Micha Thompson, MD
Adapted from Erika Yazawa
Mentor: Dr. Sudha Kashyap
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Standardizing Gastric Residual Volume Assessment in Early Enteral Feeds of ELBW and VLBW Infants, a Quality Improvement Project

Abbreviated Title: Gastric Residual Volume Assessment Quality Improvement

A. Study Purpose and Rationale:

In very low birth weight (VLBW, <1500g) and extremely low birth weight (ELBW, <1000g) preterm neonates, nutrition is a critical component of comprehensive care. Nutritional management in the neonatal intensive care unit (NICU) aims to approximate intrauterine growth of a normal fetus at the same postmenstrual age (reference fetus; RF). A large observational study demonstrated that most NICU infants did not match median birth weights of RFs. In fact, most NICU infants were <10th percentile birth weight by the Fenton curve.[1,2] Inadequate early nutrition in this period dramatically impacts developmental outcomes, including behavioral, learning, and memory deficits as well as short stature and poor head growth.[1,3] Due to poor evidence of optimal methodology of feed advancement, there remains substantial variation in clinical practice regarding initiation and advancement of enteral feeds affecting nutritional status in NICU babies.

Preterm infants frequently have gastric residuals (GR) related to gut immaturity. The presence of a residual prior to feeding have often been misinterpreted as feed intolerance when they may be physiologic for this age group. High GR have been clinically felt to be related to risk of necrotizing enterocolitis (NEC) and ventilator-associated pneumonia (VAP), although the evidence is poor.[4,5,6] There are limited data on the relevance of gastric residuals and whether these may serve as truly informative metric of feed tolerance. In fact, early advancement of enteral feeds has been associated with improved maturation of the GI system, reduced NEC incidence, and even improved neurodevelopmental outcomes in recent studies [3,4,7,8]. A randomized controlled trial recently suggested that cessation of routine pre-feed GR checks was associated with a 6-day shorter time to reach 150ml/kg/day and 6 fewer days with central venous access, without increasing incidence of NEC.[9]

It is still common practice in many NICUs, as it is in ours, to routinely perform pre-feeding gastric residual assessments, which when present may delay feed advancement and thus unnecessarily prolong time on TPN. Furthermore, within our institution management decisions surrounding feed advancement as related to presence or quantity of GR varies among practitioners. TPN is used to support early metabolic demands when an infant is unable to take in sufficient nutrition through enteral feeds. While TPN may be necessary to sustain life, it comes with risks, most notably cholestasis, sepsis in the setting of a central line, and hyperglycemia. Furthermore, reduction in time to full enteral feeds could potentially reduce length of stay in the NICU, which may have implications on cost and resource utilization.

The presence of gastric residuals without other signs of feed intolerance (ie abdominal distension, abdominal discoloration, emesis, absence of bowel sounds, temperature instability, or signs of cardiopulmonary instability), should not drive the decision to hold feeds. The purpose of this study is to assess the impact of implementing gastric residual assessment guidelines. Within 6 months of implementation, we aim to eliminate unnecessary pauses in enteral feed

advances. We hypothesize that reducing the routine assessment of gastric residuals will shorten both time on TPN and the mean time for advancement to full enteral feeds in ELBW and VLBW infants.

B. Study Design:
We will use the IHI Model for improvement to iteratively test the clinical practice changes. The study will include two phases. The first phase includes a retrospective chart review of all ELBW and VLBW infants admitted to the CHONY NICU from March 2020 to August 2020 (6 months of baseline data). The second phase will include a prospective chart review from September 2020 to February 2021 (after implementation of the guideline). All data will be collected from Epic.

The gastric residual assessment guidelines outline a systematic approach to checking residual volumes and advancing feeds. This protocol outlines contraindications to feed advancement namely signs of feed intolerance which include abdominal distension, abdominal wall discoloration, decreased or absent bowel sounds, emesis, temperature instability, or increased number or severity of A/B/D events from baseline. Clinical practice changes include the following: (1) GR assessments will be discontinued in infants receiving trophic feeds, defined as feeds providing ≤20cc/kg/day (2) feeds will be advanced if GR <30% volume of the previous feed. (3) The medical team will be notified if the residual appears grossly bloody or bilious, GR volume ≥3cc and >30% of prior feed, or residual volumes are progressively increasing.

The guidelines have been developed by a multidisciplinary team and approved by the neonatology faculty to be disseminated to all caregivers, including nurses, residents, fellows, and attendings. Nursing educational outreach will span the course of two weeks to both day and night shift nurses. The guidelines will be presented to the fellows and residents during NICU educational conferences. Through direct observation weekly on rounds by either a neonatologist, a resident physician, or a dietitian, we will collect qualitative observational data to be incorporated into future PDSA cycles. Upon review of the Phase 2 data, we will assess adherence to guidelines, distribute a questionnaire to assess staff responses to guidelines and barriers to adherence, re-educate and refine guidelines as needed.

C. Subject Selection: Infants admitted to the CHONY NICU will be included if they are born premature weighing ≤1500g. Infants will be excluded if they have anomalies that impair feeding, have NEC prior to initiation of enteral feeds, or have deceased.

D. Statistical Procedures: An estimated 260 patients meet inclusion criteria for this study, of which an estimated 130 patients will be studied in the pre-intervention analysis and 130 patients in the post-intervention analysis. The cohort may be further equally subdivided by birth weight to two groups, ELBW infants (<1000g) and VLBW infants (1000-1500g). Data collected will include birth weight, gestational age, sex, feed type (expressed breast milk, donor milk, formula), and age at initiation of enteral feeding.

Analysis of cohort demographics will be calculated using t-test for continuous variables and chi-squared test for categorical variables. Standard error of the mean will be used to calculate 95% CI. The primary outcome (days on TPN from the time of enteral feed initiation) will be compared before and after clinical practice change using unpaired t-test and Wilcoxin ranksum. To assess whether guideline implementation is associated with a change in outcome, we will plot the primary outcome by time (in months pre- and post-guideline implementation) on a run chart. Given that the primary outcome may depend on multiple independent variables, we will perform a multiple regression analysis as a function of pre- and post-guideline implementation and birth weight.

The secondary outcomes include time to full feeds (defined as 150cc/kg/day) and time to regain birth weight. Additional outcomes under consideration include frequency of necrotizing enterocolitis, rates of sepsis, duration of central venous access, and length of stay.

E. Study Procedures: No procedures will be performed in this study.

F. Study Drugs: No study drugs, approved or investigational, will be given in this study.

G. Medical Device: No medical devices will be used in this study.

H. Study Questionnaires: We will assess staff response to guideline implementation and any barriers to adherence with a questionnaire to be distributed at the end of Phase 2.

I. Recruitment of Subjects: We request a waiver of consent for data collected retrospectively in Phase 1 and prospectively in Phase 2. The study qualifies for a waiver of consent as per 45CFR46.116(d) as the following criteria are met in this study.

(1) The research involves no more than minimal risk to the subjects
    a. Justification: This is a non-interventional, quality assurance study.
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.
    a. Justification: The research involves no more than minimal risk of loss of confidentiality and waiver of consent will not adversely affect the rights of the subject.
(3) The research could not practicably be carried out without the waiver or alteration.
    a. Justification: For subjects whose charts will be reviewed retrospectively, it would be very challenging to contact parents to obtain consent for the subjects. We also request a waiver of consent for the prospective cohort, as obtaining consent can introduce bias from participation and non-participation in the study. This study requires 100% subject participation and cannot be performed without a waiver of consent.
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
    a. Justification: In the event that we learn something new or pertinent, we will make accommodations to reach out to patients.

J. Confidentiality: Data will be de-identified and each subject will be assigned a unique study ID. All data will be encrypted on an encrypted, password protected computer.

K. Potential Conflict of Interest: None of the investigators have any conflicts of interest to report.

L. Location of Study: The study will take place at the Morgan Stanley Children's Hospital neonatal intensive care unit on 7 Tower and 8 Central.

M. Potential Risks: The research involves minimal risk of loss of confidentiality, as this is a chart review. This risk will be minimized by limiting access to the database to qualified study personnel, maintaining the data on secure, password-protected hospital workstations or encrypted computers, and removing any unnecessary identifying information from the dataset.

N. Potential Benefits: If there is a decrease in the frequency of paused or held feeds, it is possible that feeds will be advanced earlier thus reducing time on TPN and possibly decreasing length of stay.

O. Alternative Therapies: There will be no experimental therapies employed in this study.

P. Compensation to Subjects: No compensation will be provided to the study subjects.

Q. Costs to Subjects: The patients will not incur additional costs as a result of participating in this study.

R. Minors as Research Subjects: Data will be collected retrospectively from the electronic medical record on infants. Numerous precautions will be taken to protect the data, as detailed above.

S. Radiation or Radioactive Subjects: This study will not employ radiation or radioactive substances.

References:

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