

Freeze-Drying of Breast-Milk

A new-old way to make breast-milk available and long-lasting for at-risk premature infants.

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For premature babies, mother's milk is food and medicine.

The Product

Mother's milk, as the most important and most natural food and, sometimes, also medicine for babies born very early, is experiencing a certain renaissance in our time. Scientifically, it is becoming clearer and clearer that the composition and uniqueness of human milk CANNOT be "recreated" – even with such good intentions – from cow's milk or other animal milk. Also, sidestepping this with mare's or goat's milk does not manage to achieve the safety of human milk. Mother's milk, which is rich in antibodies, stem cells, RNA and other important components from the mother, who transmits them to her own child, manages to provide a perpetually wholesome food for the newborn at any age, along with a high caloric intake. Allergization against a variety of allergens and the development of diabetes in later life are observed significantly less frequently when the normal, healthy newborn receives mother's milk – ideally for at least 6 months. If this does not work for various reasons, substitution with a donor-mother's milk (which is then called "human milk") should be available. For babies born very early, from the 24th week of pregnancy, the mother's milk or "human milk" is frequently something like a medication, through which the greatly-feared necrotizing enterocolitis (NEC), which occurs in about 12% of these babies, can very often be prevented. For these babies, a breast-milk substitute made from cow's milk or the milk of other animals, is completely unsuitable. A milk "diet", as much as possible of human origin, dramatically lowers the incidence of NEC, reduces food intolerances and is a guarantor for significantly shorter hospital stays for the affected infants (Assad et al, 2015). Mother's milk, as the biologically classed ideal food for infants, particularly prematures, is thus, again, uncontested. The (German) National Breastfeeding Commission, which was established especially for this in 1994, also documents this impressively. >



Freeze-dried breast-milk has 12.8% of the solid parts of the previously fluid milk. The powder is simply shaken with body-temperature, sterile water.

Need and Resources

To cover the need for human milk for infants, especially premature infants, whose mothers, for various reasons (illness, medications, drugs, etc.) cannot make a sufficient amount of – or any – milk available, there were still, until 1989, in what was then West Germany, around 40 of the original ca. 60 milk banks. However, these were then closed due to the dwindling demand and the hygiene problems arising from the emergence of HIV. The former East Germany retained a portion of the ca. 25 existing milk banks and today there are 13 of them. They can, on request, cover a vanishingly small fraction of the need in other neonatology hospitals in Germany by sharing the mother's milk that is not used in their own hospitals. Meanwhile, for this reason, seven human milk banks have been opened in West Germany. Three more are being planned

After evaluating scientific statistics, we, in Germany, can assume, with some 720,000 births in the year 2015, that ca. 260,000 liters of breast-milk, which are needed to feed all at-risk newborns exclusively with breast-milk, are lacking every year. Unfortunately, making this amount available is currently not possible since the number of mothers with excess milk and their readiness to make this excess available, without the professional logistics to support it, limit the resources.

We want to do this differently in the future. We assume that, with optimal advertising and the help of midwives, it would be possible to collect up to 350,000 liters a year. This would represent the amount of milk that, with a four-to-five-month donation of 150-200 mls a day, by 2% of all mothers of newborns in one year, could produce ca. 350,000 litres, minus 40% of IgG-CMV-positive mothers whose milk is

pasteurized and processed further to (milk) fortifiers, since, without anti IgM-formation, active CM-viruses would again be set free in the milk).

Thereby, we can make this kind of freeze-dried breast-milk available to pediatric hospitals for primarily medically-indicated purposes. A company (AMMEVA GmbH), with headquarters in Potsdam, has been started. For logistical reasons, we are beginning to collect in Potsdam and Berlin, because here, a concentration of ca. 35,000 births per year makes possible the perfecting of completely new logistics in a small area. In a second step, we then want to operate Germany-wide

Unique features

Such breast-milk banks do not yet exist in Germany. By contrast to the institutional breast-milk banks of various hospitals, the participating midwives and breastfeeding counsellors will be remunerated financially. We have another plan for the donors: Up until now, mothers prepared to donate have mostly had to bring their excess milk to the breast-milk banks of the hospitals daily and procur, at their own expense, the milk pumps along with the accessories. By contrast, we want to make the various technology and equipment for pumping and storage available to the mothers and pick up the milk from the mothers' homes. The mothers will receive vouchers for diapers or other drug store products. In this way, we want to prevent mothers from donating milk for financial reasons and possibly then no longer fully breastfeeding their own babies.

As the first breast-milk bank of this kind, we will then conserve the breast milk in a freeze-dry process. The significantly higher biological quality of freeze-dried

breast-milk compared to the pasteurized milk at all the current collection points, has been scientifically proven multiple times. The quality advantages consist in the retention of the most important substances, such as the typical proteins and antibodies of human milk which, unfortunately, are, destroyed by pasteurization. There are considerably more components which make the milk valuable and irreplaceable, as already described. Up until now, the freeze-dry process was considered to be too expensive compared to pasteurization and, thereby, not economical, even though it is demonstrably better.

The freeze-dry process which has been further developed and used by us, allows a less expensive, gentle and innovative freeze-drying of breast-milk of the highest quality (the relevant evidence was furnished by authorized laboratories). Thereby, our company can, for the first time, offer long-lasting (at least a year and a half) breast-milk in soluble powder form, which can be prepared by the user with warm water (sterile, but, at least, previously boiled and then cooled to 36°C). The milk is prepared in exactly the same way as powdered infant formula.

The process of human milk donations and collection

The world-wide return to donor milk as a desirable food for both premature and full-term newborns, when sufficient mother's milk is not available, also makes regulation in Germany necessary, as reflected in the renowned, unique and expert document by Dr. Skadi Springer: "Guidelines for Establishing and Operating a Breast-Milk Bank". Published by the Leipziger Universitätsverlag (Leipzig University Press) in 1998, it has proven its worth. Dr. Springer was also appointed to the National Breastfeeding Commission. In her document, the basic hygienic ground rules, which we must observe with the establishment of our breast-milk bank, are clearly outlined and explained exactly. These regulations have, to a very great extent, been incorporated into many guidelines of other nations, such as, for example, the Swiss guidelines (Frischknecht & Waelchli, 2010) or the Italian guidelines (Arslanoglu & Moro, 2010).

The required parameters and hygiene controls there will be managed by us as follows and strengthened by applying our own additional controls.

A woman who applies to be a donor must have a home visit by one of the midwives or lactation therapists contracted by us before being taken into the donor pool.

Discussions on this have already taken place with the Federal Representative on Breastfeeding from the German Midwifery Association, Ms. Aleyd von Gartzen (Hannover), who is also a member of the National Breastfeeding Commission, and with the Chairwoman of the Lower Saxony Midwifery Association, Ms Bujny Leer. We have also spoken with the president of the Professional Association of German Lactation Consultants, IBCLC, e.V., Ms Monika Jahnke, (Laatzen) and secured their cooperation. The broad lines and the arrangements for the control tasks as well as the agreements to be signed between the midwives/lactation consultants, have been discussed with them and agreed to. First, the contracting partner must be convinced that the donor is exclusively breastfeeding her baby. Then, the data in the mother's maternity record booklet on pathogens detected and other medical information are collected and the donor is informed about the donation process and has the hygienic measures that must be followed explained. Should blood tests be necessary in addition, they will be carried out by our contract partners at our cost. A clear distinction is made between CMV-positive and CMV-negative donors. The donor will be assigned a bar code from which both she and her milk can be identified. The donor will freeze her milk at home, in her own freezer, at -18°C to -20°C - in containers developed specifically for this purpose and which we supply. The containers are so constructed that, after filling them with breast-milk and sealing the shell, they do not have to be opened during transport and the freeze-drying itself, which means a near-total avoidance of contamination during this procedural step. The frozen milk will be picked up at the donor's home address by the company's own transport and, with appropriate deep cooling, brought for processing. It will be ensured that it is verifiable whether the cold-chain has been interrupted. Supplying the milk pumps will initially be taken over by ARDO.

Ethics of the Company and of the Process

It is fully clear to this company, which has now been set up, that there are some key features of the process, which must be subject to ethical review. Among them is the supervision of the donors in light of the fact that they must be fully breastfeeding their own babies when they donate. Further aspects are the target groups, which will consist mostly of the pre- >



When Breastfeeding Alone is Not Sufficient

Author: Andrea Hemmelmayr

The vast majority of mothers can and should breastfeed, just as the vast majority of babies can and should be breastfed.

For the few situations, in which direct breastfeeding is not possible, the Global Strategy for Infant and Young Child Feeding (WHO, 2003) provides clear guidelines. When the baby cannot or should not feed at the breast, mother's milk (the expressed milk of his own mother) should be fed – ideally in a breastfeeding-friendly way (i.e. cup feeding). If there is no mother's milk available, the next choice should be human milk: either from a healthy wet-nurse or from a human milk bank. Only when there is no human milk available, should infant formula be fed..

Global Strategy for Infant and Young Child Feeding, WHO /UNICEF, 2003

1st Choice	Breastfeeding directly on the mother's breast
2nd Choice	Expressed mother's milk (milk of the baby's own mother)
3rd Choice	Human milk (milk of a healthy donor or a wet-nurse)
4th Choice	Infant formula

mature infants, who are undersupplied with mother's milk. Along with this, are the production process and the price of the finished product, neither of which must lead to an ethical lapse, just because it is on the market. Here, cooperation with the midwives and lactation consultants will also be put to the test.

For this reason, the company is establishing an ethics board which, in the current planning, will consist of a member of the Board of Directors, a representative of the midwives and a representative of the lactation consultants, a donor and a representative of the neonatologists who use this product in our hospital.

On the process of freeze-drying

At the latest, since the fundamental document of C.A. Sager (1958), who wanted to set up breast-milk freeze-drying at the University Hospital in Kiel, it has been clear that freeze-drying represents the absolutely most suitable process for the preparation and storage of donor breast-milk. Due to very unfortunate circumstances, which negatively affected some people, this could not be realized. It has been repeatedly shown – in a great many scientific publications in the past, in the previously cited guidelines of Dr. Springer (1998) and in the Swiss guidelines from 2010 up to Lanzano et al., (2014) – that, while the standard process for sterilization and hygienic preparation is pasteurization, lyophilization is considerably better. However, this process has been considered to be too complex and expensive to implement on a large industrial scale.

Pasteurization has the rather substantial disadvantage of destroying the protein. The comprehensive document, "Breast-feeding and Breast-Milk Feeding, (Springer S.), issued by the (German) National Breastfeeding Commission, under the leadership of Prof. Dr. Psychyrembel, Cologne 2001) and published by the German Federal Office for Health Education, comments on pasteurization: "The heat treatment, in particular, has negative effects on the immunological and anti-infective components of the mother's milk as well as on enzymes, vitamins and, in particular, folic acid (Donnelly-Vanderloo et al, 1994). Pasteurization does, indeed, guarantee the inactivation of bacteria, fungi and most viruses (Orloff et al., 1993), but it also destroys lipase (Wardell et al., 1984)" (a. a. Ort S. 168) and "the smaller and less mature the baby is, the more important it is to retain the biological value of the mother's

milk. Particularly with patients at high risk for necrotizing enterocolitis, giving fresh, non-pasteurized mother's milk is desirable" (Henker, 1987; Henker and Futschik 1993; Radke 1992, Springer 1995) (a. a. Ort S. 169). This damage through heat exposure does not occur with freeze-drying of breast-milk. Most of the valuable components are retained and, after dissolving the powder in body-temperature water, are available again. The storage and transport of milk powder are also considerably less complicated and are possible for a longer period of time than is the case with pasteurized milk, which must be stored frozen.

Why, despite the clear facts, no one, until now, has taken up this process commercially, remains speculative. The fact is, the decisive impulse-giver, Dr. Prof. Dr. C.A. Sager lost the opportunity, through unfortunate circumstances, to use the technologically more developed freeze-drying process.

The end product achieved by freeze-drying, a breast-milk powder, is not only easy to reconstitute with body-temperature water, it also reduces the pathogens, thanks to the processing technique (Sager 1958, Krieg H. 1966) and, with storage at under 20°C, very likely retains its bactericidal property (Honour & Dolby, 1979 and Carbonare et al., 1996). At least, the pathogen count is reduced significantly with dry storage after the freeze-dry process, which is certainly due to the low chance of survival of bacteria, which have already been attacked by the slow freezing in the freezer at (the mother's) homes and are damaged again by the withdrawal of the water during the freeze-dry process, so that the survival time is considerably reduced. Friedberg and Steinheuer (1958) even proved that the powder resulting from the freeze-drying can be heated to 100°C over a period of 4 hours, without the proteins suffering any great damage – because – yes – the water is withdrawn through the freeze-drying process. Salcedo et al. (2015) describe the successful reduction of germs in breast-milk powder after freeze-drying and storage at –80°C.?

Thereby, there are many processes available for germ-reduction (incl. viral loads), which we have not yet reviewed for their practical use with breast-milk after freeze-drying in a commercial process. However, even the simple freeze-drying that we have occasionally carried out on pooled breastmilk for research purposes -without other germ-killing measures - has led to a reduction in the germ count in the

powder or in the reconstituted milk, which remains considerably below the maximum load stipulated in the literature (Springer, 1998). Of course, the batches from donors will also be examined bacteriologically, virologically and toxicologically before the end product ("breast-milk powder") comes on the market

With respect to the end product, today's knowledge about the structure and the contents of breast-milk indicates that, with the method of freeze-drying, we could not only cover the total need for premature infants, but even, by extracting and freeze-drying the individual components (fat, sugar, protein), the current still-common enrichment of mother's milk for her own baby with a bovine "fortifier product" could be made superfluous and, thereby, a very great allergization potential of such feeding would be eliminated (Fusch & Samiee-Zafarghandy, 2014).



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