Human milk feeding, considered the optimal nutrition for infants, is recommended by the American Academy of Pediatrics and the World Health Organization. It is also part of the Healthy People 2020 national health agenda. For preterm infants, human milk reduces the incidence of necrotizing enterocolitis, improves feeding tolerance, promotes cognitive development, and decreases respiratory tract infections and sepsis. As a result, many hospitals have significantly increased their human milk feeding rates over the past 10 years.

Similar to national breastfeeding trends, NICU breastfeeding rates have also recently increased. Often, expressed human/breast milk (EBM) is the only option during the early postnatal period for NICU-admitted infants due to oral feeding restrictions. Ensuring safe EBM in the NICU is a complex process; EBM needs to be...
received, stored, and prepared with fortifiers or additives, and the bottles combined/divided before feeding. There is potential for error at any of these steps. When considering the large volume that is handled to feed many infants, each receiving multiple feedings per day, this risk is compounded. Medication errors are 3 times more likely in hospitalized children compared with adults, a similar error frequency may also extend to human milk handling and administration.

One of the most serious human milk errors that can occur is administration of the wrong milk to the wrong infant. This can result in the transmission of infectious diseases that may be present in human milk and leads to in-depth infectious disease testing of the donor mom, recipient infant, and recipient mom as well as authorization to disclose results to the recipient’s parents. Wrong human milk administration errors can erode the trust and confidence of patient families and result in increased costs from additional tests.

In 2008, the NICU at Nationwide Children’s Hospital (NCH) in Columbus, Ohio began a quality improvement (QI) initiative in an attempt to eliminate errors of the wrong milk being scanned in response to actual breast milk errors reported by nursing staff voluntarily through the hospital event reporting system. The purpose of the initiative was to decrease errors and the number of opportunities for actual errors. This report describes the interventions targeted at eliminating scanned wrong milk errors and improving overall breast milk safety.

METHODS

Context

NCH is an academic, nonprofit, free-standing children’s hospital located in Columbus, Ohio. Annually, the total inpatient and outpatient visits at NCH exceed 1.3 million. Neonatal services (neonatology) is a joint venture between NCH and central Ohio maternity hospitals. It is one of the largest neonatal intensive care programs in the United States with >250 neonatal beds. The main campus NICU consists of 114 neonatal beds divided among 3 level IIIC NICUs with >2100 neonates admitted per year. Twenty percent of these infants weigh ≤1500 g at birth, and >30% have major surgical problems. Currently, the NCH NICU consistently administers >6000 human milk feedings monthly, and up to 60% of infants are on human milk at any given time.

Interventions

The original breast milk administration process included handwritten labeling of milk bottles, and preparation/administration of bottles by nursing staff, without dedicated space to thaw, prepare, and warm the bottles. Thus, in response to actual breast milk errors reported by nursing staff voluntarily through the hospital event reporting system in 2008, a multidisciplinary QI team was established. The team consisted of representatives from clinical nutrition and lactation, neonatology (including nursing staff), information systems, and QI services. Using tools from the Institute for Healthcare Improvement Model for Improvement and Six Sigma, the QI team flowcharted the original process of collecting, storing, and administering breast milk; examined existing policies related to the process; and identified areas in the workflow where the system failed (failure mode effects analysis). The QI team identified key processes and implemented several strategies to reduce error rates.

First, the QI team revised and updated the EBM storage and handling process. Second, they sought approval from the hospital administration to purchase the Timeless Medical Systems’ electronic breast milk tracking system (a barcode medication administration system [BCMA] known as “Women and Infants” [W&I]). W&I was chosen because it allows for comprehensive tracking of EBM bottles. The team was confident that the decision to implement W&I would have a dramatic effect on reducing the number of wrong-milk-to-wrong-infant errors. The effort to reduce scanned and actual errors was based on previously defined best practices for breast milk administration.

W&I was implemented for use by nurses to check in, prepare, and administer EBM feedings via centralized scanners. At this time, bedside medication barcoding was unavailable in the NICU; therefore, to use W&I optimally, scanners had to be purchased. Because of budgetary constraints, only a limited number of scanners were initially purchased. These were installed in centralized locations throughout the NICU. Training and implementation of W&I took a few months to assess small processes of change needed before full implementation. The partial implementation of W&I in 2009 provided a baseline scanned error rate, which was used to assess subsequent improvement interventions to reduce scanned and actual errors. Scanned errors were then documented and graphed on statistical process control charts.

Six months after W&I implementation (April 2010), the nursing staff began using magnets on the outside of the breast milk refrigerators to identify the location of patient feeding bins in an attempt to reduce the risk of inadvertently selecting the wrong bottle. Additionally, in July 2011, additional scanners were purchased and installed at each bedside, which eventually were used to scan medications.
In 2011, another actual wrong-milk-to-wrong-infant error occurred. A full root cause analysis was completed with a detailed timeline of events and identification of individual and system related causal factors. A revised comprehensive human milk handling and storage process (exclusive of donor milk) was developed and audited for compliance (Fig 1). Moreover, the process for the evaluation and follow-up of wrong human milk administration errors was standardized. In addition, a full-time dedicated milk technician was hired, and plans for a centralized milk room were developed.

**Measures and Analysis**

The W&I system provides 66 possible scanned error codes. Ten codes were evaluated as “critical errors.” These were grouped into 3 categories: human milk expiration, wrong milk to wrong infant, and human milk preparation (Table 1). The monthly error rate, the primary outcome metric, was defined as the number of errors scanned in the W&I system divided by the total number of bottles fed per month as logged in W&I. The scanned error rate and the impact of additional improvement interventions from 2009 to 2015 were monitored by using statistical process control charts. Control charts were generated for the total number of scanned errors, as well as for each individual category of errors. A Laney adjustment was used to account for overdispersion in the data. We used a combination of linear regression, the 6 successively increasing or decreasing points rule, and the 8 consecutive points rule to assess trends and shifts in the data. The first 3 months of error data were not included in the centerline/control limit calculations because they reflected a W&I system software and hardware training period.

The main process measure was to estimate the concordance between the numbers of bottles fed as reported from either W&I or from medical records. The number of voluntarily reported errors followed a similar pattern.
Ethical Issues

This QI work involved implementing evidence-based interventions or best practices designed to reduce and ultimately eliminate human milk administration errors for neonates admitted to NCH neonatal services. Therefore, per human research protection program policy, this QI project was not considered human subjects’ research, and formal approval by the institutional review board was not required.

RESULTS

From 2009 to 2015, the most common scanning errors identified were due to expired milk, wrong-milk-to-wrong-infant, and preparation errors, respectively (Fig 2). During this time period, the total number of scanned errors declined from 97.1 errors per 1000 bottles to 10.8 (Fig 2). Specifically, the number of expired milk error scans declined from 84.0 per 1000 bottles to 8.9. The number of preparation (4.8 per 1000 bottles to 2.2) and wrong-milk-to-wrong-infant errors scanned (8.3 per 1000 bottles to 2.0) also declined. These scanned error rates have been sustained through 2015. The first centerline shift was observed in June 2011, in conjunction with the implementation of bedside scanners (Fig 3). The second shift was a continuous downward trend observed in 2012 after the implementation of a dedicated full-time milk technician. This trend was interrupted after only 5 points, but then continued after a small 1-point reversal. The application of linear regression to the entire 8-point slope from March 2012 to December 2012 (constrained at the end points to intersect the 2 flat stages, exactly as plotted) yielded a highly significant result ($P < .001$), making it clear that we do indeed have a valid downward trend. Therefore, we have plotted the centerline to conform accordingly (trend identification with regression confirmation is built into our control charting tool, so this did not require separate analysis).

Control charts for each individual category of errors scanned indicate that the decrease in errors scanned related to expired milk was associated with the use of magnets on the outside of the breast milk refrigerators and the implementation of dedicated milk technicians (Supplemental Figs 4–6). Similarly, the decrease in scanned milk preparation errors was also primarily associated with the hiring of a milk technician. Finally, the decrease in scanned wrong milk errors was associated with the installation of bedside scanners.

FIGURE 2
Breast milk errors scanned, 2009 to 2015. Data were based on errors scanned in the breast milk BCMA. After examining all 66 possible error codes in the BCMA, 3 categories of errors were identified: human milk expiration, wrong milk to wrong infant, and human milk preparation (Table 1).

In terms of process measures, we found ~92% to 100% concordance between the number of bottles scanned (data directly from W&I) and the number of bottles fed (abstracted from medical records), indicating W&I is capturing the vast majority of bottles fed on a regular basis. We also examined the number of all documented breast milk errors in the hospital event reporting system to determine if the number of voluntarily reported breast milk errors also declined. Although the event reporting system began before 2013, the W&I system was not fully implemented on all units administering breast milk until 2012. In 2013, data were categorized with more granularity to allow for more specific categorization of breast milk errors. We found that the number of voluntarily reported events also declined from 58 in 2013 to 29 in 2015.

DISCUSSION

We observed a decrease in the number of wrong milk errors scanned from 2009 to 2015. We also observed a decrease in the number of errors scanned related to breast milk expiration and preparation. Before the W&I system implementation, these errors were unrecognized. Declines in voluntarily reported breast milk errors during the same time period corresponded with the decreases in scanned errors. These decreases in scanned errors were primarily associated with 2 specific interventions: installation of bedside scanners and hiring of staff dedicated
to handle milk. Although examining scanned errors does not explicitly indicate a reduction in actual errors, such data indicate reductions in opportunities for actual errors to occur.

Current recommendations and reports of best practices suggest that centralized handling and use of barcode scanning improve human milk patient safety and contribute to time and cost savings. Thus, our interventions followed these recommended best practices. For example, hiring dedicated staff to handle milk was associated with decreases in milk preparation and expiration scanned errors. Similarly, installation of bedside scanners was associated with decreases in wrong milk errors. Both of these interventions highlight the need to effectively implement change(s) into the workflow of the unit.

Barcoding is recommended by the Institute of Medicine as a safety intervention and "proactive approach" to prevent problems with patient identification. The Joint Commission also lists barcoding as a way to meet National Patient Safety Goal 1. In response to these recommendations, BCMA systems are applicable to breast milk because breast milk is considered medicine. Others have shown that BCMA systems for human milk reduce wrong milk errors. As our study and other studies have demonstrated, BCMA has highlighted new, previously unmonitored scanned errors, such as the potential for feeding expired milk or incorrectly prepared milk.

As with medications, attention must be paid to the expiration date on human milk. With every freeze/thaw cycle of milk processing, some of the protective properties (such as antibodies) are destroyed, increasing the susceptibility of contamination, overgrowth of harmful bacteria, and risk of infection. As a result, NICUs must follow conservative shelf-life recommendations to protect their immune-compromised patients. Moreover, incorrect milk preparation, such as combining bottles that have already been fortified, has the potential to expose infants to inappropriate micronutrient concentrations that can cause harm.

FIGURE 3
Annotated control chart (u-chart) depicting the breast milk error rate. Data were based on errors scanned in the breast milk BCMA (bar code medication administration). PCA, patient care assistant. * Control limits are wider (or narrower) than standard because data variation in ≥1 baselines is too large (or too small) to meet usual u-chart statistical assumptions.
A risk of BCMA systems is the potential to develop work-arounds to circumvent the system and bypass safety features.\(^{28}\) For example, to facilitate the patient scanning process, staff may place a patient’s printed ID band on a report sheet and scan it instead of the band attached to the patient. Most nurses manage >1 patient at a time, and thus, by not scanning the infant ID band attached to the patient, they risk scanning the wrong patient band. A second example is the ease of skipping the disposal step for expired milk. If an expired bottle is scanned, an error appears on the screen. This should be a hard stop to additional milk preparation and feeding. Ideally, the expired bottle should be disposed before scanning a new bottle for feeding. However, after an expired error is logged, the system does not force disposal of the expired milk. These occurrences of expired milk are monitored and manually reviewed by nursing staff to determine if the proper procedures were followed.

The generalizability of this study is limited, because not all NICUs have a BCMA. The expense associated with implementing a human milk BCMA may be more appropriate for larger units and systems such as ours. Costs associated with the human milk BCMA include software, hardware, and staff time. Conservatively, the initial costs of a human milk BCMA system for a small- to mid-sized NICU could range from $100,000 to $200,000 with an additional $50,000 to $100,000 annually for ongoing support.

The success of this initiative was also influenced by the culture of safety established at NCH in 2009 with the implementation of our “Zero Hero” program to eliminate preventable patient harm.\(^{28,34}\) Because the implementation of this safety program preceded the implementation of W&I system, the clinical staff were already focused on QI and patient safety.

Although we observed a decrease in the scanned human milk error rate, our rate is not 0. Recently, we have begun tracking errors specific to donor breast milk. The local human milk bank implemented the same BCMA technology used by NCH. This allows seamless use of donor milk bottles. Additionally, the W&I system is used not only on our main campus (the focus of this study) but also in the satellite nurseries NICUs that are managed by NCH in birth hospitals throughout Columbus, Ohio. Error rates at these satellite units have not yet been examined. Finally, NCH has plans to integrate feed orders from the electronic medical record into the W&I system. This integration would allow the milk technicians to have the information for bottle preparation (eg, fortification) within W&I, eliminating the need to manually look up each patient’s feed orders in the medical record (which is our current process).

By reporting human milk errors, an uncommon practice in hospitals,\(^{1,6,27,28}\) and the strategies to reduce them, our study brings transparency in sharing data to improve outcomes. Sharing data between institutions (“all teach, all learn”) can facilitate rapid spread of best practices, potentially achieving optimal outcomes more quickly.\(^{35}\) Without a thorough understanding of the rates of human milk errors, and which human milk errors are occurring at which point(s) in the process, strategies to prevent harm are difficult to implement.

**CONCLUSIONS**

We have shown a decrease in the number of scanned human milk administration errors after a series of interventions. However, errors still occur. Thus, additional efforts are needed to additionally reduce the scanned error rate to ultimately eliminate errors. With human milk feeding increasing among infants admitted to the NICU, volumes of milk will continue to increase as will opportunities for errors. Patients and families should be able to trust the proper handling and administration of this aspect of medical care. Thus, continued efforts are needed to improve and disseminate successful strategies to ultimately eliminate human milk administration errors.

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**ABBREVIATIONS**

- BCMA: barcode medication administration system
- EBM: expressed human/breast milk
- NCH: Nationwide Children’s Hospital
- QI: quality improvement
- W&I: Women and Infants

**REFERENCES**


A Quality Improvement Project to Decrease Human Milk Errors in the NICU
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