

Patient Safety Tip of the Week

April 8, 2014

FMEA to Avoid Breastmilk Mixups

Our November 17, 2009 Patient Safety Tip of the Week “[Switched Babies](#)” had an extensive discussion of the risk factors and contributory factors to incidents of both switched babies and breastmilk mixups. Breastmilk mixups are far more common than switched babies and have potentially serious consequences. Our December 11, 2012 Patient Safety Tip of the Week “[Breastfeeding Mixup Again](#)” further defined the magnitude of the problem and described the numerous factors that contribute to such occurrences. We noted that if you do a FMEA (failure mode and effects analysis) in your own organization we suspect that you will find numerous potential vulnerabilities to these errors. We’ve done FMEA’s with hospitals in the past on both topics (switched babies and breastmilk mixups) and are always amazed at the complexities involved.

We came across a newly published FMEA on breastmilk feeding ([Zhang 2014](#)) that provides a good model for organizations to use for their own FMEA on the topic. Their interdisciplinary team of involved stakeholders began with a mapping of the baseline processes and flow in their level IV NICU. They then developed an evaluation grid that included the risks associated with each failure mode from three perspectives (severity, occurrence, and detection). A scale of 1 to 10 was used for each of those risks and an overall risk priority number (RPN) was estimated by multiplying the ratings for those three risk ratings. They then tested the feasibility of potential interventions and did benchmarking with both regional and national similar organizations.

One extremely important point they found is that it’s simply not enough to flowchart the processes you think are in place. You need to actually observe and talk to all involved parties. You will typically find that, in practice, things are frequently done differently than expected. For example, though their policy required that only nurses could receive and handle breastmilk they found that breastmilk was often handled by family, visitors or unit coordinators. Even though nurses were the only ones who could prepare the milk and mix in any additives and warm the milk, parents (who would feed the baby) in some cases had unrestricted access to the preparation area and could conceivably take the wrong milk to their baby. As we’ve pointed out in many of our columns, when you identify a workaround or deviation from expected processes you always need to find out why. Workarounds are a red flag that you have a flawed process and you need to do a root cause analysis (RCA) to determine the factors contributing to the need (perceived or

real) for that workaround. The authors did just that. Whenever they found a deviation of process steps they did an RCA.

Their flowcharting sorted the process into three phases: (1) intake and storage (2) milk preparation and (3) feeding. They found 32 failure modes that had a severity of 10 and would not be detected automatically. They found multiple complexities and potential risks in all phases. For example, they found that a nurse needed to make 18 different decisions in the preparation phase for just one patient. Compound that with the need to prepare milk for multiple patients and the issues of multiple users, interruptions and multiple handoffs. Moreover, the same nurse preparing the milk likely had multiple other patient care duties.

They did a Pareto diagram of the potential interventions ranked by the RPN scores. The top six interventions (that put them above 80% on the Pareto diagram) were:

1. having a separate milk processing area
2. a milk inventory system with barcoding
3. increased refrigerator storage capacity
4. having an FTE designated to milk handling and prep
5. using private patient rooms
6. establishing a milk feeding administration record

Other interventions identified included patient and nurse education, communication and handoff issues, and others.

After the FMEA, RCA's and benchmarking, some of the key recommendations they made were finding dedicated preparation spaces, developing a staffing model that included milk technicians, and creating a process for tracking feedings in the electronic medical record.

This is a well-done FMEA and should help you and your organization do your own FMEA. We are often asked by hospitals what topics are best for FMEA's (remember you have a Joint Commission requirement to do FMEA's). For those hospitals that have obstetrics or otherwise care for neonates and young infants, we usually recommend doing a FMEA on either the risk of switched babies or switched breastmilk

We again refer you to our Patient Safety Tips of the Week for November 17, 2009 "[Switched Babies](#)" and December 11, 2012 "[Breastfeeding Mixup Again](#)" for comments on multiple other risks and contributing factors you are likely to find. Among such are issues related to similar names, language barriers, room changes, and failure to correctly identify the infant or milk preparation. We discuss technologies (barcoding, RFID) and bedside tools (checklists, timeouts) that are important considerations in your interventions.

In our December 11, 2012 Patient Safety Tip of the Week "[Breastfeeding Mixup Again](#)" we also noted the Pennsylvania Patient Safety Authority had issued a Patient Safety Advisory on Mismanagement of Expressed Breast Milk in 2007 ([PPSA 2007](#)) after 20 reports of infants being fed another mother's expressed breast milk. They identified risk

factors that involved not only identification issues but also labeling issues, and problems with verification, storage and dispensing. The Advisory has good recommendations on risk reduction strategies and an **excellent section on how to respond and manage patients when such exposures do occur, particularly managing the risk for infectious disease transmission**. All those recommendations obviously would also apply in cases where infants were directly exposed to breastfeeding by the wrong mother.

And, lastly, don't stop after you've implemented changes. Make sure you go back and audit your new processes to ensure you've not created new workarounds and unintended consequences. Because the outcomes you are trying to prevent (giving the wrong breastmilk to the wrong baby) are rare, you'll have to measure other parameters to assess that you are likely reducing the risk of such undesired outcomes.

References:

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