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Decreasing Intubation for Ineffective Ventilation after Birth for Very Low Birth Weight Neonates

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Abstract

Introduction: Despite recommendations promoting noninvasive delivery room (DR) ventilation, local historical preterm DR noninvasive ventilation rates were low (50%–64%). Project aims were to improve DR noninvasive ventilation rate in very low birth weight (VLBW) neonates (<1500g) with a focus on decreasing DR intubations for ineffective positive pressure ventilation (PPV). **Methods:** We addressed drivers for improving noninvasive ventilation and decreasing intubations for ineffective PPV through plan-do-study-act cycles. Outcome measures were intubation for ineffective PPV (defined as intubation for heart rate <100 despite ongoing PPV) and final respiratory support in the DR. Our process measure was adherence to division-wide DR-intubation guidelines. Balancing measures were maximum FiO₂ and hypothermia. We analyzed data using statistical process control charts and special cause variation rules. **Results:** There were 139 DR intubations among 521 VLBW neonates between January 2015 and February 2020. The noninvasive ventilation rate upon intensive care nursery admission was higher than historically reported at 73% and sustained throughout the project. The intubation rate for ineffective PPV was 10% and did not change. The number of VLBW neonates between intubations for ineffective PPV increased from 6.1 to 8.0. Ten intubations did not comply with guidelines. Balancing measures were unaffected. **Conclusions:** Noninvasive ventilation rates were higher than historically reported and remained high. After plan-do-study-act cycles, the number of VLBW neonates between intubations for ineffective PPV increased without impacting balancing measures. Our data demonstrate that effective ventilation (heart rate > 100) using noninvasive support is possible in up to 90% of VLBW infants but requires ongoing PPV training. (*Pediatr Qual Saf 2022;7:e580; doi: 10.1097/pq9.0000000000000580; Published online August 1, 2022.*)

INTRODUCTION

Most extremely premature newborns require positive pressure ventilation (PPV) to

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rr transition from fluid-filled fetal to aerated neo-

natal lungs.¹⁻³ The Neonatal Resuscitation Program prioritizes establishing effective PPV in the initial steps of delivery room (DR) stabilization for apneic or bradycardic neonates.⁴ The American Academy of Pediatrics endorses using DR noninvasive respiratory support as an alternative to routine intubation to reduce the risk of bronchopulmonary dysplasia or death for extremely preterm infants.⁵⁻⁹

However, facemask PPV is technically challenging, and many preterm infants undergo DR intubation even when noninvasive respiratory support is prioritized.² In the Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT), 34% of neonates randomized to noninvasive support were intubated in the DR, and 95% of these intubations were for resuscitation within the first minutes after birth.² Reducing intubations during the transition after birth in preterm infants may prevent long-term respiratory morbidity associated with mechanical ventilation. Additionally, providing effective PPV to establish ex-utero hemodynamic stability before an invasive, high-risk procedure allows more controlled intubations and may prevent physiological deterioration.

In 2010, our Division of Neonatology developed a DR respiratory support consensus for preterm infants, emphasizing noninvasive support.¹⁰ Despite the consensus, the Vermont Oxford Network data demonstrated that local DR-intubation rates for very low birth weight (VLBW) infants (<1500g) remained high, ranging from 36% to 50% in 2012–2014, with 57% supported noninvasively upon intensive care nursery (ICN) admission (Supplemental Table 1, http://links.lww.com/PQ9/A389).

We initiated a quality improvement (QI) project entitled Improving Newborn Transition Respiratory Outcomes to address the disconnect between the literature, consensus, and local practices. Our goal was to improve DR noninvasive ventilatory support for VLBWs with a specific focus on decreasing intubations for ineffective PPV [defined as intubation for heart rate (HR) <100 despite ongoing PPV]. We had 2 Specific, Measurable, Attainable, Relevant, and Timely aims: (1) increase the proportion of VLBWs on noninvasive respiratory support upon ICN admission by 15% within 18 months from 57% to 66%, and (2) decrease the proportion of VLBWs intubated for ineffective PPV in the DR by 10% in 18 months.

METHODS

Rationale

This project evolved from the disconnect between the literature, consensus, and local practices. Our first aim was to increase noninvasive respiratory support for VLWBs upon ICN admission. We included the second aim of decreasing intubations for ineffective PPV because we hypothesized these would represent the majority of DR intubations (as observed in the SUPPORT trial).² Our local practice is to spend up to an hour stabilizing infants in a dedicated infant resuscitation room (IRR) before ICN admission (see Context); we felt focusing on intubations for ineffective PPV during immediate resuscitation would generalize to hospitals that spend limited time in the DR. Our second aim became a higher priority after our initial phase showed that rates of noninvasive respiratory support were higher than historically reported. Additionally, a review of intubation indications demonstrated the contribution of intubations due to ineffective PPV. We thus targeted project interventions toward strategies to improve PPV to optimize noninvasive ventilation.

Through our driver diagram, we identified key drivers for improvement of noninvasive ventilation and decreasing intubations for ineffective PPV: (1) perform effective facemask PPV to achieve a rise in HR for bradycardic infants at birth; (2) prioritize noninvasive support during stabilization; (3) obtain staff and faculty buy-in; and (4) improve communication during postnatal stabilization. We developed interventions to address these drivers (Fig. 1).

Context

The Hospital of the University of Pennsylvania is a level III academic delivery hospital with ~4200 deliveries/y, including ~120 VLBWs/y. High-risk neonates, including VLBWs, are delivered in the operating room and immediately brought to the adjoining IRR. We perform initial VLBW resuscitations with a T-piece device (NeoPuff, Fisher & Paykel Healthcare Inc, Irvine, CA) using an appropriately sized round mask (Fisher & Paykel Healthcare Inc, Irvine, CA). After initial stabilization, we transition neonates to a ventilator (Evita XL Ventilator, Drager Medical Inc, Telford, PA) for continued support. Noninvasive ventilator support is delivered through a nasal interface [Medicomp Infant Nasal continuous positive airway pressure (CPAP), Medicomp Inc, Princeton, MN]. Providers place umbilical lines and obtain a blood gas in the IRR. Patients remain in the IRR for up to 1 hour; they are intubated and given surfactant if they meet intubation criteria.

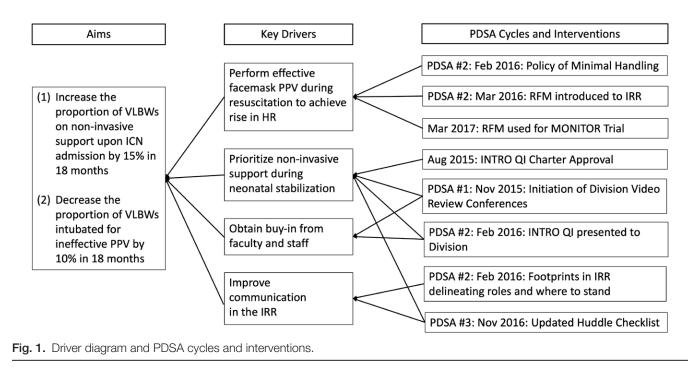
At least 6 providers staff high-risk resuscitations: a leader (attending or fellow), 2 medical providers (fellows, nurse practitioners, physician's assistants, or residents), 2 nurses, and 1 respiratory therapist. Before high-risk deliveries, the team huddles using a preresuscitation check-list.¹⁰ During the resuscitation, a dedicated recording nurse documents on a paper record in real time. High-risk deliveries are video recorded for QI purposes. Recordings include audio and three video feeds. These are synchronized and stored on a secure server using medical software (B-line Medical, Washington, DC). Per policy, videos are deleted after 28 days.

Interventions

We created a multidisciplinary team of stakeholders, including respiratory therapists, nurses, fellows, and attendings. After identifying drivers, we began plan-dostudy-act (PDSA) cycles to address these drivers (Fig. 1).

We performed PDSA ramps consisting of multiple cycles for each driver, as outlined below and in Figure 1. Many cycles addressed more than 1 driver. As our first PDSA cycle, we initiated video review conferences for the division in November 2015. We review high-risk delivery videos during conferences and discuss resuscitation decisions, including noninvasive ventilation techniques and timing and rationale for intubations. These sessions increase provider education and create an open culture of accountability and feedback. The initial review revealed too many providers handling the neonates, interfering with assessment and respiratory support, and delaying acquiring an electrocardiogram (ECG) signal. To address this, we instituted a minimal handling policy (no more than 2 providers with hands on the neonate simultaneously). Additionally, we asked providers to defer wrapping neonates in plastic until achieving a reliable ECG signal. Finally, to minimize handling and better delineate roles, we placed footprints surrounding the bed to optimize provider positioning.

The second PDSA cycle (February–March 2016) included changes described above, formally presenting Improving Newborn Transition Respiratory Outcomes QI to the division and introducing a respiratory function monitor (RFM) in the IRR. The RFM uses an in-line flow sensor between the T-piece and facemask to calculate pressure, tidal volumes, and leaks during PPV. We used



the RFM to record but not display information about DR PPV quality. Providers reviewed their performance and RFM recordings ad hoc after the resuscitation. As a third PDSA cycle, we added an intubation indication review to the preresuscitation checklist in November 2016.

Finally, though not conceived as a PDSA cycle, we began the Monitor Neonatal Resuscitation (MONITOR) trial enrollment in April 2017. Preterm infants in this trial were randomized to have their resuscitation performed with a visible versus masked RFM to determine whether a visible RFM increased the proportion of PPV inflations delivered within a target tidal volume range.¹¹ As part of the study start-up, we taught providers to interpret the RFM. We also instituted general PPV education, including hands-on practice and a review of corrective steps for establishing noninvasive ventilation.

Measures

A research coordinator extracted data through weekly reviews of videos, resuscitation records, and patient charts. One attending determined intubation indication and adherence to intubation guidelines through record review. We included only VLBWs resuscitated in the IRR without known congenital anomalies.

The outcomes were the highest respiratory support during DR resuscitation (invasive versus noninvasive) and intubation for ineffective PPV. We defined invasive support as a successfully placed endotracheal tube during the resuscitation, even if removed before ICN admission. Noninvasive support encompassed all other forms of respiratory support, including none. Neonates in whom intubation was attempted but not successful were classified as noninvasive. We defined intubation for ineffective PPV as intubation for a HR persistently less than 100 despite ongoing facemask PPV. Intubation was classified as ineffective PPV if performed for both ineffective PPV and other indications.

Our process measure was adherence to the 2010 DR intubation consensus guidelines as a proxy for prioritization of noninvasive support and staff/faculty buy-in. Intubation criteria included HR less than 100, carbon dioxide (CO₂) more than 65 mm Hg, FiO₂ more than 60% to maintain target saturations,⁴ apnea, or severe distress.¹⁰ Because our practice is to stay in the IRR for up to 1 hour after birth, these guidelines are specific to this environment. They may not reflect intubation indications after ICN admission. The 2010 DR intubation consensus guidelines did not change during this project.

We chose FiO_2 exposure and hypothermia as balancing measures as we did not want neonates inadvertently exposed to increased FiO_2 or hypothermia due to delaying plastic wrapping for reliable ECG signals. We operationalized FiO_2 exposure as maximum FiO_2 during resuscitation and hypothermia as ICN admission temperature <36.5°C.

Analysis

We interpreted data through statistical process control charts using QI Macros 2019 (KnowWare International, Inc., Denver, CO). We annotated statistical process control charts with PDSA cycles, interventions, and historical rates. We adjusted centerlines according to rules for special cause variation.¹² The article was written using the Standards for Quality Improvement Reporting Excellence 2.0 guidelines.¹³

Ethics

The University of Pennsylvania Institutional Review Board determined this project a QI initiative.

RESULTS

We collected data on all VLBWs resuscitated in the IRR without known anomalies from January 2015 to February 2020. The QI charter was approved in August 2015, with subsequent interventions implemented over time (Fig. 1).

Table 1 depicts patient characteristics. There were 521 eligible infants born during the project; 139 were intubated, among which 52 were intubated for ineffective PPV. For all control charts, baseline rates were calculated using the first 12 data points. In our baseline period, 73% of neonates were supported solely on noninvasive support, which did not change throughout the project (Fig. 2). The percentage of infants on noninvasive support was higher than the 2012-2014 historical rate (57%). A mean of 10% of neonates underwent intubation for ineffective PPV, which did not change (Fig. 3). With more than 25% of points on the extreme (zero) of the p-chart, we created a g-chart depicting the number of VLBWs between intubations for ineffective PPV (Fig. 4). The system was stable until a point of special cause above the statistical upper control limit in January 2018, when 55 VLBWs were resuscitated between intubations for ineffective PPV leading to a significant increase from 6.1 to 8.0 after our PDSA cycles. There was no change in the process measure as only 10 intubations (7.2%) did not adhere to intubation guidelines. Neither the average maximum FiO₂ (57.7%) nor the number of hypothermic neonates per 10 VLBWs (0.07) changed significantly. Four patients were missing maximum FiO₂ data, and 12 patients had no documented admission temperature as they died in the IRR or were transferred directly from the IRR to another hospital.

DISCUSSION

Our QI efforts modestly increased VLBWs between DR intubations for ineffective PPV. While we did not see a

Table 1. Patient Characteristics

Patient Characteristics	N = 521
Gestational age (wk), median (IQR)	28.3 (25.6–30.5)
Weight (g), median (IQR)	1030 (710–1299)
Male, n (%)	252 (48.4)
Antenatal steroids [*] , n (%)	452 (86.8) N = 519
Vaginal Delivery, n (%)	183 (35.1)
Respiratory Support ⁺ , n (%)	
None	30 (5.8)
CPAP	425 (81.6)
PPV	367 (70.4)
ETT for any indication [‡]	139 (26.7)
ETT for ineffective PPV [§]	52 (10)
Chest compression [¶] , n (%)	13 (2.5) N = 520
Epinephrine, n (%)	8 (1.5)

*Included both complete and incomplete antenatal steroid courses, 2 missing.

+Support given at any point during the resuscitation, can select multiple.
‡Defined as successful intubation for any indication, including ineffective PPV.

§Defined as successful intubation for HR <100 despite ongoing PPV. ¶One missing.

CPAP, continuous positive airway pressure; ETT, endotracheal tube.

change in the rate of noninvasive ventilation over time, we maintained a rate of 73% throughout our project, higher than the 2012–2014 historical rate of 57% and the 2014 rate of 64%. We did not observe changes in the balancing measures of maximum FiO_2 exposure or rates of hypothermia. Almost all intubations adhered to intubation guidelines.

Numerous single-center studies reported decreased rates of DR intubation after adopting early CPAP strategies for preterm neonates versus intubation for prophylactic surfactant.^{14–19} More recent publications, including RCTs, retrospective cohort studies, and QI projects, explored different ways to decrease DR intubation.^{20–28} These interventions include nasal interfaces, sustained inflation, establishing DR guidelines, and QI projects.^{20–28} To the best of our knowledge, this is the first study to target decreasing intubations for ineffective PPV and overall DR intubations.

We did not achieve our first aim of increasing the rate of noninvasive ventilation. Our high baseline rate (73%) for this endpoint, which is higher than reported in many QI projects for similar patient populations, may explain this failure.^{22,25,26} In those studies, noninvasive ventilation rates ranged from 43% to 57% and improved to 60%-67% after interventions.^{22,25,26} One QI project that improved the noninvasive ventilation rate from 77% to 95% included patients \leq 33 weeks and younger gestation, and only 55% were VLBWs.²¹

We hypothesize a combination of factors led to the high rate of noninvasive ventilation seen and maintained throughout the project. These key elements were: (1) a culture that supports/prioritizes noninvasive ventilation; (2) provider education and skill with noninvasive ventilation; and (3) proper preterm equipment. The intubation guidelines from the 2010 DR consensus laid the initial groundwork for a culture shift through standardization of intubation criteria and promotion of noninvasive ventilation.¹⁰ The gap between the 2010 consensus and improvement in noninvasive ventilation rates demonstrated that policy alone was not enough. Instead, improvement came after 2 additional changes, dedicated DR ventilation training, and preterm-specific equipment. We participated in the Sustained Aeration of Infant Lungs trial beginning in August 2014, which randomized initially apneic or bradycardic preterm infants to sustained inflation versus PPV as initial DR respiratory support.28 Trial training and education started immediately before launching our project. This training increased focus on establishing noninvasive ventilation and could have influenced PPV performance and use of noninvasive support. The higher noninvasive rates in 2014 compared with 2012-2013 support this possibility.

Additionally, in January 2015, we transitioned from larger masks not designed for preterm infants to round preterm masks for VLBW resuscitations, which could have improved the success of noninvasive ventilation before project initiation. However, the policy, appropriate

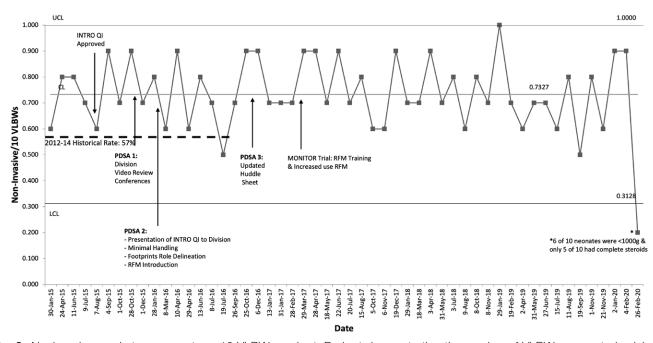


Fig. 2. Noninvasive respiratory support per 10 VLBWs p-chart. P-chart demonstrating the number of VLBWs supported solely on noninvasive respiratory support per block of 10 VLBWs. The dotted black line represents the local historical (2012–2014) noninvasive rate of 57%. CL indicates center line; LCL, lower control limit; UCL, upper control limit.

equipment, and training created the initial high noninvasive ventilation rates. We hypothesize that we could sustain this rate through continued reinforcement of the prioritization of noninvasive ventilation through video review, minimal handling, and further PPV education for the MONITOR trial. We observed an increase in VLBWs between intubations for ineffective PPV, suggesting fewer infants were intubated for failure to establish effective noninvasive PPV. We created a g-chart for this metric as more than 25% of the data points fell on the extreme (zero) of the p-chart. G-charts depict the number of events between

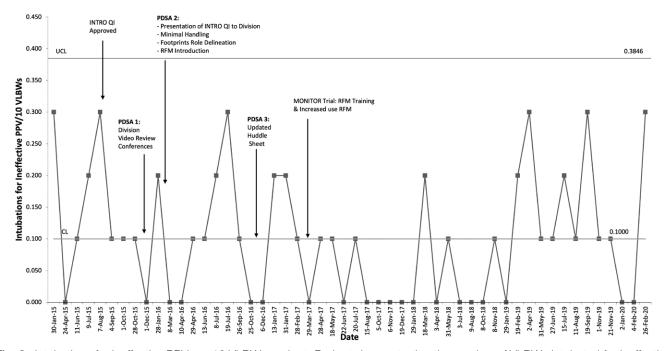


Fig. 3. Intubations for ineffective PPV per 10 VLBWs p-chart. P-chart demonstrating the number of VLBWs intubated for ineffective PPV per block 10 VLBWs. Ineffective PPV was defined as HR <100 despite ongoing PPV. CL indicates center line; UCL, upper control limit.

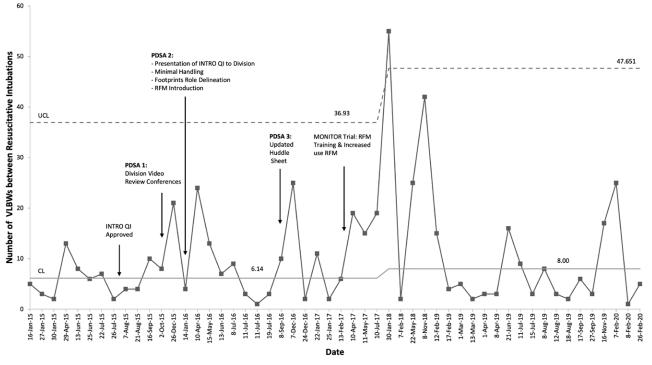


Fig. 4. Number of VLBWs between intubations for ineffective PPV g-chart. G-chart demonstrating the number of VLBWs between intubations for ineffective PPV. The centerline shifted due to the special cause rule of 1 point above the UCL. Ineffective PPV was defined as HR <100 despite ongoing PPV. CL indicates center line; UCL, upper control limit.

rare events and are a more sensitive method for detecting improvements in rare events.²⁹ Most studies did not differentiate intubations for ineffective PPV from other DR intubations, making it difficult to compare our data. In a single-center retrospective study comparing VLBW DR intubations before and after the introduction of nasal intermittent PPV, "emergency intubations" ranged from 24% to 56%, with an overall rate of 39%.²⁰ Our rate of intubation for ineffective PPV, 10%, was much lower, but this may be due to different definitions. We defined intubations for ineffective PPV as a HR less than 100 despite ongoing PPV, while Biniwale et al²⁰ defined "emergency intubations" more generally as intubations "required during the active phase of Neonatal Resuscitation Program." A single-center DR QI project for neonates 24–26+6 weeks gestation reported the incidence of rapid intubation within 20 minutes of life but did not specify intubation indication within that time.²⁷

The increase in VLBWs between intubations for ineffective PPV was most temporally associated with local initiation of the MONITOR trial. Notably, most preterm infants in our hospital were not enrolled in this trial, and there was no difference in DR intubation outcomes between treatment arms.³⁰ Therefore, it is unlikely the RFM intervention contributed to the observed improvement in effective PPV performance. As previously described, ICN providers received general education on PPV performance before and during the study. We hypothesize this training, and increased emphasis on effective PPV likely impacted all neonates, even those not enrolled in the trial. A similar trend was seen after the SUPPORT trial, with decreased DR intubations for all infants observed in study sites that had not previously prioritized DR CPAP. This finding suggests that participation in randomized trials may affect nonenrolled patients.³¹ The temporal association between education for the trial and the increase in VLBWs between intubations for ineffective PPV reinforced the importance of continued and maintenance PPV training. We did not adopt visible RFM use after the trial as there was no improvement in the primary outcome.

While the shift from 6.1 to 8.0 infants between intubation for ineffective PPV was technically sustained, numerous subsequent points below the centerline may limit the clinical significance of this shift. These data points reinforce PPV is a challenging skill to master and sustain that requires ongoing dedicated training. Given this, intubation for ineffective PPV should not be a "never" event, as the American Heart Association neonatal resuscitation algorithm indicates using an alternate airway to establish ventilation in the setting of persistent bradycardia.³² Because provider judgment influences the decision to intubate during resuscitation, there are limited data to inform expected rates of DR intubation for ineffective PPV for VLBWs. However, our data demonstrate that it is possible to successfully establish effective ventilation (indicated by HR > 100) using noninvasive support in up to 90% of VLBWs. Our data also demonstrate that providers can stabilize more than 70% of VLBWs in the DR with noninvasive ventilation. We achieved and maintained these

high rates through creating a culture that supports and prioritizes noninvasive ventilation (intubation guidelines and video review for education, feedback, and accountability), preterm-specific equipment, and ongoing noninvasive ventilation education.

Our project had several strengths. First, we differentiated between intubations for ineffective PPV and other indications. This differentiation is important as different intubation indications present different targets for QI efforts to increase noninvasive support. Second, video recordings augmented the validity of abstracted data. Third, we assessed many resuscitations (>500) over 5 years.

We acknowledge limitations. Results may not generalize to other settings because this was a single-center QI project in an academic hospital with a separate resuscitation room. Despite this, our primary drivers, performing effective PPV to increase HR, prioritizing noninvasive support, obtaining buy-in, and improving communication, are likely applicable to all DR environments. Furthermore, our targeted interventions can be more impactful at institutions with higher rates of DR intubation. Finally, our data for intubations for ineffective PPV suggest decreased gains in the maintenance phase, emphasizing the need for continued efforts to improve DR PPV.

CONCLUSION

We demonstrated an increase in VLBWs between intubations for ineffective PPV through our QI project to improve DR noninvasive ventilation. Our data demonstrate effective ventilation (HR > 100) using noninvasive support is possible in up to 90% of VLBWs and can be sustained with ongoing and maintenance training in PPV.

DISCLOSURE

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