The preferred nutrition for all newborns is mothers’ milk. Research supports the argument that breast milk provides added benefits to an infant’s health, nutrition, immune system, development, psychological and social well-being, and economic status. Mothers’ milk is especially favored for vulnerable infants in the neonatal intensive care unit (NICU). A recently reported prospective study indicates that feeding mothers’ milk to extremely low-birth-weight babies improves their “cognitive skills and behavior ratings” and even reduces the need for special education later in life. Newborns also receive their mothers’ antibodies in the milk, which may provide protection from infectious diseases. The American Academy of Pediatrics (AAP) emphasizes the benefits to newborns in their 2005 policy statement.

However, breast milk can carry bloodborne pathogens and therefore may transmit disease when ingested. When mothers and babies are separated in the hospital environment, the risk of breast milk mismanagement increases. Ensuring consistent delivery of the correct mother’s expressed breast milk (EBM) (i.e., breast milk that has been pumped and stored) to the correct baby is a challenge. Considering the thousands of feedings delivered and the multiple steps in handling EBM, relatively few occurrences in which a baby received the wrong EBM have been reported to PA-PSRS. Yet, when an infant is fed the wrong mother’s EBM, both the family and staff experience anxiety regarding the potential risk to the infant, as well as uncertainty regarding how to respond to exposure when an error occurs.

Because the advantages of breastfeeding far outweigh risks related to infection, mothers are encouraged to breastfeed their infants. It is important for facilities to identify risk factors related to infants receiving incorrect EBM, implement strategies to mitigate the risk of EBM mismanagement, and follow a good plan of care in the event of EBM mismanagement.

PA-PSRS Reports
More than 30 cases involving breast milk have been reported to PA-PSRS. Of these, approximately 20 reports indicated that an infant had been fed another mother’s EBM. Other problems identified include labeling issues, identification or verification issues, and storage issues (i.e., refrigeration or freezing systems malfunctioned). The following cases are indicative of these problems:

- Nurse removed wrong breast milk from refrigerator to be given to baby. Mother started to feed and noticed a different label on bottle. Mother brought mistake to nurse’s attention. Baby took 5 cc before error realized. Certified registered nurse practitioner was informed of error. HIV testing done on mother whose milk the baby took, and all tests negative.

- During finger feeding, it was discovered that a baby was receiving breast milk intended for another baby. The infant was fed approximately 15 cc of breast milk.

- After a baby received two feedings of breast milk from a bottle labeled with the baby’s name, the baby’s mother reported that she had not expressed any milk. Investigation revealed that the bottle had been mislabeled.

A refrigerator used to store breast milk was found not working; the milk was warm, although the temperature on the refrigerator had been checked daily and recorded within the appropriate range. All EBM was discarded, and a new refrigerator was obtained.

This article will focus on the mismanagement of breast milk in the care of hospitalized infants, either in the NICU or newborn nursery setting. Discussion will center on the risk factors involved, risk reduction strategies to reduce the incidence of infants receiving another mother’s EBM, and recommendations for the plan of care when an error occurs.

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Mismanagement of Expressed Breast Milk (Continued)

Accompanying Resources
Visit the Patient Safety Authority Web site (http://www.psa.state.pa.us) for a mismanagement of expressed breast milk toolkit that includes the following:

- A copy of this article that can be downloaded and e-mailed to colleagues
- A stand-alone, plan-of-care algorithm for when mismanagement occurs
- A sample policy that can be adapted to be facility-specific
- Informative handouts for patients and staff about the risk of infection related to mismanagement

To view the toolkit, click on "Advisories and Related Resources" in the left-hand column of the Authority’s home page. Then, click on "Resources Associated with Patient Safety Articles."

Risk Factors Contributing to Infants Receiving the Incorrect Breast Milk

Identification Issues
The greatest risk identified in the literature and supported by PA-PSRS data is infant misidentification. A common misidentification error in the NICU involves feeding a mother’s EBM to the wrong infant. In a study conducted by Gray et al. in a 40-bed NICU in Massachusetts over one year, it was determined that, "Not a single day was free of risk for patient misidentification." Gray et al. also cited results from the Vermont Oxford Network, a voluntary error-reporting system conducted for one year, in which 25% of reported misidentification errors (i.e., 11% of 1,230 submitted reports) involved EBM. The factors identified in these events included "incorrectly labeled specimens, difficult-to-read handwritten specimen labels, errors in verification of patient/aliquot identification, and systematic problems with the way EBM aliquots are stored."

The PA-PSRS data is consistent with this finding of high-risk misidentification in the NICU. Of reports received from June 2004 to February 2007 for babies younger than two years of age, a total of 1,475 cases were related to identification issues of one type or another, with 358 of these reports (24.3%) initiated in the NICU. Additionally, there were 447 reports (31%) initiated in the newborn nursery, obstetrical/nursery unit, pediatrics, and pediatric intensive care unit. Other care areas associated with misidentification reports in this age group included: labor and delivery with 145 reports (10%), the emergency department with 128 reports (9%), and the laboratory with 107 reports (7%). The remaining 290 reports were identified in miscellaneous patient care units and nonclinical areas, such as admissions and registration.

Labeling
Labeling is a multistep process. When labels are created at a facility, label selection, imprinting, and attachment are all potential points of breakdown. Bar coding is similarly affected if bar-coded labels are not verified when made.

Verification
Verification is the process of confirming that the label on the infant matches the label on the EBM. Verifying the baby’s armband and the EBM label may not occur due to the following:

- Missing identification bands (Identification bands are often affixed to the bedside or chart to avoid skin injury to infants.)
- Inconsistent or inadequate procedures
- Inexperienced staff who are unfamiliar with verification procedures
- Staff workload and busy units where processes are interrupted

Storage Organization and Management

- Lack of dedicated space for refrigerator and freezer to store EBM
- Lack of adequate storage space
- Lack of standardized containers with appropriate labels
- Lack of alarms for monitoring appropriate temperature
- Storage of known-infectious EBM

Dispensing

- Inadequate procedure for selecting the correct milk
- Problems with transporting milk from storage to mothers at bedside
Mismanagement of Expressed Breast Milk (Continued)

Administering/Feeding
- Inadequate process for verifying and matching baby to mother's milk
- Failure to follow doctors' orders for amount of feeding and additives

Risk Reduction Strategies
The following strategies can help to ensure reliability through standardization and with deliberate redundancy of verification. Following these guidelines can prevent an infant's exposure to another mother's EBM.6

Separation of Mother and Baby
- Unless clinically indicated, avoid separating infants from their mothers.
- When infants are separated from mothers, implement a process with high reliability for correct identification.5

Identification Issues5,8
- Maintain infant identification in two sites at all times. Preferably, affix one identification band on the baby.
- Only apply identification bands that are complete and legible.
- Always check the identification band before administering any medications or feedings and before performing any treatment or intervention.
- Educate parents on the importance of maintaining identification bands on their baby at all times.

Labeling
- Label all EBM containers consistently, correctly, and clearly, using moisture-resistant ink.5
- Include on the label the baby’s and mother’s name, baby’s medical record number, date and time the milk was expressed, and, if applicable, the date and time the milk was thawed.5
- Provide the mother with the container and complete label, as noted above, at the time she is expressing her milk. Instruct the mother to document the date and time that the milk was expressed on the label, and immediately apply the label to the storage container. Apply the label to the container in such a way that it would need to be reconciled when opening the container.
- Inspect the label for accuracy/complete information before storing the container in the refrigerator or freezer.5

Storage Organization and Management
- Establish a designated area for both a freezer and refrigerator for storing EBM.5
- Maintain refrigerated EBM at 2 to 4 C°. Use or freeze the EBM within 48 hours.9
- Maintain temperature of freezer used for EBM at -20 C° to -18 C°.9
- Provide sterile containers with a solid cap to provide airtight seal.5
- Allocate an area with a labeled storage basket/container for each baby.5
- Maintain a log of refrigerator/freezer temperature checks every shift.5
- Install alarms that are programmed to sound if there is unacceptable change in temperature.5
- Separate containers with the same or similar names on label.5
- Do not store known-infectious EBM with non-infectious EBM.

Dispensing
- Maintain a current log with mother’s name and the date and time milk was expressed, and have staff initial the entry when dispensing milk to a baby.6
- Have staff verify with the mother that the label on the milk container matches the mother’s and baby’s identification band, just as they would with a medication.6 If mother is unavailable at the time of dispensing, have staff verify with another healthcare worker.

Education/Communication
- Educate all staff about the protocols outlined above; verify that they can demonstrate correct procedure when handling EBM.
Mismanagement of Expressed Breast Milk (Continued)

- Develop a process to ensure all casual/pool/agency/relieving staff are aware of and understand EBM protocols.
- Provide parents with education, including verbal and written information on the collection, labeling, storage, and dispensing process for the management of EBM.7

When an Exposure Occurs: A Plan of Care

If an infant is fed another mother’s EBM, there is concern regarding possible exposure to HIV, hepatitis B virus (HBV), and other infectious diseases, including hepatitis C virus (HCV) and cytomegalovirus (CMV).7 There have been no reports in the medical literature of any cases of HIV transmission through EBM fed to the wrong infant.7 However, transmission of HIV through breastfeeding has been documented with HIV-positive mothers.7 The risk of HIV transmission is low but not zero when an infant is fed another mother’s milk.

When a mistake occurs, inform both the source and biological mothers of the event, and advise them of the protocol for an exposure. The following plan of care, based on the clinical literature, includes options and guidance for staff and mothers when an EBM mistake occurs.

Consent for Record Review and Testing

Obtain written consent from both mothers for review of their prenatal7 and obstetrical laboratory reports for HIV and HBV. Reviewing both of the mothers’ prenatal and obstetrical records can help to determine whether the baby involved was exposed to any pathogens prior to the EBM mistake.

Soliciting consent for review and disclosure of protected patient information is always sensitive and governed by federal law. In Pennsylvania, Act 148 is an additional consideration when HIV testing or results are involved. Act 148 requirements include the following actions:10

- Obtaining informed consent, preceded by an explanation of the test, its purpose, potential uses, limitations, and meaning of its results
- Providing information about the prevention, exposure, and transmission of HIV before an HIV test is performed
- Informing the patient of the test results (e.g., a good faith effort on the part of the ordering physician to personally inform the patient)

In Pennsylvania, it is essential that facility policies and procedures regarding HIV testing be in accordance with Act 148, including the use of designated forms for HIV consent and disclosure to assure protection of individual rights.

HIV

If any test of a mother is confirmed to be HIV positive, breastfeeding by that mother is contraindicated.7,11-13 Storing EBM from identified HIV-positive mothers is likewise contraindicated, and existing stores may need to be checked to verify that such EBM is not present.

Prenatal test results.

If a prenatal test is HIV positive, there will probably be ongoing antiretroviral therapy for the identified HIV-positive mother and prophylaxis for her baby.11 An infectious disease consult can guide this therapy.

If the results are positive for the source mother of the EBM, then the infant who received her milk needs to be tested, as well as her biological infant, and managed according to the infectious disease consultation.11

Significant time may have lapsed between prenatal care, delivery, and the EBM mistake, and both mothers’ risks of exposure may have changed, warranting additional follow-up postpartum testing. Therefore, manage each case on an individual basis.2,7 If neither mother is considered a candidate for retesting and both mothers test negative for HIV, provide standard nursery care for both babies.

Postpartum test results. If either mother is identified as HIV positive, test her infant and any other infant who has received her milk for HIV. Obtain a consult with an infectious disease specialist for treatment of the HIV-positive mother, her biological infant, and the recipient infant. If this is a new finding, the risk to the infant(s) is increased secondary to the possibility of the HIV-positive mother having a high viral load associated with a recent infection.11

If both mothers test negative for HIV, provide standard nursery care for the infants.

Unknown status. If either mother has unknown HIV status, was not screened, or refuses screening, CDC promotes routine screening for HIV of any infant who received her milk.13 Either mother may not have had prenatal care or refused testing during pregnancy. Refusal to consent for review of the prenatal and obstetrical
Mismanagement of Expressed Breast Milk (Continued)

records or consent for blood testing may occur. There is no standard for use of prophylactic antiviral treatment, but its use could be considered in high-risk situations. Medications used in HIV prophylaxis have potentially serious side effects and the risk versus benefit of chemoprophylaxis should be considered on a case-to-case basis. This treatment would be determined by an infectious disease specialist.

HBV

**Prenatal test results.** If the prenatal test is positive for hepatitis B surface antigen (HBsAg) for either mother, verify that HBV vaccine has been given to both infants. (AAP recommends that all newborns receive this vaccine at birth.) Additionally, if the source mother tests positive, give hepatitis B immunoglobulin to any infant who received her milk as well as to her biologic infant. This provides enhanced protection from HBV.

If the prenatal tests are negative for HBsAg, it may be reasonable to retest based on the time lapse from testing to the event.

**Postpartum test results.** If the source mother or the biological mother tests positive for HBsAg, give hepatitis B immunoglobulin as noted above. HBV-positive mothers are encouraged to breastfeed their infants. Despite the fact that particles of HBV have been found in human milk, there have been no reported cases of HBV transmission via human milk.

If the postpartum test result is negative for both mothers, verify that HBV vaccine has been given to both infants.

**Risk of HCV**

HCV particles have been identified in human milk from infected mothers. However, the transmission of HCV has not been documented in the literature. The CDC guidelines do not list HCV as a contraindication to breastfeeding. Therefore, no testing is recommended.

**Risk of CMV**

CMV is widely prevalent and known to be transmitted to neonates in breast milk. Full-term infants are at minimal risk, probably due to the antibodies present in breast milk. However, the CMV controversy continues to unfold. Although freez- ing breast milk does not eliminate the virus, it does significantly decrease the viral load. There have been no reported cases of a breast milk mishap causing a CMV infection. Given the limited exposure when an infant is fed another mother’s EBM, and the lack of potential treatment and interventions, routine testing for CMV is not recommended.

### Staff/Mother Education

Education and communication are crucial to providing safe feedings of EBM. Staff knowledge of EBM management is essential to maintain a reliable system. Mothers require education at the time of admission, with emphasis on the importance of following labeling and storage directions for EBM. Additionally, mothers need basic instruction in how to safely express or pump their milk, as well as guidelines for storage, including transporting EBM. The prevention strategies presented in this article are crucial to limiting mistakes with breast milk.

However, when an event occurs, staff and parents experience anxiety. Implementing a standardized approach to the management of EBM mistakes can provide comfort and reassurance. Nurses should be knowledgeable of the risks to the infant, as well as testing to be performed. A primary goal is to provide support and education to families when an error occurs. Include the following information in educational packets:

- Fact sheets with clear and simple explanations of infectious risks to infant
- Plan of care with rationale and description of blood tests to be done
- Consent forms for testing and releasing results
- Follow-up care for infant if indicated

### Notes

Mismanagement of Expressed Breast Milk (Continued)


The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI Institute, as contractor for the PA-PSRS program, is issuing this publication to advise medical facilities of immediate changes that can be instituted to reduce Serious Events and Incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s Web site at www.psa.state.pa.us.

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