Unintended Extubation Prevention Bundle in the Neonatal Intensive Care Unit

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Abstract

Problem: Endotracheal intubation is a common procedure in the Neonatal Intensive Care Unit. Unintended extubation is defined as the accidental dislodgement of the endotracheal tube from the trachea and is a common adverse event in NICUs. Unintended extubation is associated with a multitude of profound consequences in neonates including airway trauma, intraventricular hemorrhage, pneumothorax, cardiovascular collapse, and death. In 2020, a Level VI Neonatal Intensive Care Unit had an unintended extubation rate of 1.2 per 100 ventilator days, exceeding the unit goal of less than 1 per 100 ventilator days.

Purpose: The purpose of the quality improvement project is to implement an initiative outlining an unintended extubation bundle with an emphasis on management of high-risk procedures to reduce unintended extubation in a Level IV Neonatal Intensive Care Unit.

Methods: A multidisciplinary team evaluated current literature along with previous unintended extubation events and developed a unintended extubation bundle that emphasized the presence of two licensed providers for all “high risk” procedures and, in addition all intubated infants greater than 35 weeks’ gestation were required to have mittens placed on their hands. Adherence to the bundle was tracked via random observation audits with verbal feedback, and success was determined thorough evaluation of by weekly run charts, over a 15-week timeframe.

Results: Results of this quality improvement project were mixed. The nursing education goal of 100% of nursing staff was achieved. The process goal of 100% compliance to the unintended extubation bundle was not met. The unit unintended extubation rate remained unchanged at 1.2 per 100 ventilator days.

Conclusions: Preventing unintended extubation in Neonatal Intensive Care Units remains a challenging problem but with supportive stakeholders and a strong commitment to organizational

change, along with a concrete framework for implementation, success can be achieved. Evaluation of the implementation over a longer period of time may produce different results.

Unintended Extubation Prevention Bundle in the Neonatal Intensive Care Unit

Endotracheal intubation is a common procedure in the Neonatal Intensive Care Unit (NICU). Unintended extubation (UE) is defined as the accidental dislodgement of the endotracheal tube (ETT) from the trachea and is the fourth most frequently occurring adverse event in NICUs (Klugman et. al, 2020, da Silva et. al, 2013). UE is associated with a multitude of serious, life threatening consequences in neonates including airway trauma, intraventricular hemorrhage, pneumothorax, cardiovascular collapse, and death. It is also associated with both longer ventilation time and longer hospitalizations (Fontánez-Nieves et. al, 2016; Galiote, et. al, 2019).

In 2020, a Level IV NICU had an UE rate of 1.2 per 100 ventilator days, exceeding the unit goal of less than one per 100 ventilator days, which is in alignment with the goal set by the Vermont Oxford Network. (Fontánez-Nieves et. al, 2016). This NICU had already implemented some measures to decrease their UE rates. These measures included the use of one standard, commercial fixation device for the endotracheal tube, standard taping practices, root cause analysis after every UE and assessment of endotracheal tube placement visually by both the respiratory therapist and the bedside registered nurse (RN). See Appendix A for a map of the current process. Despite these measures, the UE rate remained at 1.2 per 100 ventilator days. To address this issue a quality improvement (QI) project consisting of an evidence-based UE bundle was developed to standardize the processes related to handling intubated infants, as well as incorporating interventions that addressed the developmental needs of the premature infant while keeping their artificial airway intact. The purpose of this QI project was to implement an initiative outlining an UE bundle with an emphasis on management of high-risk procedures that have been associated with UE in a Level IV Neonatal ICU.

Literature Review

Evidence supports the use of an UE bundle that standardizes processes related the handling of intubated infants along with the use of commercially available cotton mittens to prevent self extubation of infants greater than 35 weeks gestation from manually manipulating their ETT. The literature review for this QI project focused on four articles, one systematic review and three retrospective cohort studies. See Tables One and Two, Summative Evidence Rating Table and Synthesis Table, for detailed information. A systematic review by Da Silva, Reis, Aguilar and Fonseca (2013) reviewed the incidence, risk factors, reintubation, patient outcomes, and prevention of UE in NICUs. Study quality was evaluated with the Newcastle-Ottawa scale, which is effective for evaluating the quality of non-randomized studies (Carson, Mertz & Loeb, 2013). Fifteen studies were deemed as high quality with a score of ≥ 5 and were included in the review. These studies included eleven prospective cohort studies, three retrospective cohort studies and one retrospective and prospective cohort study. The authors found that interventions such as standardizing ETT securement, sedation and analgesia, physical restraints or mittens, the use of two qualified staff members for "high risk" procedures, continuous QI programs and maintaining adequate nurse/patient ratios are all effective measures in reducing UE rates in NICUs.

A multicenter QI project aimed at reducing UEs by Klugman, Melton, Maynard, Dawson, Madhavan,, Montgomery, Nock, Lee, and Lyren, (2020) enrolled patients from pediatric, neonatal, and cardiac intensive care units at 43 hospitals. Interventions included a QI bundle that required consistency in securement devices for ETTs, a new protocol for moving intubated infants in high-risk situations, and multidisciplinary root cause analysis for all UEs. Results from

these measures across the 43 children's hospitals reflected a 24.1% reduction in UE, from a baseline of 1.135 UEs per 100 ventilator days to 0.862 UEs per 100 ventilator days.

A third article reviewed was a multidisciplinary QI project by Merkel, Beers, Lewis, Stauffer, Mujsce, and Kresch (2014) that implemented five Plan Do Study Act (PDSA) cycles over the course of three years aimed at reducing UEs in a Level IV NICU. Rates of UE were analyzed monthly and causes of UE were also analyzed by Pareto charts. The results of this study showed significant decreases in UE rates, from 2.38 UEs to 0.41UEs per 100 ventilator days. Interventions implemented were two qualified staff members involved in high-risk procedures, airway alert cards at the bedside, consistent documentation of ETT position, the use of a commercially available ETT securing device, real-time analysis of each UE event and the use of mittens for all infants >35 weeks and greater.

A QI project by Nair and Smith (2020) reduced UE rates by over 80% from 7.2 UEs per 100 ventilator days to 1.4 per 100 ventilator days. These reductions were achieved by using a UE bundle that included standardizing the ETT fixation, continuous checks, and documentation of ETT position, requiring two qualified staff members when moving infants and adverse event reporting for all UEs.

All the studies reviewed determined that the use of two licensed providers to perform high-risk procedures, with one provider whose sole responsibility is to stabilize the ETT, is an effective intervention that can help prevent UE in NICUs and other pediatric critical care units. Additionally, two articles determined that the use of cotton mittens was effective as part of an UE bundle. The settings of the QI studies varied from a large, level VI NICU to smaller community hospitals. Differences in the studies include different lengths of time for the project implementation and additional interventions besides the use of two providers for high-risk

procedures and the use of cotton mittens. These differences could have causality for the effectiveness of the interventions in this UE bundle. Despite the differences in these studies, the results are consistent and a bundle to decrease UE to improve outcomes is warranted.

Theoretical Framework

Utilizing a nursing theory is often helpful to understanding a complex problem like UE in a NICU. One theory, Levine's Conservation Model (Levine, 1996), provides a theory that the goals of nursing care are the conservation of the patient and the patient environment. Within the context of the NICU, preterm birth disrupts both normal intrauterine and extrauterine development simultaneously. Utilizing Levine's Conservation Model, nursing care is provided in a way that is both therapeutic to the infant, but also protects the totality of the health of the premature infant (Mefford, 2004). Unintended extubation of a preterm infant can severely disrupt both their extrauterine development and their wholeness of health in a way that threatens their conservation of energy, another critical aspect of Levine's Conservation Model (Mefford, 2004.) The evidence-based UE bundle is a critical piece of therapeutic nursing care that promotes conservation of energy in premature infants. See Figure 1 for more details on Levine's Conservation Model.

In addition to having an appropriate nursing theory to help understand complex problems, it is also helpful to have a conceptual framework that helps to capture key determinants for implementation (Helfrich et al., 2007.) According to Helfrich, Weiner, McKinney and Minasian (2007) these include management support and innovation-values fit, both of which are needed for successful implementation. When both Levine's Conservation Model and Helfrich and colleagues are used together, it allows for the most successful implementation and for sustainability of the project. This is because both nursing theory and QI frameworks provide a

stepwise approach to successfully executing this QI project. A structured framework provides consistency, common thinking, and language across organizations. This approach is particularly helpful in healthcare organizations which are complex, adaptive systems, with multiple moving parts and factors influencing care, activities, events, and outcomes. Figure 2 outlines the conceptual framework.

Methods

This QI project took place on a 52-bed Level IV NICU in a large academic medical center. This academic medical center serves a large community of persons of low income and black or African American heritage. (Baltimore City Department of Planning, 2021). All infants that were hospitalized and intubated were included, without any other ethical considerations. At any given time, there are approximately 8-12 intubated infants and approximatley155 staff nurses are available on the unit to implement the UE bundle and reduce UE rates. Common diagnoses for this NICU include prematurity of 22-weeks' gestation and up, congenital heart disease, respiratory distress, genetic and metabolic syndromes, and surgical conditions.

This QI project included two of the interventions outlined by Merkel and colleagues (2014). The two interventions in this bundle include the following: a) the use of two team members for all "high risk" procedures such as turning, repositioning, weighing, bathing, and moving the infant to be held; held, b) use of mittens for all intubated babies who are greater than 35 0/7 weeks to prevent self extubation. See Appendix B for a visual of the desired state. Training was conducted for all RNs and respiratory therapists (RTs), either in-person or through the hospital online training portal. See Appendix C for a copy of the training materials.

Implementation progress and impact was followed through frequent auditing of structure and process measures. The structure measure of education goals for nursing staff were met

through completion of training via online, in-person, or email content. Educational fliers were also posted throughout the unit to alert all staff members to the practice change. The process goal of "two team members for all "high risk" procedures and b) cotton mittens for qualifying infants 100% of the time" was tracked with random audits using a tracking tool developed for this implementation. Refer to Appendix D for a copy of the tracking tool. Seven clinical RNs and one RT served as change champions for this project and conducted random audits. UEs were monitored through Mini-RCAs conducted and led by the physician staff. These Mini-RCAs occurred immediately after the UE and included any team members that were involved in the UE or the post-UE resuscitation.

Staff application to the bundle was evaluated through random audits. The project lead and champions conducted these audits throughout both day- and nightshift. The data collection sheet from Appendix B Chart Audit Tool was used. Weekly compliance rates were calculated for bundle compliance based on daily audits. This calculation was completed by looking at the actual number of infants that were intubated and audited. If the infant was less than 35 weeks gestational age, only the use of two providers was considered. If the infant was greater than 35 weeks gestational age, the use of two providers and the use of mittens. For infants greater than 35 weeks gestational age, both questions must be answered with a YES to be considered compliant. If one of the questions was answered no, that observation was considered not compliant. Compliance was calculated by the total number of observations for the week divided by the total number of YES, with a percentage calculated. The chart audit tools for the week were stored in a secured locker. Change champions placed chart audit tools into the locker using the slots at the top of the locker to ensure security. Additionally, once the chart audit tools were

removed by the team lead and data was extracted for the week they were shredded. There were no patient or staff identifiers on the chart audit tools.

Unintended extubation rates were collected by unit Neonatology Fellowship physicians and were shared with the project lead for the duration of the QI project. No PHI was collected. While the project involved interventions with, and data collection from infant humans, the intent to improve clinical practice and outcomes in a NICU and was not designed to infer correlation and/or causality or generate new scientific knowledge. Furthermore, the outcomes of this project would not be generalizable to other health care settings or populations because the project is specifically designed to address a practice gap in this NICU. This QI project was reviewed by the project site's Institutional Review Board and designated non-human subjects research.

Results

Results of this QI project were mixed. The structure goal was met. RNs on this unit were educated over a course of three weeks. Education was primarily accomplished online through a training module on the hospital's education portal. If the RN was unable to complete this training online, in-person training was offered and if the RN was not able to achieve either of these options, the training module was emailed in PowerPoint form with follow-up after one week.

The process goal was not met. There was a shift below the median over a course of three weeks resulting in compliance rates of 81%, 89% and 67%. Around the time of the first shift below the median, week 9-October 2021, there was an influx of new RNs employed in the NICU. Additionally, week 15-November 2021, it must be noted that patient acuity on the unit was higher than normal resulting in an increase in intubated infants. See Figure 3 for full results of the random audits. For each point below the median, re-education was provided via reminder emails to all staff members detailing bundle components, as well as including reminders in the

weekly RN huddle. These downward shifts were likely a consequence of staffing issues, multiple competing QI projects and the previously mentioned barriers.

Data collection showed overall RN compliance with the UE bundle. Despite compliance, UE rates remained unchanged. It should be noted that when reviewing the Mini-RCAs one UE occurred when an infant was wearing mittens appropriately and a second UE occurred when a staff member was moving infant without a second staff member to assist. Limitations for this QI project included a short data collection period of 10 weeks, and implementation on one unit versus multiple.

Discussion

Despite the mixed results of this QI project, there are still implications for practice not only in the neonatal ICU, but other pediatric settings where intubations occur. Unplanned extubations can be reduced through staff education and standardizing the process of patient care. The 10-week period of implementation of this QI project may have impacted the effectiveness of the UE bundle because oftentimes, meaningful change does not occur for months, if not years for most healthcare organizations (Brickman, 2016). In addition to this short timeframe for implementation, this QI project was implemented on a unit that had multiple competing QI projects being implemented at this same time. Those two factors, along with the world-wide COVID-19 pandemic and a severe nursing shortage on the unit were all major barriers to success.

The effectiveness of this project contrasts with the four articles in the above literature review. The results of all three of the cohort studies reflected favorable reductions in UE rates. However, all three implemented their projects over a period of several months to three years and

all the bundles included additional interventions in addition to the bundle components of this QI project. Additionally, the systematic review by da Silva and colleagues (2013) reviewed 16 articles that all had favorable reductions in UE rates but again studies were conducted over an extended period and had multiple interventions.

Conclusions

Contextual factors such as supportive stakeholders and unit leadership are always beneficial when implementing QI projects on a unit, and without their support an effective implementation may not occur. Stakeholders for this QI project were supportive and enthusiastic about the bundle components, despite the limited success and inability to decrease UE rates in this NICU. The use of two team members proved to be difficult, in part due to the high turnover rate and staffing issues, as well as to the overall high patient acuity level during the implementation period. Coupled with the COVID-19 pandemic, compliance with using two team members for high-risk procedures was variable. Feedback sought from staff after the completion of this QI project revealed that staff members often found it challenging to utilize two team members as required.

Continued observations on the unit after the conclusion of the data collection period show that the cotton mittens were much more widely accepted and in fact are used on many intubated infants, regardless of gestational age if the RN or provider has concerns about UE. This use contributes to sustainability of the project long-term and could lead to further investigations about the effectiveness of the use of cotton mittens for all intubated infants in this NICU.

Sustainability and spread of this QI project can also be achieved by education related to the UE bundle will be incorporated into nursing orientation and the integration of the UE checklist into the nursing flowsheet. A *Steps to Prevent Unintended Extubation (UE)* visual

(Figure 4) was created and hung in each room to optimize sustainability after the conclusion of this QI project. The visual was developed in coordination with two attendings and the clinical practice coordinator for this NICU and include not only the bundle components for this QI project, but also other general reminders about preventing UE and what to do if UE occurs. Preventing UE in NICUs remains a challenging problem but with supportive stakeholders and a strong commitment to organizational change, along with a concrete framework for implementation, success can be achieved.

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Klugman, D., Melton, K., Maynord, P., Dawson, A., Madhavan, G., Montgomery, V., Nock, M., Lee, A., & Lyren, A. (2020). Assessment of an unplanned extubation bundle to reduce unplanned extubations in critically ill neonates, infants, and children. *JAMA Pediatrics, 174(6)*, e200268. https://doi-org.proxy-hs.researchport.umd.edu/10.1001/jamapediatrics.2020.0268

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Merkel, L., Beers, K., Lewis, M. M., Stauffer, J., Mujsce, D. J., & Kresch, M. J. (2014). Reducing unplanned extubations in the NICU. *Pediatrics, 133(5),* e1367–e1372. https://doi-org.proxy-hs.researchport.umd.edu/10.1542/peds.2013-3334

Table 1

Summative Evidence Rating Table

Citation: da Silva, P. S. L., Reis, M. E., Aguiar, V. E., & Fonseca, M. C. M. (2013). Unplanned Extubation in the Neonatal ICU: A Systematic Review, Critical Appraisal, and Evidence-Based Recommendations. Respiratory Care, 58(7), 1237–1245. https://doi-org.proxy-hs.researchport.umd.edu/10.4187/respcare.02164					**Level I** **Quality B**
Purpose, Aim Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
"To update the state of knowledge un unplanned extubations (UEs) in neonatal ICUs. This review focuses on the following topics: incidence, risk factors, reintubation after UE, outcomes, and prevention."	Systematic review with meta-analysis conducted by panel of physicians that specialize in neonatal/pediatric intensive care.	**Search Strategy:** A search was conducted using PubMed, EMBASE, CINAHL, and Cochrane Library. The following keywords were used: "unplanned extubation," "accidental extubation," "self extubation," "unintentional extubation," "unexpected extubation," "inadvertent extubation," 'unintended extubation, "spontaneous extubation," "treatment interference," and "airway accident." Two authors independently reviewed citations, abstracts, and full-text articles. They then independently rated each study and variations in grading	**Control:** Controls varied and included standard of care **Intervention:** Focused on prevention measures against UE and included endotracheal tube fixation, physical restraints, sedation, two qualified staff members for high-risk situations, nurse-to-patient ratio, and quality improvement programs **Protocol:** N/A to SR	**DV**: Articles were selected with the primary outcome of reduction in UE per 100 intubation days from the start of the intervention to the end date. **Measure:** unintended extubation per 100 intubation days.	**Level of Measurement:** Analysis of studies conducted using Newcastle-Ottawa scale for assessing the quality of non-randomized studies. Studies with a score less than or equal to 5 were deemed high methodologic quality. **Outcome Data Retrieval:** Data was pooled from selected articles **Analysis:** Descriptive statistics according to variable characteristics were used. The median and interquartile range (25^{th} and 75^{th} percentiles) are presented for continuous variables and Pareto charts summarized the data. **Conclusions:** UE rates range from 0.14 to 5.3

		were reconciled via discussion. **Eligible Studies:** Cohort, case-control or cross-sectional studies were evaluated using the Newcastle-Ottawa scale for assessing the quality of non-randomized studies. Studies with a score less than or equal to 5 were deemed high methodologic quality. **Excluded:** no explanation was given as to why studies were excluded. **Included:** 16 studies were included. 12 were prospective cohort studies, 3 retrospective cohort studies and 1 was a retrospective and prospective cohort study. **PRISMA:** included detailing decision and scored for low and high methodological quality. **Power analysis:** N/A to systematic review.			UEs per 100 intubation days. Risk factors include infant agitation, poor fixation of endotracheal tube, performance of a patient procedure at the bedside, an association between birth weight/gestational age and days on mechanical ventilation increasing UE. **SR Bias Risk:** use of Newcastle-Ottawa scale to determine methodological quality, bias risk is low.
Citation: Klugman, D., Melton, K., Maynord, P. O., Dawson, A., Madhavan, G., Montgomery, V. L., Nock, M., Lee, A., & Lyren, A. (2020). Assessment of an Unplanned Extubation Bundle to Reduce Unplanned Extubations in Critically Ill Neonates, Infants, and Children. JAMA Pediatrics, 174(6), e200268. https://doi-org.proxy-hs.researchport.umd.edu/10.1001/jamapediatrics.2020.0268					**Level I** **Quality B**
Purpose, Aim Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**

"To determine if a multicenter quality improvement initiative targeting all intubated neonatal and pediatric patients is associated with a reduction in UEs and morbidity associated with UE events."	Retrospective cohort study	**Sampling Technique:** Convenience **Eligible Participants:** All patients with an endotracheal tube requiring mechanical ventilation at 54 network hospitals **Excluded:** any patient with tracheostomy tube and any UE occurring outside the hospital during transport. **Accepted:** 43 hospitals submitted data with at least 80% reliability and were included in the analysis **Control**: Historical comparison (HC) of UE per 100 ventilator days was compared pre- and post-implementation. **Group Homogeneity:** all mechanically ventilated patients with an endotracheal tube cared for in participating hospitals.	**Control Protocol**: Historical control **Intervention Protocol:** Standard anatomic reference points and securement methods, protocol for high-risk situations, and a multidisciplinary apparent cause analysis following each UE **Treatment Fidelity:** Evidence-based quality improvement initiative based on review of literature. Material was reviewed by 10 national experts from 8 hospitals, including physicians, nurses, and respiratory therapists from PICUs, NICUs and CICUs.	**Dependent Variable**: Unintended extubation rate, rate of harm and cardiovascular collapse. **Measure:** The dependent variables are measured by monthly metrics that were submitted by each hospital. Hospitals were instructed to submit at least 30 factor compliance audits per month for each factor. Factor compliance was defined as adherence to each respective factor definition. Hospital teams were encouraged to measure process reliability using visual observations and kamishibai cards. Data was submitted for 8 months to gather preliminary data and for 11 months post-implementation. The data submitted included total UE events, events by ICU location and the UE severity.	**Statistical Results:** Pre/post intervention outcomes were measured for each factor and the impact of reliability of each factor was tested using response plots and analysis of covariance (ANCOVA). 43 hospitals with at least 80% reliability were included. The results were as follows: 24.1% aggregate reduction in UE events across the cohort. Baseline data was 1.135 UEs per 100 ventilation days compared to 0.862 UEs per 100 ventilation days post intervention. 58.3% of UEs required reintubation within 1 hour, followed by 37.9% not requiring reintubation. Additionally, there was a 36.6% decrease in UE that resulted in cardiovascular collapse. Extrapolation of that data into an average number demonstrated that 3 patients per month avoided cardiovascular collapse.

Citation: Merkel, L., Beers, K., Lewis, M. M., Stauffer, J., Mujsce, D. J., & Kresch, M. J. (2014). Reducing unplanned extubations in the NICU. Pediatrics, 133(5), e1367–e1372. https://doi-org.proxy-hs.researchport.umd.edu/10.1542/peds.2013-3334					**Level I** **Quality C**
Purpose, Aim Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
"Our goal was to reduce unplanned extubations to <1 unplanned extubation per 100 patient-intubated days."	Prospective/retrospective cohort study	. **Sampling Technique:** Convenience **Eligible Participants:** all infants admitted to the NICU at the Penn State Hershey Children's Hospital who required mechanical ventilation **Excluded:** no exclusionary data provided **Accepted:** all ventilated infants from January 2010 to November 2013 **Control:** comparison of UE per 100 ventilator days was compared pre- and post-implementation **Group Homogeneity:** infants requiring ventilation in the neonatal ICU	**Control Protocol:** Historical control **Intervention Protocol:** Two qualified staff involved in "high risk" procedures, airway alert cards at bedside, documentation of ETT position and security, use of commercially available ETT-securing product, real-time analysis of UE events, display "days since last UE," and use of mittens for infants >34 weeks postmenstrual age **Treatment Fidelity:** **Evidence-based** quality improvement project by interdisciplinary team of nurses, physicians, and respiratory therapists. Multidisciplinary team developed several bundles and rolled out process changes in PDSA cycles with staff education by "unit champions" and data collection throughout.	**Dependent Variable:** Unintended extubation rates **Measure:** UE per 100 ventilator days	**Statistical Results:** Cycle 1 – 0.8 UE per 100 days intubated, mean UE rate of 1.03 Cycle 2 – 1.4 UE per 100 days intubated, mean UE rate of 1.03 Cycle 3 – 1.8 UE per 100 days intubated, mean UE rate of 1.03 Cycle 4 1.1 UE per 100 days intubated, mean UE rate of 1.03 Cycle 5 – 0.8 UE per 100 days intubated, mean UE rate of 1.03

Citation: Nair, V., & Smith, H. (2020). Phased Quality Improvement Interventions in Reducing Unplanned Extubation in the Neonatal ICU. Respiratory Care, 65(10), 1511–1518. https://doi-org.proxy-hs.researchport.umd.edu/10.4187/respcare.0764					**Level I** **Quality C**
Purpose, Aim Hypothesis	**Design**	**Sample**	**Intervention**	**Outcome**	**Results**
The object of this study was to evaluate the effectiveness of the quality improvement interventions in reducing UE in a tertiary neonatal ICU."	Retrospective cohort study	. **Sampling Technique:** Convenience **Eligible Participants:** all ventilated infants cared for in the neonatal ICU **Excluded:** no exclusionary data identified **Accepted:** all ventilated infants from April 2016 to March 2017 **Control:** comparison of UE per 100 ventilator days was compared pre- and post-implementation **Group Homogeneity:** infants requiring ventilation in the neonatal ICU	**Control Protocol:** Historical control **Intervention Protocol:** standardization of the ETT fixation technique using a commercially available device, implementation of a 2-person requirement for providing care to neonatal patients, continuous scrutiny of the ETT and fixation during rounds and during cares and the introduction of UE log sheets for real-time UE reporting. **Treatment Fidelity:** a multidisciplinary team consisting of neonatal consultants and practice development nurses performed hands on training for the commercially available fixation device and manikins. Regular education sessions were incorporated into nursing training on raising awareness of the importance of regular	**Dependent Variable:** Unintended extubation rates, reasons associated with UE, method of fixation, temperature before and after UE and requirements for cardiopulmonary resuscitation **Measure:** each intervention was introduced as a stand-alone intervention, with data collected retrospectively after each intervention.	**Statistical Results:** There was a statistically significant reduction of 80% (7.2 per 100 ventilated days pre-implementation versus 1.4 per 100 ventilated days post-implementation) in UE rates of the QI interventions were implemented. There was a rate of 0 UEs for 3 consecutive months and for >8 months the UE was below the mean, which depicts special cause variation.

			checks and emphasizing the importance of UE reporting.		

Table 2

Synthesis Table

Evidence Based Practice Question (PICO): In intubated infants in the NICU, is the use of an unplanned extubation bundle compared to the standard of care effective in preventing unplanned extubation?			
Level of Evidence	**# of Studies**	**Summary of Findings**	**Overall Quality**
I	1	Da Silva et al. (2013) reviewed 15 articles and evaluated their quality using the Newcastle-Ottawa scale for assessing the quality of non-randomized studies and found that 12 were considered low methodological quality and 3 high methodological quality. The authors found that unintended extubation can be prevented by endotracheal stabilization and securement, proper sedation, physical restraints and utilizing two providers for moving and turning the infant.	B, there were no double-blind, randomized, controlled designs included. The use of the Newcastle Ottawa scale to assess the quality strengthens internal validity. Multivariate analysis was required to reduce confounding and two reviewers independently rates all studies. The grading system was based on the Oxford Centre for Evidence Based Medicine's level of evidence. Recommendations suggested further research was needed to validate results.
IV	3	Klugman et al. (2020) initiated a quality improvement project at 43 children's hospitals that was associated with an aggregate 24.1% reduction in UE events, from a baseline rate of 1.135 UEs per 100 ventilator days to 0.862 UEs per 100 ventilator days. The QI project included an unintended extubation bundle that included standardized anatomic reference points and securement methods for ETTs, a protocol requiring two licensed providers be present during repositioning and other high-risk situations and a multidisciplinary root cause analysis for all unintended extubations. Merkle et al. (2014) implemented an unintended extubation bundle that included the use of airway cards at the besides, the use of a commercially developed ETT securement device, a policy that required two qualified providers to lift or reposition intubated infants, root cause analyses for each UE event and the use of mittens for intubated infants greater than 34 weeks gestational age. Results included a statistically significant reduction in UE, from 2.38 per 100 to 0.58 per 100 patient days intubated.	B, there was no randomization or control in this retrospective cohort study and no consistency in implementing the various factors in the UE bundle, instead using a variety of methods, which included high-reliability strategies ranging from education to checklists to risk-stratification tools. Baseline and post-intervention outcomes were measured for the three interventions in the bundle using response plots and analysis of covariance (ANCOVA), strengthening internal validity. To detect statistically significant changes in outcomes related to the interventions, Shewhart control U-charts were used to track monthly outcomes data. C, this was a retrospective cohort study that did not have any randomization or controls implemented. There were unequal sample sizes, which can threaten internal validity. Pareto charts and statistical process control analyses were performed to evaluate variation in the process and to determine the effectiveness of each intervention. U charts were constructed and means, and control limits were calculated by using statistical process control methods that conformed to U chart primary assumptions.

		Nair & Smith (2020) reduced UE from 7.2 per 100 ventilator days to 1.4 per 100 ventilator days with a quality improvement process that included standardization of ETT fixation, a 2-person requirement for providing care to neonatal patients, daily documentation of ETT fixation length and real-time UE reporting and analysis.	C, the retrospective cohort study had no randomization or controls. Statistical process controls were used to understand the special cause variations and trends. Outcome data of UEs was constructed on a control chart with means and control limits calculated using the process control methods in SPSS 26 and Montgomery rules were used to analyze the stability of the process before and after implementation of interventions.

Table 2. Synthesis table.

Figure 1.

Theoretical Framework

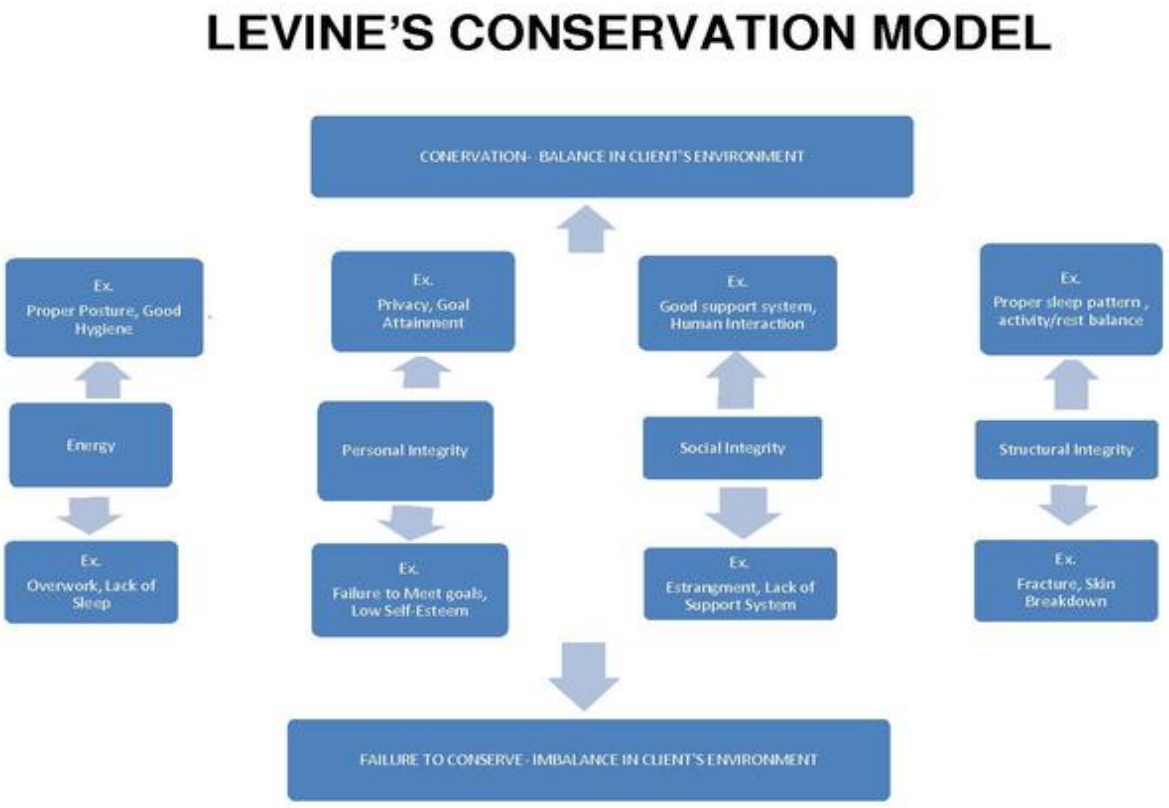


Figure 1. Levine's conservation model.

Figure 2

Conceptual Framework

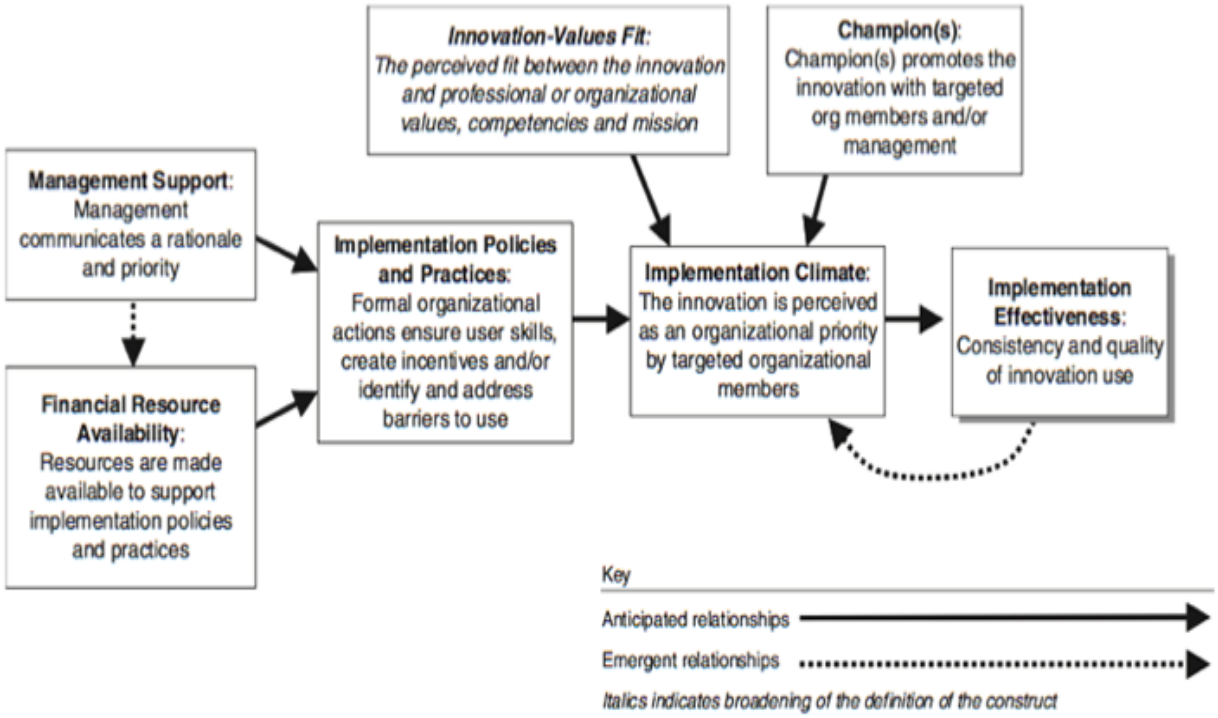


Figure 2. Conceptual framework of complex innovation.

Figure 3

Staff Nurse UE Bundle Compliance

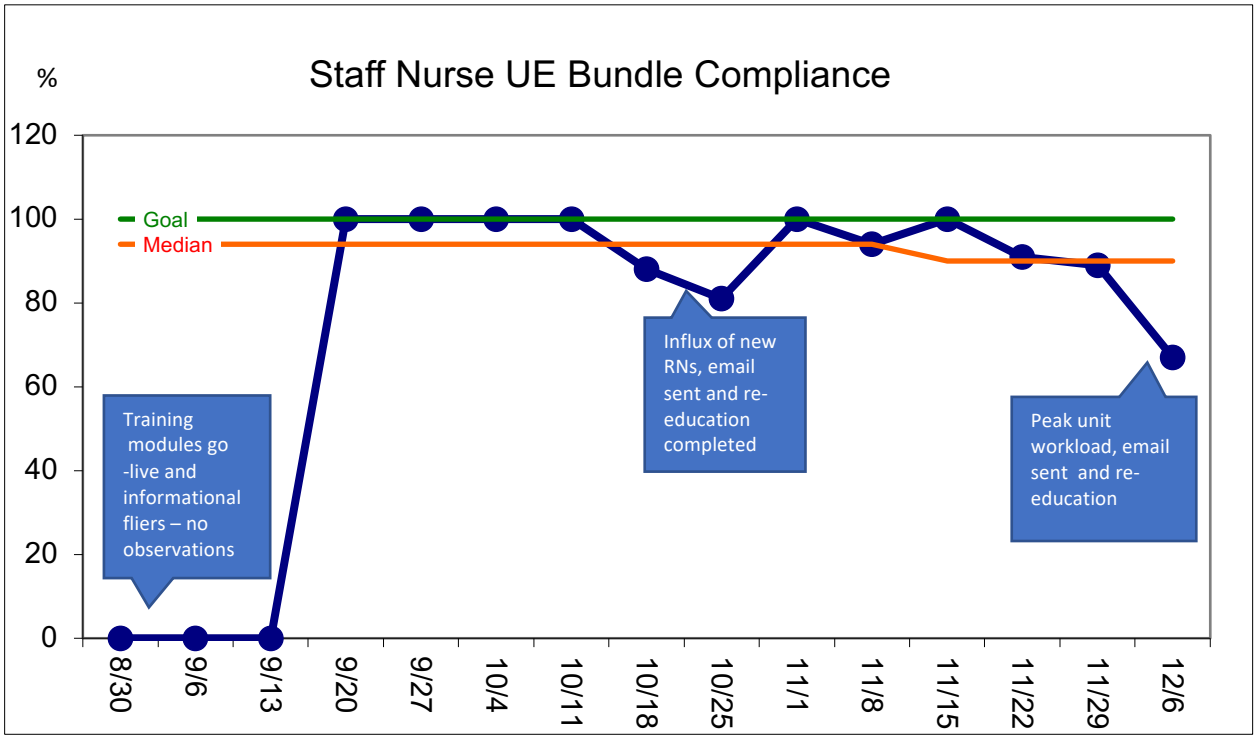


Figure 3. Staff nurse UE bundle compliance.

Figure 4.

Steps to Prevent Unintended Extubation

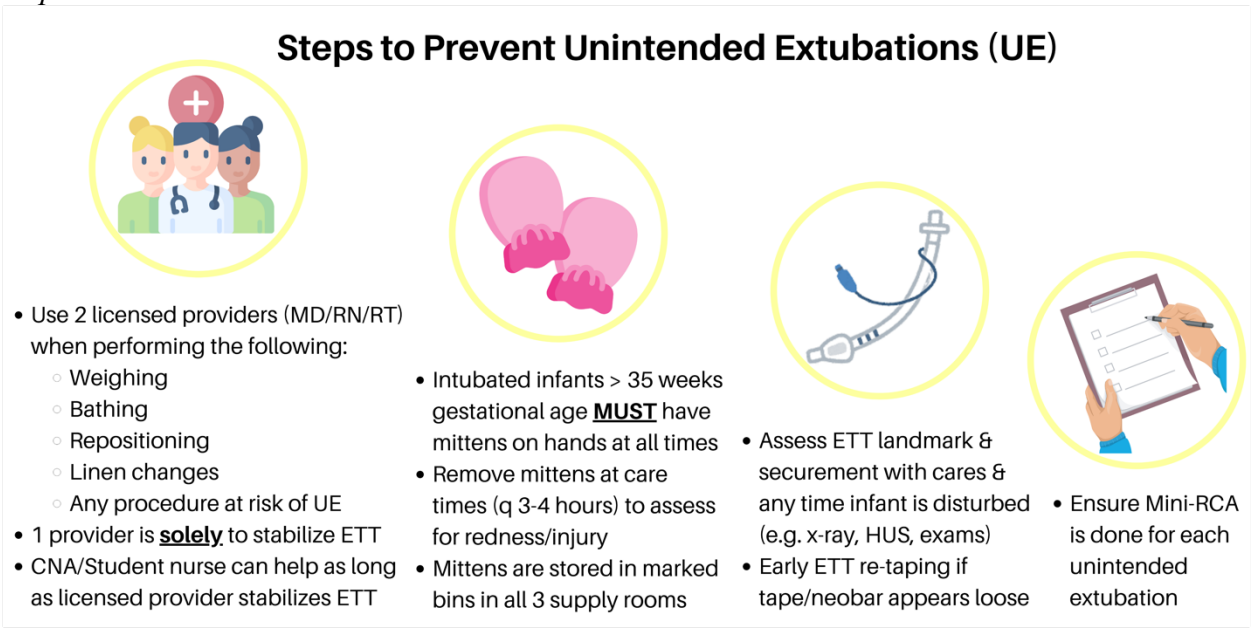
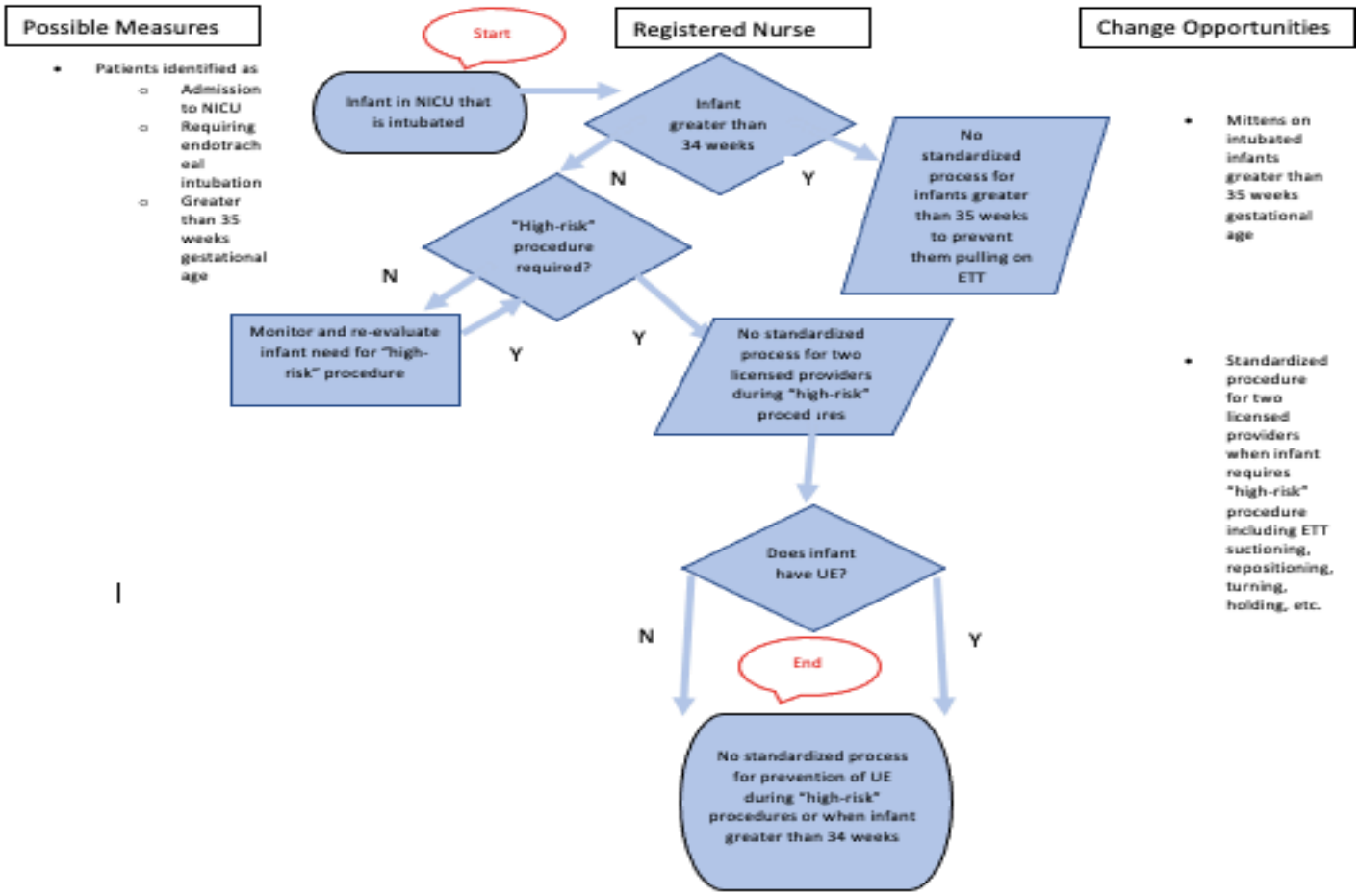


Figure 4. Steps to prevent unintended extubation.

APPENDIX A

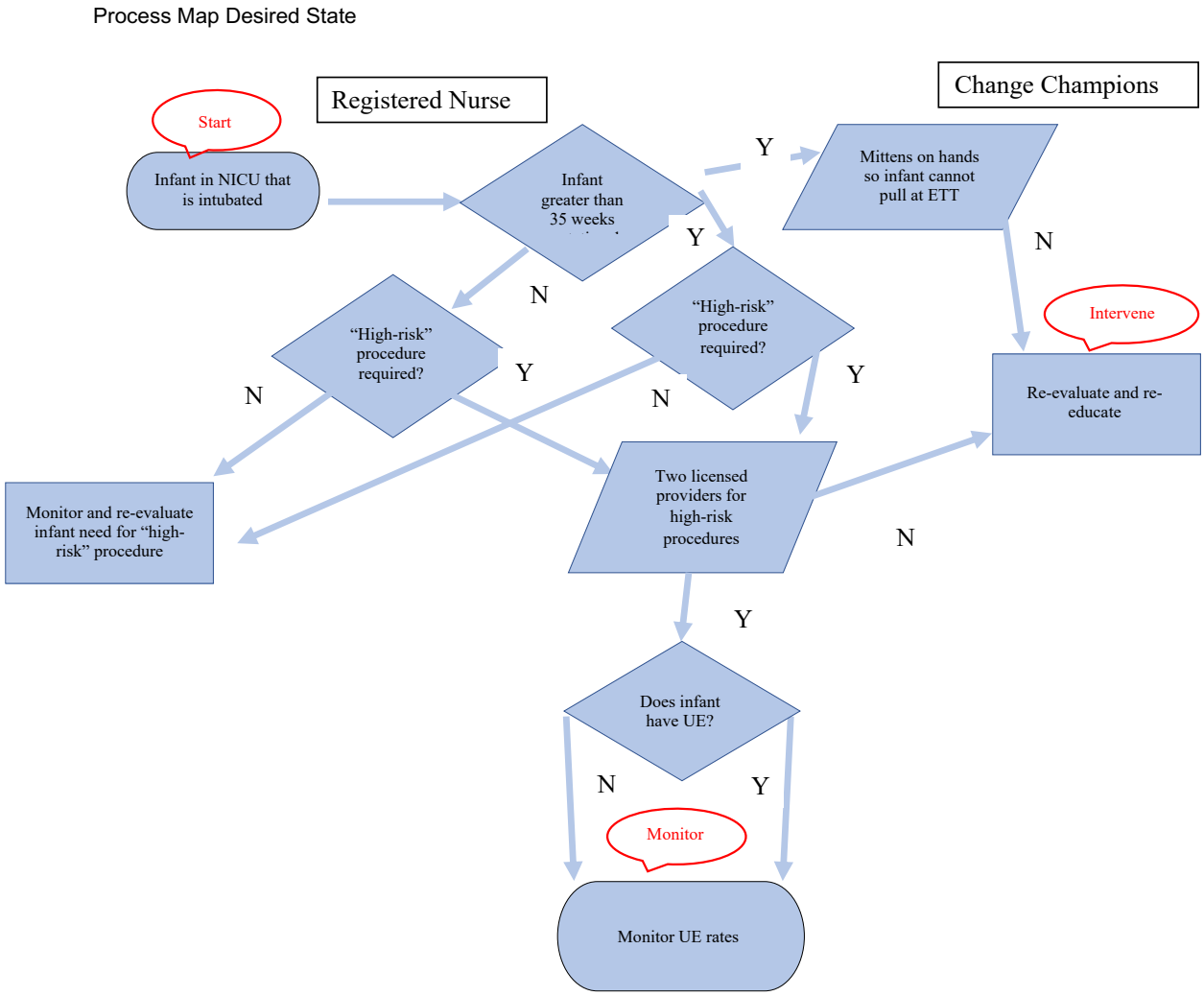
Current Process Map



Appendix A. Current process map.

APPENDIX B

Desired Process Map



Appendix B. Desired process map.

APPENDIX C

Unintended Extubation Bundle Training

UNIVERSITY of MARYLAND
SCHOOL OF NURSING

Unintended Extubation Bundle

Letitia Gallant, MS, RN

Background

- Endotracheal intubation is a common procedure in NICU
- Unplanned extubation (UE) is the accidental dislodgement of the ET tube (Klugman et. al, 2020)
- Consequences include airway trauma, intraventricular hemorrhage, pneumothorax, cardiovascular collapse, death (Fontánez-Nieves et. al, 2016; Galiote, Ridoré & Carman, 2019)
- Associated with both longer ventilation time and longer hospitalizations (Fontánez-Nieves et. al, 2016)

2

Purpose Statement

The purpose of this quality improvement project is to implement an iniative outlining an unintended extubation bundle with an emphasis on management of high-risk procedures to reduce unintended extubation in the Neonatal ICU

3

Interventions

- When caring for an intubated infant, use two licensed providers (RN or RT) for:
  - Weights
  - Bathing
  - Repositioning
  - Moving the infant to be held
  - Linen changes
  - If RN/RT have any concerns about the infant accidentally extubating
- One provider solely to stabilize tube and/or calm baby (can also use CNA/student nurses to help as long as the RN stabilizes ETT)

4

Interventions Cont.

- Intubated infants greater than 35 weeks gestational age will have mittens on hands at all times to prevent pulling of ETT
  - Specifically provided for this iniative and separate from regular unit linen
  - Located in all 3 supply rooms in specially marked bins and labeled with a UE on them
  - Remove at each set of cares to assess skin for redness/breakdown

5

Interventions Cont.

Roll Out Date

- Interventions begin September 19, 2021

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APPENDIX D

Chart Audit Tool

Chart Audits/Random Observations				
Date: _____ Day of week (circle) M Tu W Th F Sa Su Time _____ am pm (circle) Observer: _____				
Room #	Patient intubated?	RN using to providers for required cares?	Greater than 35 weeks?	Mittens?

Appendix D. Chart audit tool.