Pediatric Nutrition
CONTINUING EDUCATION FOR CLINICIANS

COURSE TRANSCRIPT

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

Overview

Caroline Steele, MS, RD, summarizes regulatory standards and recommendations for human milk and formula handling. She outlines potential failure points that can lead to formula and breast milk mishandling and misadministration and highlights best practices to reduce these risks.

Ms. Steele is an expert on pediatric nutrition and lactation, and is co-editor of the newly released, third edition of *Infant and Pediatric Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*.

Content Areas

- Formula preparation
- Breast milk handling
- Feeding best practices
- Preventing contamination
- Reducing misadministration errors

Target Audience

This activity was developed for physicians, pediatric nurse practitioners, nurses, registered dietitians, and other health care providers who have an interest in newborns, infants and toddlers.

Section

Learning Objectives

At the conclusion of this activity, participants should be better able to:

- Recognize the risks associated with mishandling and misadministration of human milk and formula
- Review current guidelines for the safe preparation of human milk and formula feeding
- Identify at least one best practice for implementation within your unit or hospital

Faculty

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The estimated time to complete the activity is 1.0 hour.

This activity was released on December 11, 2020 and is eligible for credit through December 11, 2022.

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Contact Information

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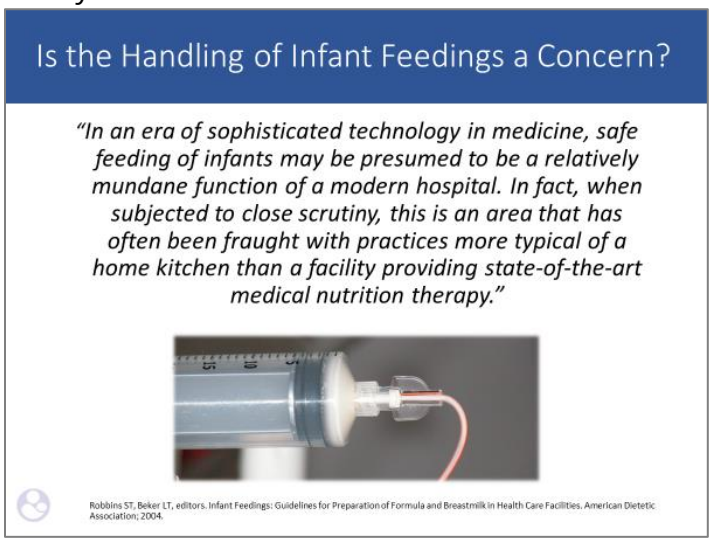
Editor's Note: This is a transcript of an audio webcast presented on December 5, 2018.

Caroline Steele: We'll be talking about risks associated with mishandling and misadministration of human milk and formula. We're really going to dig into the current guidelines and best practices to provide safe feedings within the health care setting.

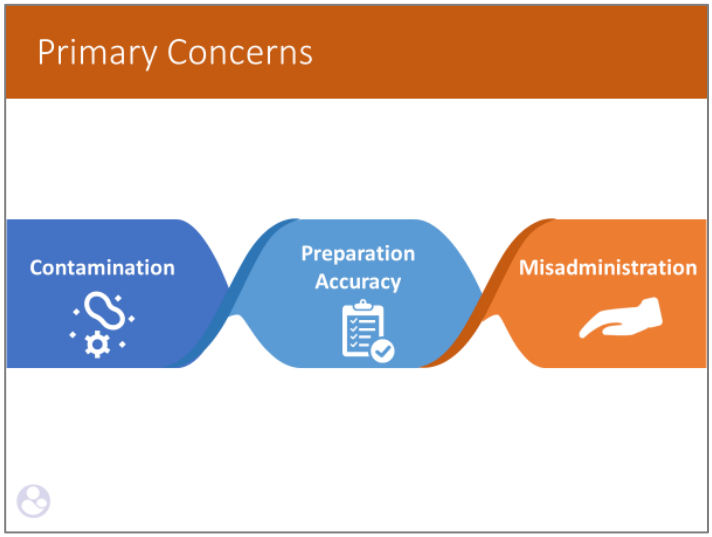
I'm going to start with this quote from Sandra Robbins. And I love it. It's from the first edition of the *Infant Feedings* book.[1] She basically says, in this era of sophisticated medicine, where we're doing very complex things, we should have very high-tech infant feeding preparation. And in fact, when we look closely, it often looks more like you would see in a home kitchen than in a state-of-the-art medical facility.



Slide 1

I think that really is true. There's a lot of things we can do to improve how we handle infant feedings.

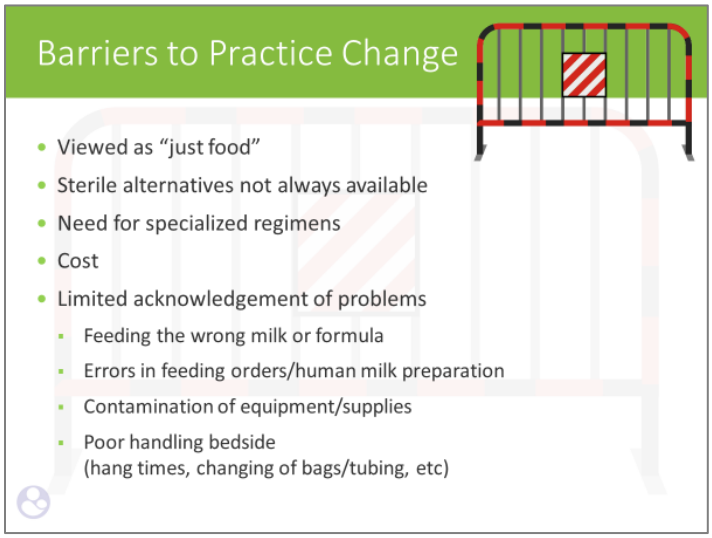
There are 3 primary areas of concern when we're talking about breast milk and formulas that we handle in the hospital. There's contamination, preparation accuracy, and misadministration. We're going to go through each of these individually.



Slide 2

But I want to state why are there barriers to practice changes. Sometimes we know we could be doing things differently, but we have a hard time facilitating that change. Sometimes it's because we view it as just food; or in pediatrics, we have such highly specialized regimens that make things complicated; we may not always have sterile alternatives to use in our feeding preparation; there's often costs associated with making major program changes; and oftentimes we don't admit that there's a problem. I hear all the time people say, "Well, we don't make breast milk errors," or "We don't make formula errors." The truth is, it's probably that there aren't mechanisms in place to

capture those errors. We're going to talk about that a lot today.



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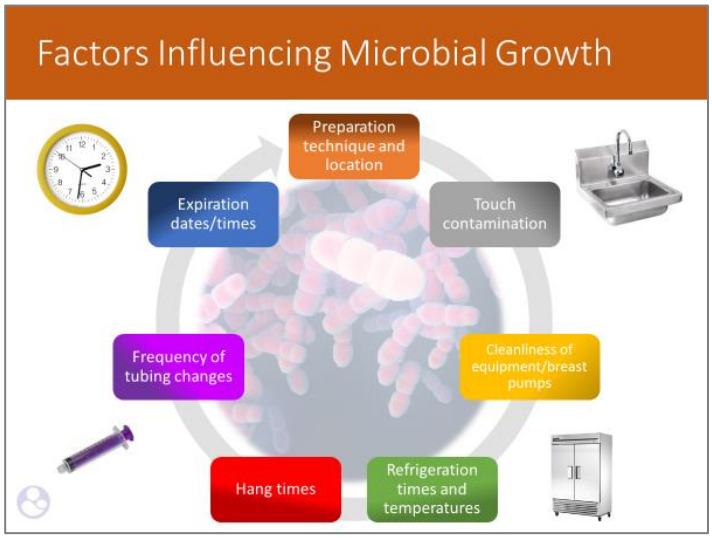
Contamination

Let's talk about contamination first. There are many factors that influence microbial growth. There's your preparation technique and location, touch contamination or your hand hygiene, the cleanliness of your equipment as well as breast pumps, because if breast pumps are contaminated at the time milk is pumped, that milk could be contaminated to start with. There's your refrigeration times and temperatures, hang times for tube feeding, frequency of tubing changes, and finally your expiration dates and times.



Slide 4

What are the consequences of contamination? Well, we know that GI illness can occur when you have 10^5 CFU/mL or higher. That could be from ingesting live organisms or toxins produced. In severe cases, this can cause gastroenteritis or necrotizing enterocolitis.

I often think about those patients that have feeding intolerance, and I sort of put that in quotes where maybe they've been on feedings for a while and all of a sudden, they're not tolerating it and we switch it because we think it's the fortifier we're adding or the formula that we're using. I often wonder if that's really just good old foodborne illness where there has been contamination at some point in the process and it's leading to GI illness.

Certainly, we know if these microbes invade beyond the mucosal barrier, you can end up with systemic disease and sepsis.

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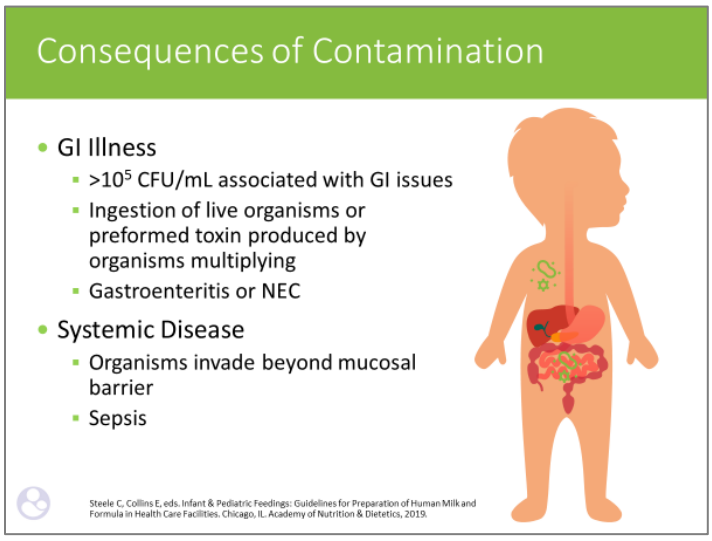

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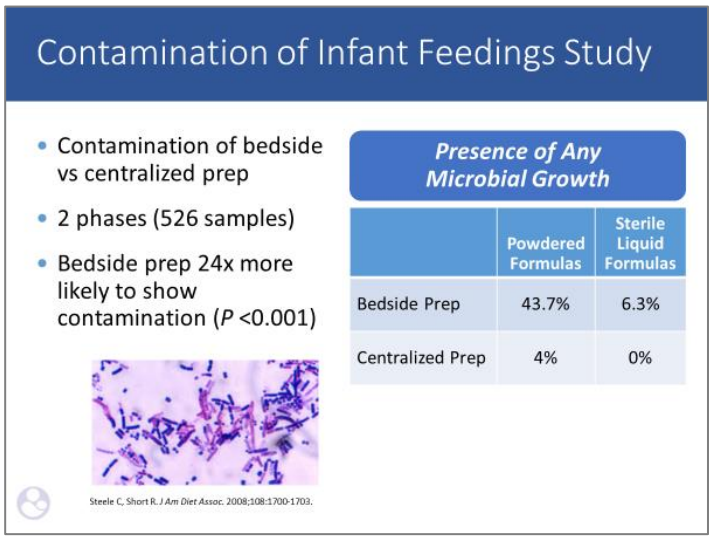

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This study was one that I did.[2] It started actually in the early 2000s and was published in 2008. At the facility I was working at, we were building a brand new NICU. We were going to go from bedside prep to centralized prep of our handling of feedings. Now, my caveat is bedside prep wasn't actually at the bedside but was at a little cart in the corner where we were preparing feedings. In this study, we only looked at formulas. The reason was, even though we had very high breast milk uses, we knew we could not control for how human milk was handled before it got to the facility: whether the mom sterilized her pump parts, whether the milk was held at appropriate temperatures. So we only looked at formulas.

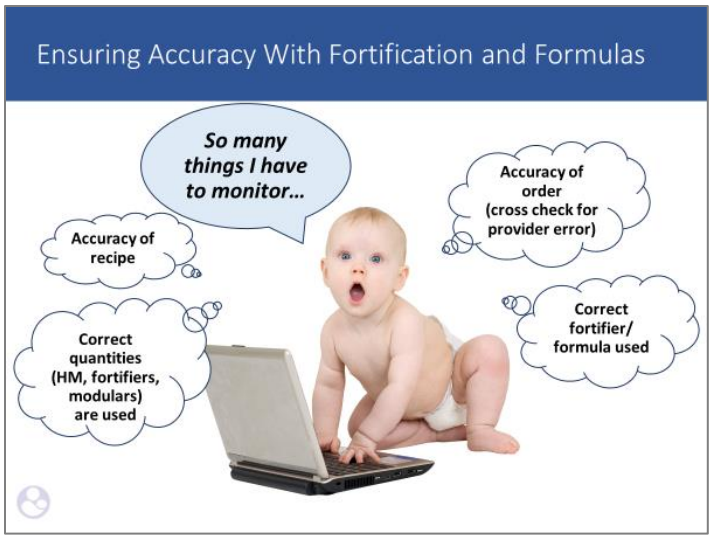
What we found was that bedside prep of infant formulas, they were 24 times more likely to show some level of contamination than centralized prep. In both phases of the study, no one knew we were studying them so when nurses were preparing bedside, they didn't know we were studying them, and when our technicians were preparing in our centralized location, they didn't know that either. Because, the first thing that people do when you're watching them is they do things differently. We wanted to see what it was like in actual practice.

You can see on the right-hand side of the slide there [Slide 6], powdered formulas, which are not commercially sterile to start with, about 44% of them showed some level of microbial growth when prepared bedside. When that moved to centralized prep, that dropped to 4%, so that was very dramatic. What that told us was that, yes, powdered formulas aren't sterile, but really it's how you handle them, rather than the product itself, that had the biggest impact. You can also see that sterile liquid formulas—these are products that are commercially sterile to start with—about 6% had some microbial growth when handled bedside. That could be merely drying it up in syringes, or some sort of handling at the bedside. When those were unit-

dosed in centralized prep, that dropped to zero. So again, starting with a sterile liquid is important, but how you handle it still makes a difference.

Accuracy of Preparation

We've talked about contamination, I want to move on to accuracy. There are a lot of things to keep in mind when you look at accuracy of feeding prep within the hospital setting. You've got your accuracy of orders. We have many products with very similar names and products for patients of all ages. We want to make sure that our providers are choosing the right product. We want to make sure once we have the right order in, that the recipe is accurate for the calories and the formula that you're wanting to prepare.



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Then once you have an accurate recipe, you still have to make sure that the person preparing it uses the correct product, that they actually grab the right item off the shelf. You want to make sure that even if the recipe is accurate, that what they've measured out from a quantity standpoint in grams or milliliters is correct for all the additives. There is really a lot to keep in mind there as you're moving through that process.

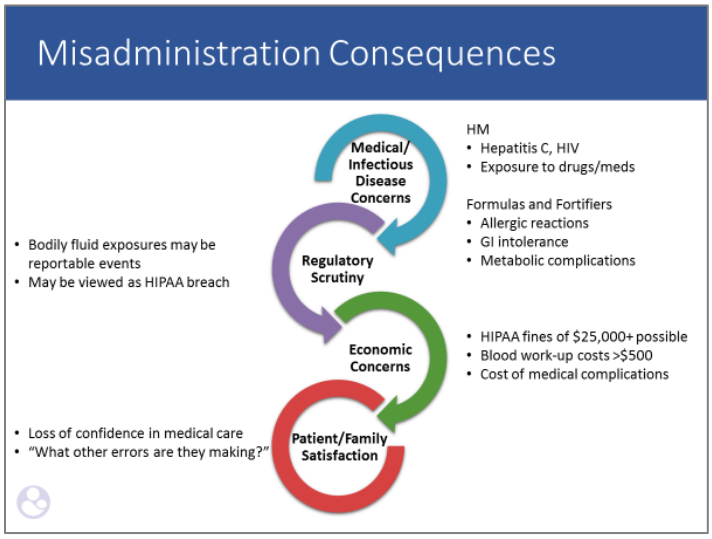
Human Milk and Formula Misadministration

We've talked about contamination and we've talked about accuracy, let's talk about misadministration. I will admit, I've been a dietitian 26 years and I started in handling of infant feedings almost 20 years ago. At the time, my big concerns were contamination and accuracy. Those were the things we were really focused on. The idea of misadministration truly never crossed my mind. It's those famous last words, "How could you possibly give the wrong breast milk or the wrong formula? Everything is clearly labeled." But we know human error happens in hospitals. We know that whether it's medications or formulas or breast milk, that errors do happen as a result of that. Misadministration is actually something that you definitely want to look into.

What are the consequences of misadministration? Well, you could have medical or infectious disease concerns. If you give the wrong human milk, you could expose an infant to viruses or drugs or medications. If you give the wrong formula or fortifier, that could result in allergic reactions, GI intolerance, or metabolic complications. There's the opportunity for increased regulatory scrutiny. Bodily fluid exposures are typically reportable events to the Health Department. If you have increasing amounts of breast milk misadministration, you may have to continue to report those and that could result in regulatory scrutiny.

These may also be viewed as a HIPAA breach. You may wonder why that's the case. But if I were to give a bottle to a mom to feed her baby, she fed the baby and then looked at the label and realized it was the wrong patient. If that label had full patient name, medical record number, maybe it has mom's name, maybe it has medications mom's taking, that could be viewed as a HIPAA breach, because you've then released protected health information. Because of

that, you may end up with economic concerns. HIPAA fines can be $25,000 or more per incident.



Slide 8

There's also the economic costs of blood workup. If a baby gets the wrong human milk, you have to draw blood on that baby, you have to draw blood on that baby's mother, and you have to draw blood on the mother whose milk it was. That can be $500 or more. Then if there were to be a medical consequence of this misadministration, there would be the cost of treating that.

Then finally, there's the family satisfaction standpoint. I really think this is probably one of the biggest ones. We know that the risk of illness from getting the wrong human milk, while it's there, is pretty low. The risk is low. But it can have a significant impact on family satisfaction and confidence in medical care because our families start to think, "Well, I labeled this bottle for my baby and you gave it to the wrong patient, what other errors are you making?" They can really lose confidence in the care that you're providing.

Regulations and Guidelines

We've talked about the 3 major concerns. We've talked about contamination, accuracy, and misadministration. Keep those in mind as we go through the rest of the presentation today. I want to go through regulations and guidelines, and we'll talk about best practices.

From a historical perspective, starting around 2000, the Joint Commission began looking for evidence of use of HACCP with enteral feedings. HACCP stands for Hazard Analysis Critical Control Point.

It's often used in food services to look at safe handling of food, and it generally centers around holding times, temperatures, things like that. But, the purpose of HACCP is to look at critical control points, or CCPs where you could have something go wrong. You want to see the points of vulnerability and identify plans to minimize them? In 2000 the Joint Commission said, "Well enteral feedings, which include human milk and formula, are food, and we should be looking at HACCP guidelines from that aspect."

In 2002, if you were practicing then, you might remember that the FDA and the CDC came out with recommendations. They said that powdered fortifiers and formulas should not be used with preterm infants in the NICU, unless no other nutritionally appropriate alternatives exist. The problem was, at the time there were no nutritionally appropriate alternatives, so we were stuck between a rock and a hard place. They weren't recommended, and yet there weren't good alternatives.

Between 2004 and 2018, a variety of guidelines have been published. We're going to walk through many of those today, looking at what are the best practices for handling feedings and to give a roadmap to hospitals of what they should be doing. We know that today practices still vary. The good news is that there are more sterile options available. We have sterile liquid fortifiers, we have increased availability of pasteurized donor human milk, but there is still a lot of variability in practices.

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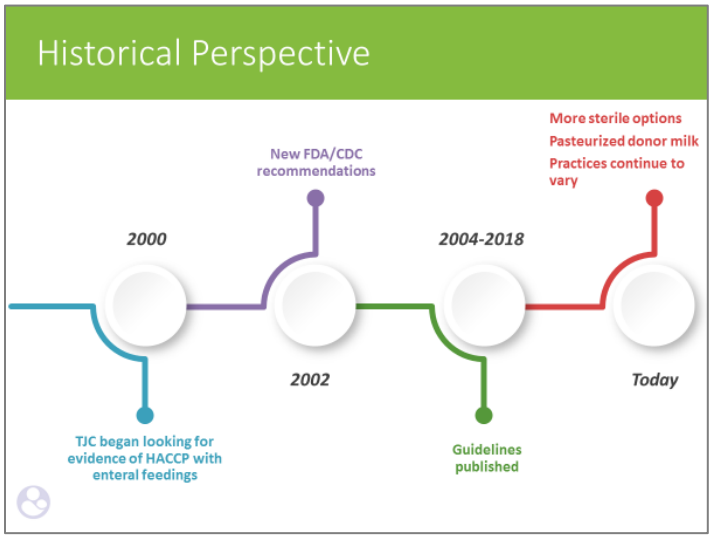

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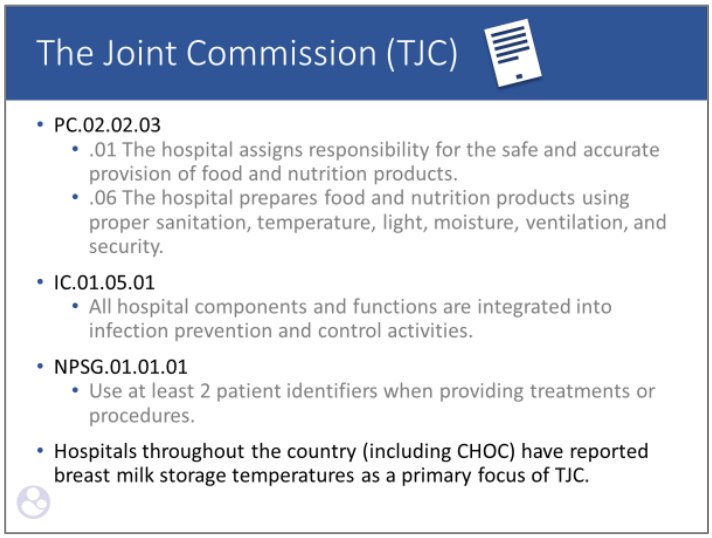


Slide 10

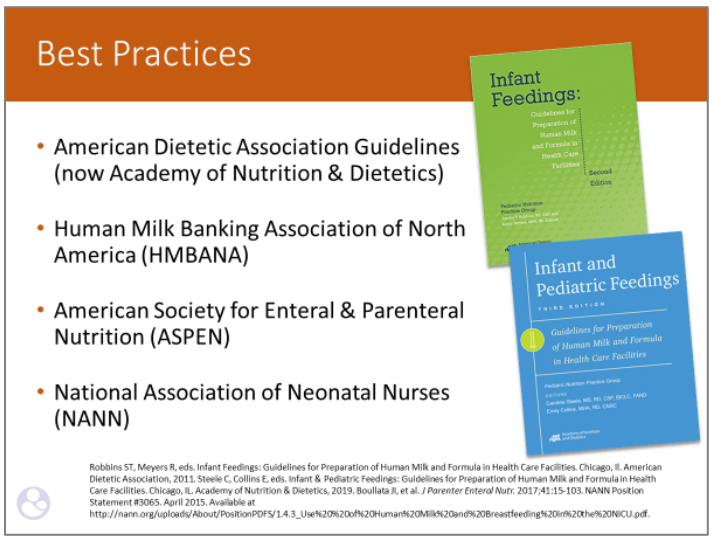
Let's start with the Joint Commission, because oftentimes we want to know what they have to say about handling of feedings within our hospitals. Provision of Care 02.02.03 indicates that the hospital assigns responsibility for the safe and accurate provision of food and nutrition products and that these are prepared using proper sanitation, temperature, light, moisture, ventilation, and security. This makes sense. The Joint Commission says our hospitals have to provide safe food sources. For our preterm and hospitalized children, a lot of times formula or human milk is their food product, so we have to make sure that we're providing that safe and accurately.

The Joint Commission also says that all hospital components have to be integrated into your infection prevention activities. And finally, one of the National Patient Safety Goals is the use of 2 patient identifiers when providing treatments or procedures. Now, human milk is not a treatment or a procedure, but it is a bodily fluid and we should be using 2 official patient identifiers anytime we're administering that or combining it. Hospitals throughout the country, including ourselves, have reported that breast milk storage temperatures have been a primary focus of the Joint Commission.

In my last 2 surveys, every surveyor wanted to see all of our temperature logs for all of our breast milk refrigerators and freezers throughout the facility. Those are really been hot buttons. Now, we know with any Joint Commission survey that they don't cover every guideline when they're there, they just don't have the time within their allotted survey window. However, you may get a surveyor that digs into this and it's important to think about human milk and formula being the food for those patients.

As I mentioned, there's a variety of best practices published. The American Dietetic Association, which is now the Academy of Nutrition and Dietetics, came

out with *Infant Feedings* in 2004.[1] The green book seen here [Slide 11] is the second edition, which came out in 2011, and the newest edition came out just in September of this year.[3] There is also a variety of publications, both a book and many position papers, available from the Human Milk Banking Association of North America (HMBANA).



Slide 11

The HMBANA publications focus both on mom's own expressed milk, as well as pasteurized donor milk. ASPEN has a variety of publications, including an excellent enteral review article published in *JPEN* in January of 2017.[4] And, the *Enteral Nutrition Handbook*, which its next edition is due out in early 2019. Finally, the National Association of Neonatal Nurses has a variety of position statements, and one looks at the use of what they call a Human Milk Management Center to promote accuracy, minimize waste, and for safety.[5]

What do all these best practices have in common? They focus on location, an area that is physically separated from direct patient care areas and that's used solely for the purpose of feeding preparation. This location has to support aseptic technique. They also focus on having specially-trained staff dedicated to preparing your feedings. Temperature control, as I mentioned, infection control, quality assurance. What you don't want to do is implement a process and then have no method of monitoring to make sure that what you think you've implemented is working the way it should.

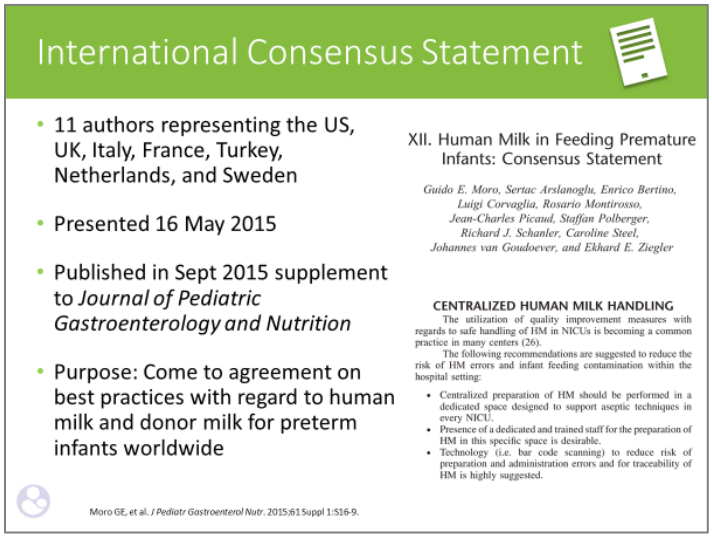
Slide 12

Unit dosing is considered a best practice. What that refers to is, you could prepare your feedings either in bulk, maybe a 12- or a 24-hour volume, or you could unit-dose those feedings where you individually draw each feeding up into a syringe or into a bottle. The reason unit dosing is considered a best practice is, the more you handle a feeding at the bedside, the more likely you are to either introduce contamination or mislabel and end up with misadministration.

If you remember the contamination study I talked about just a moment ago, even sterile products that were handled at bedside, about 6% ended up with some microbial growth. If you can minimize that risk through unit dosing, that's definitely preferred. Proper labeling is considered a best practice. Oftentimes when feeds are handled at the bedside, just the patient label goes on that feeding. But, we want to make sure the labels include all the important information so that it's as safe as

possible. And finally, barcode scanning is considered a best practice. We'll talk about that in a moment.

An international consensus group came to the same conclusions.[6] This was a paper published in 2015. They concluded that NICUs worldwide should all have centralized preparation of human milk in a dedicated space that supports aseptic technique, and that they should use dedicated and trained staff, and that the use of technology such as barcode scanning is highly suggested to promote safety.



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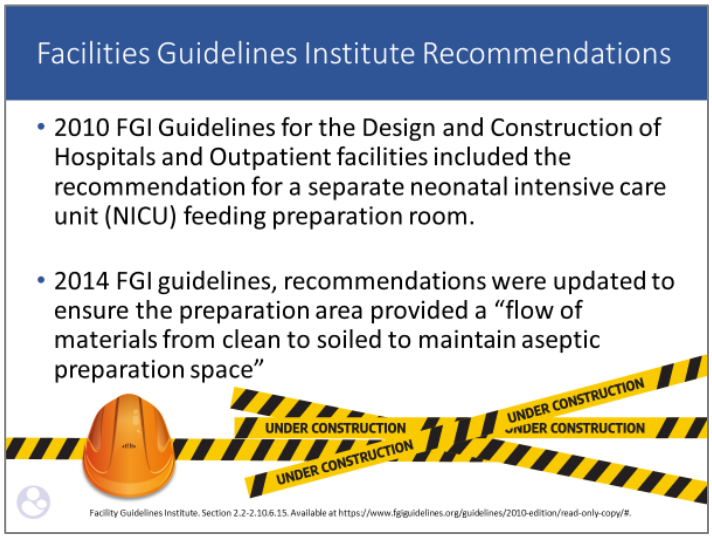
The Facilities Guidelines Institute (FGI) are recommendations that are used by hospitals when they're doing new construction.[7] They also concur with the parts that have to do with location. In 2010, their guidelines came out and said, "If you are building a new NICU, you should have a feeding preparation room." In 2014, those guidelines were updated to say that that preparation area should provide a flow of materials from clean to soiled, so that you're always maintaining that aseptic preparation space. The FGI guidelines are used throughout the US and Canada. They're considered the gold standard if you're doing construction in hospital settings.



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Many states have similar building codes, whether that's part of their hospital construction regulations or their licensing requirements. And again, there's a lot of commonalities. They talk about an area or room used exclusively for preparing feedings, and that area should be separate from patient care. Now, it can be adjacent to your unit, your NICU, or whatever unit you're preparing for, but it could also be located somewhere else in the hospital. Most indicate that you need appropriate equipment: a refrigerator, a work counter, storage facilities, proper hand-washing station, and if you're not using all disposables, a separate clean-up area.

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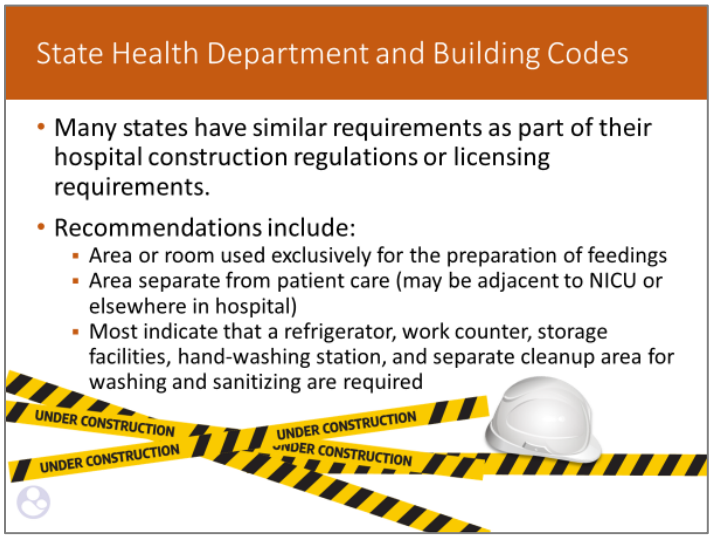

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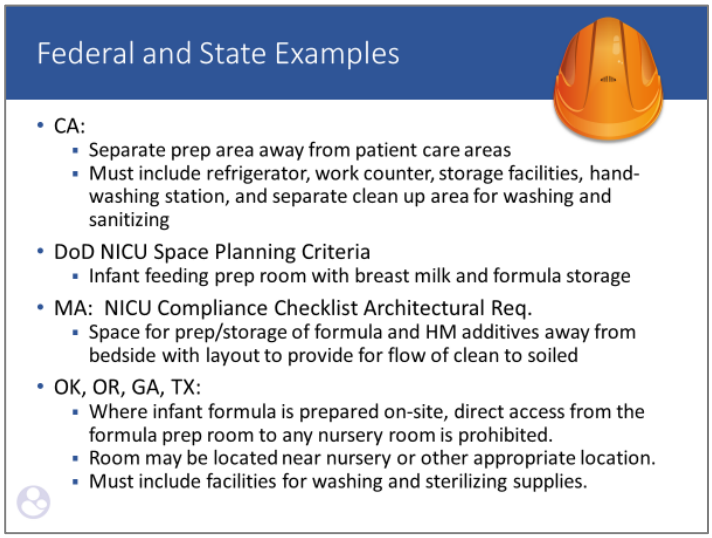

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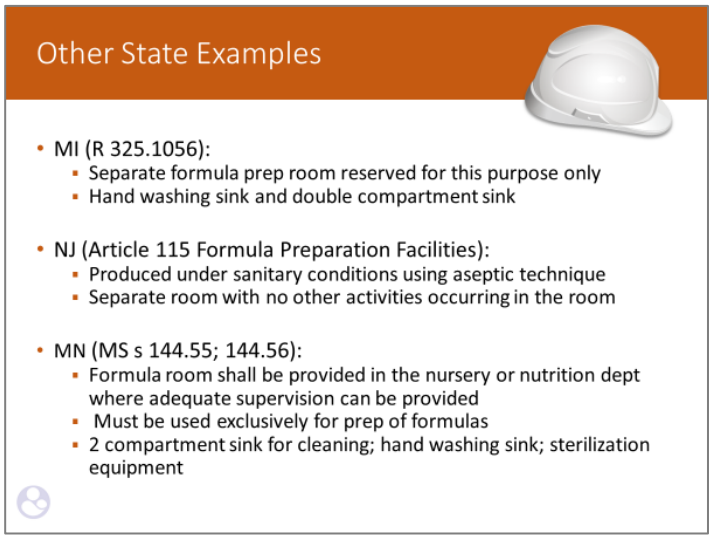
I'm not going to read you every state here, but I want to briefly go through states that have very specific examples. The Department of Defense—so any military facility—recommends a separate feeding prep room. In the state of California, you must have a separate prep area away from patient care. Massachusetts, same type of things: separate area with a layout to provide flow of clean to soiled. As you can see, many of them pretty much copied the FGI guidelines. Oklahoma, Oregon, Georgia, Texas all talk about that same thing, as do Michigan, New Jersey and Minnesota. Many states are indicating that if you're going to prepare infant feedings within your hospital setting, you have to have the right location to do so.



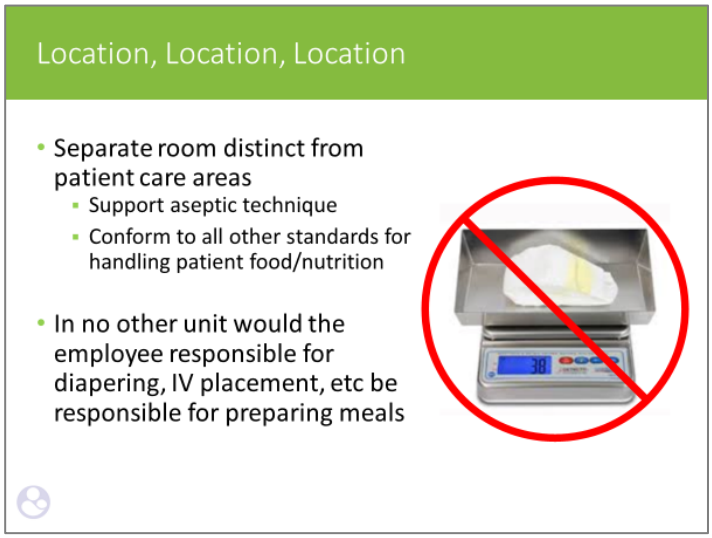
Slide 17

Think of it like real estate. It's just like [in] real estate, they say location, location, location. A separate room that is distinct and separate from your patient care areas, it has to support aseptic technique. That is really the key here. It should also conform to all other standards for handling patient food. If you think about it, in no other place in the hospital would you prepare patient food in the room. And, not only location, but dedicated staff. Nowhere else in the hospital would the person who changes

diapers, or places IVs, or gives medication, prepare a meal.

You wouldn't have in your PICU, or your adult ICU, your bedside nurse wouldn't be making sandwiches in the room. It's not an appropriate place for food preparation. And yet, we do it with human milk and formula all the time. One of the most common places, I've seen it in many hospitals, and I've had many people report back to me they see this as well, is next to the diaper scale. It makes sense if you're in the NICU, you usually have a sink where you can wash your hands and you have a counter, and on that counter is the diaper scale.

What people tend to do is they go up and they wash their hands, then they lay down a paper towel—because in health care we think a paper towel is a magic barrier that protects us from all sorts of microbes—and they bring the bottles that they're going to prepare and start preparing infant feedings. I encourage people to think of it this way: if I washed my hands and laid down a paper towel next to the diaper scale and started making you a sandwich there in the NICU, would you eat that? Would you think that was an appropriate place to prepare food? You really have to think about location.



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Even *US News & World Report* in their best hospitals rankings takes location and dedicated staffing into consideration. Starting in 2015, hospitals that are applying for designation in the area of neonatology with the *US News & World Report* have to answer these questions. Does your hospital offer a dedicated area within the facility, but away from the bedside for human milk and formula preparation? In order to say "Yes," you have to have a prep room that uses aseptic technique, that has restricted access, and healthy personnel, with no other activity occurring in the room.

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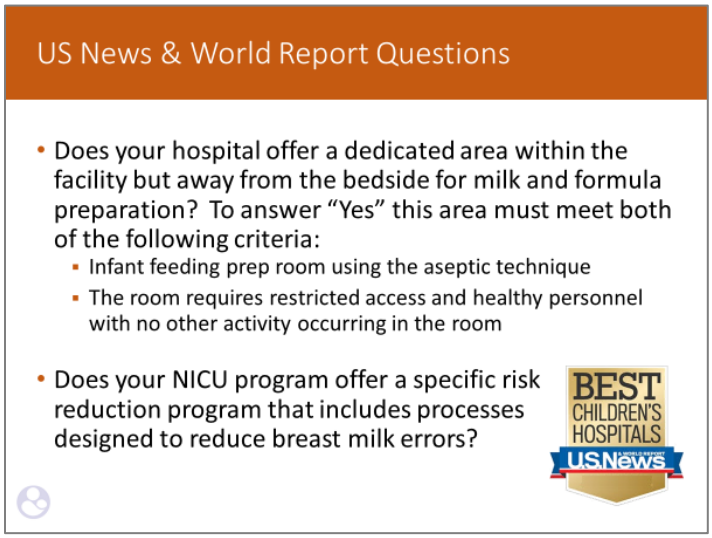
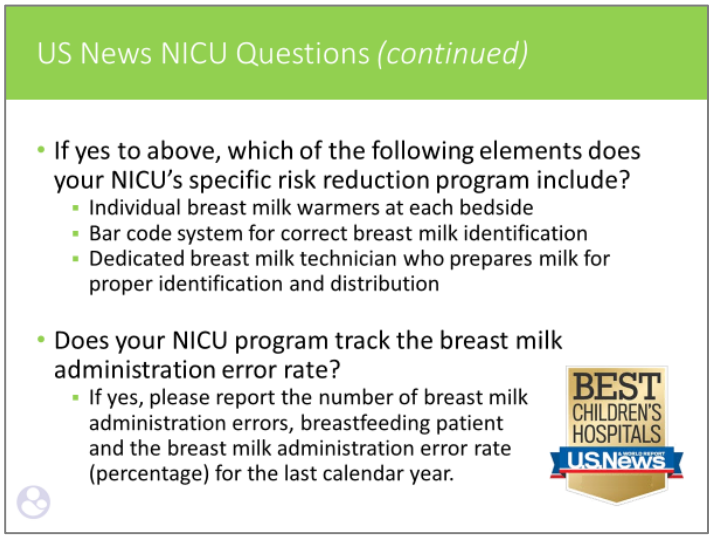


Slide 19



Slide 20

They also ask if you offer risk reduction to reduce breast milk errors. What they mean by that is, if you say "Yes," what program elements do you include? Do you have individual milk warmers at each bedside? The rationale behind that is if you have communal warmers in a centralized location, you could easily grab the wrong milk for the wrong patient. They ask if you use barcode scanning to make sure breast milk is correctly identified. And, do you use dedicated technicians who prepare milk and ensure proper identification and distribution? Then finally, they want to know if you track your error rate in conjunction with how many feedings you actually prepare.

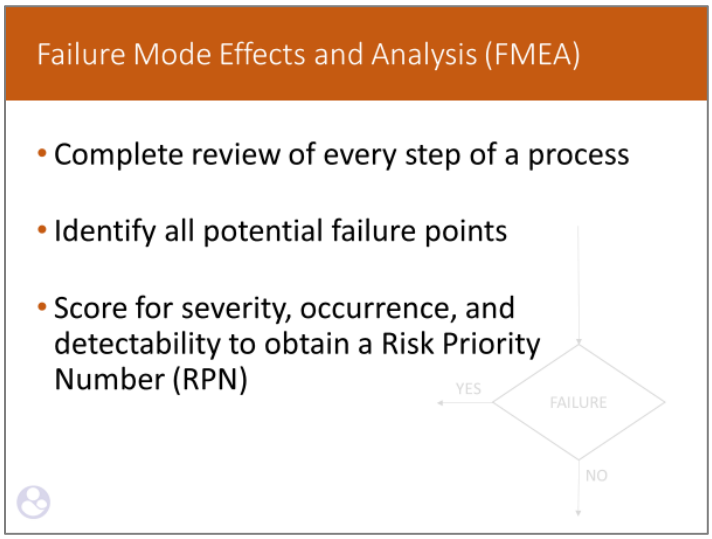
You can see there's many, many endorsements for the use of proper location, dedicated technicians, and the use of technology [Slide 21]. There are other organizations that focus specifically on barcode scanning, or the use of technology, to improve patient safety. The Agency for Healthcare Research and Quality, the Institute for Safe Medication Practices, HIMSS, and the National Patient Safety Foundation all talk about how barcode scanning technology specific for human milk reduces errors and improves patient safety.[8]

Slide 21

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

Implementing Best Practices: Our Journey at CHOC

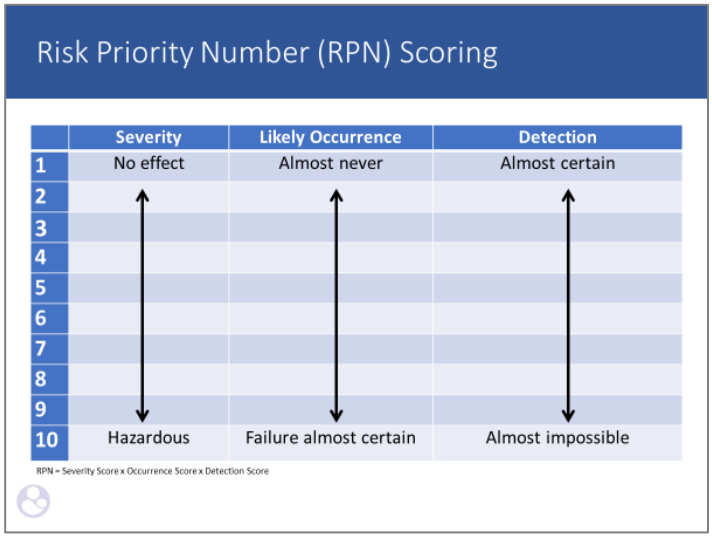
For the rest of the time, I want to talk you through our journey at CHOC, because I think it's important to think through the entire process. You may be sold on the fact that these are best practices to have a central location, to have dedicated staff, to use barcode scanning, but how do you really get started in facilitating process change within your facility? With any project, it's always good to start with a failure mode effects and analysis, or FMEA. If you've never done one, oftentimes I know people think they're a little bit painful, but they are really an important way to start a project. If you don't know how to get started, usually the quality department in your facility can help you with this.



Slide 22

What an FMEA does is, it's a complete review of every step in the process, where you identify all potential failure points. For example, for human milk, you would look at from the time mom pumps that milk at home, labels it, maybe stores it at home, transports it to your facility, you receive it and store it, maybe you thaw it, prepare feedings, administer those feedings, and potentially send leftover milk home at the time of discharge. You would want to look through every step of that process and see, what are the points where something could go wrong and cause error or illness?

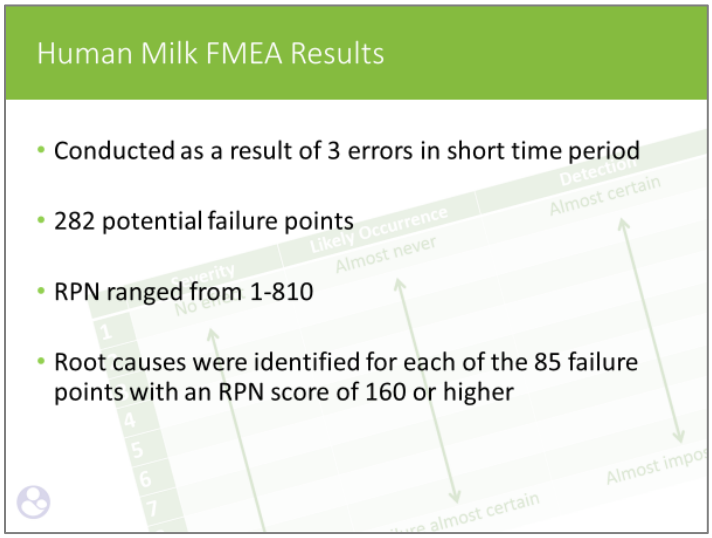
Once you have those potential failure points, you can score each of them to get what we call a risk priority number (RPN). Your (RPN) means, for each potential failure point, you look at the severity. Does it have no effect or is it hazardous? What is the likely occurrence? Does this rarely occur or is it pretty common? And then, what is your ability to detect that? Do you have good systems in place to detect those errors vs the inability to detect that? If you multiply these 3 numbers together, it gives you your risk priority number, or your RPN.



Slide 23

Here at CHOC, we did a human milk FMEA, because we had 3 errors in a pretty short amount of time. Three babies had gotten the wrong breastmilk and we wanted to see what was the problem and what we could do to fix it. At the time, we did not have centralized handling of human milk and we did not have barcode scanning. Through our FMEA, we determined that there were 282 potential failure points. This surprised everybody, myself included. We kept thinking, “we're not administering chemo,

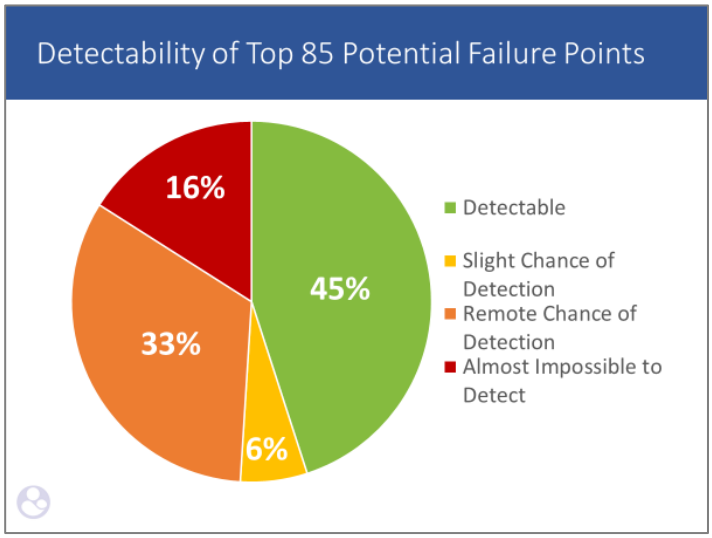
we're not doing neurosurgery," but breastmilk alone had 282 potential failure points.



Slide 24

Now, the RPN scores ranged widely. A score of 1 is probably not something we're particularly concerned about, but a score of 810, we were pretty concerned. What we noticed in the scoring is that there was a natural break where there was a big gap in scores. We looked at everything with a score of 160 or higher and determined that there were 85 top potential failure points.

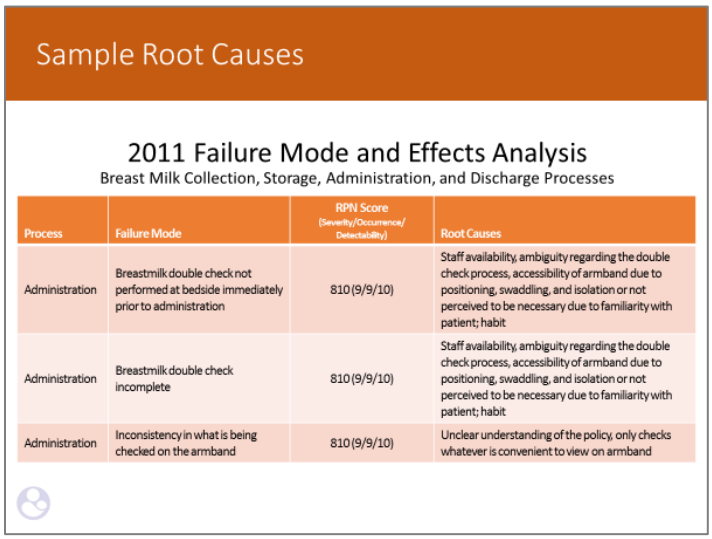
Now, the thing that kept me up at night was that when we looked at these top potential failure points, about 45% of those were detectable. That meant that 55% were unlikely to be detected by our current measures. That made sense to us. Think of the example I gave before. If I give mom a wrong bottle of milk, she feeds it, we throw it away and neither one of us looks at it, we may never know that baby got the wrong milk, so we have no way to detect that. Or, if I'm fortifying breastmilk and I need to combine 2 bottles together, I might combine those, add my fortifier, label that bottle. We might check that bottle before we feed it, but if we didn't double-check at the time we combined the 2 together, we may have mixed 2 patients up and never know it. I think the detectability is one of those things you really have to critically look at.



Slide 25

Then what we did was, we took our potential failure points and we looked at the root causes. It was critical to have all the right players in the room for this because we wanted to make sure that the bedside staff, that management, that people from all departments could weigh in as to what the barriers were. I'm just going to go through the top one here, but our most critical potential failure point we determined was when breastmilk was not double-checked at the bedside immediately prior to administration, so we looked at what were the causes of that.

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities



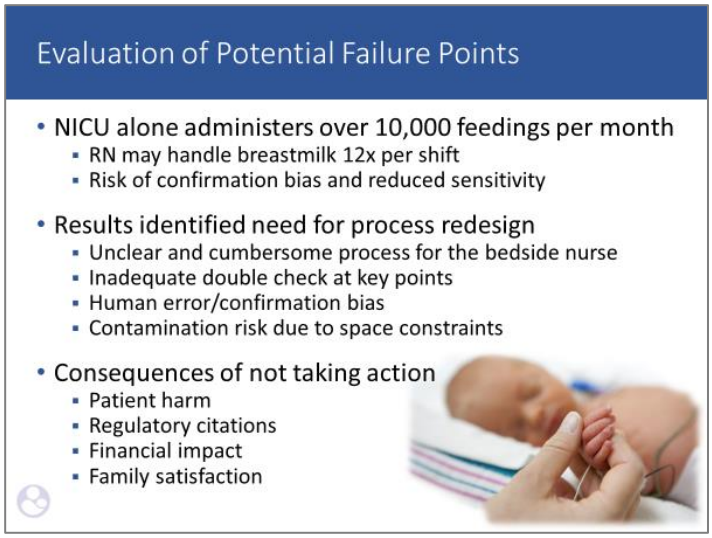
Slide 26

Some of that was staff availability—you couldn't find someone else to double-check with you. There was some ambiguity regarding the double-check process. The nurses weren't sure, "Do I double-check it before I combine bottles to fortify it? What if I draw it up in a syringe and relabel it, do I double-check at that time? Do I double-check when I connect it to the patient or do I double-check before I warm the milk up?" There was a lot of ambiguity.

There was the accessibility of the armband. We all know that you never wake a sleeping baby. If your baby is swaddled and you can't get to the armband, then how are you supposed to double-check your feed? There was the idea that maybe it wasn't necessary. Often our babies are here a long time. A nurse could have the same patient every day for 3 months. So, do I really need to do that double-check? And, sometimes it was just a bad habit.

Once you have your potential failure points, again, you want to go through and figure out what your root cause is because you won't be able to determine how to fix it if you don't know what the barriers are.

What we determined when we evaluated our failure points was that our NICU alone administered over 10,000 breastmilk feedings a month and since we're a children's hospital, we can have breastmilk anywhere in the hospital, so we knew it was even higher than that. That our nurses could handle breastmilk 12 times during a shift. They have 12-hour shifts, they could have 3 babies, and they could all be on breastmilk feed.



Slide 27

We knew that led to the risk of confirmation bias and reduced sensitivity. Confirmation bias is where your brain fills in what you expect to see. Think of those puzzles you see on the internet where letters are turned upside down or replaced with numbers, but you still can read the sentence. It's sort of like if I bring 3 bottles out of the freezer to prepare for a baby's feedings and 2 are Johnson and 1 is Jones, my brain may fill in what I expect to see.

There's also reduced sensitivity. There was some thought early on when we had these errors that the problem was probably nurses who had floated or travelers. We laugh about that because we always want to blame the person who's not in your unit normally. But the truth is, we determined—and I think you'll see it at other facilities as well—when you're not in your home environment, you're actually pretty diligent about following processes,

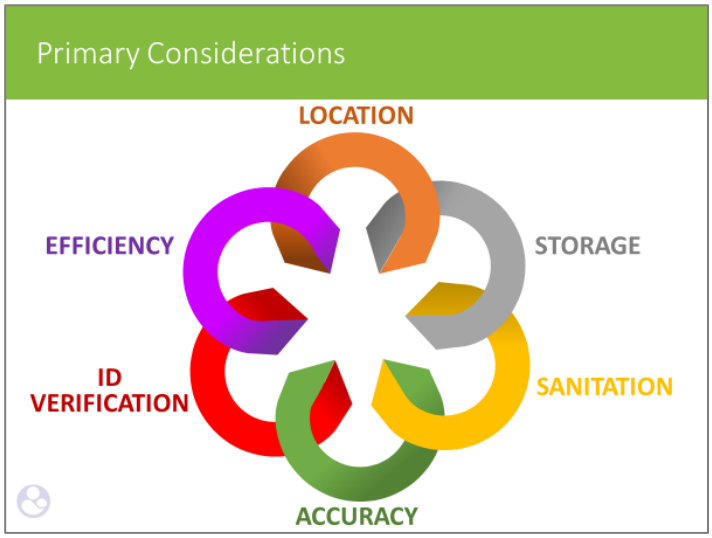
because you're uncomfortable already, so you want to follow the process.

Where people tend to cut corners is when we're comfortable. We have a reduced sensitivity. If I handle breastmilk 12 times in a shift, I'm not as worried about it as someone who doesn't routinely do that. Our FMEA determined, based on that, we determined that we needed a process redesign. We realized it was unclear and cumbersome for the bedside nurse. As I mentioned, there's a whole bunch of places that you would need to do a double-check, and it wasn't realistic that our nurses could find someone to do all that in addition to their other patient care duties.

We knew there were inadequate checks at key points, there's that risk of human error and confirmation bias; and because we didn't have centralized handling, we were concerned about contamination. But anytime you do an FMEA and you're proposing process change, you have to step back and say, "What are our consequences of not taking action?" Because, we know that not every program in hospitals gets greenlighted; not everything can happen at the same time. We really had to look at if we do nothing, what are the concerns?

Our biggest concern was patient harm, but we were also concerned about regulatory citations. These were reportable events to the state. We were concerned about the financial impact, HIPAA breaches, blood workup, and if our families lost confidence in the care we were providing and sought care elsewhere, that would also have a financial impact. Then there was that family satisfaction. We knew we were providing great care for these patients, and we didn't want our families to lose faith in us because of something like a breastmilk error.

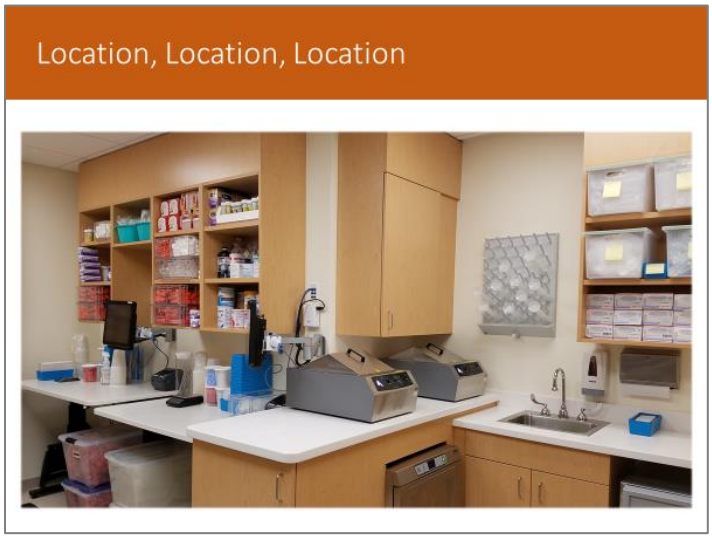
So, we sat down and thought, “What are our primary considerations?” We knew we had to think about location, storage of our human milk and formulas, sanitation, accuracy, verification of both human milk and other products, but that we had to be efficient because it doesn't matter how good our process is, we don't have unlimited resources.



Slide 28

We started with locations, and here is a picture of our preparation room [Slide 29]. We thought about sanitation for workstations, hand-washing sink. We were unable to have a dedicated anteroom, so we looked for a way to use this peninsula as a barrier, so we have the peninsula that sticks out by the dishwasher there. Anything to the right of that, that's our dirty zone. You come into the room, you wash your hands, you put on a bonnet, you put on gowns, and then you move into the back part of this slide, which is the actual preparation area, so we had to look at location.

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

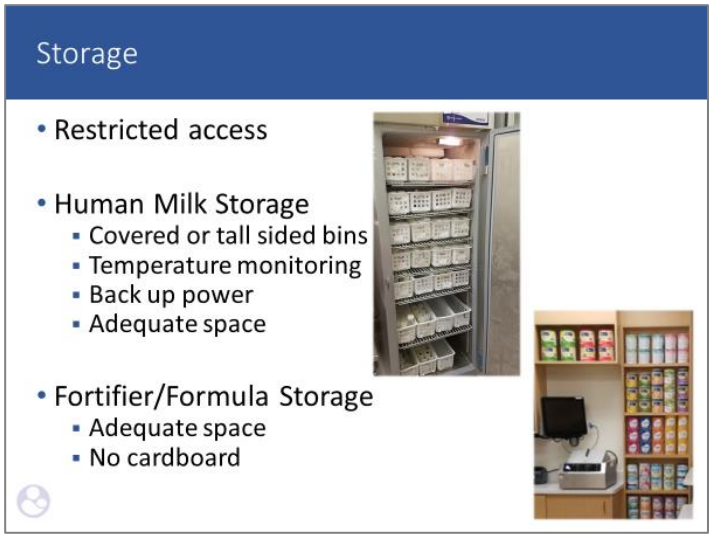


Slide 29

We wanted to look at storage. You want to have restricted access. We knew that our mom's milk needed to be somewhere that not anyone could just get to. We wanted to have adequate human milk storage. We knew one of the problems in our old location was that we only had 2 breastmilk freezers in our NICU, and a lot of times we had a lot of milk in there. So, the nurses were often forced to stuff milk on top of bins. You can see the white bins here in the picture [Slide 30], and we knew at times those bottles toppled over into another bin.

We needed to have plenty of freezers. We chose bins that had nice tall sides like this, so that milk couldn't topple into another bin. We knew that our fridges and freezers needed to be on backup power, in case of a power outage so that we didn't lose milk, and that they needed to have temperature monitoring systems that would alert us 24 hours a day in the event that temperatures went out of range.

From our formulas and fortifiers, we knew we needed adequate space for our products. This wasn't just for infant formulas, but for the enteral formulas that we provide to the entire hospital. And, we knew we needed to have a place where there wasn't cardboard. If you think about cardboard, it is an excellent medium for little critters that you don't want in your prep room to find their way into your facility. We had to think about how we brought product into our facility and then having no cardboard and adequate space within our actual preparation room.



Slide 30

We moved on to thinking about sanitation and infection prevention, so all of the personal protective gear: gowns, gloves, hair covering. Having hands-free sinks, making sure our refrigerator temperatures were accurate and within range, using a dedicated dishwasher for our non-disposable items. We wanted to make sure we were using sanitizers that were appropriate for food contact surfaces because we were preparing feedings. And then, you want to make sure that you have trash cans available, but they can't be open trash cans, so we needed something that was foot-controlled, from an infections standpoint.

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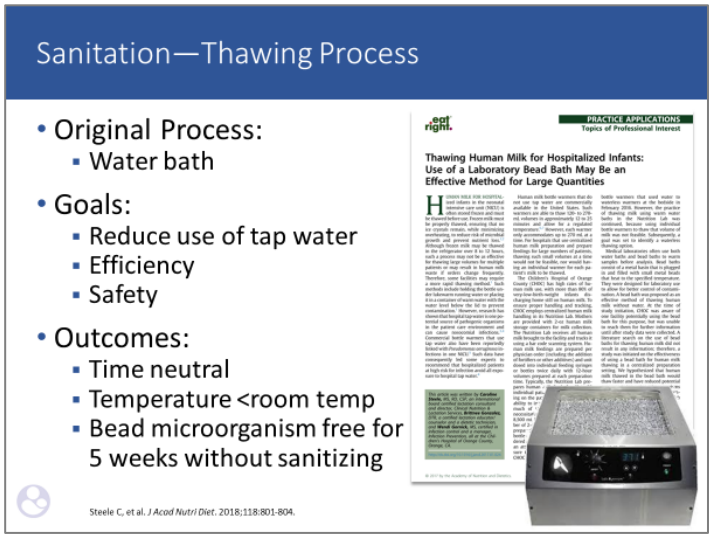
Slide 31

Slide 32

We also really looked at our hand-washing process. It may seem simple, but we found that there were people that were a little bit confused. I'm going to talk you through this poster here [Slide 32]. We have our staff wash their hands at the start of the process, sanitize the workspace with sanitizing wipes, but then they have to wash their hands again, because now you've come in contact not only with the dirty surface, but with the wipes. Then you put on your gloves, prepare your feeding, but then what we found people were doing was they were leaving the gloves on to re-sanitize their workspace and the gloves are considered dirty. You have to remove those dirty gloves, sanitize your workspace, wash your hands again, and then start the process over. Just outlining that and going through that with our staff we felt was really important.

We looked at our thawing process from a sanitation standpoint. Our infection prevention department really wanted to get away from any standing tap water within the facility because it is a contamination risk. So, at the bedside, they switched to waterless breastmilk and formula warmers. The problem was in our preparation room, we were still using water to thaw human milk. The reason was, is that those individual warmers weren't big enough for us to thaw the volume of milk we needed.



Slide 33

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

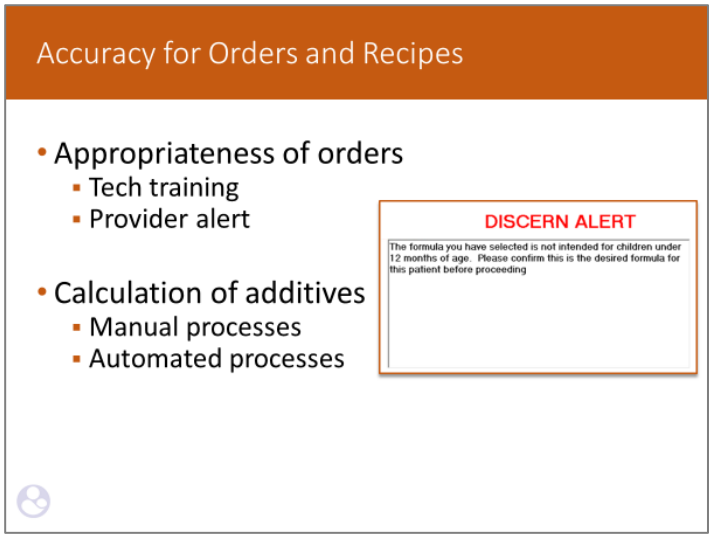
We knew of a few hospitals that were using bead baths. Bead baths are a piece of laboratory equipment, and there's a picture of one here [Slide 33]. They have little metal BBs in them that get hot. You literally just push the bottles down into the BBs to thaw them. But we didn't know of any research that had been done on it. We thought, because we're using it off label, we wanted to make sure that it was safe.

So, we did a research study where we compared thawing with our original process, with a water bath compared to thawing in the bead bath.[9] We checked the internal temperature of milk because we didn't want to be cooking the milk in this bead bath. We checked the time it took to thaw from an efficiency standpoint, and we cultured both the water—the tap water that we were thawing in—and the beads, to make sure that the beads weren't growing microorganisms.

Basically, what we found was that it was time-neutral, and that the internal temperature of the milk remained less than room temperature, which was really positive because you have the bead bath set at about 80° C, so it's very, very hot. We wanted to make sure we weren't damaging or cooking the milk, and that our beads remained microorganism-free for 5 weeks, without sanitizing. We knew we could feel comfortable sanitizing our beads once a month.

We moved on then from sanitation to look at accuracy. We wanted to look at appropriateness of orders, and did a lot of tech training because we didn't want our techs to blindly follow the orders just because that was the order. For example, if it said to thaw 4 liters of milk for a patient, we wanted them to question that, that maybe someone hit the wrong number within the electronic health record.

We also did provider alerts. This is an example of one here [Slide 34]. If you have an infant and they accidentally order a formula designed for children 1 year of age or older, they will get this alert saying this is not intended for infants, and please check to make sure this is the formula that you want. We also had to come up with accurate systems for calculating our additives. We came up with both manual processes as well as automated processes.

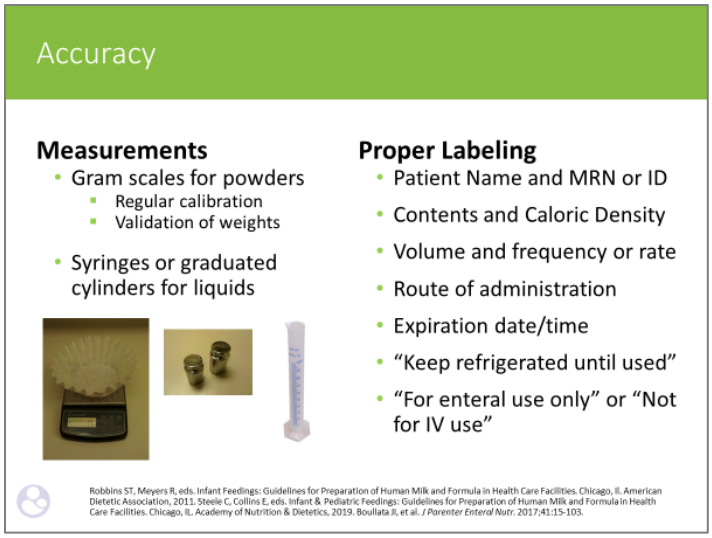


Slide 34

It's always good to have a manual process because invariably, at some point, you will have a computer downtime and your staff need to know how to do those math calculations. We do this as an annual competency to make sure that everybody's prepared in the event of a downtime. Automated processes could be spreadsheets that have calculations embedded where you enter your caloric density you want and the volume you want, and it calculates for you, or it could be your barcode scanning system. Our barcode scanning system calculates all of our human milk and formula recipes for us.

We also wanted to look at accuracy with regards to our measurements.[3,4,10] Gram scales are really important for powders. They have found that household measurements, particularly the scoops in the cans of formulas can vary anywhere from 10% to 25%, sometimes up to 40%. The reason is not

because the measuring tool itself is inaccurate, but because of how we measure. If you scoop formula up in a scoop, there may be a pocket of air in the bottom you can't see, some people press the powder down very tightly as opposed to just loosely filling the scoop, so we knew that we had to use gram scales. You also want to regularly calibrate those and validate your weights. For any liquids, you want to use syringes or graduated cylinders to make sure you're getting accurate down to the milliliter.



Slide 35

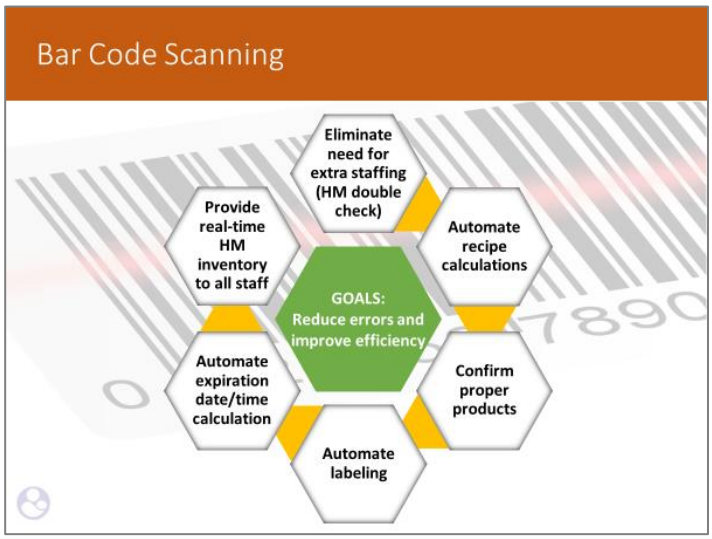
As I mentioned earlier, we knew that proper labeling was critical.[3,4,10] You want to have 2 patient identifiers on your label, such as name and medical record number, or some other ID number. It's important that the contents, caloric density, volume, and frequency or rate, are all included on there. Really, the feeding order should be included. The route of administration, expiration date, and time. And, it's important to think about for enteral use only or not for IV use. This becomes critical because we know unless you're using ENFit systems, which are designed to keep you from connecting enteral connectors to IV connectors, that you could end up accidentally connecting human milk or formula to an IV line. You want to make sure that that is labeled as another double safety check.

As I've mentioned throughout today, you want to make sure that you're properly identifying human milk at all the points that it's critical. Anytime you're combining bottles, before you do that you want to make sure that both belong to the same patient, such as for fortification. Anytime you're relabeling. If I have a prepared feed and I need to draw it up in a syringe to give it and I'm putting a label on that syringe, I should be confirming identification at that time. Prior to feeding you want to confirm, and then at discharge.

One of our 3 errors was we were sending home 100 bottles of milk with a mom and 1 of those bottles belonged to somebody else. The problem was, she didn't read the label at home. Why would you? You're at home, this is your milk, and after she fed her baby realized that that bottle did not belong to her baby. You want to make sure that at the time of discharge, you're making sure all of those are going with the right patient. Now, that ID verification can be low tech, it can be a 2-person double-check, but it should be 2 recognized patient identifiers. Again, full name, medical record number, date of birth, or it could be barcode scanning.

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

Slide 36

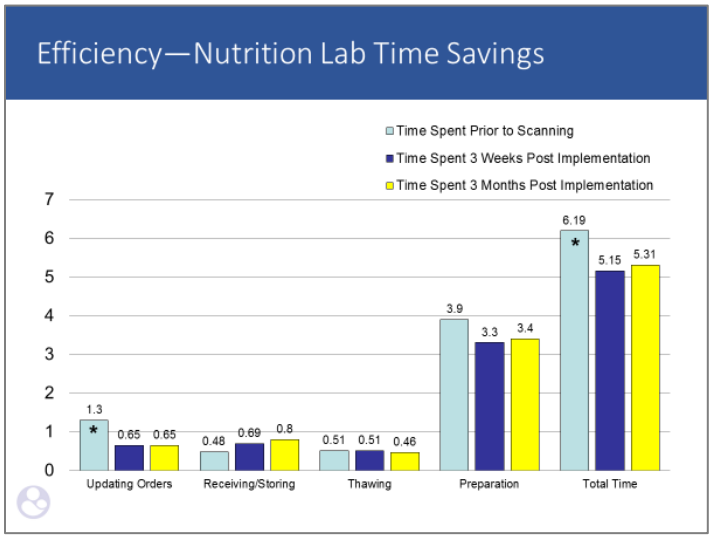


Slide 37

When we first implemented centralized handling, we'd had centralized handling of human milk, but we did not have barcode scanning. We had a 2-person double-check at every point in the process there, but we knew we wanted to implement barcode scanning and did that about a year later. Our goals of that were to reduce errors and improve efficiencies. We knew that barcode scanning would eliminate the need of extra staffing because I had to have 2 people at all times, just in case I needed to prepare breastmilk so that we could do the double-check.

We wanted to automate our recipe calculations because we knew that anyone could make a mathematical error. We also wanted to be able to confirm all of our formulas, fortifiers, and additives to make sure that they were the right products. We wanted to automate our labeling process and automate the calculation of expiration date and time. And finally, we wanted to be able to provide a real-time inventory to our staff. If a nurse knew how much mom's milk there was, she could either encourage mom to bring more milk in or could work with the mom if pumping had dropped off. There was a good reason for them to have that information.

When we implemented barcode scanning, we looked at efficiency. The main thing to look at is the bars on the far right of this graph where it says total time [Slide 38]. The light blue bar was the time it took us to prep feeds prior to barcode scanning, so about 6.2 hours a day. We then checked our time 3 weeks post implementation, and 3 months post implementation. The reason was, we didn't know if we would get better over time. But in the end, it was about the same, [a] little over 5.25 hours, so we saved about an hour a day. What's not shown here is that we were also able to eliminate a 20-hour a week position that was solely for the purpose of doing a 2-person double-check.

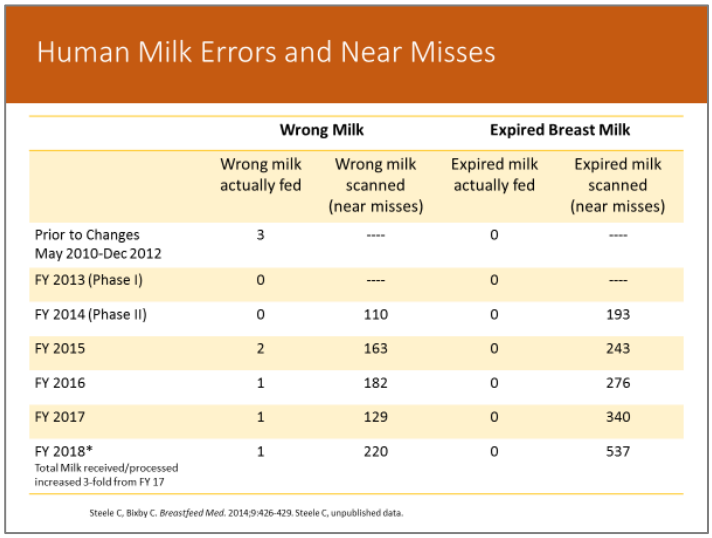


Slide 38

Outcomes at CHOC

Prior to process change, as I mentioned, we had 3 babies that were actually fed the wrong milk.[11] We looked back over 2 ½ years and came up with only these 3 errors in our Incident Reporting System. Phase 1 was centralized handling of human milk and formula, but without barcode scanning. During that time, we had no reported human milk errors. When we added in barcode scanning in phase 2, we had no errors, but you can see that 110 times the wrong milk was scanned for the wrong patient [Slide 39]. Those are near misses.

That could've been any time in the process, whether it was preparation, or feeding, or discharge. You can also see that 193 times, expired milk was scanned, and we know that expired milk is more likely to be contaminated or lead to illness. You can see here [Slide 39] for fiscal year 15, 16, 17, and 18, we continued to have anywhere from 110 up to 220 wrong-milk scans per year. Now, I will say one thing, and that is we've done a lot of initiatives to get more moms pumping and pumping more milk, so our milk between fiscal year 17 and fiscal year 18 increased 3-fold, which is also why the wrong milk scans almost doubled, because we were handling so much more milk.



	Wrong Milk		Expired Breast Milk	
	Wrong milk actually fed	Wrong milk scanned (near misses)	Expired milk actually fed	Expired milk scanned (near misses)
Prior to Changes May 2010-Dec 2012	3	----	0	----
FY 2013 (Phase I)	0	----	0	----
FY 2014 (Phase II)	0	110	0	193
FY 2015	2	163	0	243
FY 2016	1	182	0	276
FY 2017	1	129	0	340
FY 2018* Total Milk received/processed increased 3-fold from FY 17	1	220	0	537

Steele C, Bixby C. *Breastfeed Med*. 2014;9:426-429. Steele C, unpublished data.

Slide 39

You can also see that we've had 1–2 errors every year. Those errors have all occurred when someone did not follow the process, when they did not scan immediately before feeding. What we knew was that the system works when people use it, and we feel like that does catch those potential errors. Now, in January of this past year, we added scanning for our formulas and our fortifiers. What we found was that 223 times in the first 2 quarters of the year, so fiscal year 18, Q3 and Q4, which was January through June, there were 223 times the wrong formula or the wrong fortifier was scanned for a patient [Slide 40].

Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

Fortifier/Formula Errors and Near Misses

	Wrong fortifier/ formula actually fed	Wrong fortifier/ formula prepared (not fed)	Near Misses (wrong product scanned)
FY 18 Q3-Q4	0	1	223

Slide 40

Published Results


Current Concept

Centralized Breastmilk Handling and Bar Code Scanning Improve Safety and Reduce Breastmilk Administration Errors


PRACTICE APPLICATIONS
Emerging Science and Translational Applications

Breast Milk Bar Code Scanning Results in Time Savings and Staff Efficiency

Slide 41

Now, that might make you cringe because it actually makes me cringe to think about 223 times in 6 months. That's only 1.7% of the total batches of feedings we prepare. It's 1.7% of the times we did scan, but that's still a lot of potential errors that could cause illness, so we feel like adding barcode scanning for our formulas was critical for safety.

I encourage you to publish your results because we all learn from each other. By knowing the challenges and barriers out there, we can help each other find new solutions. So we published our results.[11,12] Some of our other outcomes were improved nurse satisfaction. I don't know any NICU nurse that the highlight of their day was thawing milk and preparing it. They wanted to come provide bedside care, so having that centralized handling, having the feeds ready to go for them, was huge from a satisfaction standpoint.

It improved family satisfaction. We explained to them that their baby's feedings, whether it's mom's own milk or formulas that we're preparing, is so important to us that we have its own dispensary. We explained, it's like a pharmacy for breastmilk and formula. We were able to have our nurses use their time better for bedside duties. We've been recognized by surveyors and by several national organizations, including the Children's Hospital Association and HIMSS, which looks at how you use technology to improve safety.

Other Outcomes

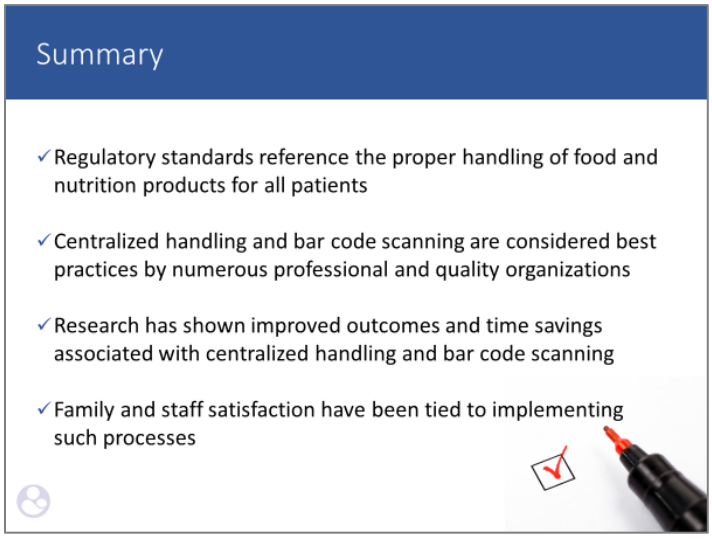
- Improved RN satisfaction
- Improved family satisfaction
- Better use of nursing time for other duties

- Recognition from surveyors
- Recognition from the Children's Hospital Association
- Recognition from HIMSS

Slide 42

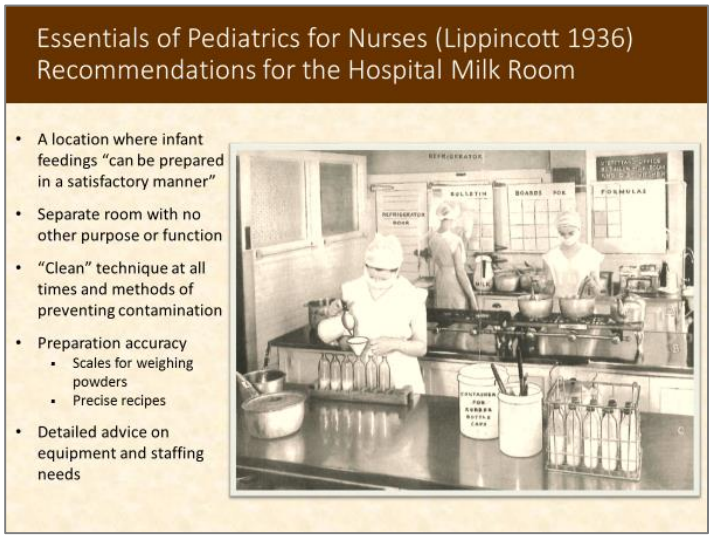
Understanding the Current Guidelines for Preparing Pediatric and Newborn Feedings in Health Facilities

Just to summarize here, we know that regulatory standards, including Joint Commission standards reference proper handling of food and nutrition for all patients, and that centralized handling and barcode scanning are considered best practices. Research has shown those practices improve outcomes, both time savings and patient safety, and that family and staff satisfaction have been tied to those.



Slide 43

I just leave you with this picture [Slide 44]. This is from the 1936 volume of Lippincott's, *Essentials of Pediatrics for Nurses*. They have an entire chapter on the hospital milk room. It talks about that this should be a location where infant feeds can be prepared in a satisfactory manner, that it is a separate room with no other purpose or function, that clean technique is used, that it's accurate using scales for powders, and it provides detailed advice on equipment and staffing needs.



Slide 44

Here we are about 80 years later still having this conversation, but this is not a new concept and I think there's a lot of great resources out there that we can make this happen within our facilities.

Question & Answer

Editor's Note: This is a transcript of audience questions together with Ms. Steele's responses from the December 5, 2018, audio webcast.

When transitioning from bedside storage to a centralized milk handling room, do you have any tips for estimating how much refrigerator and freezer storage you might need?

Caroline Steele: That's a great question. I do have, and I don't have them on the slides here, but I do have some calculations and they're in the *Infant Feeding Book*, the third edition. A general rule of thumb is, you want to think about how much milk you're using per patient for your unit. We have found that if you use 1.5 kg, 160 cc/kg and then multiply that by your number of babies, that gives you a pretty good idea, just as a rough estimate. What is your philosophy of how many day's supply? We have a lot of families that come from far away,

so we like to have 1–2 weeks supply at least on hand.

We literally did that math to figure out how many babies we normally have on human milk. Using that calculation, what would be a 7–14-day supply? Then we looked at our freezer size, and you saw the picture of the long, narrow, white bins. We figured out how many bottles would fit in a bin, how many bins a baby would need and used that to determine the freezers. We have about 50 babies at any given time that are on human milk. We have a bigger NICU than that, but that's about our human milk census at a time. We calculated with that, and donor milk, we would need at least 6 freezers, and we have 8, just so that we have extra storage space.

How does your facility measure breast milk?

Caroline Steele: We measure breast milk using plastic, graduated cylinders that we run through our dishwasher. We use the 100 mL size because we feel like it's pretty accurate. We do have to replace those regularly because they do get warped in the dishwasher. For measuring smaller volumes, we either use some sort of graduated feeder, the little 2 oz bottles that have 1 mL markings, or a syringe.

What is the process that you use for cleaning between each measurement for mother's milk in those graduated cylinders?

Caroline Steele: You have to have plenty, because you don't want to be running your dishwasher all the time, so we have enough that we can then run them through and continue with our preparation.

Did you end up using the water bath thawing or your bead bath?

Caroline Steele: We ended up switching to a bead bath. We felt like it allowed us to get away from standing water and that it was a good way of doing it. We found it to be very effective.

Does your staff wear face masks during preparation of breast milk or formula?

Caroline Steele: We do not routinely wear face masks. We ask people if they're sick to stay home, but if they have something that's maybe like a tickle and they're not sure if they're getting a cold, as a precaution they would wear a face mask. But we do not routinely wear face masks.

What level of staff do you use in your milk prep rooms?

Caroline Steele: We use DTRs, or dietetic technician registered. I think that's the question that's being asked. We wanted staff that we could, during downtime, use for other duties. So, they can provide education, they can do nutrition screening, things like that. You can train other staff to do this. They don't have to be a DTR. What I like about the DTRs is again, not only can we use them for other functions, but because they have training in nutrition and they have to do continuing education, they are well-suited for both food handling—breast milk and formula—and they are also in a good spot to understand nutrition products, estimating nutrition needs. I feel like they are a good level of staff member to use for these duties.

When using a laminar air flow hood as part of milk preparation, is there a difference between a vertical or horizontal hood or can you use either?

Caroline Steele: I will preface this by saying I'm not an expert in laminar flow hoods, but it is my understanding that you can use either. Laminar flow hoods are not required, and we do have some information on that in the third edition of the *Infant and Pediatric Feedings* book just because questions on that do come up. I do like to tell people that it's not required—it's not required for the use of preparation of PO meds in most states either because what you're preparing isn't sterile. Human

milk's not sterile and if you're adding formula powder, it's not sterile, so it shouldn't be a substitute for aseptic technique. But if you do use it, you just want to make sure you're following those proper procedures and it's my understanding that either is acceptable. I have never worked anywhere that had a laminar flow hood, so I have no personal experience with it.

How do they prepare breast milk and formula in non-NICU units? Do they also have a centralized room?

Caroline Steele: We have one centralized room for our entire hospital, that is NICU and all other units. Milk is dropped off at each individual unit. The technicians pick it up and bring it back to the central location. Then all human milk and formulas that we prepare, as well as enteral formulas—either 1-liter closed system bags or cans of formulas—are delivered for that specific patient labeled with the barcode to each individual nourishment kitchen.

Does your barcode system work for both formula and human milk? Is it integrated to scan for both?

Caroline Steele: It is. It interfaces with our EMR so any human milk and formula orders interface into the system, it does the calculations. We scan any human milk, donor milk, fortifiers, modular, or formulas and it will record the lot number and expiration date. It will confirm that the product matches the order that's in the system so that you make sure you're giving the right product.

Do you allow preparation of formulas with probiotics? If so, are they excluded from patients with central lines?

Caroline Steele: That's a good question. Probiotics are always a sticky situation. We do carry a formula that has probiotics. We do prep it in our prep room. Again, we use aseptic technique and when we prep our formulas, we are very systematic in the order in which we prep formulas. Whether the patients that use that comes down to the dietitian for that unit and the medical team to determine, is this the appropriate product and what are the risks with that if they have a central line? We don't have an across-the-board policy one way or the other, but it's patient-specific.

What is the shelf life for your human milk and what temperature do you hold it at storage?

Caroline Steele: We have storage at -20° C or -4.4° F. We allow a year at that level. The guidelines are 6–12 months. For the most part none of our milk is actually stored that long, but it's 6–12 months at that temperature.

How long can you safely keep expressed breastmilk at room temperature?

Caroline Steele: Guidelines for healthy newborns at home oftentimes is 6 hours. There's a lot of information out there. In the hospital setting, or if you have a preterm or immunocompromised patient, I tend to use 4 hours because they are just at greater risk. When you think about, with feedings, hang time at room temperature, we usually say 4 hours. I don't ever feel real comfortable going beyond that. Now, I wouldn't throw milk away if it was 4½ or something, but I think you really have to be careful about too long at room temperature.

How do you check the temperatures during the preparation of breastmilk?

Caroline Steele: We spot check, but as an audit process for quality assurance. We don't check all temperatures every day, but we do routinely. We use a temperature gun, which you can purchase online. It uses a beam that tests the internal temperature. You can also use a food safe thermometer, but you have to use proper sanitation if you are going to stick this into the feeding that's

going to be fed. We just use the infrared temperature gun, spot check a few feedings. We've spot checked both in our prep room and at the final destination because we deliver throughout the hospital and we wanted to see, did the delivery time result in temperatures going outside of the goal range?

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