

Miris Interviews

Alongside our mission to make individual nutrition available globally to improve neonatal health, our goal is to create awareness, inspiration and dialogue.

One of the ways we do this is by organizing a series of interviews with our customers, partners and other prominent experts on topics relating to neonatal health and nutrition for preterm babies.



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Targeted fortification for improved growth in preterm babies

The survival rate for children born premature has increased substantially during the last two decades. One of the reasons behind this are improvements in the nutritional care of these infants. In 2010, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) issued their nutritional recommendations, but differences in breast milk macronutrient content between and within mothers can make achieving these recommendations challenging.

With colleagues at McMaster University in Canada, Prof Dr Christoph Fusch recently published a single-center, double-blinded, randomized controlled trial in Clinical Nutrition on how an individualized nutritional strategy called target fortification can help improve outcomes for preterm babies. Miris interviewed Prof Dr Christoph Fusch to hear more.

Can you shortly explain the concept of target fortification for our readers?

Some moms produce breast milk that is rich in nutrients, other moms produce breast milk that is low in nutrients. This variation affects all three macronutrients (i.e. fat, carbohydrates, and protein), but the changes are not related to each other. So, the variations are not just caused by a higher or lower water content, it is more complex than that. Some mothers deliver milk with high protein content, but not enough fat and some mothers do it the other way around, so there is a wide variety in the composition of the breast milk available in the NICU. In real NICU life, the assumption of a standard composition of breast milk does not apply and if we then add a standard fortifier babies are at risk of getting an unbalanced diet. However, if we would manage to measure what breast milk contains and then add fortifiers to match the content, we would truly know

what we end up with. Our goal is to achieve an intake according to ESPGHAN recommendations. For example, our goal is to have 8.0 grams of carbs per 100 mL, but if the measurement tells us that after standard fortification we would reach only 6.8 or 7.2 then we will add the missing carbs, and we will do the same for fat and protein. With this approach we fairly reach the ESPGHAN target, so babies get what they are supposed to get and we see appropriate growth that usually runs in parallel to their intrauterine percentile with an offset of -0.7 SD, which we believe is the correct ex-utero trajectory.

How did you come to start your research into nutritional care of preterm babies and target fortification? What's the story behind it?

The true story behind it is that one day in the 80s I heard the great neonatologist and former chief from Berlin, Professor Michael Obladen, saying we need to feed babies breast milk, but maybe we need more components than just standard fortification because it looks like only focusing on protein is not enough. He just put this idea into my head and when I became chair and chief in Greifswald, Germany, I started working on it and we saw that by improving nutrition we got better growth. When I moved to Canada, I had the opportunity to really work on this



"I think it is all about education, about bringing the science and evidence to the bedside. We were lucky that we had really open-minded staff who said, yeah let's try it. We also admitted that if it doesn't work after a year then we stop it, but it worked, and even much faster, and so we did continue"

concept by introducing bedside measurement of breast milk content. You know what, it's like blood gas analysis, but instead of adjusting the ventilator settings you adjust the fortification and then you get better results.

So why is it important to know the macronutrient composition of breast milk, isn't breast milk already optimal for babies?

Mother nature has adjusted the breast milk content to fulfill the needs of term babies, but breast milk has a huge variability between mothers and also within the same mother. The good thing is that term babies

can self-regulate their feeds. If they still feel hungry, they stay longer at breast, if the breast milk is rich in fat they drink less. They sense what the actual milk is composed of - in the same way as we as adults regulate eating depending on satiety feeling. For example, if we eat a cheese fondue or we eat fondue bourguignonne, we eat with at different speed and also with different duration as the fat and protein content of cheese fondue effects a faster satiety feeling already after a few bites. That is not different in term babies.

However, preterm babies do not have this chance to self-regulate because they are usually gavage

fed, especially the tiny ones. Therefore, they must deal with what our neonatal team is filling into their stomach. While the biological components of breast milk are of superior digestive quality and tolerability, native breast milk per se is not perfect for preterm babies: these infants need approximately three times as much protein as the average content in breast milk, because their growth rate is three to four times higher compared to term babies. Also for fat there's a huge variability. Some moms only have 1 g/100 mL of fat in her milk and we would like to have 4.5 at least, while some moms have up to 6-7 g/100 mL.

Energy is needed to build up lean mass from amino acids and if you have an imbalance with not enough fat, then babies can't grow. That's why breast milk, which by digestibility and immunological properties is ideal, can lead to a dietary intake that is uncontrolled and might not be enough for up to 30 - 50 percent of the preterm babies even with standard fortification.

What is the risk for preterm babies if nutritional needs are not met, could you explain the need for growth for preterm babies?

Term babies grow at a rate of about 5-9 g/kg/day. Preterm babies grow up to 20 g/kg/day, so they have higher growth rates by a factor of two to four. Growth is mainly determined by buildup of lean mass and lean mass mainly means protein mass. Protein you get via amino acids, by ingesting protein. Growth is more or less a direct linear function of protein intake, more protein gives you more growth, less protein gives you less growth, provided that you have enough energy onboard.

If you don't give enough energy, you instead initiate protein breakdown. In this situation, the amino acids are being oxidized and are used for gluconeogenesis: the carbon skeleton is stripped off and fed into pathways of glucose metabolism. The remaining ammonium groups need to be excreted in the form of water-soluble urea, which is an energy and water consuming process. So, the two consequences of inappropriate intake are on one hand that the babies don't grow sufficiently and, as a consequence, you will experience postnatal growth retardation, which means they are below their expected percentile or they lose percentiles. On the other hand, you can do

metabolic harm because the protein is not utilized the way it should be but is excreted by forming urea. This process costs energy and a lot of water, as urea is a strong osmolyte and is the unfavorable metabolic pathway for protein.

Before we were able to measure milk composition, we sometimes saw babies where we tried to increase protein intake because they were not growing. Some of them deteriorated and looked septic, but there was no sepsis and there was no infection, nothing. Instead we saw that the urea went up massively, for example from 40 to 110 mg/dL. When we reduced protein intake babies came back to normal again. So, you can really make a baby sick with an unbalanced diet, giving too much protein compared to what they can build in.

"I am confident to say that when you do this approach the right way then it will work. I would like everyone to see our growth curves right now, they are unbelievable"

When you started to analyze breast milk in your NICU what did you find?

We found the, already well-known, variability in macronutrients between and within mothers. What we also found, which was more unexpected, was that the content of macronutrients is not correlated, that moms with low protein do not necessarily have low fat and low carbs levels. It is not a question of a kind of diluted or concentrated milk. This finding was different from what we initially thought and from what was in the literature.

These results were published in *Acta Paediatrica* in 2015. If you plot the three macronutrients in a

3D-diagram you see a cloud of points, which means the levels are not correlated. For me, this finding was an eye-opener towards the true reason why a significant number of preterm babies cannot grow well on standard fortification. The current practice to fortify breast milk with a standard fortifier, which means adding fixed amounts of macronutrients, leads to these babies being fed a diet with a random composition - something that you would never decide to apply in daily routine. For example, we do not do that in parenteral nutrition and not in enteral nutrition, that one day we give 3.5 grams of fat and the next day we give 2.7 grams of fat, or we choose to give one day 3.8 g of protein and the next few days only 3 g of protein, but that is what we do to these babies when feeding standard fortified breast milk. It is appropriate for half of the babies where the breast milk composition is within the assumed limits, but not sufficient for the others. That is what we found, and we said this calls for action, let's see that we get rid of it, and then as a consequence we implemented the program of target fortification.

How long have you been running target fortification in your NICU as standard of care?

Here in Nürnberg we started about 18 months ago and it works beautifully. Everybody is now used to it and it is part of the daily routine. We do the measurements twice a week, on Mondays and on Thursdays, and all babies below 34 weeks get target fortification on a routine basis and we really have beautiful growth curves.

How are you set up in your NICU, who does the analysis and who prepares the feeds?

Feeds are prepared by the staff in the milk kitchen. Previously bedside nurses prepared the milk for their babies themselves, but we changed it so there's a dedicated nurse team who prepares the milk. We have a group of nurses who perform this task, but every day it is one dedicated nurse who prepares the milk for all our babies. We have a study coordinator who runs the analysis and gives us the data, and the doctors calculate the fortification with a standard algorithm. The recipes are then given to the milk nurses and they prepare the milk according to the recipe. It is not complicated; it takes maybe five to ten minutes extra if you take everything together. It is a little bit of extra work, but it is all worth it as at the end you see really nice growth curves for the babies and



realize that we can discharge babies earlier because they are metabolically more stable and keep their body temperature better, which are prerequisites for successful discharge at home.

How has target fortification been taken onboard by the nurses and the rest of the staff?

Our unit went through a transition with this new approach. Growth in the past was not optimal and NICU care was very much about lab diagnostics, ventilation and circulation. We have now expanded our focus on sepsis prevention and on nutrition and growth into daily routine. To achieve this, we started with lectures and educational sessions about why growth is important and how you can achieve appropriate growth, and if you care for growth you should also care for nutrition to impact growth and improve growth patterns. Then we gave educational sessions on the process of target fortification in the NICU. We started with the doctors first so that they understood, especially the attending and fellows, and then we also talked to nurses. They first had their concerns about workload, but as we started integrating target fortification into our routine and they could see the results and how beautiful the babies grow, nobody questioned to continue with this strategy.

I think it is all about education, about bringing the science and evidence to the bedside. We were lucky that we had really open-minded staff who said, yeah let's try it. We also admitted that if it doesn't work after a year then we stop it, but it worked, and even much faster, and so we did continue.

I am confident to say that when you do this approach the right way then it will work. I would like everyone to see our growth curves right now, they are unbelievable. We analyze the breast milk, adapt the fortification accordingly, and babies grow. And we have no side effects, we have no increased rate of NEC, people talk about milk curds, we do not see that. Babies just get what they are supposed to get, we do not do super fortification, that is the most important point, it's really only that target fortification makes sure that all preemies get what they should have gotten all along.

Why are you so concerned about growth, why does it matter if the babies are growing or not?

Historically for many years or decades NICUs were focused on making preterm babies survive. The main research was on ventilation and only a few units were looking at feeding or growth. Feeding was frequently considered dangerous because of the risk to develop NEC, fluids were dangerous because of PDA and BPD and so on, so neonatologists in the earlier days got used to preterm babies not growing well. Everybody was happy if their weights moved somewhere and somehow in the growth charts, but many kids didn't grow well at all. We have data of cohorts that started with 30% SGA kids and at discharge there were 60-70% SGA, so in terms of growth we as neonatologists did a "lousy" job, and we got used to it.

That is why many neonatal staff saw undernourished preterm babies and this was considered as being normal. Literature is full of papers presenting such growth patterns, which today we would consider as inappropriate growth. With the modern paradigm shift on better growth you focus on feeding these babies more and as a consequence they grow differently, I'd like to say a bit more normal. With this practice you will see how these babies now visibly accumulate some more fat mass, but to our understanding that is normal, and nowadays we are also able to measure body composition and percent fat mass. So far, we do not have too robust data on what the appropriate trajectory of a preterm baby looks like once it left its intrauterine apartment.

We have further investigated this problem and were able to publish data on postnatal trajectories in a large cohort of preterm infants with mostly undisturbed postnatal transition – as a role model how "healthy" preterm infants would adapt to extrauterine conditions. We now are quite confident in assuming that these babies, once they are getting out of the uterus, drop their weight by 0.7-0.8 z-scores, and then continue to grow to get back to and merge with their corresponding WHO percentile a few weeks after term. We think that this pattern does reflect appropriate growth. If one would aim to follow that trajectory from the early beginning then one would avoid starving a baby, which then all of a

sudden at around 34-35 weeks, when most babies - regardless what kind of NICU care they receive - get stable and you start feeding them better, will become obese. With target fortification we do not make them starve, already from the beginning we let them grow on this postnatal trajectory. We accept 0.7 z-scores difference to the intrauterine one, because we think that this is physiological because of the one-time, irreversible contraction of extracellular fluid space which results in a 7-12% loss of body water, and then keep them growing in that trajectory. Interestingly with the ESPGHAN recommendations on enteral intake, if you achieve them, you get exactly that kind of growth. But you need to start from the beginning, already during the first days of life. If you manage to do that, I think you will have the optimum outcome. We have looked into data for the long-term outcomes of kids where we compared different growth trajectories and we saw that coming close to "our" proposed trajectory really improves outcomes, and that's why we think growth matters.

I think a lot of what is still in the literature comes from older studies where babies experienced different periods of growth: first insufficient intake and growth and then too high growth because once babies stabilized after this cautious initial approach, babies tolerated nutrition and staff may unintentionally have overfed babies to catch up. But that is not what we are aiming for. If you have patterns of slow initial growth leading to postnatal growth restriction then it might be better – once you are able to feed them more - if they grow slower, if you improve them more slowly. It may be similar to 14 -15-year-old adolescents who became anorexic and - if you feed them too fast - they might experience a refeeding syndrome and may even die, so you need to do that kind of refeeding very slowly. The same would be true in preterm infants initially exposed to growth restriction. However, our approach is to avoid this initial anorexic phase and at any given day provide the baby with appropriate nutrient intake so they can accumulate that body composition that they would have accumulated in utero. But to "play" this approach it is definitely helpful to know a little bit about nutrition and growth physiology, and why it is so important to ensure that we give a balanced diet - something which many neonatologists are not aware of and don't do today.

You say that you see improvement in clinical outcomes, what clinical outcomes are you looking at?

On one hand we studied short-term outcomes which is just anthropometry, head circumference, length and weight. We have also done body composition at McMaster and we will do it very soon also in Nürnberg.

Then in a more sophisticated way you can also compare metabolic parameters and look at triglycerides, hormones, glucose etc, and also blood pressure, as well as other metabolic markers that are linked with early onset of adult diseases. You should also investigate neurodevelopmental outcome at the age of two or five years, or even later.

We have also looked into complications during the hospital stay and we found less sepsis and interestingly also lower NEC rate with target fortification. It was not statistically significant at a 5% level, but the trend was clear. We also found less feeding intolerance. We believe this is because the baby gets the same composition every day and not one day a lot of fat and then less fat and so on, and the gut is working under more steady state condition.

Is your feeling that your targets for nutrition are met in your NICU?

Yes totally. We have very few babies that do not grow despite sufficient intake. These babies apparently seem to not digest well and experience an additional problem, like relative exocrine pancreatic insufficiency, and is therefore not reaching the expected trajectory. That has been reported, but this is in maybe one out of 50 babies, and for these babies we investigate other digestive issues.

What would your advice be if you were talking to a NICU director that is doing standard fortification, but thinking about changing to target fortification? Where would you advise them to start?

First, I would propose that they come over to our unit to see how we are doing it, because it's running smoothly in routine here and that could be encouraging for them.

If I realize that they are experiencing compliance problems with their team, then I would ask:

- Question: Are you ventilating babies?

- Answer: Yes

- Question: On a ventilator?

- Answer: Yes

- Question: Are you doing blood gas analysis?

- Answer: Yes, why are you asking?

- Question: Why are you doing blood gas analysis?

- Answer: Because I have a baby on the ventilator and I need to guide the settings

- Question: Do you know any kind of randomized controlled blinded trials that compare ventilator respiratory management with and without using a blood gas machine?

- Answer: No

- Question: Then why are you using blood gas analysis in ventilated babies? There's no evidence that using a blood gas machine is useful, but you are using it.

Now go to nutrition, there is now some evidence that measuring breast milk content will improve growth. You are using a blood gas machine without evidence, but you won't analyze breast milk though there is evidence. What is the rationale behind that behavior? And - with breast milk analysis you don't even need to take blood. You just take breast milk, you get it for free, it is a painless procedure and you measure nutrient contents precisely, at the same speed as you do using a blood gas machine and then you take the data, do a quick calculation, fortify accordingly, and then you see one or two days later that growth improves, why aren't you doing it already?

Once you understand that breast milk composition is not always the same, then you also understand that

you're feeding the same baby a different diet every day. We would not accept that strategy in any other part of the care of these babies.

I think the ESPGHAN recommendations are very sound and they are based on a lot of nutritional physiology research from the 70s, 80s and 90s - research which nobody's doing anymore. The data is very consistent overall and from my experience, if you really manage to provide ESPGHAN recommended intakes to these babies then 95 percent of the babies will grow, whereas if you don't meet these intakes the babies won't grow.

With your recent findings do you see a future for target fortification as standard of care for preterm babies?

For us it now has become standard of care, but it might take another 5-10 years until other units are ready to adopt it as standard care. In this context it needs to be mentioned that currently some studies claim to do target fortification, but unfortunately reduce it to adjusting only protein intake, forgetting to also look at energy intake which is of equal importance. Such approaches violate nutritional physiology and they add a lot of nutritional research noise and it might take a while until that is all cleared out. But I for sure see target fortification as the standard of care for preterm babies in the future.

When Bo Lönnerdal and Staffan Polberger in the 90s in Sweden showed that by analyzing breast milk and subsequently fortifying according to content, you could improve growth of preterm babies, Swedish NICUs changed their practices in the following

“Once you understand that breast milk composition is not always the same, then you also understand that you're feeding the same baby a different diet every day. We would not accept that strategy in any other part of the care of these babies.”

years. Why do you think the rest of the world didn't follow, what is the hang-up on actually implementing this practice?

That's a good question. Look at what happened with respiratory support: in the 80's everybody was on mechanical ventilation and later also to replace surfactant. However, Sweden already in the 70s and 80s provided non-invasive respiratory support using CPAP. Other parts of the world were not interested in doing so, they were just ignoring it. However, some 30 years later - thanks to the CPAP inventors, thanks to the Swedish guys, but also thanks to Jen-Tien Wung at Columbia Babies Hospital in New York, CPAP was in the end adopted world-wide. It finally had to do with intelligent adaptation of findings that influence clinical practice, and this is the same with nutrition. Sweden is a small country, so people say who cares what they do, right? But they were right, and I can only support that they were fully right to do so.

How come you chose the Miris HMA for your NICU in Nürnberg?

The Miris was validated by our group, and so we know that it works. We also like the device because it's small and easy to handle. And also support was good, Miris support has really improved over the last 10 years. I must say Miris has really taken on the challenge that in part was also opened by us by the results obtained in the validation studies. Miris has taken that on and continuously worked on improving their device, which I cannot say is true for other bedside milk analysis devices. And I'm not paid by Miris, I want to say I'm independent.

You just published a study on target fortification in Clinical Nutrition, what did you find?

We found that babies that get target fortified breast milk grow better. One very interesting finding is what we found when we did subgroup analysis. If we look at the group of babies whose mothers produce breast milk with naturally high protein, the effect of the intervention is relatively small. And honestly, that was to be expected from existing physiology data. But for those whose mothers produce breast milk with naturally low protein content, the difference between the intervention and non-intervention group was massive with about 350 grams of weight

difference. There was only a small increase in fat mass, which is normal, but they experienced mainly an increase in lean mass.

I think in all honesty it's the only trial that has been made with a validated device and by using good laboratory practice and by adjusting all the components, namely protein, fat and carbs individually, and therefore really met the ESPGHAN recommendations.

Are you measuring BUN in your unit or are you confident that you're not overshooting on proteins?

We are measuring BUN every other week, that was already part of the standard practice before I took over the unit, but we rarely need to adjust our feeding prescriptions. We seldom see high BUN, which might be due to the fact that we provide a balanced diet with this kind of approach.

How is the set-up in your NICU? Are parents able to stay in the NICU with their babies?

No, we unfortunately don't have enough space. We are planning a new Children's Hospital, but currently it's not possible. Moms stay at home or they can stay here in the hospital, but not in the NICU. We have an open-door policy; parents can visit whenever they want. We have two mother-child rooms, but those are for the families when our patients are coming close to discharge.

Are your parents still allowed on the unit in the current covid-19 situation?

We allow both parents to visit, there are no restrictions as long as both are healthy and don't show any covid-19 associated symptoms. We recently had kids from covid-19 positive parents in the unit, but that's a different story. It may become hard, but as long as relatives are covid-19 positive, they are not allowed in. But other than that, we allow both parents in the unit. This is important: if you get a new child it's not only the mother-child dyad that needs to be established, if there is a partner then it is equally important for the partner to be able to form that bond as well.

If a covid-19 positive mother gives birth to a preterm baby, do you consider the baby to be positive or negative?



We are in discussion on that topic right now. I think the risk of transition is relatively low so we would rather like to consider them as covid-19 negative, but of course we follow the directions given by our infection control though sometimes they have a different opinion. They consider them as positive and we need to test them and continue for 14 days at least and until then they should be in a single room.

But we sometimes are running short on space, so I think we are still trying to find the tools there. It's hard times for everyone.

The full publication can be found here:

<https://www.sciencedirect.com/science/article/pii/S0261561420302028>

Individualized target fortification of breast milk with protein, carbohydrates, and fat for preterm infants: A double-blind randomized controlled trial.

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Clinical Nutrition May 2020, in press



Target fortification at the Wake Forest Baptist Health NICU

The Miris HMA™ was cleared by FDA in the end of December 2018. Soon after the company received a request from the Wake Forest Baptist Health NICU and they subsequently became the first NICU in US with the FDA cleared version of the Miris HMA™. Over a year down the road we checked in with Doctor Amit Chandel, Assistant Professor of Pediatrics, to hear how the Miris HMA™ has improved the nutritional care of their smallest babies.

How did you come to hear about the Miris HMA™?

I had always wondered that with so much advancement in science and tests moving from labs to bedside, that there would be something available to analyze the components of breast milk, so that we could really know what nutrition we are giving to our most vulnerable preterm newborns. Infant nutrition is one of my core interests. Our Neonatology Chief Dr Shenberger was aware that there is a breast milk analyzer by Miris which is used in NICUs in Europe and that it had recently been approved by US-FDA. I was immediately drawn to this and we purchased the milk analyzer in the ensuing months for our NICU.

We were using the standard and adjustable techniques for fortification of human milk in our

NICU, both these approaches either under or over shoot the optimal nutritional needs for the infant. So, we were very excited to hear about Miris HMA which could help these infants by analyzing the maternal milk and giving us the information about the macronutrient composition of mom's milk.

What did you find when you started analyzing mother's milk in your NICU?

Research has shown variation in maternal milk composition with dietary intake, gestational age, corrected gestational age of the infant in the same mother and large variation between mothers. When we started analyzing maternal milk in our NICU, we found similar variation in maternal milk macronutrient composition which was very fascinating.

"Mothers feel very empowered and satisfied that they are giving the milk for analysis and upon analysis if any optimization is required it is provided to their infants."

"Our target fortification program has been running for 9 months now and, despite our numbers being small, we are definitely seeing a positive trend towards better weight gain and linear growth in babies receiving target fortified milk."



What has been the benefits of the analysis?

We are currently analyzing the milk of mothers who had babies born less than 31 weeks gestational age. We wanted to focus on the babies who are the most vulnerable and we can get at least 4 weeks of analysis and target fortification. Our target fortification program has been running for 9 months now and, despite our numbers being small, we are definitely seeing a positive trend towards better weight gain and linear growth in babies receiving target fortified milk. An additional benefit that is hard to quantify is that mothers feel very satisfied providing their milk for analysis knowing that it would help their little ones grow better.

What does the target fortification process look like in your NICU? Who does what?

Our team consists of lactation consultant, NICU nutritionists, milk technicians and myself. We currently analyze two times per week. Our lactation

consultant provides information regarding milk analysis to eligible mothers during her lactation consultation and provides mothers with the milk collection kit. When mothers return milk for analysis, it is analyzed by our lactation consultant. The report generated by the HMA is reviewed by the NICU nutritionists and macronutrient components are put into an automated excel based calculator, which tells us how much protein needs to be added to the maternal milk. This information is relayed by the nutritionists to the milk technicians, who will finally prepare the milk to specification and forward the target fortified milk to the nurse who is caring for the individual baby.

How do you manage billing of the analysis as it does not have a CPT code?

We currently have not been billing the analysis, but this is something that we are thinking about for the future.

“This approach of fortification is very precise and has growing evidence about improving growth. It gives us an objective way to fortify human milk instead of just guessing with standard and adjustable fortification techniques.”

Clinicians, not analyzing in their NICU, often asks us if mothers react negatively to the analysis of their milk, that they would get the impression that there is concerns regarding the content of their milk. What is your experience, how have you informed mothers of the purpose of the analysis and what have their reaction been?

I think it is a genuine concern which cannot be brushed away. We discussed this question within our team when we were implementing the milk analysis in our NICU. To address this concern, we developed a standard way for communicating the benefits of analyzing and emphasized that it is being used to optimize maternal milk to the needs of the growing preterm infant. So far, our experience has been really good, and mothers feel very empowered and satisfied that they are giving the milk for analysis and upon analysis if any optimization is required it is provided to their infants.

One year in, what would your advice be to a NICU considering implementing human milk analysis and target fortification in their NICU?

Optimal Nutrition is one of the cornerstones for good growth and development of these vulnerable preterm infants who are predisposed to growth failure because of being born preterm and various other comorbidities associated with prematurity, like chronic lung disease. With macronutrient variation in human milk being a known fact, human milk analysis provides a quick way of analyzing these variations and targeted fortification a tool to overcome them. This approach of fortification is very precise and has growing evidence about improving growth. It gives us an objective way to fortify human milk instead of just guessing with standard and adjustable fortification techniques. I think this is going to be adopted in more and more NICUs in coming time.



Making the change to Targeted fortification

Dr Jiří Dušek spent 10 years working in a Swedish NICU seeing firsthand how an individualized nutritional program benefits preterm babies. Upon his return to Czechia he was determined to implement individualized nutrition at České Budějovice Hospital NICU, and after only one year he reached his goal. Miris met up with Dr Dušek to hear about how he managed to achieve this change and what results they have seen in their patients.

How did your interest for preterm nutrition start?

I worked 10 years at the neonatal care unit at Umeå University Hospital. This NICU has a long history of excellence in neonatal nutrition and their nutritional program is used in many countries. This is where my interest in neonatal nutrition sparked.

When I returned to Czechia and started work as medical director at České Budějovice Hospital NICU, I had seen firsthand the great results that can be achieved with a controlled nutritional program. There was no question for me that we needed to implement this also in our hospital. I started work immediately and in only one year managed to switch our practice to an individualized nutritional program and I was surprised of the effect this had on the babies.

Can you tell us about what changes you made?

We started with a new system containing three important steps:

1. Implemented a nutritional program for fluids and macronutrients. We dedicated one of the rounds per week to nutrition, according to the Swedish model. During this round all doctors go through the nutritional status and growth of their patients.
2. Implemented high concentration low volume parenteral nutrition.
3. Implemented targeted fortification with Miris Human Milk Analyzer.

What challenges have you faced?

In fact, I did not meet any challenges that slowed down the progress. As we quickly achieved noticeably better results with the change, my colleagues quickly saw the benefits and worked alongside me to establish all routines with the new nutritional program.

The whole process with calculation of both enteral and parenteral nutrition takes maximum 10 minutes per baby. As babies get their nutritional intake optimized and as such are more stable, challenges for doctors are reduced.

"I had seen firsthand the great results that can be achieved with a controlled nutritional program. There was no question for me that we needed to implement this also in our hospital"

"Earlier when our patients were discharged from the NICU you could immediately see that this baby was born premature. Now when you compare our former patients at 36 weeks with another baby born at week 36 you can't see any difference"



We have reduced the non-nutritional fluid intake. In one year, we saved 35 000 EUR on Curosurf and PDA treatments alone. We were also excited to see that we reduced time on PCVC and antibiotics.

Earlier when our patients were discharged from the NICU you could immediately see that this baby was born premature. Now when you compare our former patients at 36 weeks with another baby born at week 36 you can't see any difference. If you do not know which baby was born premature you cannot tell. In the photos we have at our NICU of earlier patients, you can clearly see if the photo was taken before or after we implemented targeted fortification.

We also see a reduction in length of stay in the NICU and the babies move earlier to the parent rooms. Being able to have these babies close to their mothers is of course of great benefit for their

“With the results we and others see after making the change to targeted fortification, it must become standard of care.”

development. Also, this shortening of stay in the NICU has reduced costs and meant that we are able to accept patients from other regions. Earlier our NICU was often overcrowded but now it is our parent rooms that are overcrowded, not our NICU.

As the babies move to the parent room earlier, where baby is kept with mother, we also see a clear reduction in sepsis.

We still have ways to go, but in just one year we have seen remarkable improvements and we are currently getting ready to publish our results.

Can you tell us more about your parent rooms?

Our NICU has 12 beds, and we also have an intermediate ward, but most of our babies now stay with their mother in parent rooms. We have room for 26 mothers in our unit. In the parent room the partner can unfortunately not stay over, as most of the rooms are shared between two mothers.

We also have two family rooms, which are reserved for families with other children under 3 years old. In these rooms partners can also stay. This is unique for our hospital in Czechia.

As our babies now leave the NICU earlier, the parent rooms are constantly overcrowded, and we have now started to cooperate with the intermediate ward to increase our parent rooms.

What is your advice to a NICU considering changing to a targeted fortification approach?

My recommendation is to stop thinking about it, just start making the changes. Take help from people that have experience in making the change. Visit a unit that has implemented the process and visit for 1-2 weeks to learn how the process works. We are arranging workshops and inviting clinicians so that they can learn. I have seen how well it works, so for me it is no question this is the way to go.

Do you see targeted fortification as part of standard care of premature babies in the future, in Czechia and worldwide?

I am convinced it will be. With the results we and others see after making the change to targeted fortification, it must become standard of care.



Advancing Neonatal Nutritional Care

- An Interview with Stephanie Merlino Barr and Sharon Groh-Wargo

Stephanie Merlino Barr and Sharon Groh-Wargo have worked together for the past six years in the Neonatal Intensive Care Unit at MetroHealth Medical Center, in Cleveland, Ohio, USA. The hospital provides medical and surgical care for both adults and children which includes about 3000 deliveries per year and the care of both healthy and high-risk newborns. Stephanie and Sharon are passionate about lactation advocacy and translating human milk and fortification research into clinical practice. We interviewed Stephanie and Sharon to hear more about what challenges and changes they are experiencing in their facility.

The MetroHealth Medical Center NICU operates within a general “safety-net” hospital. How are the challenges different for you than other surrounding specialty children’s hospitals?

Sharon:

Several things come to mind. First, regarding being a general hospital that has both adult and pediatric patients, our NICU tends to have a more homogenous patient population than a children’s hospital. For example, our patients are primarily, but not exclusively, preterm and VLBW (Very Low Birth Weight) infants whereas children’s hospitals usually have large surgical and cardiac units.

Secondly, regarding being a “safety-net” hospital, we are committed to serving everyone regardless of their ability to pay. This means our maternal population tends to be very high risk and often have multiple barriers to accessing healthcare. Subsequently, their newborns are often at increased risk at delivery and may have increased co-morbidities upon birth. The inequities of social determinants of health experienced by our patient population were exacerbated during the COVID-19 pandemic.

In addition, hospital resources can be limited due to reliance on public programs, such as Medicaid, for reimbursement, versus private insurance.

Stephanie:

Knowing these barriers, our patients and their families deserve access to innovative and collaborative care. We are extremely proud at MetroHealth to be national leaders in clinical anthropometric assessment – we are one of only a few units in the country to have standard utilization of air displacement plethysmography in our NICU care. We are also excited to join the growing number of units utilizing human milk analysis to better individualize the nutrition of our preterm infant population. ones grow better.

What role do neonatal dietitians play in the context of improving human milk feeding and fortification?

Sharon:

I think NICU dietitians are seen as experts regarding human milk composition. Their clinical experience and training positions them to translate knowledge into the creation of individualized nutrition plans in the NICU. Having a human milk analyzer available brings the discussion of human milk composition variability to the forefront. It also highlights that human milk is the best feeding for nearly all newborns but requires fortification to meet the nutritional needs of VLBW infants.

Most neonatal dietitians, and some neonatologists who have a special interest in nutrition, are following

the literature closely and trying to figure out how to operationalize improvements in human milk feeding and fortification. Stephanie and I are especially interested in the unique role of the registered dietitian on the multi-disciplinary team in the NICU. We recently collaborated with other colleagues on a survey of North American clinical dietetic practice in the NICU. Stephanie is the first author on a paper entitled “The role of the neonatal registered dietitian nutritionist: past, present, and future” that discusses some of the results of the survey. It was recently published in *Clinics in Perinatology*.

In addition, we have a group of neonatal dietitians in Ohio that are in close contact, including twice yearly in-person meetings. We share our practices, challenges and solutions freely.

Stephanie:

In terms of our specific goals – Sharon has been a leader in establishing the importance of both neonatal nutrition as well as the role of the neonatal dietitian. We are invested in better understanding how neonatal dietitians, both in terms of staffing and job responsibilities, improve NICU outcomes.

“We are also excited to join the growing number of units utilizing human milk analysis to better individualize the nutrition of our preterm infant population.”





We are also working on implementing concepts and technology long discussed in the literature into standard clinical care. Utilization of body composition assessment and individualized fortification to inform care plans and improve upon nutrition-related outcomes are two primary areas of focus.

Considering the recent feasibility of human milk analysis in the US, could you share the current state of the implementation process?

Stephanie:

In short, it's a new clinical practice in the US, whereas individualized fortification using human milk analysis is a much more common practice in the EU. The differing structure of the healthcare system between the US and the EU also create some differences in how resources are regulated, implemented, and billed for.

To give some perspective on the US timeline, human milk analysis in a clinical setting has only been feasible since December 2018, when the US Food and Drug Administration (FDA) granted marketing authorization of the Miris HMATM, allowing for its use in clinical laboratories. Within 15 months of this decision, the WHO declared COVID-19 a global pandemic and hospital resources shifted to respond. NICUs around the US, including ours, who were considering implementation of human milk analysis into their clinical practice were delayed in their efforts. We are in the early stages of lactoengineering and human milk analysis in the clinical space here in the US, and thus are working through challenges with implementing this change in clinical practice.

Could you provide insights into the process of performing human milk analysis in the NICU? What factors are involved in the analysis and what challenges do you see?

"Having a human milk analyzer available brings the discussion of human milk composition variability to the forefront."

Sharon:

Securing funding to acquire the analyzer can be challenging, but the positive aspect is that there are often available grants that can cover the equipment costs. Moreover, once purchased, the analyzer represents a one-time expense, alleviating further financial burden. However, the primary challenge lies in the ongoing expenses associated with the necessary personnel for targeted fortification implementation. Instructing lactating parents on milk collection, running the analysis, and creating individualized fortified milk recipes for each baby. This personalized care must be facilitated through adjustments to yearly NICU budgets.

Stephanie:

Outside of the necessary system required to implement and sustain Human Milk Analysis in a hospital setting, there are significant and intriguing questions that warrant exploration. These include:

- Should individualized fortification become a standard of care? And if so, which populations would benefit most from this personalized approach?
- What constitutes the ideal nutritional composition to support the unique needs of preterm infants, considering factors such as their disease state, birthweight, and gestational age? Additionally, what specific products should be employed to achieve these goals within a clinical setting?
- Does the implementation of individualized fortification lead to improved clinical outcomes for this vulnerable population?

These questions hold great promise and excitement for researchers, as they pave the way for a deeper understanding of the growth and nutrition requirements of preterm infants. Through ongoing

research, we can continue to unlock valuable insights and ultimately provide enhanced care and better outcomes for these fragile newborns.

Human milk analysis and individualized fortification requires a collaboration between the family, milk room staff, neonatal dietitians, nurses, and the medical team. We are currently working towards a sustainable implementation of this technology into our daily clinical care.

What are some of the potential benefits of targeted fortification in a NICU setting? How does this personalized approach to fortification contribute to the health and well-being of premature infants, and what positive outcomes can be expected from its implementation in the care of these vulnerable newborns?

Sharon:

The greatest potential benefit of targeted fortification in the NICU may be the ability to more closely meet nutritional requirements. If the composition of a feeding is not known, if it is only a "best guess," there is no way to assure that we are reaching estimated macronutrient needs. One positive outcome that could be expected from implementation of targeted fortification is improved protein intake. Protein intake in the expected range is associated with better length gain which, in turn, is associated with high quality weight gain. For example, improved accretion of fat free mass as opposed to just gains in adiposity. Fat free mass accretion is associated with improved neurocognition, an extremely important indicator of long-term outcomes.

Stephanie:

In addition to what Sharon mentioned, I think there is potential to tie targeted fortification to malnutrition prevention and intervention in the neonatal population. Better understanding of the true daily provision of energy and protein to preterm infants will

continue to corroborate our understanding of clinical best practices and interventions to support growth. A necessary next step in targeted fortification research will be to determine how this feeding practice influences nutrition-related preterm infant outcomes in the short term (e.g., bronchopulmonary dysplasia) as well as the long term (e.g., neurodevelopment).

In your view, what are the potential areas for growth or necessary developments in human milk research as we look into the future?

Sharon:

I feel that an individualized approach to feeding high risk newborns, specifically milk analysis and targeted fortification, is the next logical innovation and improvement in how we feed preterm and VLBW infants. Assessment of micronutrient content of human milk is not currently feasible but may be a next step in creating individualized feeds for preterm infants.

Stephanie:

There is absolutely a need for human milk research beyond the NICU environment. Human milk is a wonderfully complex biological system and should be studied as such. The Breastmilk Ecology: Genesis of Infant Nutrition (or, BEGIN) project was formed to identify gaps in the literature and to create a framework to help guide our exploration into the unknowns of human milk science. Sharon and I were contributors on this incredibly multidisciplinary project, and our work was just published.

When discussing human milk analysis and human milk fortification with families, how do families generally perceive the benefits and value of these practices in optimizing the health and well-being of their infants? Additionally, could you elaborate on the positive outcomes and improvements in neonatal care that families commonly appreciate and embrace when human milk analysis and fortification are part of the care plan for their newborns?

Stephanie:

In the NICU, families have had a traumatic end to pregnancy, a traumatic start to parenthood, and are not having the newborn experience that they expected or planned for. Infant feeding and nutrition are often the only ways that families feel they can contribute to their child's care. As modifications to nutrition plans are made to meet the elevated nutrient requirements of preterm infants, families can often feel like they are doing something wrong to make their breast milk insufficient to nourish and grow their infant. Thus, discussing tools used to optimize nutrition in the NICU is an important conversation to have with families.

In these conversations, I like to emphasize the known benefits of human milk (reducing risk of NEC! Unique composition to optimize digestion! Its role in immune system development!). I also like to focus on both short- and long-term goals – for the short term our goal typically focuses on meeting the unique nutrition requirements and supporting growth, whereas discussing long-term goals include discussing how long a parent wants to pump and/or breastfeed, what nutrition will look like post-NICU discharge, and what breastfeeding goals the lactating parent has.

How do you communicate the difference between Mothers' milk versus donor milk to parents

Sharon:

Donor milk is not equal to mother's own milk. The discussion about donor milk with mothers in the NICU needs to be carefully delivered so that the message focuses on how mom's own milk is special and specifically intended for her baby. Donor milk needs to be presented as a secondary option. All team members need to deliver a unified message around donor milk so that mothers and other family members are not confused.

What are your thoughts regarding human milk analysis for healthy full-term infants versus preterm patients?

Sharon:

We have received occasional requests from hospital colleagues to analyze their breast milk. In general, I think analysis of human milk that is being fed to healthy babies should be discouraged. Historically, babies have been fed human milk and have done well nearly all of the time without knowing if the milk is high fat or low, etc. It's the same with having a scale in the home to weigh a healthy term breast fed baby – too much emphasis on technology.

Stephanie:

I think all depends on the intent. Personally, I think it could be awesome to have ways of showing how unique and dynamic human milk is at the individual level. However, the potential for this information to be exploited is incredibly high. We don't need to go looking for problems and marketing solutions for any vulnerable family. However, in the preterm and critically ill infant population, human milk analysis can be a tool to help better understand and improve upon nutritional care.

"I feel that an individualized approach to feeding high risk newborns, specifically milk analysis and targeted fortification, is the next logical innovation and improvement in how we feed preterm and VLBW infants."

Empowering parents through human milk analysis

Laura Serke (RD, CSPCC, LD, IBCLC) has worked as a dietitian and lactation consultant at the University of Louisville Hospital (USA) since 2011, offering her expertise in a Level III NICU. After beginning her work in the NICU, she realized how much she needed to learn about human milk. Her interest grew when her team included her in conducting research with the Miris Human Milk Analyzer™ (Miris HMA™) and updating their human milk policies. Her facility currently uses the Miris HMA™ for research and bedside use. We interviewed Laura to hear more about her journey.

How did your interest in breastfeeding and lactation start?

When I started working in the NICU, I got to take a Certified Lactation Counselor (CLC) course. I realized how little I knew about lactation, despite my training in nutrition. After certification, I helped parents with pumping and direct breastfeeding in the NICU. I still had a lot to learn, so I checked in regularly with our IBCLC lactation consultants.

At the same time, our facility was updating our human milk handling policies. I reviewed the literature to identify best practices for milk expression, transport, storage in the refrigerator or freezer, thawing, mixing, labeling, feeding administration, and charting. There was so much to think about!

How has the situation for breastfeeding mothers changed since you started working in this field?

There has been growing awareness and knowledge about breastfeeding in recent years –from medical professionals, parent groups, social media posts, and lived experiences. There are improved pumping innovations like custom settings, battery packs, quiet motors, and flanges in different shapes and sizes.

Workplaces are starting to provide parental leave, parents are asking about pumping when they return

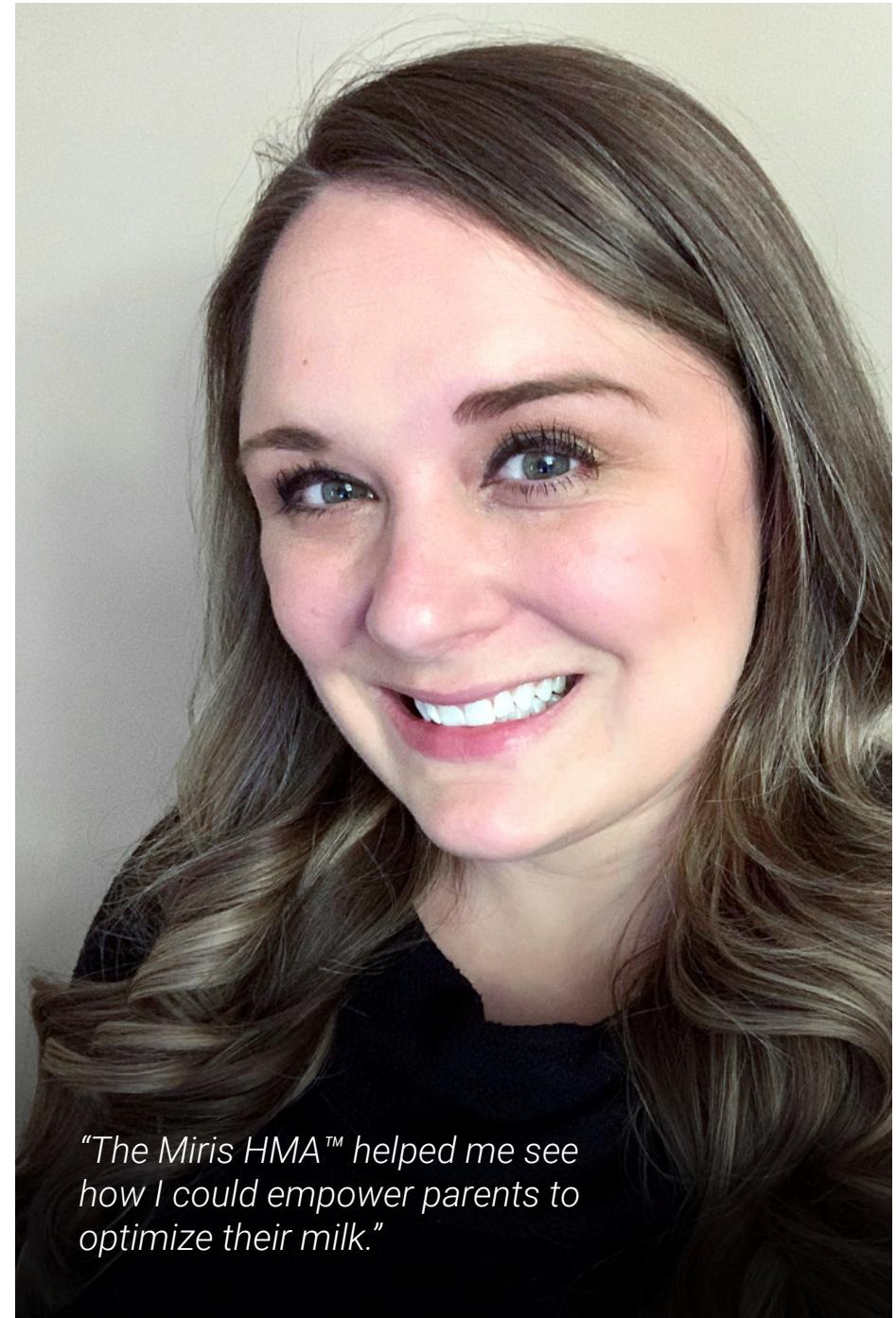
to work, and parents are more empowered to nurse in public. You can even see more breastfeeding themes appearing in movies and television shows. It's great that more people are talking about lactation! Parents with previous unfulfilling breastfeeding experiences may find healing in understanding the odds they were up against and learning about new support that is available.

Our culture is shifting to see the bigger picture of parenting. The AAP recently aligned with the WHO to expand breastfeeding recommendations until two years of age or longer. While this can feel overwhelming to parents and providers alike, it highlights the need for continued education and support.

How did you begin working with human milk analysis?

When I joined the NICU, our neonatal nutrition research team was already using the Miris HMA™ to learn more about preterm milk. Analysis days always felt so exciting, and they still do!

The first thing I learned was that early milk is the highest in protein. Seeing these results reinforced our practice of using the earliest (highest protein) milk first. To accomplish this, we use laboratory bins



"The Miris HMA™ helped me see how I could empower parents to optimize their milk."

"With this proactive, lactation-focused approach, the parent is in the driver's seat to optimize the nutritional content of their milk, and the medical team is armed with a wealth of information to make informed feeding and fortification decisions."

with dividers to organize each parent's milk. Analysis results from Miris HMA™ continue to reinforce this practice as we care for extremely preterm infants, ensuring we use the milk with the highest protein content for the longest duration of time.

Next, I learned about the energy in human milk, which appeared to be mostly unpredictable. Then we analyzed fractionated milk and I saw the striking difference between the beginning foremilk (12 kcal/oz) and the ending hindmilk (32 kcal/oz). How many parents stopped their pumping session when an undersized bottle was full? Or switching undersized bottles in the middle of pumping? Did they know how to get those last drops of hindmilk out?

The Miris HMA™ helped me see how I could empower parents to optimize their milk. If they pumped early and often, they could increase their supply of the earliest highest protein milk. If they expressed fully each time, they could increase the consistency of the energy in their milk. Achieving adequate volumes of this milk is beneficial for the NICU baby, but instilling confidence and self-efficacy in the parent is critical for the success of the long-term lactation journey.

Does your NICU use freshly pumped milk?

Our IBCLC helped me realize that freezing breast milk kills living cells, and fresh milk contains timely bioactive factors that change in response to the baby's sucking environment.

When preparing feeds, we still use the earliest frozen milk for half of the daily feeding volume. Early milk is not just higher in protein, it is also higher in

essential electrolytes, vitamins, minerals (like zinc), and bioactive factors. We don't want this stored in the freezer when the baby needs it the most!

We encourage parents to bring fresh milk daily and pump after holding their baby skin to skin. The remaining daily feeding volume comes from the most recently pumped fresh milk and any leftover fresh milk gets moved to the freezer – in the back of the parent's organized bin.

How is the Miris HMA™ used in your facility today?

Instead of a reactive "your milk has this, we are going to add this" approach, we are trying for a more proactive approach. With fresh milk, we can easily analyze milk at 7, 14, and 21 days before storing it in the freezer. This results in multiple benefits, the most important being "Targeted Lactation Support" to encourage and empower parents to optimize their milk for their baby.

First, we always have great news about the high protein content in their early milk. "Your milk is unique and important. Keep pumping!" Over time, we never say it is low in protein – because it's not! It's simply "normalizing" to mature levels that would be adequate for a term infant. Early milk has extra protein to help a baby that came early and has increased needs.

If we notice some variability in energy, we reassure the parent that it's normal and redirect our conversation to curiosity about pumping practices. With this proactive, lactation-focused approach, the parent is in the driver's seat to optimize the nutritional content

of their milk, and the medical team is armed with a wealth of information to make informed feeding and fortification decisions.

How has milk analysis impacted your fortification practices?

We base our feeding protocols on the normalized mature values in human milk. That way, all babies meet their minimum needs whether they are feeding on early or mature milk – or anything in between.

If milk has a higher protein content, we can avoid excessive fortification, which decreases the provision of the parent's own milk and increases the risk of feeding intolerance. Milk analysis allows us to pinpoint when the early frozen milk normalizes, usually around 3-4 weeks, so we can switch to all

fresh milk. It also allows us to select specific dates of milk that are higher in energy.

If an infant has poor growth, we can rule out the milk as a cause and look for other interventions. As we gain a better understanding of the macronutrients in human milk, we are finding the need to supplement micronutrients to support growth. An analysis is rarely necessary for healthy, term infants, but we occasionally use it to help with clinical decisions and to empower parents in their breastfeeding journey.

I am excited about using the Miris HMA™ to better understand human milk and, most importantly, support families to meet their lactation and health goals.

"I am excited about using the Miris HMA™ to better understand human milk and, most importantly, support families to meet their lactation and health goals."

Human Milk Banking in Poland

In 2012 Poland opened its first Milk Bank. Today there are 16 Milk Banks in the country. This development has to a large extent been possible by the efforts of the community and the creation of the "For Life" initiative. Miris Interviewed Dr Aleksandra Wesolowska, Head of Laboratory of Human Milk and Lactation Research at Regional Human Milk Bank The Holy Family Hospital in Warsaw and President of Human Milk Bank Foundation of Poland to learn more about human milk banking in Poland.

How did milk banking start in Poland and how are milk banks organized?

The first advanced human milk bank in Poland started in 2012. Today there are 16 human milk banks operating across the whole country under the support of the Human Milk Bank Foundation.

All of them are located within hospitals with high-level neonatology units (usually a level III NICU). Most of them are providing their services locally based on the agreement with other hospitals in the region. Depending on the local requirements, a regional human milk bank supplies donor milk for a few to a dozen neonatology units. The most extensive Human Milk Bank is located in the Holy Family Hospital in Warsaw and is affiliated with Warsaw Medical University. This milk bank also functions as a Laboratory of Human Milk and Lactation Research and is led by me.

Are all the milk banks in Poland analyzing their milk for macronutrient content?

Almost all the human milk banks in Poland are equipped with a Miris human milk analyzer. It is a golden standard within Poland to assess the nutritional value for each pool of donor milk.

What are the results of macronutrient analysis used for?

The results of human milk analysis are primarily used to evaluate how much energy and macronutrients that are provided by the donor milk given to the

recipient baby. The results are also a basis for making decision on fortification of human milk. It is especially important for assessing the nutritional value of milk intended for preterm infants. This diagnostic purpose can also be used for term babies with symptoms of undernutrition, but only under the recommendation of a lactation consultant.

How are the milk banks in Poland financed?

The revival of human milk banks in Poland resulted from fruitful efforts of nursing mothers holding a firm belief in the importance of breast milk. This effort is gathered around the Human Milk Bank Foundation – an organization supported by neonatal physicians. The first milk banks in Poland were founded by cities governments with the support of local partnerships.

In 2016, Poland introduced a support program for families called "For Life". This program ensures an increase in quality and availability of medical services for women with complicated pregnancies or babies who are diagnosed with severe disabilities during the prenatal period or during labor. One of the aims of the For Life program is the provision of better access to human milk for newborns and infants by creating the network of human milk banks in Poland. Between 2016 and 2019, 11 additional human milk banks were created with the support of the For Life program. This program does however not cover the running costs of milk banks.



"Almost all the human milk banks in Poland are equipped with a Miris human milk analyzer. It is a golden standard within Poland to assess the nutritional value for each pool of donor milk."

Human milk banks in Poland are part of the health care provided by hospitals to mother and babies. The National Health Fund (NHF) in Poland operates as the "single payer" in the health care system. NHF finances public health care through agreements with hospitals, which are the system's beneficiaries and health care providers.

The cost of guaranteed medical procedures is fixed by the NHF and reimbursed at the same level to every hospital, based on an annual agreement for the provision of health care services. Enteral feeding is a guaranteed service in Poland during hospital treatment and tube feeding is reimbursed.

From 2017 a new product in tube feeding was implemented: feeding with human milk (Expressed

Own Mother Milk and/or Donor Human Milk). The reimbursement point value for the product human milk amounts to 3.42 points, which equals 40 euros per day per preterm infant receiving tube feedings. Based on my best knowledge, Poland is the only European country where reimbursement for human-milk-based nutritional therapy has been implemented.

Is there an age limit or weight limit for babies eligible to receive donor human milk?

There is no age or weight limit for which babies that are eligible to receive donor milk, but as the cost spending for obtaining a portion of donor human milk is partially reimbursed only in the case of tube feeding a premature baby (born before 37 weeks of gestation), donor milk is usually offered only to

preterm babies, if the mother's milk supply is low. This causes some ethical concerns, as medical procedure availability cannot be based only on its reimbursement, and medical indications for donor human milk administration is various and health benefits are not only restricted to minimal enteral feeding or tube feeding.

Approximately what percentage of babies in the NICUs in Poland receive Donor Human Milk or Mothers Milk as compared to formula?

In 2018, the first year where the product human milk was included in reimbursement, 85 (61.6%) service providers (i.e., hospitals with NICUs) in Poland reported tube feeding with Mothers Milk and/or Donor Human Milk. In total 5,530 patients. Of these, 2,323 newborns were fed Donor Human Milk as a supplement to mother's milk, not only by tube feeding but also by bottle, when infants could not breast feed. Only 1,925 newborns received formula tube feeding (source NHF). This is to be compared to 2015 when only 500 newborns received Donor Human Milk. Comparing statistic data on 2019 and 2020 the number of Donor Milk recipients was similar – above 3300 babies per year given about 4650 liters of milk but the number of Donors were reduced from 480 to 380.

Your research has looked at factors affecting macronutrient composition in human milk. What have you found?

Indeed, in recent years we have performed several studies which aimed to identify the factors affecting macronutrient contents in human milk. The main results of our studies were as follows:

- Protein (total and true) and carbohydrate concentrations in human milk were significantly affected by the period of lactation - from the first to the sixth month of lactation, protein concentrations significantly decreased.
- There was no significant correlation between nutritional value of maternal daily food consumption (based on 3-days dietary record) and macronutrients composition of human milk, however we observed that the habitual intake of fatty fish affected omega-3 fatty acids concentrations in human milk.
- Maternal body mass index (BMI) and adiposity

were positively associated with the total protein content of human milk and what is more, pre-pregnancy BMI was positively correlated with milk energy content.

- Carbohydrate concentrations in human milk was correlate with infant sex - we reported that mothers of male infants produce milk with greater carbohydrate content than mothers of female infants (7.09 ± 0.27 g/100 ml vs 6.9 ± 0.41 g/100 ml, respectively).

Overall, our findings revealed that maternal and infant factors, especially maternal nutritional status, and infant sex, interact and affect human milk composition. These findings suggest that macronutrient and energy content in Mothers Milk may be determined in pregnancy and may have unique compositional profile for every mother–infant dyad.

“Based on my best knowledge, Poland is the only European country where reimbursement for human-milk-based nutritional therapy has been implemented.”

What is the future for milk banking in Poland? Do you see an increase in the number of milk banks and percentage of babies in the NICU receiving a human milk diet?

I am proud to have seen a constant strengthening of the human milk banks in Poland during the last decade. Based on the operation of human milk banks in Poland, adequate policies have been developed for operating procedures of these institutions. The “For Life” initiative allowed numerous hospitals to acquire funds essential to the development of new human milk banks. A sign of the increasing position for Poland in the human milk banking community is that the upcoming 6th European Milk Bank Association Conference will be held in Warsaw in October 2021.

On the other hand, we still we have a gap in donor milk legal definition and regulation to establish a system that would effectively supervise human milk banks. The Human Milk Bank Foundation makes the best efforts to ensure its employees have access to all latest developments in this narrow, and interdisciplinary field. Today in the midst of the COVID-19 pandemic it is really important to take force. The requirement for donor milk is increasing for many reasons in this pandemic, such as serious COVID-19 symptoms postpartum and loss of milk

supply as a result of postpartum depression, which is more often seen in the third wave of the pandemic that we are experiencing right now. In Poland still, unjustified mother and baby separation is taking place in health care. I hope providing pasteurized donor human milk also to term newborns, deprived of mother's milk, will become increasingly widespread in polish hospitals as a bridge until the mother's supply comes in.

“I am proud to have seen a constant strengthening of the human milk banks in Poland during the last decade. Based on the operation of human milk banks in Poland, adequate policies have been developed for operating procedures of these institutions.”



Human Milk Practices in Norway

Anne Grøvslien has been working within the area of human milk in Oslo, Norway, for nearly forty years. However, her life-long dedication to breastfeeding and human milk reaches far beyond Norway's borders as she also commits her time to educational collaborations abroad. Miris asked Anne to give us a glimpse into milk banking in Norway, her international engagements, and her hopes for human milk banking in the future.

How did your interest in breastfeeding, lactation, and milk banking start?

I have been interested in breastfeeding since I started to work as an assistant in the milk preparation room at Oslo University Hospital in the late 80s. I had my first child in 1988, and with this my interest in breastfeeding increased, and I got engaged with a mother-to-mother support group called Ammehjelpen (translation: Breastfeeding help). Then in 1995, I was involved in establishing the milk bank at Rikshospitalet in Oslo. Since then, I have continued my education within this field and today I devote my time as a breastfeeding and multicultural healthcare consultant.

How do you provide support to mothers in your care?

Most mothers in our NICU need counseling on initiating and maintaining the production of milk until the baby can breastfeed. We are a very specialized unit caring for the most fragile infants; most patients are transferred from our NICU to their local hospital when the critical phase is over. As a consequence, my role is less focused on breastfeeding support and more focused on support for the mothers while pumping. However, I love being a breastfeeding consultant and highly value the cases I see every week with latching and the early phase of breastfeeding. Nothing can compare to witnessing an infant having its first go at breastfeeding, regardless of whether they are newborn or several weeks old.

How is human milk analysis used in your facility?

We do not analyze human milk regularly; however, we use the analyzer when there is concern that an infant's growth is not as expected. It will typically be the doctor that asks us to test the milk. For example, if an infant grows more than expected and the result shows that the milk has more calories than the average, we can reduce the amount of fortification used. I find that some mothers worry their milk is not good enough, but when we run milk analysis, they see results and are assured that their milk is perfect for their infant.

How are the milk banks in Norway financed?

The first milk bank in Norway opened in 1941. The health care system in Norway is founded on the principles of universal access, it is controlled centrally by the government and tax funded. Each hospital's NICU budget funds their milk bank.

There are currently 12 milk banks in Norway surveying the country's 20 NICUs. The milk bank in my facility is the largest one, and we supply milk to five hospitals. There are no private milk banks in Norway, and there is no charge to the recipients for the milk.

What is your experience with milk donor recruitment?

Compared to many other countries Norway's breastfeeding rates are high, and we have many donors. We work systematically to increase awareness about milk banking. Our network of milk



"Nothing can compare to witnessing an infant having its first go at breastfeeding"

"With high breastfeeding rates and active support groups for breastfeeding mothers, we have seen improvements over the years"

banks collaborate and help each other if there is a need for more donors or milk in another part of the country.

The recruitment of new donors is constantly ongoing. We recruit donors through varied channels, but for us Facebook campaigns have been very successful. As there is no time for social media during working hours, this has become my hobby.

Our best ambassadors are our donors. If they have a positive experience donating their milk, they tell others about it, recruiting future donors for us. If a mother for some reason is unable to donate, we still ask if they are willing to share information and knowledge about us, and they always are!

We do have a lot of donor milk available here in Norway. At the moment we only supply for ill infants. However, with some structural changes, more resources, and the will to achieve it, I believe that in the future we will be able to provide donor milk also for healthy infants, when the mother cannot breastfeed due to illness or medication. Donor milk, not formula, should be the bridge to breastfeeding.

How is Norway working to ensure high breastfeeding rates also in the future?

Today we have substantial parental leave that is flexible for both parents, and many choose to breastfeed for a year or longer. With high breastfeeding rates and active support groups for breastfeeding mothers, we have seen improvements over the years, and we experience fewer problems than many other countries. However, there is always room for improvement, and we cannot rely only on past trends. The National Resource Center for

breastfeeding at the Norwegian Institute of Public Health actively works on a national level to increase breastfeeding knowledge and give advice to the authorities.

Can you tell us about your engagement in policy changes for Milk Banking in Europe?

I have been involved in the European Milk Banking Association (EMBA), first as a founding member and board member and then as the secretary for many years until 2022. EMBA has been an important stakeholder in the field of milk banking and has undoubtedly contributed to the expansion of milk banks and the spreading of knowledge throughout Europe and beyond.

Still, there are many differences in guidelines for milk banking around the world. I hope that there will be more research available and that in the future there will be standardized operating procedures for how to operate a milk bank. There will always be a need for local adjustments, as the financial situation and other circumstances vary significantly between countries, but I believe it will be possible to agree on a minimum standard for some of the procedures or guidelines.

What projects are you currently engaged in?

Primarily, I have been working on several projects in India through Oslo University Hospital. This is part of an ongoing collaboration between Oslo University and governmental hospitals in India to improve newborn care in India. When you get the chance to work in different environments, you really see the importance of breastfeeding counseling and donor milk. It is estimated that more than 800.000 lives could be saved each year globally just by

breastfeeding alone. These projects have changed me, and I am more eager than ever to fight for the infant's right to get the best start.

All infants should receive their mothers' own milk or donor milk as their first meal. I know this is a very bold target, but at least all preterm and sick

children should have access to donor milk if the mother cannot produce enough milk in the first days. We need to increase availability of breastfeeding counseling in many places, even in Norway. It does not cost much, but the health benefits for infants, mothers, and society are immense.

"I hope that there will be more research available and that in the future there will be standardized operating procedures for how to operate a milk bank."



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