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A Improving Birth-dose Hepatitis-B Vaccination in a Tertiary Level IV Neonatal Intensive Care Unit

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Abstract

Background: Perinatal hepatitis B is a global public health concern. To reduce perinatal hepatitis B and its complications, the Hepatitis B vaccine (HBV) is recommended by the New York State Department of Health and Advisory Committee on Immunization Practices within 24 hours of life for infants born with a birth weight ≥2000 g. Infants admitted to the neonatal intensive care unit (NICU) weighing over 2000 g missed their birth dose HBV frequently, which prompted the implementation of a quality improvement initiative to increase birth dose HBV immunization in a level IV NICU in New York. Methods: May 2019 to April 2021 baseline data showed the birth dose HBV rate of infants born ≥2000 g at 24% and 31% within 12 and 24 hours, respectively. The multidisciplinary QI team identified barriers using an Ishikawa cause-and-effect diagram. Our interventions included multidisciplinary collaboration, electronic medical record reminders, education, posters, and improved communication between staff and parents. We aimed to achieve a 25% improvement from the baseline. Results: After 19 months of QI interventions (four Plan-Do-Study-Act cycles), the rate of administering birth dose HBV within 12 hours of life increased from 24% to 56% and within 24 hours from 31% to 64%. Process measure compliance improved, exceeding the 25% target, and showed sustained improvement. Conclusion: This QI initiative improved the rate of eligible infants receiving HBV within the first 24 hours of life in the NICU. This work can serve as a model for other healthcare institutions to improve HBV immunization rates in NICUs. (Pediatr Qual Saf 2023;8:e693; doi: 10.1097/pg9.000000000000693; Published online October 7, 2023.)

INTRODUCTION

Chronic hepatitis B infection is a worldwide public health problem. Approximately 4-5 million children QUALITY worldwide have acquired the infection from SAFETY their chronic hepatitis B infected mothers.^{1,2} In the United States, about 25,000 infants are born to women infected with Hepatitis B.³ Infants exposed to Hepatitis B at birth

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without prophylaxis are at 90% risk of acquiring perinatal infection.⁴ Receiving Hepatitis B immunization at birth is crucial to reduce the risk of vertical trans-· SAFETY

mission from mother to infant, as the HBe antigen status of the mother is unknown in most cases, and the transmission risk QUALI can vary from 30% to 85%, depending on the HBe antigen status.⁵ In 2017, the American Academy of Pediatrics (AAP) SAFET issued a policy statement recommending the administration of the Hepatitis B vaccine (HBV) to all newborns with a birth weight greater than or equal to 2000 gm, to receive the HBV by 24 hours of age.⁶

The revised AAP policy for birth-dose HBV aligns with the recommendations of the Advisory Committee on Immunization Practices (ACIP), an advisory panel to the Center for Disease Control and Prevention (CDC).⁷ The New York State Department of Health recommends the administration of HBV within 12 hours of life to all newborns with a birth weight of 2000g or more to protect infants from vertical transmission, household exposure, and at-risk infants missed from medical errors.8 The New York City birth dose vaccination rate was 69.9% for HBV within one day of life in the 2020 annual report, and the estimated national birth dose vaccination rate in 2014 was 71.1%.9-11 Most previously published QI projects outlining improved adherence to birth dose HBV were mainly limited to infants in newborn nurseries. At our institution, administering the birth HBV vaccine within 12 to 24 hours to all neonates in the newborn nursery is a routine practice, which aligns with the national average. However, in our Neonatal Intensive Care Unit (NICU), we had a different practice of administering the HBV at any time before hospital discharge, even for neonates with a birth weight greater than 2000g. From May 2019 to April 2020, the baseline data at our NICU indicated that compliance with the nationally and state-recommended 24-hour time frame was suboptimal. Based on this observation, we initiated a quality improvement project in July 2020 intending to increase the monthly average of eligible infants who receive HBV within the first 24 hours of life by at least 25% within 19 months.

METHODS

The QI initiative was implemented in the NICU of our 35-bed level-IV regional perinatal center, which handles 4000 deliveries each year, and has an annual admission rate of approximately 700, consisting of both inborn and outborn cases. We collected the baseline data for HBV at birth for one year, from May 2019 to April 2020, by doing a retrospective chart review of all the infants admitted to the NICU at our institute. Data were obtained on rates of HBV immunization in the first 12 hours, before 24 hours of life, and before discharge from the hospital. We excluded outborn infants admitted after day 1 of life, infants with hemodynamic instability, palliative care infants, and death within 24 hours. Among the 404 eligible infants admitted to the NICU, the rate of birth dose HBV administration before discharge from the hospital was high at 97% (392/404), the rates of birth dose HBV administration within the first 12 hours of life and before 24 hours were low at 24% (98/404) and 31% (127/404), respectively (Fig. 1).

As our baseline birth dose HBV rates were low, we launched a QI initiative to improve timely administration rates by at least 25% above the baseline levels for the birth dose HBV vaccination of all hemodynamically stable neonates with birth weight of 2000g or more and admitted to our NICU. The initiative was carried out from July 2020 to January 2022, covering 19 months. We implemented four Plan-Do-Study-Act (PDSA) cycles to institute, modify and improve our immunization rates per the Institute of healthcare improvement model. The institutional review board of our institute approved the QI protocol.

Planning the Interventions

A multidisciplinary QI team included neonatal faculty, neonatal-perinatal fellows, pediatric residents, neonatal nurse practitioners, physician assistants, registered nurses, PharmD, and patient care coordinators. We identified the barriers to birth-dose HBV immunization using the Ishikawa cause-and-effect diagram or Fishbone diagram (Fig. 2). The team convened every 3 months to review the project objectives and ensure proper monitoring and implementation of activities related to the processes. In addition, email communication was used concurrently. Our QI team devised a Key Driver Diagram (Fig. 3) to pinpoint the key drivers for improving the birth-dose HBV rates.

PDSA Cycle 1

During the first cycle, the interventions involved educational sessions for all healthcare professionals on the immunization schedule and raising awareness of the QI project to improve the HBV birth dose rate. The team

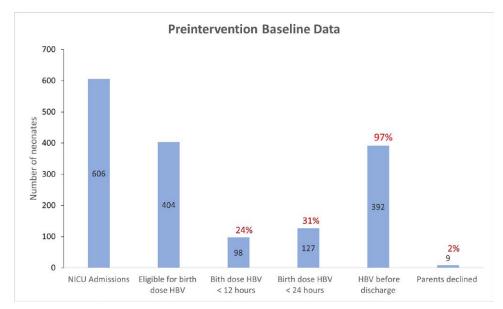
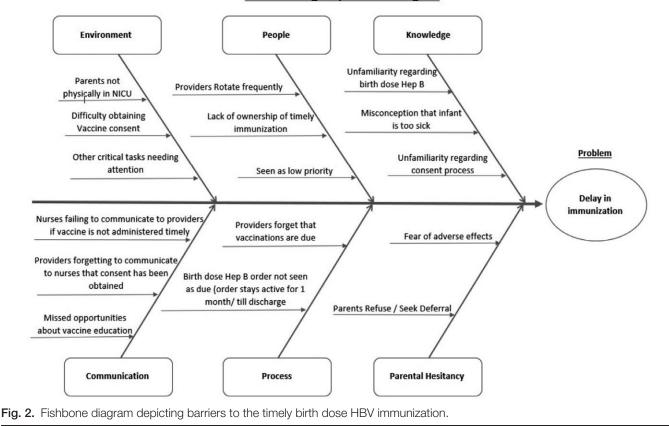


Fig. 1. Baseline immunization rates.



Ishikawa Diagram/Fishbone Diagram

developed a smart phrase on the electronic medical record (EMR) to document parental assent and entered it in an easily accessible "Yellow sticky note" on the EMR.

PDSA Cycle 2

During the November 2020-February 2021 cycle, we implemented the interventions from the initial PDSA cycle. We conducted a well-organized educational session focused on the HBV birth dose and the utilization of EMR smart phrases. After a short survey of all providers, we identified that the primary hindrance to birth dose immunization was obtaining parental consent. The unavailability of parents in the NICU was a significant challenge in securing vaccine consent. Even though we only included inborn babies, obtaining parental consent was particularly challenging due to our unit's practice of allowing only physicians, residents, or practitioners to get immunization consent, resulting in nurses feeling uncomfortable obtaining it.

PDSA Cycle 3

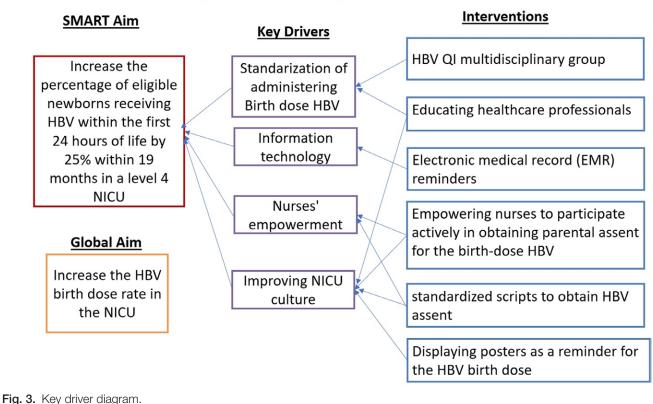
During the four months from March 2021 to July 2021, we implemented the third PDSA cycle. The intervention involved changing the unit's practice by empowering nurses to play an active role in obtaining parental consent for the birth dose of HBV. The nurses received education on taking consent from parents and providing them with updated information on vaccine safety. When nurses could not contact mothers, the clinical care team provided assistance. Additionally, we conducted monthly education sessions for residents and sent monthly reminders to other providers to ensure continued success.

PDSA Cycle 4

We implemented several interventions during the fourth PDSA cycle, from August 2021 to December 2021. One of these interventions was the creation of a poster promoting the universal birth dose hepatitis B vaccine. The poster was displayed in the huddle board, residents' room, and practitioner's office as a reminder. We implemented a standardized script for nurses to follow when seeking parental consent for the Hepatitis B vaccine. The script reads as follows: "It is our hospital's policy to administer the first dose of the hepatitis B vaccine within 12 hours of birth, in accordance with CDC, AAP, and New York State Department of Health guidelines. I will soon administer the vaccine to your baby. The Hep B vaccine is highly safe and usually has no side effects. It is the best protection for your baby against hepatitis B viral infection." We recruited our nurse educator as a stakeholder to educate the nurses on immunization.

Study Measures

The primary outcome measure in this study is the proportion of infants receiving birth dose hepatitis B vaccination before 12 hours and 24 hours of life. Process



Key Driver Diagram

measures included documentation of immunization consent in the EMR and an immunization checklist in residents' sign-out. We collected demographic data on all the infants admitted to NICU, which included admission, discharge dates, gestational age, birth weight, and age at immunization. Data from these infants were entered into a protected, secure database. The QI team monitored for balancing measures, which included tracking any adverse events following immunization, such as fever, increased apnea, bradycardia, or desaturation events, as well as the rate of inappropriate immunizations, such as administering vaccines to infants with a birth weight less than 2000g or errors related to inadvertent repeat immunization.

Analysis

The data on the time of NICU admission and hepatitis B vaccine administration for all infants with a birth weight greater than or equal to 2000g was recorded. We plotted the monthly data on P-charts in the statistical process control (SPC) method. Control limits were established as three SDs above and below the mean to aid in identifying special cause variation.

Ethical Considerations

The institutional review board reviewed and approved the study protocol as a quality initiative measure.

RESULTS

During the baseline data collection period from May 1, 2019, to April 30, 2020, there were 606 admissions, including 403 neonates weighing more than 2000 grams. The proportion of infants who received HBV before 12 hours of life and within 24 hours of life was 24% and 31%, which was low compared with the national estimated birth dose vaccination rate of over 70%. Over 19 months, from July 2020 to January 2022, 540 neonates weighing more than 2000g at birth were enrolled in the QI project.

After the first PDSA cycle, the SPC chart displayed a consecutive run of eight data points above the preintervention baseline centerline for both the <12 hours and <24 hours birth dose HBV. This resulted in the recalculation of the mean as 56% for <12 hours HBV and 64% for <24 hours HBV, indicating a shift in the center line of the SPC chart (Figs. 4 and 5). The observed special cause variation was likely due to implemented interventions, such as healthcare providers' education and EMR reminders.

Despite experiencing four consecutive data points below the new central line during the third PDSA cycle, we were able to sustain the improvement of the birth dose HBV rate during the fourth PDSA cycle. The interventions implemented in the fourth cycle, including posters and standardized scripts for obtaining consent, along with

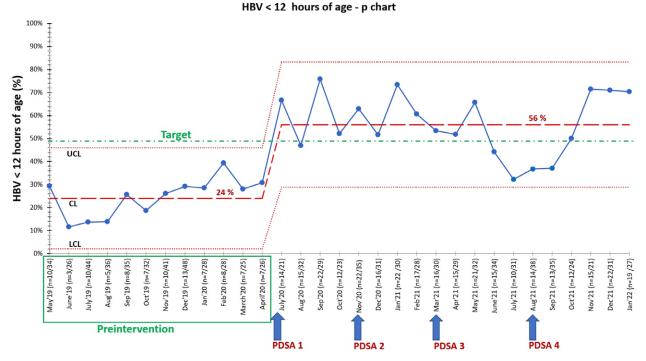


Fig. 4. Statistical process P-chart of the percentage of infants receiving birth dose HBV within 12 hours of life. LCL, lower control limit; UCL, upper control limit; CL, central line.

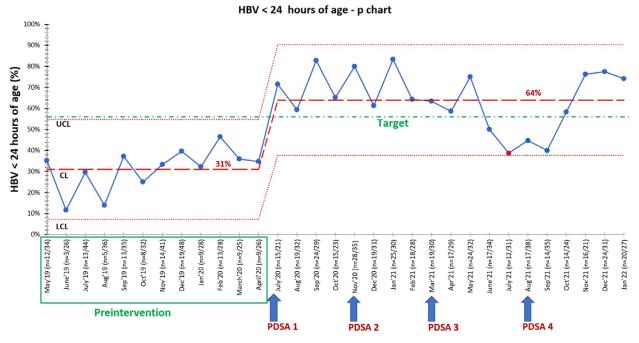


Fig. 5. Statistical Process P-chart of the percentage of infants receiving Birth dose HBV within 24 hours of life. LCL, lower control limit; UCL, upper control limit; CL, central line.

continuing previous interventions, played a vital role in sustaining the improvement. After our four PDSA cycles with multiple QI interventions, the proportion of infants receiving birth dose HBV in less than 12 hours and within 24 hours has increased to 56% and 64%, respectively, exceeding the target set for this QI project. We successfully achieved our target of increasing the birth dose HBV rate by 25% above baseline by implementing various interventions, including multidisciplinary collaboration, EMR reminders, posters, and provider and staff education. During our QI project, we also monitored the rate of parental refusal of the birth-dose HBV vaccine. Throughout the QI project, the rate of parental refusal for the birth-dose HBV vaccine exhibited no significant variation and remained steady at around 1%–2%.

During the monitoring period, the QI team diligently monitored the balancing measures, including tracking any adverse events following immunization and the rate of inappropriate immunizations, such as administering vaccines to infants with a birth weight of less than 2000g or errors related to inadvertent repeat immunization. After the administration of the first dose of hepatitis B immunization during the QI period, there were no reports of fever, increased apnea, bradycardia, or desaturation events. Additionally, there were no errors related to inadvertent repeat immunization or administering vaccines to infants with a birth weight of less than 2000g.

DISCUSSION

A quality improvement project by Nemerofsky et al, a Level 3 NICU, showed a sustained improvement in the HBV birth dose administration within 12 hours as per NYDOH recommendations from 13% to more than 65%.12 Immunization is often delayed in late preterm infants due to a lack of knowledge about the safety and effectiveness of vaccines and fear of adverse events.¹³⁻¹⁸ Before implementing the QI initiative, newborns with a birth weight of 2000 grams or more who were admitted to our NICU received the HBV immunization before being discharged or at 1 month of age without necessarily receiving it within the first 12 or 24 hours of life. Our QI project sought to increase the birth dose HBV immunization rates for eligible infants in our tertiary level 4 NICU. However, one significant hurdle we encountered was obtaining vaccine consent due to the unavailability of parents in the NICU. This was particularly challenging because our unit allowed only physicians, residents, or practitioners to get immunization consent, making nurses uncomfortable obtaining it.

Assembling multidisciplinary stakeholders and following the IHI model of PDSA cycles helped us achieve our target. Initial PDSA cycles focused on identifying barriers to immunization by constructing the Ishikawa diagram, focusing on provider education and nursing awareness of the timing of administration of birth dose HBV. Through these efforts, we achieved the desired central line shift of over 25% from the baseline. Subsequent PDSA cycles aimed to maintain this improvement by making changes to our immunization policy, specifically by empowering nurses to take an active role in obtaining parental consent for the birth dose HBV.

From June to August 2021, there was a decline in immunization rates for three consecutive months. The QI team investigated the reasons for this delay in immunization. Contributing factors included the surge of the SARS Cov-2 pandemic in New York state, which may have disrupted routine healthcare delivery. Another significant barrier was the responsibility of nurses in obtaining parental consent for immunization, which may have been challenging to navigate given the circumstances. Additionally, the presence of new residents and fellows in July 2021 may have also contributed to declining immunization rates. To address the challenge of obtaining parental consent for the birth dose HBV immunization, we made changes to our immunization policy that aimed to empower nurses to play a more active role in this process. Published data9,12,19,20 corroborates this approach in achieving success. As part of these interventions, nurses were educated and encouraged to take the initiative to obtain parental consent within 12 hours before the end of their shift. In cases where the parent could not be reached, nurses were instructed to inform the physician team members of the situation. We also introduced a standard script in the fourth PDSA cycle, which was effective in the QI initiative published by Bradshaw et al.¹⁷ Another successful strategy our team found helpful was printing posters on the universal birth-dose hepatitis vaccination algorithm. After PDSA cycles 3 and 4 interventions, the HBV immunization rates improved significantly and were sustained.

The intervention we implemented faced certain challenges and limitations. Even though late preterm infants with a birth weight over 2000 g were eligible for the birth dose Hep B immunization, there was still some hesitancy among providers, nurses, and parents. Moreover, administering the birth dose of HBV was not always considered a priority, especially in cases where the infant required respiratory support. To address these challenges, we have been working to foster a culture change among providers. It should also be noted that a small percentage (approximately 2%) of parents in our study population refused the HBV birth dose immunization and preferred to have it administered by their primary care pediatrician. Despite this, we did not exclude these infants from the study.

The implementation of multilevel and multidisciplinary interventions significantly enhanced the birth dose HBV rate in our level 4 NICU. Our QI project has a few limitations, including being conducted in a single NICU, which may limit generalizability, and not evaluating the longterm impact of interventions on HBV birth dose rates.

To sustain the achieved improvements, we devised a plan that includes provider education, nursing education, and the continued implementation of our nurse-driven intervention for obtaining vaccine consent. Additionally, we plan to modify the hepatitis B order set in our EMR to ensure the vaccine is administered within 12 hours of life. The ultimate goal is to increase the immunization rate beyond 70%. Looking toward the future, we plan to expand our efforts to include other types of vaccinations and continue educating our staff on the importance of timely and appropriate immunizations. We also hope to collaborate with other hospitals and healthcare systems to share best practices and improve immunization rates more broadly.

CONCLUSIONS

Using the QI methodology, we identified barriers to birth dose HBV immunization in our NICU. Multidisciplinary collaboration, EMR reminders, posters and provider, and staff education, are effective in improving the immunization rates in a timely manner of infants admitted to NICU. This improvement has been sustained over the past few months. The interventions we applied can serve as a standard model for other nurseries to improve their immunization rates. However, we recognize the need to address vaccine hesitancy among parents who refuse the HBV vaccine at birth. Future efforts will focus on developing strategies to address this issue and ensure that all eligible infants receive the recommended immunizations.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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