Use of the Six Sigma Methodology to Reduce Incidence of Breast Milk Administration Errors in the NICU

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Abstract

Breast milk is the optimal source of nutrition for infants. According to research, neonates fed breast milk have a reduced risk of sepsis, increased feeding tolerance, a decreased incidence of necrotizing enterocolitis, and better neurodevelopmental outcomes. Unfortunately, researchers have not identified practices to reduce or eliminate the risk for errors in breast milk administration. This article discusses the potential hazards of incorrect administration of breast milk. It then describes how the tertiary care center at Children's Hospital of Illinois implemented a policy utilizing six sigma quality improvement methodologies to improve breast milk administration. Since implementation of this policy, the NICU at our hospital has reduced the risk of breast milk administration errors to less than 3.4 mistakes per million opportunities.

Breast milk is recommended as the optimal source of nutrition for infants. It contains immune properties that can reduce the risk for morbidity and mortality in neonates.[1] Research has shown that providing mothers' breast milk to premature infants can help reduce the incidence of necrotizing enterocolitis, reduce infection rates, improve feeding tolerance, and improve neurodevelopmental outcomes.[2–5]

Unfortunately, because of their infant's prematurity and/or severe illness, mothers of premature infants cannot begin breastfeeding immediately. They therefore begin expressing their milk soon after giving birth. Despite research detailing the benefits of breast milk, little research has been published demonstrating ways to reduce or prevent potential errors associated with the administration of expressed breast milk (EBM).

RISK OF INFECTION THROUGH BREAST MILK

Breast milk is classified as a body fluid similar to blood or plasma, and contact with any type of body fluid carries a risk for transmission of infection. Health care organizations throughout the world have adopted safety protocols and procedures for handling and administering body fluids to reduce this risk of infection. These precautions should be utilized when handling and administering all types of body fluids. It is important to remember that breast milk, like other body fluids, can carry infectious agents. The many possible infectious diseases that can be present in breast milk include human immunodeficiency virus (HIV), hepatitis, cytomegalovirus (CMV), herpes simplex virus (HSV), and methicillin-resistant *Staphylococcus aureus* (MRSA).[6,7,8] These agents can cause devastating consequences, especially if the wrong mother's milk is given to an infant.

Human Immunodeficiency Virus

Since the start of the HIV epidemic, nearly 4 million children worldwide have died of acquired immune deficiency syndrome (AIDS). Approximately one-third to one-half of the 1.5 million HIV-positive children in the world today acquired their infection via breastfeeding.[9] In the U.S., infants rarely contract HIV through breast milk because breastfeeding is contraindicated for HIV-positive mothers.[10] Unfortunately,

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the true risk of acquiring HIV from the wrong mother's breast milk is unknown.[11] This risk can lead families to seek legal advice about the possible transmission of the HIV infection. Attorneys currently advertise on the Internet offering legal assistance for potential medical malpractice litigation regarding HIV transmission through breast milk.[12]

Hepatitis

Hepatitis B (HBV) transmission through breast milk has been proven.[13] Studies have not found breastfeeding to significantly increase the risk of infection to infants, however.[14] An infant born to a mother who is HBV-positive should be given the hepatitis immune globulin and hepatitis B vaccination after birth, and these are believed to effectively reduce the risk of postnatal transmission, particularly in breast milk.[15] A baby given the wrong breast milk from an HBV-positive mother, however, would be at risk for developing HBV. This risk of acquiring HBV from misappropriated EBM would appear to be extremely low.[11] But it is theoretically possible. Hepatitis C (HCV) has also been identified in human milk, but its transmission has never been documented in medical literature. HCV is not listed as a contraindication to breastfeeding.[14]

Cytomegalovirus

CMV is in a family of rather ubiquitous herpes viruses.[16] About 50 percent of women test seropositive for CMV. It can occasionally be found in secretions, including breast milk, even when no symptom of disease appears.[17] The CMV found in breast milk of most seropositive mothers is not overtly dangerous, and the infants of these mothers can successfully breastfeed. Infants who are not provided maternal antibodies to CMV may be exceedingly susceptible to the virus present in breast milk, however. Breast milk from CMV-positive mothers should therefore never be fed to unprotected infants.[16]

CMV is able to survive even when breast milk is stored at −20°C. In a recent study, Hamprecht and colleagues obtained breast milk from two seropositive mothers and froze it at −20°C for ten days. The study revealed that CMV was still present in the milk fat of the breast milk and that CMV infectivity was reduced by only about 80 percent. In some cases, the virus load actually increased 3.8-fold in relation to the control level. Hemprecht and coworkers concluded that freezing breast milk at −20°C for ten days does not sufficiently reduce high loads of CMV.[18] Of the viruses discussed here, CMV is probably most likely to be contracted by an infant.

Other Viruses and Bacteria

Traditionally, active lesions on the breasts were thought to be responsible for the transmission during feeding of herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2). These viruses have been isolated in human milk even when the mother's breasts have been clear of vesicular lesions or drainage, however.[19] Kotronias and Kapranos investigated the presence of HSV-1 and HSV-2 in the EBM of 34 mothers who had recently given birth. The HSV DNA was present in 16 samples of expressed breast milk. In 10 of the 16 cases, HSV DNA was present in breast milk that had been expressed from both breasts. Kotronias and Kapranos concluded that HSV-1 and HSV-2 are shed into breast milk in significant proportions and that breastfeeding may be an important route for the transmission of these viruses to infants.[6]

Methicillin-resistant *Staphylococcus aureus* has been described as an important cause of hospital-acquired infection in the NICU. Transmission of MRSA to infants through breast milk has been described from mothers who had mastitis or a breast abscess. Behari and associates published a case report of preterm triplets who contracted MRSA through the mother's breast milk during their hospitalization in the NICU. In this case, interestingly, the mother had never shown any clinical evidence of mastitis or other local breast infection.[7] MRSA can also be known as oxacillin-resistant *S. aureus,* depending on which antibiotic the hospital lab uses for sensitivities.

Nonmedical Risks

In addition to the potential medical consequences of an infant receiving breast milk from the wrong mother, parents may experience psychological stress–induced anxiety if they think their infant may have contracted a potentially fatal disease. This can lead to a loss of confidence and to mistrust in the organization taking care of their infant(s). This mistrust of the organization could motivate parents to seek legal counsel or contact local media to discuss their infant receiving the wrong breast milk, creating negative publicity for that organization.

SIX SIGMA METHODOLOGY TO REDUCE RISK

Third Order of Saint Francis–St. Francis Medical Center is a 710-bed, not-for-profit, "magnet" designated tertiary care facility located in Peoria, Illinois. Children's Hospital of Illinois (CHOI), located within this facility, provides pediatric inpatient and outpatient services to 25 counties throughout central Illinois. The neonatal intensive care unit at CHOI is a 35-bed, Level III, multidisciplinary unit and annually has over 700 high-risk admissions. At CHOI, approximately 12,840 breast milk and formula feedings are administered monthly, with the NICU administering about 56 percent of them. A registered nurse or other health care professional feeding an infant the wrong mother's breast milk could lead to a cascade of negative events.

In the NICU at CHOI, the registered nurse administers expressed breast milk as a bolus feeding via an oral or nasogastric feeding tube. The process that begins when mothers bring in their expressed milk and ends when it is actually administered to the infant(s) is complex, with multiple steps

TABLE 1 ■ Definitions for the DMAIC Quality Improvement Process

Define: Identify the problem, create objectives for the project, and initiate the project.
Measure: Understand the current process in need of improvement.
Analyze: Use statistical analysis to understand causes and effects in relation to the current process.
Improve: Develop a plan that can be validated by statistical data to improve the process.
Control: Establish a monitoring tool or mechanisms to ensure that the process will be sustained.

involving a variety of health care professionals, including registered nurses and ancillary staff, and a variety of patient care technicians. The act of giving an infant the wrong breast milk in this complicated process of storing, preparing, distributing, and administrating EBM is called *misappropriation*.[11]

Over the years, misappropriation of expressed breast milk has occurred periodically at CHOI. During the month of October 2003 alone, three incidents of EBM misappropriation occurred at CHOI. The perceived reasons were multifactorial. They included high census and high acuity as well as parents obtaining the wrong bottle of breast milk for their infant. The administration at CHOI wanted to investigate the recurrence of misappropriation of EBM at the facility. In November 2003, it instructed the Six Sigma Quality Improvement Department to investigate reasons for the recurring misappropriation of EBM and then to develop and implement a hospitalwide system to meet six sigma standards.

Six sigma is a new management philosophy that seeks a nonexistent error rate.[20] Sigma, the 18th letter of the Greek alphabet, is also the statistical symbol for standard deviation. The fundamental objectives of six sigma are to use data to reveal defects in procedures, to employ customer-driven measures to establish the target for ideal performance, and ultimately to operate within six standard deviations of average performance. Once the goal is achieved, the organization operates at a level that is "defective" only 0.003 percent of the time.[21]

Six sigma originated in the manufacturing industry. The Motorola Corporation created it in the early to mid-1980s, and many other Fortune 500 companies have since adopted it to improve quality systemwide. Six sigma, a quality-improvement plan developed in response to customer dissatisfaction, uses data analysis and other problem-solving techniques to evaluate the ability of a process to perform defect-free.[22] The primary goal of six sigma is to eliminate the number of defects that can occur in a given process.[23]

In health care, six sigma methodologies seek to provide patients with near-perfect products and services and to reduce costs incurred by organizations. DMAIC—defining, measuring, analyzing, improving, and controlling—is a method used to allow the team to define and implement appropriate goals. The six sigma quality improvement team utilizes the five-step DMAIC process for every project.[24] Table 1 defines each phase of the DMAIC process utilized in six sigma.

The DMAIC process differs from other quality-improvement efforts such as total quality management (TQM) in that other efforts encompass data collection and analysis, but do not often involve the level of detail required to understand process variation.[20] TQM, for example, has drawbacks in the health care community. Its downfall is in determining what quality actually is and in defining it. The literature has shown that TQM has not produced results in health care as hoped.[23] TQM techniques seem to work best for individualized projects or departments, with the resulting changes limited in scale and impact. Furthermore, little evidence supports the claim that TQM programs can act as a means to achieve organizationwide change.[25] Unlike six sigma methodology, which attempts to reduce defects and errors throughout an entire organization, the TQM model fails to take into account the complexity of the health care environment and the professional knowledge of clinicians and other staff. Finally, the TQM model lacks the capacity to successfully improve health care quality without redesign or the incorporation of other quality improvement programs.[23]

The Six Sigma Quality Improvement Department at our institution created a project team that consisted of members of the administration, six sigma department, NICU, pediatric intensive care unit, general pediatrics, and mother/baby unit. The project leader was a blackbelt (a person who has received formal training in the six sigma methodology and is able to use different types of statistical methods to analyze potential causes of defects in the process) from the six sigma department.

The Defining Phase

In step 1, the defining phase, our project team determined that the current process for managing intake, storage, preparation, and distribution of breast milk was inconsistent among patient care units. These inconsistencies resulted in infants receiving the wrong breast milk, placing them at risk for infection, and causing stress for parents and family members. As an end result, parents and family members mistrusted the organization taking care of their infant. Identification of this problem occurred after the six sigma team completed a number of exercises, such as process mapping and fishboning, that dissected the problem into smaller, single categories that then allowed the team members to analyze each category in more detail.

The Measuring Phase

In step 2, the measuring phase, the team determined that the organization was functioning at a 5.2 sigma performance level with the current breast milk identification system. This level reflects a potential for causing 104 errors for every million feeding opportunities, or 1.04 errors for every 10,000 feeding opportunities. The six sigma project team found this number significant at CHOI, where approximately 12,840 feedings a

TABLE 2 ■ Sigma Levels and Percentage of Defects

Sigma	Percentage of Defects	Defects per Million Opportunities
1	69%	691,462
2	31%	308,538
3	6.7%	66,807
4	0.62%	6,210
5	0.023%	233
6	0.00034%	3.4
7	0.0000019%	0.019

TABLE 3 ■ Root Cause Analysis Results

- Inconsistencies and variation in management processes regarding bottled breast milk throughout Children's Hospital of Illinois
- Inconsistencies in educating parents about identifying, storing, and transporting expressed breast milk
- Staff errors due to multitasking requirements and an increased incidence of distractions
- Lack of formal and unified processes and limited space for breast milk storage and preparation
- Lack of accountability, with no written policy to enforce
- Lack of communication between patient care units as to proper handling, storage, preparation, and delivery of expressed breast milk

month are given. If the hospital continued with the current breast milk identification system, one misappropriation of breast milk could occur within the organization each month. Table 2 gives the sigma levels and percentage of defects per million opportunities.[26]

When the six sigma project team reviewed previous occurrence reports documenting the misappropriation of breast milk at CHOI and in the mother/baby unit, it found that most errors had occurred when a hospital employee grabbed the wrong bottle of breast milk because babies had similar names. In other scenarios, the staff person had not verified the name on the bottle of breast milk prior to administration, the staff person had not verified that the name on a bottle of breast milk delivered to an infant's bedside matched the name of the infant in the bed, a milk bottle had fallen from an overflowing storage bin in the freezer into another storage bin with another mother's breast milk, and frozen breast milk distributed at discharge had not been checked to verify that it actually belonged to the infant being discharged.

The Analyzing Phase

In step 3, the analyzing phase, the six sigma project team analyzed the data collected from the root cause analysis exercises. A root cause analysis identifies the underlying source of the defect so that the six sigma team can create solutions and modify the process in an attempt to permanently eliminate the defects. The root cause analysis revealed many opportunities for misappropriation of EBM. The six sigma project team identified six possible causes for these errors, as shown in Table 3. Inconsistencies in the breast milk management process throughout CHOI—a lack of consistent identifiers and breast milk identification processes on each unit—had led to errors. At the time these errors had occurred, no account numbers or identifiers other than the baby's name was being used. Furthermore, when staff transferred infants to different units, they did not check the labeled bottle of breast milk against the patient's armband to ensure that the correct milk was with the baby. Only NICU staff double-checked to make sure that the family had the correct breast milk upon discharge. The absence of a written policy for handling and distributing breast milk led the staff to believe that the substance was benign. Although breast milk is a body fluid, the staff perceived it as being different from a medication or blood and therefore did not think it necessary to have a double-check system for administration. This perception stemmed from a senior nursing memory: Prior to HIV/AIDS and hepatitis public awareness, community mothers had been able to donate extra EBM to a milk bank to be used for infants admitted to the NICU at CHOI.

Daily responsibilities of the staff require multitasking, which has the potential for error, especially without a safety check system in place. Also, the facility lacked formal written guidelines to give to parents or family members on how to handle expressed breast milk. At CHOI, the seven different patient care units gave parents different information on this process, all verbally. Refrigerator and freezer space in each of the patient care units were insufficient. Some patient care units lacked labels on the storage bins used to hold frozen breast milk. Unthawed breast milk from different mothers was placed on the same shelf of the refrigerator, making it easy to grab the wrong mother's milk. Finally, incident reports and information about misappropriation of expressed breast milk were shared only on the particular patient care unit where an error had occurred. Lack of communication between patient care units prevented hospital staff from learning about breast milk administration issues and from implementing practice changes that could have helped to prevent future misappropriation of expressed breast milk.

The Improving Phase

In step 4, the improving phase, the six sigma project team created a standardized system for intake, storage, preparation, distribution, and administration of expressed breast milk throughout CHOI. Table 4 outlines the implementation process, CHOI's new breast milk management and administration procedure, instituted on December 15, 2003.

The Controlling Phase

Step 5, the final step, is the controlling phase of the DMAIC process. In this stage, effectiveness of the newly implemented six sigma project is monitored. In December 2003, the six sigma team held an education day to explain the new process to patient care managers and nursing educators in the hospital. Nursing educators began holding inservice trainings to get the information to

TABLE 4 ■ New Breast Milk Management and Administration Policy for CHOI

Label Pumped Breast Milk

- Have mother complete preprinted label, including the following, and place it on the bottle:
  - Mother's name
  - Infant's first and last name
  - Date and time pumped
  - List of medications mother has taken in the previous 24 hours

Receive Milk

- Read label to be sure it is complete.
- If label is not complete, return bottle to mother/family member for completion.
- Add infant's account number to label before storing.
- Place milk in labeled bin designated for the infant and store in freezer or refrigerator.

Prepare Milk

- Clean Surface
  - Clean countertops with Virex™ wipes prior to milk preparation and between every two patients.
  - Wash hands and then put on clean gloves.
- Prepare Formula
  - Prepare formula bottles (from Nutritional Support Services or premixed) before breast milk bottles.
  - Store prepared formula above all breast milk and distribute in a separate bin after preparation.
- Prepare Breast Milk
  - Remove bottle from the proper bin in the refrigerator/freezer; double-check bottle label against bin label to verify correct breast milk.
  - Thaw breast milk in individual unlabeled containers.
  - To prevent cross-contamination, use clean measuring spoons for each can of powdered formula/fortifier and for each preparation time.
  - Measure powdered formula/fortifier and transfer to a clean medication cup; then add to breast milk.

Relabel Prepared Milk

- Relabel freshly prepared breast milk bottles, including the following information on the preprinted label:
  - Baby's first and last names (A, B, C, etc., if multiples)
  - Baby's account number
  - Baby's room number
  - Time thawed
  - Time of scheduled feeding
  - Type of breast milk (preparation/calories ordered by physician)
  - Name/initials of preparer
- Verify correct bin and bottle and then place newly labeled bottle in refrigerator in baby's designated holding bin.

Distribute Prepared Milk

- At designated feeding times, place prepared and relabeled milk in a centralized location for distribution by the bedside nurse.

Verify Milk for Administration

- RN: Read aloud the ID bracelet on the infant while another staff member or mother/family member follows along, reading the label on the bottle and silently verifying the following information:
  - Baby's name
  - Baby's account number
- RN or mother/family member: Upon verification of the correct milk with the correct infant ID band, feed the infant from the bottle.
- Never leave the milk at an infant's bedside unless the bedside RN has verified that this is the correct milk and the correct infant.

Verify Milk upon Transfer

- Transferring and receiving staff: Verify each one of the infant's bottles.
- RN: Read the milk label, name, and account number while another staff member verifies the label.
- Receiving staff: Place the milk in a newly labeled bin in the unit's refrigerator/freezer.
- Transferring staff: Document that all bottles have been verified with the receiving unit.

Verify Breast Milk at Discharge

- RN/PCT: Remove bottles from the refrigerator/freezer; take to the infant's bedside; read aloud while the mother/family member verifies, by silently reading along, that the label is correct. Verify each bottle of milk (fresh or frozen) with the mother or a family member.
- Staff person and family member: Verify each bottle label in this manner and then place the bottle in the transportation vessel provided by the mother/family member.
- If process is completed prior to discharge day, complete documentation in progress notes; have the mother or family member sign agreement with verification.
- RN: Upon completion of verification, check the checkbox on the discharge summary sheet.
- Mother: Sign the discharge summary sheet upon completion of discharge instructions; keep the yellow copy.
- Keep the white copy of the discharge summary sheet as a permanent part of the chart.

the staff in each unit. Patient care managers from each of the patient care units at CHOI signed a responsibility statement making them accountable for their unit's successful implementation of the breast milk management and administration procedure. The Six Sigma Quality Improvement Department, through direct observation of the process, performed weekly checks for four weeks and then monthly checks to ensure compliance with the new policy.

RESULTS

Hospital staff accepted the new breast milk administration policy with little resistance. Between December 2003, when the new policy was first implemented, and March 2006, the NICU of CHOI has had no documented cases of misappropriated breast milk. A few near misses were reported and successfully addressed before misappropriation of EBM occurred, however.

In conclusion, the six sigma methodology is an effective strategy to eliminate problems within any organization that aims for better quality in its care. An appropriate and effective breast milk administration policy can lead to reduced misappropriation of EBM for any health care facility. Staff must be consistent in following the policy and also must be aware of the seriousness to the infant and the families of the NICU.

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