 8:00 PM and 7:59 AM, followed by 690 deliveries (34.3%) between 8:00 AM and 1:59 PM, while 472 deliveries (23.5%) occurred between 2:00 PM and 7:59 PM). None of the birthing units reported any problem in giving the vaccine. No immediate or late AEFI were reported.

## Discussion

The present study showed that administration of timely HepB-BD in the delivery unit by the delivery nurse to new-borns in this cohort was both highly feasible and nearly universally implemented. Further, there was no additional cost to the health system, and there was minimal additional documentation that did not add to the workload of the health care staff. Delivery nurses are already trained in giving intramuscular injections to new-borns; therefore, they required minimal training to administer HepB-BD. None of the sites reported any issues in giving the vaccine in the delivery units.

Though HepB-BD is available in Punjab and Sindh provinces, coverage is low and the timeliness of the vaccination at these sites is unknown. The major reasons for low coverage reported by these provinces were intermittent supply of the vaccine, its high cost, and lack of clarity on the role and responsibilities of the FDI (responsible for collecting/collating these data), MNCH (responsible for timely vaccine), and the hepatitis programme (procuring department). This pilot project showed that these challenges can be overcome by giving the responsibility of HepB-BD procurement to hepatitis programme, its storage and supply to the FDI and its administration to the (MNCH) nurses and midwives working in the delivery units, while, in the long run, procurement should also be done by the FDI.

In Pakistan, the birth rate is 29.3/1,000 population, or four million children are born every year,<sup>5</sup> while 33% of births occur outside of health care facilities.<sup>7</sup> Therefore, 67% of births in the healthcare facilities can be easily administered HepB-BD. Home deliveries can be addressed using other care providers like the Lady Health Workers.<sup>9</sup>

Increasing institutional delivery rates and skilled birth attendant rates could further increase coverage of timely HepB-BD.<sup>10</sup> In addition, increasing community awareness about the

importance of timely administration of HepB-BD, providing HepB-BD to Lady Health Workers (a cadre of trained female community workers who deliver door-to-door health services in Pakistan) to administer to children born at home, and using HepB-BD outside the cold chain where needed could increase HepB-BD coverage and prevent chronic infections among children born at home.<sup>6</sup>

## Conclusion

Following the successful implementation of this pilot project, UNICEF showed interest in not only sustaining this model in these two pilot hospitals but also scaling up in other hospitals in Islamabad and subsequently more broadly throughout Pakistan. This pilot project has proven that providing HepB-BD to delivery units and assigning its administration to delivery unit staff can successfully lead to high rates of timely Hep B-BD. The administration of first doses of BCG and polio vaccines concurrently with HepB-BD would provide integrated services and protection against multiple vaccine preventable diseases.

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**Table:**

Maternal demographic characteristics and new-born hepatitis B birth dose vaccination information—two large tertiary care hospitals in Pakistan, 2022–2023.

|                                                                      | Total       | Hospital       |               |
|----------------------------------------------------------------------|-------------|----------------|---------------|
|                                                                      | n (%)       | FGPH<br>n. (%) | PIMS<br>n (%) |
| <b>Mothers</b>                                                       | 2008 (100)  | 1000 (100)     | 1008 (100)    |
| <b>Age of mother</b>                                                 |             |                |               |
| Under 20                                                             | 76 (3.8)    | 28 (2.8)       | 48 (4.8)      |
| 20–29                                                                | 1170 (58.3) | 593 (59.3)     | 577 (57.2)    |
| 30–39                                                                | 711 (35.4)  | 366 (36.6)     | 345 (34.2)    |
| 40 and above                                                         | 51 (2.5)    | 13 (1.3)       | 38 (3.8)      |
| <b>Place of Delivery</b>                                             |             |                |               |
| Obstetric theatre                                                    | 849 (42.3)  | 419 (41.9)     | 430 (42.7)    |
| Labour Room                                                          | 1159 (57.7) | 581 (58.1)     | 578 (57.3)    |
| <b>Mother's HBsAg status</b>                                         |             |                |               |
| Non-reactive                                                         | 2004 (99.8) | 997 (99.7)     | 1007 (99.9)   |
| Reactive                                                             | 4 (0.2)     | 3 (0.3)        | 1 (0.1)       |
| <b>Mother's anti-HCV status</b>                                      |             |                |               |
| Non-reactive                                                         | 2004 (99.8) | 999 (99.9)     | 1005 (99.7)   |
| Reactive                                                             | 4 (0.2)     | 1 (0.1)        | 3 (0.3)       |
| <b>Hepatitis B vaccine Birth dose given within 24 hours of birth</b> |             |                |               |
| Yes                                                                  | 2000 (99.6) | 1000 (100)     | 1000 (99.2)   |
| No                                                                   | 8 (0.4)     | 0 (0)          | 8 (0.8)       |

FGPH: Federal Government Polyclinic Hospital; PIMS: Pakistan Institute of Medical Sciences; HBsAg: Hepatitis B surface antigen; anti-HCV: antibody to hepatitis C virus.