Individual QI projects from single institutions

Improving On-time Administration of the Initial Hepatitis B Vaccine in the NICU

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Abstract

Introduction: Despite the updated American Academy of Pediatrics recommendation for universal administration of the hepatitis B vaccine for newborns, delays in routine prophylaxis are common in the Neonatal Intensive Care Unit (NICU). Delayed immunization can increase perinatal acquisition risks and lead to subsequent delays in routine childhood immunization. This study aimed to increase the on-time administration of the birth dose of the hepatitis B vaccine from 46% to ≥70% at a level III and level IV NICU within the same health system. **Methods:** The stakeholder group developed project interventions using quality improvement methods, including implementing unit guidelines and a prompt in the progress note template. The outcome measure was the percent on-time administration of the initial hepatitis B vaccine for inborn NICU patients born to hepatitis B-negative mothers. The process measure was the percent on-time administration or a valid reason to delay immunization following the guidelines. Statistical process control P-charts graphically represented the measures to assess for change from January 2019 to May 2021. **Results:** In total, 2192 patients were included. The percent on-time administration improved from 48% to 57%. The percentage of on-time administration or valid reason to delay increased from 76% to 80%. **Conclusions:** Quality improvement methodology facilitated the identification of barriers to on-time hepatitis B prophylaxis in the NICU and the improvement of the timeliness of administration across 2 sites. Guidelines tailored to this population and changes to the progress note template successfully created and sustained change and may benefit other NICUs. *(Pediatr Qual Saf 2023;8:e658; doi: 10.1097/pq9.0000000000000658; Published online June 7, 2023.)*

INTRODUCTION

The American Academy of Pediatrics (AAP) guidelines for universal administration of the birth dose of the hepatitis B vaccine[1] are important for preventing the perinatal transmission of hepatitis B. Because the vaccine acts as a safety net for misinterpretation and/or false negative maternal laboratory results, delayed immunization can increase risks for perinatal acquisition. Since the release of the 2017 guidelines, many units have demonstrated improvement in the rates of healthy newborns receiving the birth dose of the hepatitis B vaccine.[2,3] However, some units struggle to achieve on-time administration, potentially related to system processes, provider opinion, and/or parental preference or refusal.[4–7] Newborns admitted to neonatal intensive care units (NICUs) are at risk for immunization delays.[8,9] These delays occur for infants born prematurely and term infants admitted with congenital anomalies or other problems.[10] Although guidance exists for administering routine immunizations for preterm infants,[11] in practice, there continues to be high variability of the timing of routine immunization. Given that the birth dose of the hepatitis B vaccine can contribute to delays in subsequent immunization schedules,[12] and that the hepatitis B vaccine is generally well tolerated,[13] it is important to optimize the on-time administration for NICU infants.

At the level III and level IV NICUs of this health system, there are practice variations and delays in the routine administration of the initial hepatitis B vaccine. The primary aim of this project was to increase the percent on-time administration of the birth dose of the hepatitis B vaccine from a baseline of 46% to greater than or equal to 70% by December 2020. The secondary aim was to identify why infants did not receive this immunization on time.

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Preliminary data were presented at Pediatric Pharmacy Association Annual Meetings in 2020 and 2021, 2020 Vermont Oxford Network Quality Improvement Congress, 2023 Pediatric Academic Societies, and 2023 Academic Pediatric Association Quality Improvement Congress.

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METHODS

This project occurred in a level III and level IV NICU from the same health system in a mid-Atlantic city. Provider staffing consists of resident physicians (only at the level IV NICU), fellows, neonatal nurse practitioners, and attending neonatologists. The fellows and attendings, and some of the neonatal nurse practitioners, rotate to both locations. In addition, support staff, including NICU clinical pharmacy specialists, are also present at both sites. The units use the same NICU-specific order sets in the electronic health record (EHR) (Epic Hyperspace, Epic Systems Corporation, Verona, Wis.).

The roles and responsibilities in the vaccine administration process are outlined in separate but similar hospital policies. The provider (resident physician or nurse practitioner) or the bedside nurse (at the level III unit) prints the vaccine administration authorization form and obtains authorization from the parent or guardian. Although this is labeled as a consent form, it is a signed confirmation that the parent received a copy of the Centers for Disease Control vaccine information statement. The status of form completion is often discussed during rounds, especially for patients >2 kg overdue for the vaccine or patients <2 kg approaching the day of life (DOL) 30. A NICU clinical pharmacy specialist is present for weekday rounds to review medications, review if the patient will soon be due or is overdue for immunizations, and provide reminders to the team. They use a pharmacy handoff tab in the EHR to track vaccination due dates. A nursing leader also provides reminders during rounds on various days using a binder to keep track of health maintenance items. The provider places the order using the NICU vaccine order set. The bedside nurse ensures the presence of the signed vaccine authorization before administering the vaccine—the record of vaccination shows in the medication administration record in the EHR.

Baseline data and observations showed that the treatment of infants born to hepatitis B surface antigen (HBsAg)-positive or unknown mothers was consistent with the timing recommended by the AAP guidelines. However, delays in routine prophylaxis for infants born to HBsAg-negative mothers were common.

INTERVENTIONS

Phase 1 (May 2019–October 2019)

In May 2019, project leaders formed a stakeholder group consisting of a neonatologist, a clinical pharmacy specialist, a student pharmacist, two neonatal nurse practitioners, local nursing leaders, and a third-year resident who planned to transition to a NICU fellowship at the institution. First, analysis via retrospective and prospective chart review of data from January 2019 to October 2019 established the baseline rates. Then, in a series of meetings, the group studied the problem, constructed a Specific, Measurable, Applicable, Realistic, and Timely (SMART) aim, and identified key drivers for improvement (Fig. 1): addressing knowledge gaps, remembering to immunize, defining patient stability for vaccination, consent issues, and unit awareness of the current problem.

The stakeholder group developed guidelines based on a literature review and expert opinion from pediatric hospital specialists (summarized in Table 1). The guidelines outlined the recommended timing for administration based on birth weight, created a consensus of exclusions for medical stability for vaccine readiness, reviewed scenarios for caution but not absolute contraindication to intramuscular vaccines, reviewed possible adverse events related to vaccine administration, and recommended continued reassessment of patient stability for vaccination until 5–6 weeks of age. For example, because 4 weeks are needed between hepatitis B vaccine administrations, if a patient has not received the vaccine by 6 weeks of age, it may be better to give the first dose with the 2-month vaccines to avoid delaying the administration of the two-month series. Medical directors of each NICU approved the guidelines.

In October 2019, the group added the vaccine authorization form to the admission packet so that providers would no longer have to print the patient-specific form before obtaining consent. A conference presentation to all pediatric residents reviewed recommended vaccine schedules, discussed the problems associated with delayed immunizations for NICU patients, and distributed the new guidelines. The group emailed the guidelines to all pediatric residents, neonatal nurse practitioners, fellows, and attending neonatologists at both NICUs. Furthermore, the team distributed laminated copies of the guidelines to provider workrooms and added them to the binders carried by nurse leaders and clinical pharmacy specialists during bedside rounds. The guidelines became effective on October 22, 2019.

Phase 2 (November 2019–October 2020)

To support the implementation of the guidelines, nurse leaders and clinical pharmacy specialists utilized the guidelines during multidisciplinary rounds to promote timely vaccination. If a patient had an exclusion to on-time vaccination aligned with the guidelines, they referenced the guidelines to determine when they no longer met exclusion criteria. For example, if a patient did not receive the vaccine due to thrombocytopenia, the pharmacist or nurse leader would advocate readiness for vaccination when the platelets increased above the threshold.

The stakeholder group reviewed data, identified the next steps for improvement, and developed an addition to the NICU daily progress note template in the EHR. Attendings, fellows, or resident physicians write the daily progress notes using the same template. In addition, the group added a SmartList to the NICU daily progress note template. Using the SmartList, the provider makes a series of choices based on the patient's birth weight and maternal hepatitis B status, guiding the provider to select the proper time of vaccine administration. For example, for a patient with a birth weight of 1800 g born to a hepatitis B-negative mother, the

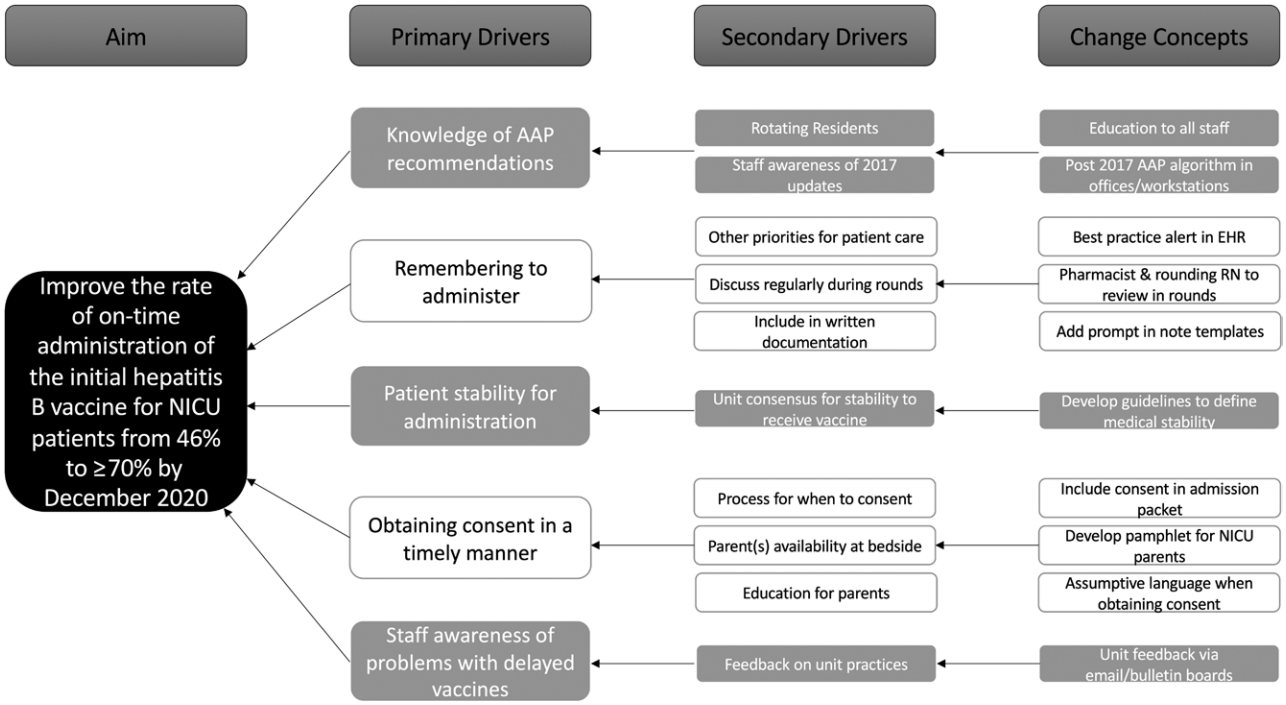

Fig. 1. Key driver diagram. RN: registered nurse.

provider would select "BW < 2 kg," then select "Mother HepB sAg NEGATIVE; AAP recommends medically stable infants receive the Hep B vaccine at DOL30 or discharge, whichever is sooner." This quotation is automatically inserted into the note and remains for subsequent daily progress notes unless manually deleted by future authors. In addition, the team designed the note template to automatically display the name and date of any vaccine administrations received. It also prompts the provider to select listed reasons why immunizations have not been received, such as "No Consent Obtained," "Parental refusal," "Unstable," or free text. Implementation of the new progress note in the EHR occurred on October 3, 2020.

Phase 3 (November 2020–May 2021)

Routine stakeholder group meetings monitored data and progress. The group reviewed charts for patients who did not receive the immunization on time to identify reasons for exclusion from on-time immunization according to the unit guidelines.

The team communicated site-specific monthly updates to staff throughout the project via electronic newsletters. In addition, data were shared with unit leadership every 1–3 months at site-specific unit-based multidisciplinary process improvement meetings.

STUDY OF THE INTERVENTIONS

Inclusion criteria included inborn infants born to HepBsAg-negative mothers admitted to each NICU between January 2019 and May 2021. Team members retrospectively collected hepatitis B vaccine administration data and demographic data from a pre-existing NICU database. Furthermore, the team abstracted other relevant clinical data from the EHR. Exclusion criteria included patients who transferred out of the NICU or died before or on DOL 1 for those with a birth weight ≥2 kg or DOL 30 for those with a birth weight <2 kg. DOL 0 is the calendar day of birth, and DOL 1 describes the next calendar day. For infants born from October 2019 to December 2020 who did not receive the hepatitis B vaccine on time, the team performed an EHR review to determine whether valid exclusions to on-time vaccination were present according to the clinical guidelines. This interval spanned the months of active interventions to help determine whether patients experienced vaccine delays due to medical instability or other reasons.

The outcome measure was the percent on-time administration for the initial hepatitis B vaccine, defined as administration within DOL 1 for infants with a birth weight ≥2 kg and within the first 30 days of life for those with birth weight <2 kg (to capture administrations on DOL 30 or day of discharge, whichever occurred sooner). The percentage of newborns who received the hepatitis B vaccine during birth hospitalization was an additional outcome measure. The process measure was the percent on-time administration or valid exclusion from timely vaccination following the unit guidelines from November 2019 to May 2021 during the intervention phase.

The measures were tracked using statistical process control (SPC) P-charts (QI Macros; KnowWare International, Inc, Denver, Colo.), and we applied Montgomery standard rules of special cause variation.[14] The team created SPC charts using data from all patients from both sites and

Table 1. Guidelines for Hepatitis B Prophylaxis for NICU Patients

Birth Weight ≥2 kg
Immunize within the first 24 h of life to those who are medically stable[1]
Exclusions:
• Hypoxic-ischemic encephalopathy requiring therapeutic hypothermia
• Congenital anomaly which may require emergent surgery in first 24 h of life
• Requiring mechanical ventilation
Birth Weight <2 kg
Immunize at 1 mo of age or at hospital discharge, whichever occurs first, to those who are medically stable[1,11]
Exclusions:
• Pulmonary hypertensive crisis requiring inhaled nitric oxide[9]
• Current administration of corticosteroid doses greater than physiologic dosing*
• Positive blood culture result, or if within 48 h of a sepsis evaluation[9]
• If within 5 d of a surgical procedure[9]
General exclusions (all weights):
• Cardiorespiratory instability (vasopressor/acute cardiac medication use or FiO_2 > 0.5)
• Thrombocytopenia (platelets < 100K)
• Known comfort care designation
• Parental refusal
• If not medically stable to receive at the recommended time, continue to reassess stability until 5–6 wk of age. Beyond then, it is better to give the 1st dose with the 2-mo vaccines so that the 2-mo vaccine series does not need to be delayed. Note: 4 wk are needed between hepatitis B vaccine dose #1 and dose #2
Cautions (not contraindications):
• Stable anticoagulation on enoxaparin or heparin with normal platelet count
• Use of medications that affect platelet function (aspirin, clopidogrel, indomethacin)

FiO_2: fractional inspired oxygen concentration.
*Supraphysiologic dosing defined as greater than 8 mg/m^2/day of hydrocortisone.

separate SPC charts to track outcomes for infants from each birth weight category for each NICU to follow emerging trends. Analysis of data not tracked on SPC charts was by descriptive statistics. The institutional review board deemed this to be a quality improvement project that did not require institutional review board review or oversight.

RESULTS

Two thousand one hundred ninety-two patients were included. For the percent overall on-time immunization administration, the SPC chart centerline representing the mean shifted in August 2020 from 47.6% to 56.7% and demonstrated sustainability (Fig. 2A). For the percent on-time administration or valid exclusion to receive the vaccine at the recommended time according to the unit guidelines (Fig. 2B), the centerline shifted from 75.6% to 79.9% in July 2020 and demonstrated sustainability. There was a decline in October 2020, but it recovered with implementing the progress note prompt in October 2020, and the rates were sustained for 7 months.

SPC charts generated for the percent on-time immunization or valid reason to delay immunization at the individual NICUs in the intervention phase demonstrated stability at 75.2% at the level IV NICU (**see figure, Supplemental Digital Content 1A**, which shows percent on-time immunization or valid delayed immunization in the level IV NICU, **http://links.lww.com/PQ9/A486**) and an upward center line shift from 85.4% to 91.4% at the level III NICU (**see figure, Supplemental Digital Content 1B,** which shows percent on-time immunization or valid delayed immunization in the level III NICU, **http://links.lww.com/PQ9/A490**). When tracked by birth weight categories, SPC charts demonstrated stability for patients with birth weight <2 kg at 86.1% (**see figure, Supplemental Digital Content 2A,** which shows percent on-time immunization or valid delayed immunization for patients with birth weight < 2kg, **http://links.lww.com/PQ9/A487**) and 75.9% for birth weight ≥2 kg (**see figure, Supplemental Digital Content 2B,** which shows percent on-time immunization or valid delayed immunization for patients with birth weight greater than or equal to 2 kg, **http://links.lww.com/PQ9/A488**). The most common reasons patients with birth weight < 2 kg did not receive the vaccine by DOL 30 per unit guidelines included FiO_2 > 0.5, recent sepsis evaluation, and supraphysiologic corticosteroid use (Table 2). The most common reasons patients ≥2 kg did not receive the hepatitis B vaccine within DOL 1 according to unit guidelines included requiring FiO_2 > 0.5 or mechanical ventilation, use of vasoactive medications, and congenital anomalies with anticipated surgery within the first DOL (Table 2). Although not an exclusion per the guidelines, the most common reason infants with a birth weight ≥2 kg did not receive the vaccine on time was antibiotic use on the first DOL.

The percentage of patients who received the hepatitis B vaccine at any time during the birth hospitalization experienced a downward centerline shift from 95.3% to 93.5% in August 2019 in the pre-implementation period, followed by an upward centerline shift to 95.7% in February 2020, and slight upward shift to 95.9% in May 2020 (**see figure, Supplemental Digital Content 3A,** which shows the percentage of patients who received the initial dose of the hepatitis B vaccine during the birth hospitalization, **http://links.lww.com/PQ9/A491**). The percentage at the level IV NICU showed a downward center line shift from 95.1% to 90.7% in August 2019, up to 94.8% in January 2020, then slightly up to 95.2% in May 2020 (**see figure, Supplemental Digital Content**

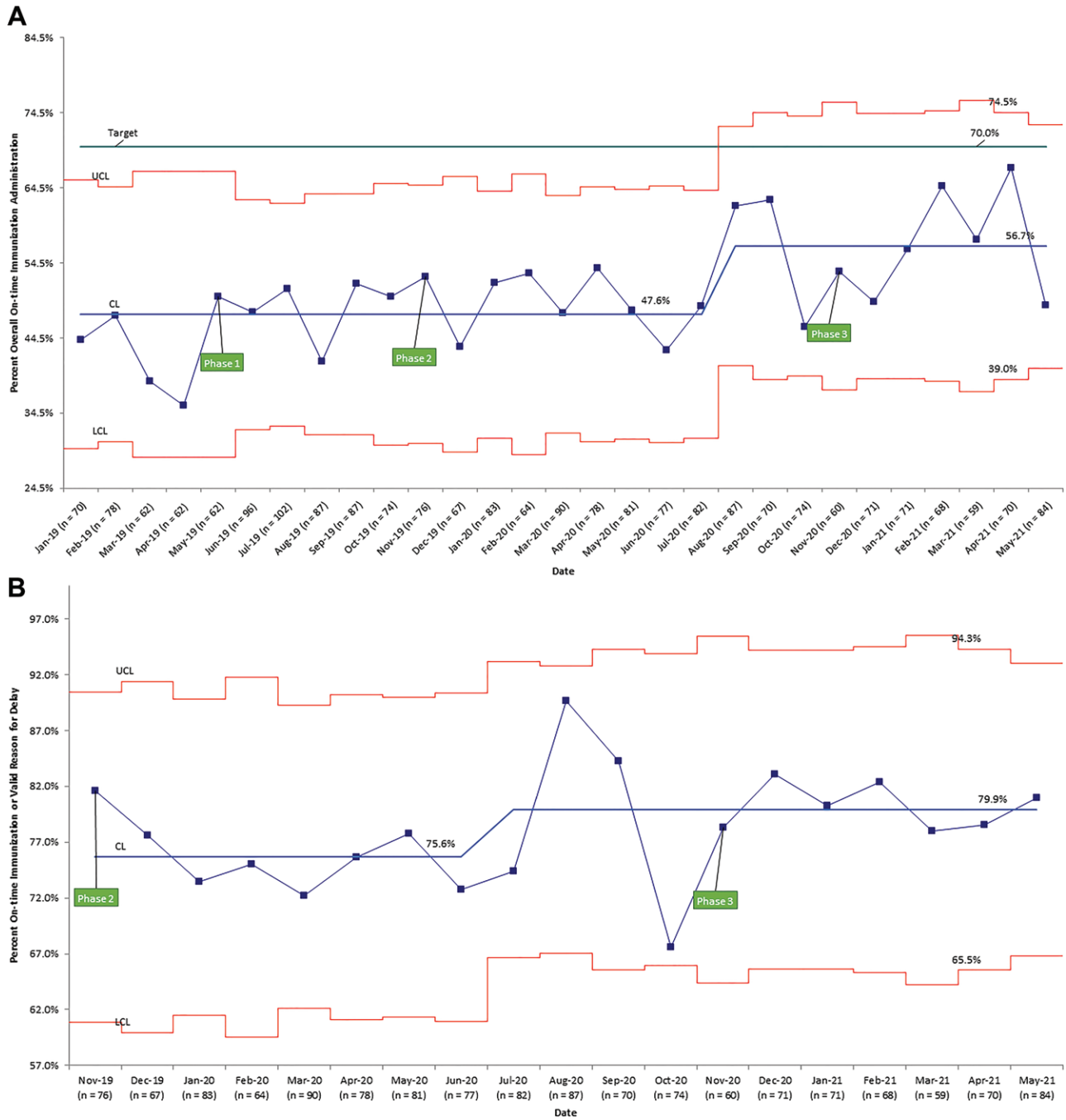

Fig. 2. Percent on-time hepatitis B immunization. SPC P-chart for percent overall on-time immunization administration (A) and percent on-time immunization or valid reason for the delay (B). CL: center line, LCL: lower control limit, UCL: upper control limit. Phase 1: Stakeholder group formation, baseline data analysis, unit guideline development and implementation, vaccine administration authorization added to admission packet. Phase 2: Development and implementation of updated progress note template. Phase 3: Chart review of patients who did not receive the vaccine on time to identify reasons for exclusion from on-time immunization.

3B, which shows percentage of patients who received the initial hepatitis B vaccine during birth hospitalization at the level IV NICU, **http://links.lww.com/PQ9/A489**). The level III NICU maintained a steady percentage of 97.6% (**see figure, Supplemental Digital Content 3C,** which shows percentage of patients who received the initial hepatitis B vaccine during birth hospitalization at the level III NICU, **http://links.lww.com/PQ9/A492**).

DISCUSSION

In this project, a multidisciplinary quality improvement team improved the timeliness of hepatitis B prophylaxis for patients in level III and IV NICUs. Although there are many published projects on improving the administration of hepatitis B prophylaxis in healthy newborns, this is the first project to our knowledge that targeted newborns receiving higher-level NICU care.

Table 2. Reasons Patients (with Birth Weight <2 Kg or ≥2 Kg) Did Not Receive Immunization on Time, in Accordance with the Unit Guidelines

Patients with Birth Weight <2 Kg who Did Not Receive Vaccine on Time	**Level III NICU (N = 4), n (%)**	**Level IV NICU (N = 99), n (%**	**Total (N = 103), n (%)**
Patients with valid reasons to delay	1 (25)	53 (53.54)	54 (52.43)
Patients without valid reasons to delay	3 (75)	46 (46.46)	49 (47.57)
Reasons patients were excluded from on-time immunization*			
Vasoactive medication use	0 (0)	7 (7.07)	7 (6.8)
FiO_2 > 0.5	0 (0)	31 (31.31)	31 (30.1)
Greater than physiologic steroid dose	0 (0)	24 (24.24)	24 (23.3)
Thrombocytopenia	0 (0)	1 (1.01)	1 (0.97)
Positive blood culture or <48 h from sepsis evaluation	0 (0)	31 (31.31)	31 (30.1)
Within 5 d of surgical procedure	0 (0)	3 (3.03)	3 (2.91)
Comfort care	0 (0)	1 (1.01)	1 (0.97)
Parental refusal	1 (25)	1 (1.01)	2 (1.94)
Cautions and precautions			
Stable anticoagulation with normal platelets	0 (0)	1 (1.01)	1 (0.97)
Antiplatelet medication use	0 (0)	0 (0)	0 (0)
Patients with Birth Weight ≥2 Kg who Did Not Receive Vaccine on Time	**Level III NICU (n = 69), N (%)**	**Level IV NICU (n = 384), N (%)**	**Total (n = 453), N (%)**
Patients with valid reasons to delay	22 (31.88)	180 (46.86)	202 (44.59)
Patients without valid reasons to delay	47 (68.12)	204 (53.13)	251 (55.4)
Reasons patients were excluded from on-time immunization*			
Vasoactive medication use	5 (7.25)	60 (15.62)	65 (14.35)
FiO_2 > 0.5 or mechanical ventilation	11 (15.94)	141 (36.72)	152 (33.55)
Hypoxic-ischemic encephalopthy requiring hypothermia	0 (0)	35 (9.11)	35 (7.73)
Thrombocytopenia	2 (2.9)	18 (4.68)	20 (4.42)
Congenital anomaly requiring surgery within 24 h of life	0 (0)	56 (14.58)	56 (12.36)
Comfort care	0 (0)	4 (1.04)	4 (0.88)
Parental refusal	7 (10.14)	21 (5.47)	28 (6.18)
Cautions and precautions			
kg	0 (0)	2 (0.52)	2 (0.44)
Antiplatelet medication use	0 (0)	0 (0)	0 (0)
Other			
Antibiotic use day of life 0-1	55 (79.7)	248 (64.58)	303 (66.89)

*Some patients with delayed or no immunization had more than one reason identified.

The baseline percentage for on-time vaccination was similar to those reported in other studies highlighting the delays to routine immunizations in NICUs.[8,9] The guidelines developed by the project team incorporated recommendations for routine vaccination for medically stable preterm infants but also provided additional evidence-based recommendations that helped to provide consistency for factors cited by providers for delaying immunizations (eg, level of respiratory support or steroid use). Milet et al experienced a similar improvement in two-month vaccination rates by implementing guidelines specific to patients with bronchopulmonary dysplasia.[9]

The clinical pharmacy specialists were imperative for implementing the clinical guidelines due to their diligent review of patient readiness for vaccination during bedside rounds. Likely, some hospitals may not have this role in their NICU; however, it is possible this role could be championed by other dedicated NICU staff knowledgeable about neonatal vaccinations.

As on-time percentages decreased slightly one year after the implementation of the guidelines, a system-level change with the addition of the prompt in the progress note template helped to increase and maintain the percent on-time administration or valid delay for the vaccine. EHRs contain many effective tools for improving consistency in clinical care, such as note templates, best practice alerts, and order sets.[15] Because the EHR at these centers already utilizes an immunization order set and there were concerns about BPA alert fatigue, the team chose to update the progress note template. Unfortunately, the older version remained available when the new template went into the EHR. In the future, the team will pursue deletion of the original note template to ensure the new version's use and may consider adding the prompt to the history and physical template.

This study has several strengths, including the multidisciplinary project team and the ability to implement interventions across two NICU sites of different levels. This

approach allowed the incorporation of patients of varying acuity, demonstrating the interventions' applicability in heterogeneous NICU populations. The team anticipated that using interventions across both sites would make it easier for providers to prescribe consistently. However, some implementation efforts may have been more effective if individualized to each unit.

The team tailored the clinical guidelines for this project to address common problems encountered by the NICU population. Although there was only a modest improvement in the overall percent on-time immunization administration, uptake of the guidelines facilitated a consensus for the definition of medical readiness for vaccination. Informal staff feedback also revealed a perceived decrease in the variability of prescribing practices. In the future, incorporating the guidelines into the EHR as a decision support tool may help to maximize use.

This study has several limitations. First, although the overall percent on-time administration demonstrated an upward centerline shift in the desired direction, it did not reach the goal of 70%. However, the team felt that following the percent on-time administration or valid exclusion to delay vaccination according to the clinical guidelines provided insight into the medical stability of the patient population and adherence to the guidelines. Although the data for valid exclusions to delay immunization were unavailable for patients from the pre-implementation period, when the team followed the percent on-time immunization or valid reason to delay immunization in the implementation period, the units demonstrated a sustained improvement to 80%. Finally, after reviewing why patients did not receive the immunization on time, it was interesting to note the high percentage of patients with a 2 kg or more birth weight who experienced early antibiotic use. Current evidence is insufficient to either include early antibiotic use in the more than 2 kg population as an exclusion in the clinical guidelines or to support the development of a new intervention to promote on-time vaccination for these patients. This evidence will need future clarification given the general frequency with which newborns undergo early onset sepsis rule-outs.

Although NICU infants with delayed immunizations are at risk for continued delays in childhood immunizations, future studies should evaluate whether interventions targeted to improve the timeliness of initial doses of routine immunizations in the NICU lead to improvements in the timeliness of future childhood vaccines.

CONCLUDING SUMMARY

This study used quality improvement methods to build a multidisciplinary team to identify barriers to on-time hepatitis B prophylaxis in the NICU and improve the timeliness of administration across two sites. In addition, implementing clinical guidelines tailored to this patient population and a prompt in the EHR progress note template successfully created and sustained change and may benefit other NICUs.

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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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