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A Case Study of Human Milk Banking with Focus on the Role of IoT Sensor Technology

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Abstract: Human milk is the biological norm for newborn nutrition, with breast milk from the mother being recognized as the best source of nutrition for infant health. When the mother's milk is unavailable, donor human milk is the best alternative for infants with low birthweights. Growing recognition of the benefits of donor human milk has led to increasing global interest in monitoring and controlling human milk's quality to fulfil the need for donor human milk. In response to this need, the REAMIT project proposed to adapt and apply existing innovative technology to continuously monitor and record human milk quality and signal potential milk quality issues. IoT sensors and big data technology have been used to monitor conditions that may increase spoilage (such as temperature and humidity) in the transportation stage. The sensors were installed in the insulated bags used to transport the milk from the donor's home or hospital to the human milk bank and vice versa. The temperature and humidity were collected every 30 min, whilst the GPS locator sent data every 2 min. The data are collected in the cloud using GPRS/CAT-M1 technology. An algorithm was designed to send alerts when the milk temperature is above the prespecified threshold specified by the organisation, i.e., above −20 °C. The experience showed evidence that IoT sensors can efficiently be used to monitor and maintain quality in supply chains of high-quality human milk. This rare product needs a high level of quality control, which is possible with the support of smart technologies. The IoT technology used can help the human milk supply chain in five different aspects, namely by reducing waste, assuring quality, improving availability, reducing cost and improving sustainability. This system could be extended to various supply chains of rare and precious commodities, including further medical supplies such as human blood and organs, to completely avoid waste and ensure total quality in supply chains.

Keywords: human milk bank; IoT technologies; temperature monitoring; waste reduction

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1. Introduction

Human milk is the optimal source of nutrition for infants, providing thousands of compounds essential for development and nutrition including proteins, lipids and oligosaccharides, as well as immunological protection [1,2]. However, for various reasons, there are numerous circumstances in which mothers are unable to lactate or provide sufficient breast milk, particularly in the first days postnatally. In these situations, especially regarding vulnerable preterm and sick infants, donor human milk (DHM) from a human milk bank is considered the first-line source of nutrition where there is a shortfall of maternal milk [1]. Preterm infants fed with DHM have a lower risk of developing necrotizing enterocolitis (NEC) and late onset sepsis as compared to those fed with formula [1,3]. The

American Academy of Paediatrics and the World Health Organization (WHO) [4] both establish DHM as the most suitable replacement for neonates when the mother's own milk is unavailable [3,5,6], but as a cost-saving intervention operating at scale, milk banking would be a highly cost-effective public health intervention [7].

Human milk banks (HMBs) play a vital role by recruiting donors and processing, storing and supplying DHM to neonatal intensive care units (NICUs) and similar settings in a safe and controlled manner [8]. According to recommendations from the European Milk Bank Association (EMBA), donor screening should include an oral interview and a written health questionnaire followed by serological testing [3]. As for handling and storage, selected donors are advised to collect expressed milk for donation in a suitable container and requested to freeze it as soon as possible within 24 h. Once donated milk is received by the HMBs, it is stored in a freezer at −20 °C until thawed and pasteurised [9]. Microbiological testing is performed before and after pasteurisation (commonly 62.5 °C for 30 min), and milk is passed according to nationally agreed guidelines [3,10]. HMBs then distribute DHM to the required medical settings or families in the community facing breastfeeding challenges. Donor milk remains a costly option, the accessibility of which is sometimes limited [6,10]. For these reasons, donor human milk is considered a valuable and limited resource. In the scope of the present study, minimising DHM loss and waste could translate to enhanced quality and less milk wastage, increasing capacity of HMBs.

The Human Milk Foundation (HMF) is a non-profit charitable organisation working to create equity of access to assured supplies of DHM. The organisation works in several ways to secure human milk in order to protect vulnerable young lives, providing screened donor milk to sick, premature babies in NICUs and to mothers suffering from cancer and other conditions. As part of the HMF, the Hearts Milk Bank (HMB) was founded to provide equitable and safe access to donor milk in the UK, as well as supporting and facilitating research. It has served over 400 families and 10,000 babies with donor milk since its creation, and it has supported 53 hospitals and assisted with the delivery of 3943 litres of donor milk in the year 2021 [11]. This has created a huge social impact in saving lives of babies at risk. The lives of several thousand babies are being saved through the HMF's initiative of transporting human milk within the UK in a safe way to ensure quality.

Although continuous and deliberate efforts are already in place to ensure the safety of donor milk, the HMF have identified room for improvement during the transportation of donor milk to their final destinations within the UK. In collaboration with REAMIT, a transnational European territorial cooperation project co-funded by the Interreg North-West Europe (NWE) Programme aiming to reduce food waste (www.reamit.eu) (accessed on 1 December 2022), HMF uses Internet of Things (IoT) sensor technology to monitor the quality of DHM during transportation. Digital tools (e.g., sensors, big data and Internet of Things) have become a viable solution for food loss and waste recovery in recent years [12]. In this regard, such tools can also be implemented for continuously monitoring DHM quality parameters (e.g., temperature), allowing corrective action in a timely manner to mitigate loss.

As part of the HMF, the Hearts Milk Bank provides screened DHM to NHS hospitals and families facing feeding challenges, including delayed lactogenesis, breast development pathology, maternal cancer treatment and other conditions. Since 2017, Hearts has supported over 500 families and thousands of infants in over 50 NICUs with over 11,000 L DHM [13]. Logistics from the donor (collection point) to the newborn babies (delivery point) involve several stages including storage, pasteurisation and correct measurement. All these operations present challenges to maintain safety and quality, presenting the need for close monitoring during transportation. Hearts was also founded to support and facilitate milk bank research. As part of continuous service improvement, the HMF wished to amend the lack of research into DHM transportation. While there is only one recent article that address monitoring of DHM [14], a review of the literature has yielded no other previous study in this context of IoT use in DHM, especially during transportation of DHM. Therefore, the objective of the present case study is to assess the implementation of digital tools, namely Internet of Things (IoT) sensors and big data technologies, for DHM loss and waste reduction during transportation, as well as to evaluate the resulting economic and social impact. This is a significant research gap because there have been no research studies to date on how IoT technologies can support DHM loss during transportation.

The aim of this case study is to identify how technology can minimise the risk of DHM wastage during transportation and support HMBs by monitoring conditions that may increase the risk of spoilage, such as temperature and humidity, whilst optimising quality control. The REAMIT project team worked to improve logistics and produce world-first data on DHM transportation. The pilot test's aims were to develop systems to monitor temperature within insulated human milk transport bags, maintain transportation temperatures and reduce the cost of transportation by optimising logistical operations whilst achieving the capacity to support 500 DHM journeys per month. To achieve our research objectives, we have conducted a detailed search of the literature for the challenges involved in avoiding DHM wastage and related policies (Section 2). We describe various processes involved in the collection and delivery of DHM (Section 3), and then describe the specific service of the case company, the HMF (Section 4). Section 5 provides solutions to quality issues from the case study observation, and Section 6 concludes the article with suggestions, limitations and future research.

2. Background Study

2.1. Challenges of Producing and Maintaining Optimal Quality of Human Milk

In 2008, the WHO promoted the safe use of human milk from HMBs [15]. Human milk banks collect and store DHM that is later consumed by vulnerable neonates [10]. However, scaling up this lifesaving intervention has been challenging [16]. DHM therefore remains a relatively expensive nutritional alternative as a result of costs associated with donor screening, milk collection and handling, transportation, pasteurisation, measurement and storage processes to create a safe product [10]. The cost of 1 L of donor human milk in the UK has been estimated at 140 to 170 €, which exceeds the price of preterm formula ten times [10]. As human milk is an expensive and limited commodity, the policies and procedures related to its transportation, processing and storage should be optimised so that this resource is not wasted.

A Health Technology Assessment (HTA) report entitled 'Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis' was published in 2009 [17]. This report used systematic review methodology and health economic modelling to assess which interventions, including the availability of DHM, effectively promote the initiation and duration of breastfeeding in neonatal, special and intensive care settings. The authors noted that in the UK, DHM is neither widely nor readily available in the majority of units; this was reflected through modelling the use of DHM by availability, not need. They concluded that if mechanisms by which DHM is provided were improved, donor milk would become cost-effective compared with infant formula. This conclusion was based on a significant improvement in the operation of milk-banking HMBs, and suggested models included establishing a national donor milk HMB banking system similar to that for blood [18].

In order to meet the growing demand for DHM, there is a need to increase donations, which requires recruiting new volunteers and monitoring each phase of processing to avoid waste [19]. A study with 30 women performed by Muller et al. [20] identified the knowledge and practice of lactating mothers regarding human milk donation. The study examined the attitudes and motivations of 27 postpartum women; "excess milk" was the main reason for nine mothers to donate. Among those who did not donate, the reasons given were: "I did not seek to donate; little milk; difficulty milking". Muller et al. [20] interviewed 36 donors registered at a human milk bank in Brazil and showed that the reasons for human milk donation cited were the overproduction of milk and altruism. Mothers of older children expressed frustration that they did not know they could have donated after previous births, primarily as a result of a lack of information, lack of institutional support or misinformation from healthcare professionals [19].

With the increasing use of DHM, maintaining its quality, preserving the nutritional and immunologic constituents of the milk and ensuring optimal infection control are important challenges. HMBs receive and process milk from donors of different ages, economic, social, cultural and nutritional conditions [21] with carefully designed standards that minimise risk to the recipient infants while ensuring that women have the opportunity to become donors. These standards also apply to the collection, transportation and storage of the milk, as well as processing (pasteurisation) and analysing to select the appropriate milk that may include consideration of the colour, off-flavour, physicochemical and microbiological composition [19]. Thus, optimizing the quality control services of HMBs is crucial.

2.2. Policies and Operation of Human Milk Bank Services

In the UK, HMBs follow guidance issued by various bodies, including the National Institute for Health and Clinical Excellence (NICE). The NICE clinical guideline #93 for the operation of human milk banks aim to minimise the risk to recipients of DHM. Maximising safety comes at a cost, and recommendations were made to observe the best possible safety standards without exceeding opportunity costs acceptable to society. According to the NICE, "the implementation of the guidelines is the responsibility of local commissioners and/or providers, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity".

3. Processes Involved in Human Milk Handling

Logistics from the donor (collection point) to the newborn babies (delivery point) involve several stages (Figure 1), including storage, pasteurisation and correct measurement. All of these operations are prone to the risk of quality. To ensure the quality of the milk in each stage, it is vital to have close monitoring of the logistics of the human milk journeys. Further explanation of each stage is given in the following sections.

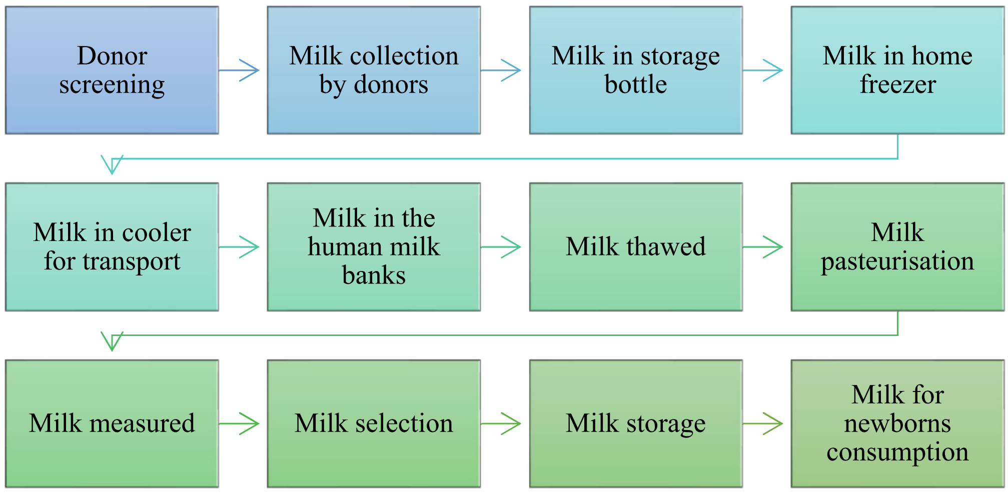


Figure 1. The human milk journeys. Adapted from Kim et al. [22].

3.1. Screening and Selecting Donors

In general, most human milk-banking countries commit to screening milk donors for the same blood-borne viruses as required by blood banks [23]. These tests meet international recommendations for human milk banking [24] and require tests of HIV, human T cell lymphotrophic virus (HTLV), hepatitis C, hepatitis B surface antigen, hepatitis B core antibody and syphilis antibody. Rationalization in some centres has led to dropping of screening for HTLV because this virus is destroyed by pasteurisation and freezing, and false positives are associated with influenza vaccination [23]. In Australia, women who have lived in the UK for 6 months or more between 1980 and 1996 are excluded as human milk donors because of the risk of transmission of variant Creutzfeld-Jakob Disease (vCJD) [23].

Donors who continue to donate for more than 3 months from the date of the initial blood test are required to repeat the blood test [25]. Milk collected during this period is stored until the results are known. Other reasons for excluding donors include an assessment of any medications or pharmacologically active products a donor may be taking that could be transferred to her breastmilk [23]. Questions relating to the use of prescription medication, smoking and alcohol consumption, etc., must be answered by the donors [24,25]. Much is known about the transference of medications to breastmilk, and exclusion of donors based on maternal drugs is rarely necessary but proceeds on a case-by-case basis [23,25,26].

According to the NICE [18], the stepped screening process detailed below should be followed when recruiting donors, and the potential donor should be advised that she is not eligible to donate milk if she:

- has previously tested positive for HIV 1 or 2, hepatitis B or C, HTLV type I or II or syphilis;
- is at an increased risk of vCJD;
- is using, or has recently used, recreational drugs;
- currently smokes or uses nicotine replacement therapy (NRT);
- regularly exceeds recommended alcohol levels for breastfeeding mothers (1 to 2 units, once or twice a week);
- exceeds more than three caffeinated drinks (150–200 ml) daily.

3.2. Milk Collection and Handling

Safe collection and handling practices are key to preventing bacterial contamination of human milk and avoid waste [27]. The Academy of Breastfeeding Medicine (ABM) created a protocol for collecting and handling human milk to minimize contamination or milk spoilage [28]. The guidelines advised women to wash their hands before expression with soap and water, or a waterless hand cleanser if their hands do not appear dirty. Unclean hands may transmit viruses and bacteria, some of which can cause illness [28]. In addition, some studies show that human milk containing fewer bacteria at the time of expression develops less bacterial growth during storage and has higher protein levels compared to milk that has an abundance of bacteria [29–31].

Milk expression can be achieved by hand or with a pump, and as long as the hand cleansing and cleaning of pump parts as per the pump manufacturer's instructions are appropriate, milk contamination with pumping versus hand expression does not present differences [28]. However, one study found that milk expressed at home [32] appears to have more bacterial contamination than milk expressed at the hospital; this is possibly related to equipment at home or transport, not to personal hygiene [33]. Several studies have been done to evaluate a range of available storage containers [22,34–37], and there is a mix of recommendations about containers to collect and store expressed milk [32]. According to Kim et al. [22], human milk collection containers should be sterile and standardized to minimize contamination risks, safeguard nutrient content and minimise maternal workload. DHM is stored in a variety of different bottle sizes typically ranging between 30- and 100-mL containers [10], depending on local HMB capability. Aronyk et al. [10] observed substantially less DHM is discarded when 50 mL bottles were used compared to 100 mL bottles in neonatal units.

Reyes-Foster et al. [27] studied the milk-handling practices of expressed human milk by donors. According to the authors, 78.9% of milk donors reported sanitizing pumping equipment and 82.3% washed their hands before handling expressed milk; 10% of milk donors reported participating in unsafe practices. Paredes et al. [19] observed a high human milk loss due to inadequate donor practices. The authors concluded that these were mainly as a result of total or partial non-compliance with the guidelines for biosecurity of human milk expression. It is noteworthy that the donors received sterile glass vials and hygiene training according to the national standards. However, this behaviour was persistent even with the prior and continued reception of guidelines. In the donors' homes, inadequate monitoring of freezer temperatures can cause microbiological multiplication and consequently increased contamination. In addition, home practice tends to differ from safety standards and most of the problems involving the quality of the human milk resulted from domestic collection and handling, with frequent contamination by elements of this environment [19].

Knowledge of appropriate human milk collection and handling is essential for breastfeeding success in these situations. According to many studies, human milk is generally kept in a frozen state at −20 °C, but it can be refrigerated (+4 °C) for at least 96 h for use at home [9,19,22,24,27,28], although NICE guidance is for all expressed milk to be frozen within 24 h of expression.

3.3. Transportation, Handling and Tracking

Transporting human milk from home to the milk bank or hospital should be standardised by maintaining cooled or frozen milk in an insulated container packed with ice or freezer gel packs [38]. The insulated container must be disinfected between each use, and the breastfeeding protocol also recommends avoiding using regular ice because it is warmer than frozen milk and will cause the milk to thaw [39].

The length of time that the milk stays frozen or chilled can vary according to the outside temperature and if donors follow the milk bank's instructions [39], but commonly, human milk can be stored safely while being transported in a cooler for up to 24 h with frozen gel packs. Additional frozen gel packs may be needed if containers are only partly filled because bottles filled partially with frozen milk will stay frozen longer than completely filled containers [39]. The opening of cooler bags should be limited because allowing milk to warm during transport will increase the risk of bacterial growth.

According to the NICE guideline, before pasteurisation, a sample from each batch of pooled DHM should be tested for microbial contamination, and if samples exceed a count of 10^5 cfu/mL for total viable microorganisms, 10^4 cfu/mL for Enterobacteriaceae or 10^4 cfu/mL for Staphylococcus aureus, then the milk should be discarded. DHM containers should be labelled clearly for identification. DHM should be supplied to hospitals or neonatal units that agree to comply with the tracking procedures for milk outlined by the milk bank.

3.4. Pasteurisation

Most human milk banks do not practice prepasteurisation testing because rigorous bacterial screening can result in approximately 30% of the milk being discarded [16]. This bacterial screening regime has shown that the bacterial content of donated milk varies greatly between donors and even between individual donations by the same donor. Discarding the milk prior to pasteurisation will outweigh the benefit of this screening test and can potentially increase the expenditure for human milk banks; for this reason, pasteurisation is commonly done prior to testing. International best practice requires that human milk be pasteurised (heated to 62.5 °C for 30 min) prior to being fed to newborns [24]. The efficacy of any pasteuriser is dependent on both the pasteurising temperature and hold time and the time taken to heat and subsequently cool the milk, which can vary between pasteurisers [24].

In most countries, human milk banks do not routinely pasteurise human milk. The risks of feeding contaminated human milk to very preterm newborns are unknown, as are the risks of feeding sterile, pasteurised human milk or formula on the development of the preterm immune system. A study compared raw and pasteurised human milk with substitute formulas and demonstrated that pasteurisation reduced the protective effects of human milk in about 14.3% for infections, but newborns fed with pasteurised human milk had lower infection rates (33.3%) than those fed with formula [40].

Alternative technologies that are currently being tested to prevent microorganism bioactivity while ensuring safety of donor milk include high-temperature short-time (HTST) treatment, high pressure processing (HPP), ultraviolet (UV) irradiation and ultrasonic processing [41]. Studies using ultrasonic processing of bovine milk and fruit juice suggested that this method may be potentially useful for pasteurisation and homogenisation of human milk because it can effectively eliminate various food-borne pathogens, including *L. monocytogenes*, *Salmonella spp*, *E. coli*, *S. aureus* and *B. subtilis* [42,43]. A real-time polymerase chain reaction method for the specific and rapid detection and quantification of bacteria and pathogens in human milk is also currently being developed. This will allow milk that is heavily contaminated or contains pathogens to be identified and discarded prior to pasteurisation [23].

Alternative approaches are used internationally to increase efficiency and reduce cost while maintaining acceptable safety. According to Simmer [23], in some countries, DHM is distributed raw or pasteurised to very preterm and term newborns based on the level of contamination and risk to the patient. For example, in Germany, either raw or pasteurised human milk with a number of bacteria < 10^3 cfu/mL is used for feeding newborns weighing less than 1500 g, whereas milk containing 10^4–10^5 cfu/mL is analysed for pathogens and pasteurised for feeding older babies [23], which appears to be a pragmatic approach to minimise the waste of donations. Most hospital policies stipulate that human milk containers can only be used to feed a single newborn and cannot be shared [10]. Although not acceptable in some jurisdictions, the implementation of policies which allow traced sharing of human milk bottles between a limited number of newborns may also mitigate the wastage of this resource [10].

3.5. Bacteriological Testing of Milk (Selection and Classification)

Human milk is not consistently bacteriologically examined after pasteurisation in all human milk banks, whilst bacterial count limits for rejecting milk vary between the banks according to the guidelines for each country [23]. These limits are required as pasteurisation may not be effective if milk is heavily contaminated [44]. In addition, although pasteurisation eliminates most organisms, the toxins produced by some bacteria may not necessarily be destroyed by heat [44]. Therefore, any bacterial growth is identified by standard microbiological techniques, and colony growth is also quantified [25].

Simmer [23] observed a human milk bank in Australia that had processed over 1400 batches of DHM since its establishment in 2006. According to the author, only 36 batches showed bacterial growth postpasteurisation. This growth usually comprised low colony counts of coagulase negative *staphylococcus*, but very occasionally high growth of *Bacillus cereus*, a known foodborne pathogen. Only five of the 36 batches showed bacteria growth greater than 10^5 cfu/mL. Although current evidence would suggest a low likelihood of bacteria that had been present in DHM prior to pasteurisation causing a clinical issue for a recipient of DHM, the extreme vulnerability of the recipients precludes their use, and these batches are discarded.

Paredes et al. [19] identified the causes of wastage in an HMB in Brazil during the selection and classification phases. Data of 383 donors were analysed, with a volume of 711.8 L human milk. According to the authors, the volume of human milk wasted due to dornic acidity tests, non-conforming off-flavour and the presence of dirt was equal to 64.3 L (9%). The dornic acidity method has been used to evaluate bacterial growth. Human milk has the sorption capacity of volatile substances, and the term off-flavour designates an unsuitable milk characteristic for consumption. The microbiological quality control (total coliform survey) after pasteurisation was responsible for a total of 31.6 L (4.4%) of human milk wasted.

Therefore, through continued actions, health education can reduce process losses and establish safe and reliable habits for the preservation and processing of DHM. Bacterial screening is a major area for further research to ensure the validity of HMB processes and efficiencies.

3.6. Storage of Milk in HMBs

Although guidelines for safe usage vary between networks, the milk in UK milk banks must generally be stored at −20 °C. If frozen, the milk can only be thawed once, and the remaining excess must be stored at 4 °C and used within 24 h [10].

Most recommendations for the optimal duration of milk storage have focused on bacterial colony counts as measurements of milk contamination. The lack of significant increases in bacterial colony counts is important and is indicative of an active host defence system in the milk [45]. Although the changes in bacterial counts are reassuring to the integrity of milk, it is important to know the major changes in macronutrients and immune factors, such as sIgA, lactoferrin, total fat and total protein, to further support the safety of refrigerator storage for 24 h.

Refrigerators for human milk storage must be able to maintain temperatures at 4 °C, and freezers must allow for temperatures at or below −20 °C for long-term storage [9]. Adequate space to store human milk while allowing for appropriate airflow is also important to ensure proper temperatures. A reliable method of temperature monitoring prevents loss and promotes safety [9]. Use of automated systems that alarm when temperatures exceed desired ranges may be beneficial. In addition, the location of refrigeration units in areas with limited access may help prevent tampering and waste, but is balanced by the need for temperatures to be monitored daily.

4. Methodology

In this research article, a case study approach was used to understand the role of technology in maintaining the quality of human milk. As part of the REAMIT project, the focus was on maintaining the quality of human milk when the milk is being transported by volunteers from homes to the milk bank. Accordingly, detailed descriptions of the technology demonstration of IoT sensors within the case organisation and records of the use of IoT sensors in the case of DHM storage and delivery are provided. Observation of the HMF's operations and trials are recorded for further analysis.

4.1. Background

The Human Milk Foundation (HMF) is a UK charity launched in 2018 to support human milk research and education and to develop nationally equitable human milk-banking services. The HMF provides DHM to hospital neonatal units for infants in neonatal care through the Hearts Milk Bank, which was initially established as a social enterprise community interest company to facilitate speed of establishment, and then merged into the HMF in 2019. Hearts Milk Bank also provides DHM and specialist lactation support to families where mothers are facing breastfeeding challenges or are unable to provide any of their own milk, and these services are free to families.

The annual capacity of the Hearts Milk Bank is 5,000 L, with donations transported via volunteer 'blood bikers' who deliver blood donations to UK hospitals outside of normal hours. This volunteer system is almost unique to the UK and Ireland. Although DHM is regulated as a food in the UK, transportation of DHM is outside the framework for the transportation of food. Some aspects of food regulation are very difficult to apply to human milk, particularly labelling. This is mostly due to every container of DHM having a different nutritional content. Therefore, this makes it impossible for the HMF to properly label each milk container with nutritional information, as required by food standards in the UK. More information about the HMF can be found in [13].

HMB models vary globally from a single human milk bank that may serve an entire country to smaller regional HMBs, or those that serve a single hospital. In the UK, HMBs are often situated within hospitals, funded by the hospital or local healthcare trust they are operating in. Hospitals reimburse HMBs for costs related to donor screening and DHM processing. It is important that the HMF ensure human milk donations are being used optimally; however, inevitably there is some milk wastage if donations fail the stringent microbiology tests before and after pasteurization. As well as the costs to the charity and reduced volume of anticipated available DHM, the negative impacts to donors for the lost time, effort and emotional investment are also important.

4.2. Hearts Milk Bank (HMB)

When donated milk arrives at Hearts Milk Bank (HMB), it is checked visually to ensure it is still frozen before being stored within the milk bank at −20 °C prior to screening and processing (microbiological assays, pasteurisation etc.). Once packed, the product is stored again at −20 °C until it is needed by a recipient and transported by volunteer courier to a hospital neonatal care unit or to a recipient's home.

4.3. Operational Conditions

Mothers are able to donate their milk to the HMF if they are breastfeeding, either from home or from a hospital, and have surplus milk. As with blood banking or tissue banking, donors all undergo prior health and serology screening. There are also strict guidelines for the storage and transportation of human milk that both the HMF and recipient hospitals must ensure are followed.

The HMF operates across England, Wales, Northern Ireland and Ireland, with donation and recipient locations ranging from a couple of miles to several hundred miles per journey. Therefore, transportation times can be up to 24 h long, so stable and robust transportation temperature is needed.

Figure 2 illustrates the DHM transportation pathway. DHM is collected either in the hospital or at home with the help of volunteers and transported to HMB using motorcycles or an electric car. Transportation is done in dedicated storage boxes with appropriate cool packs. After visual check, the milk is stored for processing and a sample is sent to the lab for screening. If the sample passes screening, it is packed and stored in HMB, ready for re-distribution to either hospitals or the homes of recipients.

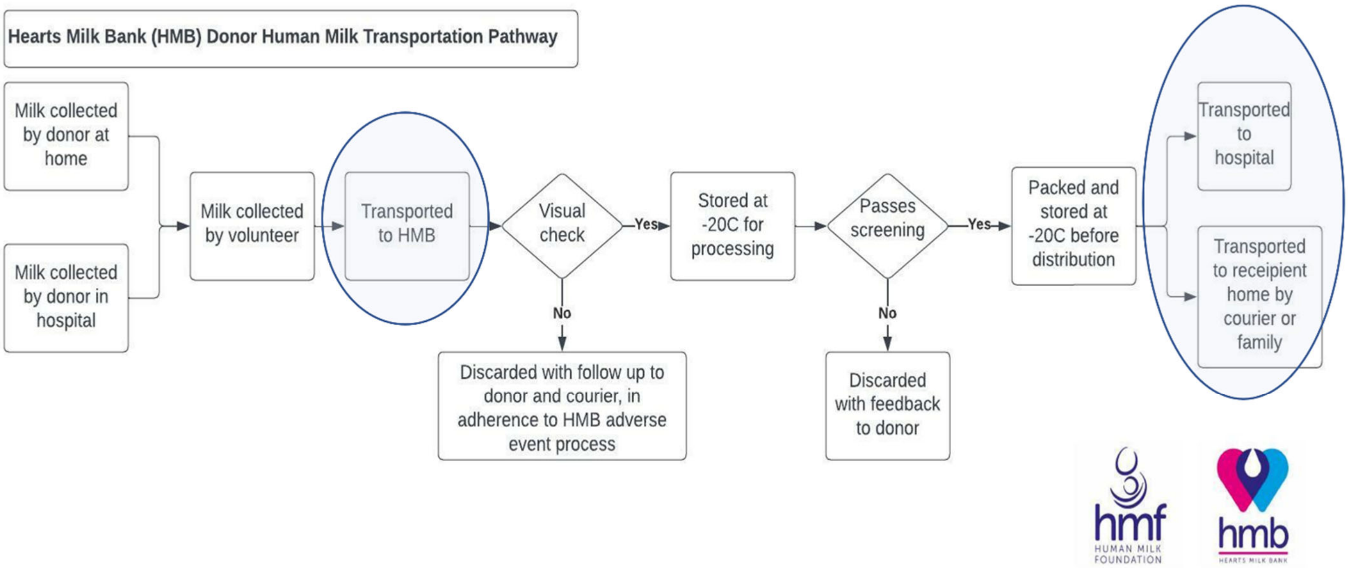


Figure 2. Hearts Milk Bank Donor Human Milk Transportation Pathway. The shaded areas in Figure 2 show when the milk is on transportation, which is the focus of the use of IoT sensors for monitoring temperature.

DHM is transported in frozen form within insulated containers as shown in Figure 2. Cool packs are used to maintain a temperature of −15 °C within the container, and there is no additional cooling operator. Several litres of DHM are transported at a time within the insulated containers on a motorcycle, with specialised insulated transport boxes able to transport up to 20 litres at a time.

At the HMF, the milk is heat-treated at 62.5 °C for 30 min and stored until tests confirm it is safe for consumption. Whilst the milk is being stored, the temperature is monitored either by the donor or by the hospital. In the milk bank, all freezers are monitored with temperature sensors that are linked with alarms that can send notifications to computers and emergency phone systems.

4.4. Problems

DHM needs to be transported safely to maintain its optimal quality; therefore, a key priority for the HMF is monitoring the temperature of the milk during transportation time. Prior to collaboration with the REAMIT project, the HMF was unable to accurately monitor the temperature during transportation. However, the charity also wanted to ensure that the milk remained in optimal conditions throughout the whole period from when milk is made available from the donor until the milk has been delivered to its recipient. Due to being unable to monitor the temperature and environmental conditions, the HMF was unsure if the milk was maintained at its optimal temperature during the transportation time. This is important as temperature and humidity are main factors of DHM wastage. The HMF discharge rate is equal to 7–8%; however, a weekly discard rate of up to 25% is not unusual in HMBs during the warmer summer months. The impact of heat waves and unstable climate may exacerbate difficulties in the transportation of DHM.

High temperatures and fluctuating levels of humidity during transportation impact quality of the human milk. However, the main factor underlying DHM wastage is microbiological contamination at the point of expression. As well as supporting donor education and providing sterile containers, HMB also uses other safeguards to minimise the risk of microbiological failure. Containers of donated milk are only opened within an ultra-microfilter Class 2 Biosafety Cabinet, and ultraviolet light is used in the biosafety cabinet to disinfect tools and containers used during processing. Equipment is then sterilised using an industrial dishwasher (Miele, Germany), which heats equipment to over 85 °C.

5. Adapting Internet of Things and Big Data Technologies to Monitor Temperature of Milk during Transportation for HMF—REAMIT Technology Demonstration

Recent literature has highlighted the growing applications of Internet of Things (IoT) and big data technologies in the food industry (e.g., [46–48] and in logistics [47]). However, an application in the context of human milk and its transportation is almost non-existent. In this section, we present the details of how we adapted existing IoT and big data technology for the HMF.

Having assessed the challenge at the HMF to monitor the temperature of the milk during the transportation stage, REAMIT proposed a series of sensors which seemed most suitable to address the challenge, i.e., Digital Matter Eagle Logger—GPS/Accel, T9602 T/RH. Twelve sensors monitored the temperature and humidity of the milk during transportation between the donor’s house to the human milk bank, and from the human milk bank to the hospital or home of a vulnerable baby. At the beginning of 2021, the HMF had one human milk collection hub that is used to concentrate the donations in order to reduce transportation needs. Currently (end of 2022), the HMF has four hubs, and three are in the pipeline.

The sensors were installed in the insulated bags shown in Figure 3. One of the lessons learnt during sensor installation is the necessity to re-position the sensors inside the milk bag in order to record the data better. The sensors were sent on trips inside the transportation bags where they collected and transmitted the data to the cloud and the big data server. The procedure for using data from sensors for monitoring quality of donor human milk during transportation is shown in the schematic in Figure 4.

Figure 3. Insulated human milk transport bag used by the HMF to transport milk.

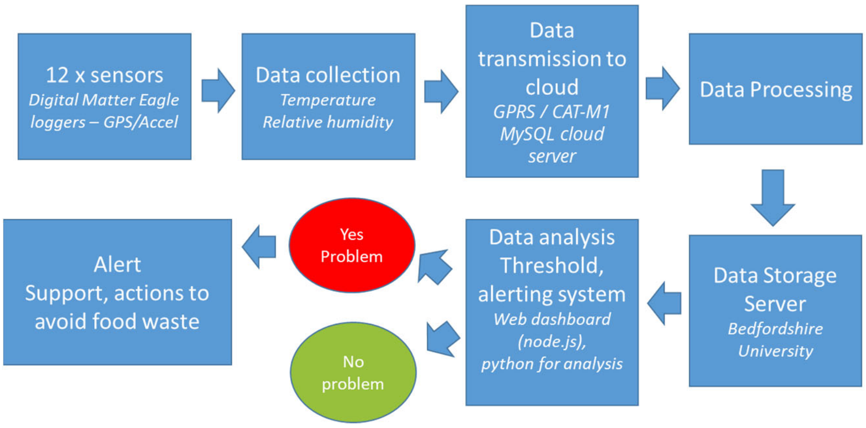


Figure 4. A schematic of using data from sensors for monitoring temperature in which human milk is transported.

As shown in Figure 4, the sensors installed in the human milk transport bags are Digital Matter Eagle loggers (Figure 5). The sensors have a GPS that generates data on the location of the milk and when the sensor is in motion. In this way, it creates an alerting system without human intervention.

Figure 5. Sensor placed inside the insulated human milk bag.

For each journey, the sensor installed within the insulated human milk transport bag monitors temperature and humidity conditions. Due to the nature of the transportation, the system has been designed as a standalone, battery-driven system. The temperature and humidity data from the sensors are collected every 30 min, whilst the GPS locator sends data every 2 min (and less frequent when the mode of delivery, bike or car, is stationary).

The data are collected in the cloud (the specially commissioned server for the REAMIT project) using GPRS/CAT-M1 technology. The server uses SQL technology for storing and retrieving data for access by a team of data analytics professionals. Data collected with sensors are uploaded to the REAMIT project cloud via an internet connection and administered by partners at the Whysor company, a Dutch-based REAMIT partner company, specialising in IoT sensors technology. Whysor created a dashboard to present data collected from all sensors installed at the HMF. The sensors are configured to record data every 5 min while in a trip, or every 12 h outside of a trip.

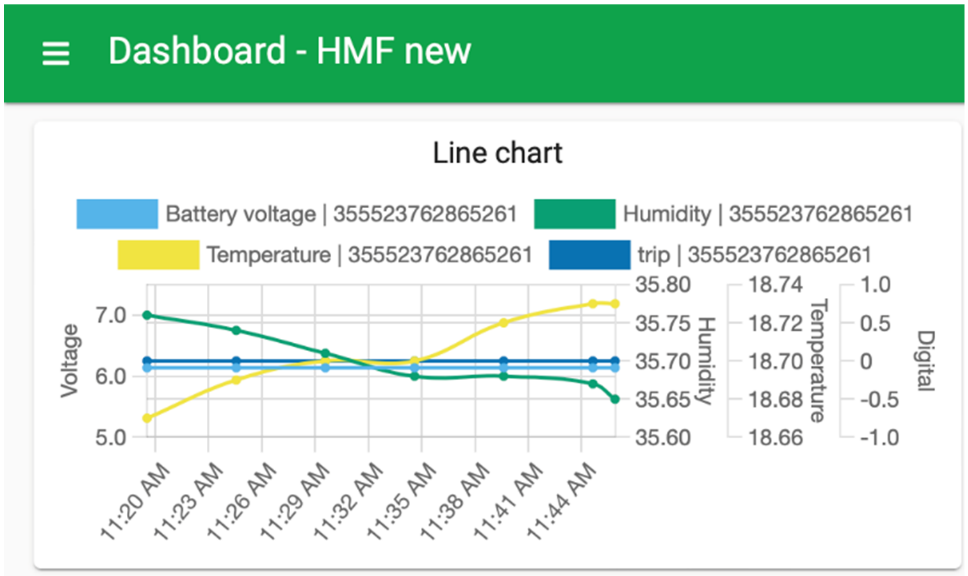
A special feature of the dashboard and the data analytics algorithms employed for analytics is that they have been designed to send alerts when the temperature of the milk is above the prespecified threshold instructed by the HMF and above −20 °C. The alerts are sent via email and as a smartphone message. These alerts are crucial in ensuring that the temperature of milk is kept at optimal levels during transportation. If the temperature is consistently within the allowed threshold throughout a journey, then it can be assumed that the quality of milk is maintained at optimal levels.

In order to prevent false alerts, the analytics algorithms have been designed to send alerts only when (i) there are three consecutive temperature values outside the threshold and (ii) when the binary sensors indicate that the sensors are being used during milk transportation and not when the bags are kept within the premises of the organisation.

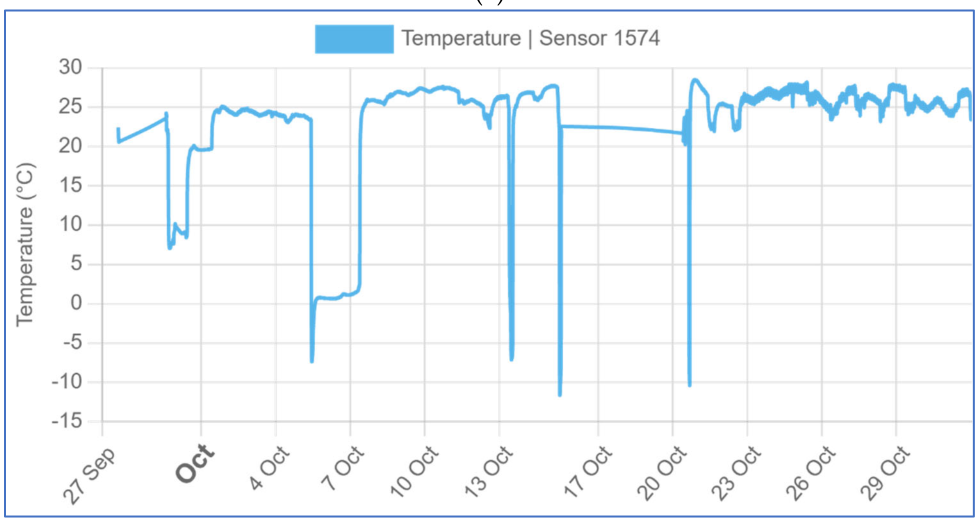
One of the challenges faced in this pilot test was to upload the data collected with sensors to the cloud, as it was the most energy-consuming part of the data collection process and lead to exhausting the batteries. Some ideas were explored, such as using rechargeable batteries (which was a challenge as it required certain voltages) and using other kinds of batteries, such as Altium. The possibility of using light (optical) sensors was also discussed, which would be able to pick up moments when the milk bag is opened and closed. The solution found to save battery energy was to disable sensor alarming functionalities when it was not necessary to send alerts, i.e., when the bags are not transporting milk.

Other, more sophisticated analytics on data from sensors were performed by a data analytics team. For example, the sophisticated statistical process control analysis was performed on the sensor data. Life cycle analysis (LCA) was also performed. LCA has been discussed in detail in another paper in this Special Issue [49]. Figure 6a shows a time-series plot of various measured parameters (such as battery level, temperature, humidity and trip details) found in the dashboard created for the HMF. Figure 6b shows a simple time-series plot of temperature for a specific set of dates. Data analytics included simple time-series plots, more sophisticated forecasting and other analytics models.

Figure 6b shows that the particular milk transportation bag was used only on specific dates: 05 October 2021, 07 October 2021, 13 October 2021, 15 October 2021 and 20 October 2021. There were some temperature changes on 29 and 30 September 2021, but it was due to the sensors being placed inside a fridge. The plot in Figure 6 has highlighted that the temperature data need to be linked to other related data to help comprehend the variations in temperature. Accordingly, it was decided to include a binary sensor in each bag to let the data analytics team know when the bag is opened and closed, which could help indicate that the bag is being used for transportation.



(**a**)



(**b**)

Figure 6. (**a**) Graphs showing the variations of temperature, humidity and other parameters from sensors placed in the milk transportation bags. (**b**) A simple time-series plot of temperature of milk in the milk transportation bags.

5.1. Strengths and Capabilities of IoT and Big Data Technologies

The technology demonstration explained in this article (see Figure 2) is a unique application of IoT and big data technologies to help the HMF increase quality of DHM and reduce waste. It fills a critical need for the charity in ensuring quality assurance when DHM is being transported. It is a bespoke system where IoT sensors not only track the temperature of the milk, but also follow the route of the volunteer. Sensor data are connected to the cloud, and the charity is able to see the temperature in real time. Automated big data algorithms help send timely alerts if the temperature fluctuates beyond acceptable levels to enable the charity to take appropriate corrective action rapidly. The collection of timeseries data from sensors provide further appropriate analytics options. For example, if there are multiple routes that the milk volunteers take, sensor data can be used to choose the most suitable route. Assessment of the rate of change of milk temperature over the distance travelled (or time) will help optimize the number of cool ice packs needed in the milk bags. These analyses form a strong scope for future research.

5.2. Saving Wastage of Milk and Improving Sustainability

While the HMF has sophisticated systems to maintain the quality of milk during storage in their premises, they found it challenging to ensure that milk is stored at the right temperature for maintaining the quality. In this case study, we have shown that modern Internet of Things sensors, cloud technology and big data analytics can help in monitoring the temperature to ensure the quality of milk and provide alerts if milk is not transported at the optimal temperature. By monitoring temperature continuously during transportation, this case study demonstrates that significant volumes of DHM could be saved and thus makes contributions towards sustainability.

1. Reduced wastage of milk: In theory, the continuous monitoring of milk temperature during transportation helps to detect quality issues on time. If the temperature of milk deviates from optimal levels, this deviation can be immediately detected with automated data analytics algorithms. Stakeholders can be immediately notified so that corrective actions are taken rapidly. However, our experience shows that milk is almost always stored at optimal temperature during transport. However, this continuous monitoring provides quality assurance as shown in the next point below.
2. Quality assurance of transported milk: Since the temperature of milk is monitored throughout transport, the organization obtains the reliability of assured quality of milk during transportation. Without this monitoring, while the organization made every effort to ensure optimal temperature, there was less reliability as temperature was not explicitly measured during the transportation of milk. It has to be noted that the organization has other means of quality assurance, for example by sending the milk to labs for testing before sending to hospitals. The monitoring of temperature of milk during transportation has added more levels of quality assurance.
3. Improved milk availability: Stocks of DHM are still relatively limited and therefore precious. By helping to minimize wastage of DHM, these technologies may increase availability, which could contribute to saving the lives of vulnerable babies through the avoidance of life-threatening complications.
4. Reduce costs: Continuous monitoring of temperature during milk transportation can help the organization reduce costs. For example, if the sensors indicate that milk is stored well below the lower threshold in which they have to be kept, it is an indication that too many resources are being used for cooling milk. This will help the organization to consider using lower energy for cooling—for example, by using fewer ice packs, which will reduce the cost of cooling.
5. Improve sustainability: The above points highlight how monitoring the temperature of milk using IoT technology can help not only save milk for organisations, but also support the social cause of improving milk availability to society. There are environmental benefits as well. For example, by helping to optimize cooling effort during milk transportation, energy can be saved, which translates to reduced carbon emissions. Thus, these technologies contribute to overall sustainability.

6. Conclusions and Future Research

Our research study is based on a real case study with observation of Hearts Milk Bank and REAMIT technology demonstrations. It is clearly evident that IoT sensors can support quality in maintaining cold supply chains of DHM. Dr. Natalie Shenker from the HMF (one of the authors) made the following statement on the benefit of REAMIT technology support:

> *"The REAMIT team have been fantastic! They've provided everything from proof of concept to the innovative sensors that we're using, that not only track temperature but are able to track humidity, acceleration, they can tell when the boxes will be actively moving—so we can really understand where the milk is, what conditions the milk is transported in and when it's arrived".*

DHM needs a high level of quality control which is possible with the support of smart technologies. IoT technology supports the human milk supply chain in five different aspects, namely in waste reduction, quality assurance, availability improvement, reduced cost and sustainability improvement. Our case study research proved that technological support is one of the easy ways to reduce waste and maintain sustainability. It was also realised by the case company in one of the interviews with the company personnel:

> *"The REAMIT project is a fantastic initiative, and they approached us about a year ago to see if we could work together to look at the cold chain technology and remote temperature sensing.*
>
> *One of the big question marks that we have about our cold chain is how well the milk is maintained at temperature, while it's being transported from donor's houses or from hospitals into the milk bank, and then again from the milk bank into the hospitals or recipient's families. It's really critical that we address that quickly and REAMIT is helping us to do that".*

Human milk requires a high level of safety and quality assurance. Although this human milk is classified as food, this requires very unique regulatory control that will not follow food transportation regulations. Future work on this topic can focus on regulatory requirements of the human milk.

While this is the first work in the context of using IoT sensors for monitoring quality of DHM during transportation, we faced some challenges when we implemented the technology. For example, there were issues with returning the sensors as volunteers chose to avoid coming to HMB for both onward and return journeys. Some volunteers chose to go to the pickup location directly from their homes. In this case, they were not able to pick up the sensors from the premises of HMB. Similarly, when a volunteer picked up milk from HMB for delivery to hospitals or the homes of recipients, they normally did not come back to HMB to return the sensors. This challenge sometimes affected the continued use of these sensors. Another limitation of the case study is the need to change the sensors' batteries. Changing batteries usually took some additional time, especially when the number of sensors was high.

As the world is going towards achieving sustainability in all possible ways, it is imperative to businesses to take the right initiatives and actions. Our study has considered one case organisation and tried to establish the use of IoT sensors in the DHM supply chain. This can be extended to other supply chains of rare and precious clinical resources, including blood and human organs, to avoid wastage and ensure total quality in supply chains.

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Data Availability Statement: REAMIT project and case-study videos are available in https://www.reamit.eu (accessed on 1 December 2022).

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