

Decentralized Human Milk Banking with ODK Sensors

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Abstract

Developing countries are faced with the daunting challenge of lowering their neonate and child mortality rates. Studies have indicated that up to 13% of the deaths of children under the age of five could be prevented by breastfeeding alone. One key barrier is the availability of breast milk for vulnerable infants (those born pre-term, with low birth-weight, to HIV-positive mothers, or orphaned at birth). One strategy to increase availability of breast milk is establishing human milk banks that process donor milk. However, it has been difficult to provide safe, pasteurized donor breast milk to infants in developing countries due to cost and lack of infrastructure. Low-cost pasteurization methods require rigorous temperature monitoring and quality assurance processes for adoption at scale.

In this paper, we present an affordable system to monitor breast milk pasteurization. It leverages mobile and sensing technologies to enhance an existing, low-cost pasteurization method called flash heat pasteurization. A mobile application, running on an Android phone that is connected to a temperature probe, monitors milk temperatures during pasteurization, and provides audiovisual feedback to guide users performing the procedure. At the end of the procedure, users are able to print a pasteurization report, and labels for pasteurized milk jars from the mobile application. The pasteurization temperature curve is also uploaded to a server that enables supervisors to remotely review procedures and perform audits to ensure that procedures are being performed correctly.

We discuss the lessons learned from ongoing deployments at two locations in Durban, South Africa. To date they have processed microbial assays for 40 donor milk samples in which 31 samples showed microbial activity pre-pasteurization, while none of the post-pasteurized samples show any microbial growth. We are currently working with the Human Milk Banking Association of South Africa to scale up the use of the system to more sites.

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1. Introduction

It is estimated that 3.3 million neonatal deaths occur within the first month of life [6], and overall, 7.3 million children under the age of five die each year [10]. According to the Lancet Child Survival Series [15], up to 13% of deaths of children under the age of five could be prevented by breastfeeding alone. The World Health Organization recommends providing donor breast milk when mothers' own breast milk is not available [5]. Availability of donor breast milk to vulnerable infants (those born pre-term, with low birth-weight, to HIV-positive mothers or orphaned at birth) can be increased significantly by establishing human milk banks (HMB). However, providing safe breast milk to infants in developing regions continues to be a challenge. Brazil's accomplishment with human milk banking is noteworthy, where the government has integrated HMBs with the national health system. Over the years (1980 – 2009), Brazil has lowered its infant mortality by 50%, and donor milk saves the public sector an estimated \$540 million annually in reduced medical costs [5].

Pasteurizing donor milk is a critical component of human milk banking. Milk from donor mothers has to be pasteurized to ensure that pathogens in the milk are destroyed, but nutrients and immunological benefits are preserved before it is fed to infants. HMBs in developed countries often use commercial pasteurizers, like the one shown in Figure 1, to accomplish this. While such pasteurizers ensure that milk is never under-heated and minimize over-heating, they tend to be expensive (up to \$50,000 USD), and require reliable infrastructure (e.g., electricity, clean water, connection to a computer for monitoring pasteurization temperatures etc.), which makes adoption difficult in low-resource milk banks in developing countries. Additionally, since these pasteurizers process large volumes of milk at a time, banks end up freezing donor milk until a large enough batch of milk-bottles can be processed. Likewise, after a large batch of milk is pasteurized,

not all of it gets fed to babies immediately, and the unused bottles are frozen again. Repeated freezing of milk, especially before pasteurization, degrades its nutrients, which is not ideal.



Figure 1: A high-end commercial pasteurizer. It provides temperature monitoring and archival on a computer, via a temperature probe that is connected to the computer. Milk bottles placed in the pasteurizer are shown in the inset.

Flash heat pasteurization (FHP) [16] has been proposed as a low-cost, low-tech alternative for pasteurizing breast milk in low-resource settings. In this method (shown in Figure 2) a glass-jar containing breast milk is placed in a pan of water (the water bath), which is then heated. When the water bath reaches a rolling boil, milk achieves a high enough temperature (about 72° C), which ensures that contaminants are destroyed. At this point the milk is removed from the water bath and cooled down, before being fed to a baby. This method was originally designed for in-home use by HIV-positive mothers to pasteurize their own breast milk before feeding it to their babies. Due to its practicality and affordability it has been implemented at a few milk banks in South Africa. However, this method does not have adequate temperature monitoring, and the interpretation of “rolling boil” of the water bath is highly subjective. For large-scale implementation, a more rigorous monitoring system is needed that provides the appropriate quality assurance.

The Department of Health in South Africa (SA-DOH) wants to significantly scale-up human milk banking across the country. In order to achieve this, they are looking for affordable methods to safely pasteurize human breast milk. They need a system that can provide adequate temperature monitoring to enable better control of the pasteurization process. Additionally, they want the system to generate proper records for the procedures performed. This is to provide the much needed quality assurance and enable supervisors to remotely monitor operations at facilities under their jurisdiction.

In this paper we present a method to pasteurize breast milk that enhances FHP to address the needs of the SA-DOH, and can be implemented in other countries as well. Our method leverages mobile and sensing technologies using the ODK Sensors Framework, and is being used at two locations in Durban, South Africa, as of this writing, with plans to scale up to other facilities. This deployment is an evaluation of the ODK Sensors Framework, and represents a class of sensing applications that process a series of sensor data in real-time.



Figure 2: Low cost, low-tech flash heat pasteurization being used at a human milk bank. A milk jar without a lid is placed in a pan of water, which is then heated. When water reaches a rolling boil, milk reaches a temperature high enough to deactivate contaminants like HIV and other pathogens.

The total cost of our system, including a Bluetooth-enabled printer, an induction stove, a jar-holder and glass jars, is under \$800 USD. We also identify requirements for an information management system for the human milk-banking ecosystem. Addressing these requirements in future work will be critical for scaling up our decentralized model for human milk banking. The work presented here is a multi-disciplinary collaboration among teams with backgrounds in engineering, maternal and child health, and commercialization. It reflects our evolutionary approach to developing appropriate technologies to address problems of developing regions. Lessons learned after building an initial prototype [1] guided the development of the solution we took to Durban. Additional learnings in the field led to further refinements of the system, making it more appropriate in addressing end-users’ needs.

The rest of the paper is structured as follows. Section 2 gives a high-level overview of the human milk banking process. We present our pasteurization solution in section 3, followed by a discussion on the deployment in Durban in section 4. Section 5 presents the results achieved to date, followed by a discussion on future work in section 6. Related work is presented in section 7 and we conclude the paper in section 8.

2. The Human Milk Banking Process

Interviewing milk-banking stakeholders in Durban has given us a clear picture of the human milk banking process that is depicted in Figure 3. Staff screen and recruit lactating donor mothers from neonate wards in hospitals or their communities. Screening involves checking for existing conditions like HIV, hepatitis, prescription drug use etc. Once recruited, mothers are encouraged to donate excess breast milk to the bank. The first time a mother donates her milk, a sample from the milk (before pasteurization) is sent to a microbiology lab to test for microbial activity. If test results indicate that microbial activity is below a certain threshold, and specific pathogens are not found (e.g. *Bacillus*), milk is considered safe for processing, and is pasteurized. Samples are taken from all post-pasteurized milk, and sent to a microbiology lab to confirm that any pre-existing pathogens are deactivated and that there has been no post-pasteurization contamination. Samples that pass post-pasteurization microbiology tests are safe to be fed to babies and either frozen and stored for future use or provided immediately to the baby.

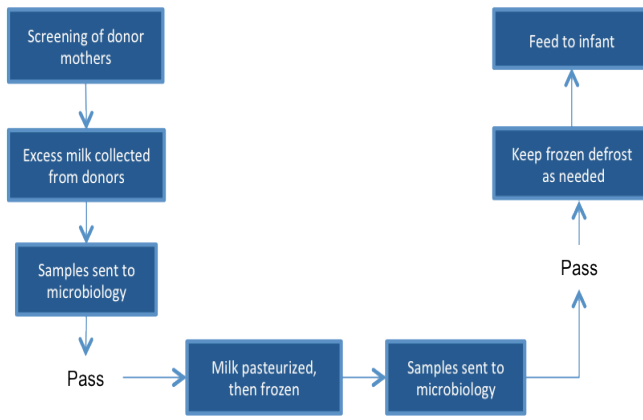


Figure 3: The human milk banking process.

Countries like Brazil follow a centralized model for human milk banking. A few milk banks are established across the country (Brazil has 200 such banks) in this model. Each bank can have a multitude of pasteurizers that process large volumes of milk. Donor milk from several organizations (e.g., postnatal care facilities at hospitals, clinics etc.) is sent to the milk bank for pasteurization. After pasteurization the milk is sent back to the organization it came from. This model is relatively easy to administer from the perspective of a state or a central government, however the capital investment required is quite high. Additionally, vulnerable infants in remote, rural areas are often beyond the reach of centralized milk banking systems.

A decentralized model for human milk banking is less common in countries today. In this model, hospitals run their own milk banks to cater to the infants in their neonate wards. This model is relatively easy to set up and operate. The capital investment is lower and more appropriate for low-resource settings; however, it is difficult to manage and monitor by administrators due to its decentralized nature.

We believe that provision for breast milk for vulnerable infants can be maximized in a country if both of these models co-exist. A better understanding of the milk banking process has helped us realize that there is a need for a unified information management system for milk banking that manages information needs for the entire process. The work presented in this paper is a start at building tools and systems to make it easier for governments to administer decentralized human milk banks.

3. Mobile Phone-based Milk Pasteurizer

We have built a pasteurization system that enhances flash heat pasteurization with real-time audiovisual feedback and temperature monitoring, as well as archiving of results. This ensures that milk reaches the target temperature of 72° C, while never being under-heated, and avoids overheating (such as boiling the milk directly). Our system runs as an Android application on a mobile phone that supports the Android Open Accessory protocol (we are using the Samsung Nexus S in Durban). It leverages the ODK Sensors Framework to communicate with a waterproof temperature probe that is connected to the phone over an Arduino USB Bridge. [8] describes the ODK Sensors Framework and the USB Bridge architecture. The application monitors and records temperature of milk during pasteurization and provides audiovisual feedback to guide users through the procedure. Figure 4 shows screenshots of the Android application that provide guidance to the user. At the end of the procedure the temperature curve is uploaded to a server for archiving. This data is accessible

over a web browser and enables supervisors to remotely monitor procedures and perform audits to ensure that minimum quality-levels are being met. In our system the server is hosted on the Amazon Cloud. Figure 5 shows a screenshot of an archived temperature curve accessible from the server.

In earlier work ([1]) we had built a pasteurization monitoring system that leveraged a low-tier mobile phone to upload temperature curves to a server. However, for the field deployment we chose to build a moderately more expensive, smartphone-based system. SMS was the only communication mechanism available to upload data to the server in the low-tier phone-based system, and each pasteurization procedure resulted in over 10 SMS messages to upload the temperature data. This worked out fine in our lab tests, however reliability of SMS is highly dependent on a service provider's network. So for the field deployment we wanted to have a more reliable transport mechanism (e.g., GPRS or WiFi) that is already available on smartphones. In the months preceding the deployment, we learned more about the human milk-banking ecosystem, which gave us the intuition that milk banking might present more opportunities for data collection, in addition to just monitoring and relaying temperature data. However, these requirements were not clear to us prior to the deployment. During the deployment we also wanted to understand from real users if having a Bluetooth-enabled temperature probe might be easier to work with, compared to a wired probe connected to the mobile phone. We felt that having a smartphone-based system that leverages ODK Sensors would give us more flexibility to implement any new requirements that might be identified in the field. In the next section we describe the enhancements we were able to implement during the deployment period itself.



Figure 4: Screenshots of the Android application that guide the user through the pasteurization process. 1) User places water and milk jars in the water bath and turns the stove on. Clicking the “Start” button on the app starts the pasteurization monitoring process. 2) A unique batch ID is generated for the procedure. Rising temperature is displayed on the screen along with the time elapsed. 3) Phone beeps twice to alert user 5° before high temperature threshold of 73° C is reached, visual indicator changes accordingly. 4) Visual indicator changes at 73° C and phone starts to beep continuously until user removes jars from water bath. 5) Beeping stops and visual indicator changes to indicate cooling when app detects drop in temperature. 6) Procedure is complete when temperature drops to 25° C.

Procedure 35 from King Edward Hospital

Click and drag to zoom, double click to zoom out. To see more data, hover over a data point.

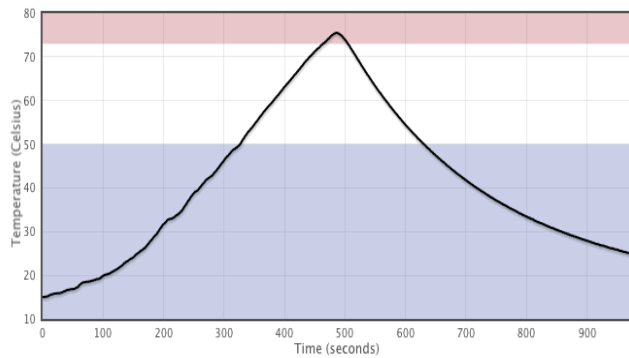


Figure 5: Archived pasteurization temperature curve from the server. This is accessible to milk bank supervisors from a web browser.

Figure 6 shows the milk pasteurization system that we took to Durban. A stand is used to hold four glass jars. In this set up we have one jar with water that has the temperature probe for monitoring pasteurization temperatures, while the other three jars have milk in them (our system can pasteurize one to three jars of milk at a time). The stand with jars is placed in a pan of water (the water bath) that is heated to pasteurize milk. We use an induction stove for heating since it is a more efficient source of heat compared to an electrical stove. The mobile phone that runs the pasteurization application and the USB Bridge connected to it are packaged together in an enclosure (the white box on the left side of the picture). The temperature probe connected to the USB Bridge is attached to the lid of the jar containing water.



Figure 6: The mobile milk pasteurization equipment. A stand holds 4 glass jars. The temperature probe connected to the mobile phone, is secured on the jar containing water; the other jars contain milk. The stand with jars containing liquid is placed in a water bath that gets heated on an induction stove. The white enclosure on the left side of the picture hosts the mobile phone and the USB Bridge that connects the probe to the phone.

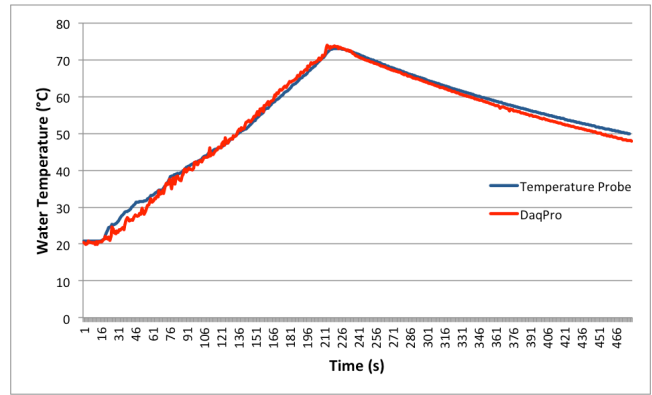


Figure 7: A graph showing the responsiveness of the waterproof temperature probe (blue) compared to a DaqPro thermocouple (red). The average temperature difference between the 2 sensors is 0.68 °C in this experimental run.

We use an off-the-shelf, waterproof temperature probe [14] that has a 1-Wire digital temperature sensor encased in a one-inch long stainless steel tube. The short tube ensures that it gets completely immersed in water to provide accurate readings. In order to ensure that the probe is responsive enough to temperature changes, we validated its readings against a DaqPro logger [4] with a thermocouple that has a fast response to temperature changes. In these experiments the waterproof temperature probe and thermocouple were immersed in a jar containing water, which was then heated. The temperature variation between the two sensors averaged over 20 experimental runs was 0.71 °C, which convinced us that our temperature probe was responsive enough for the application. Figure 7 shows the temperature curve of the two sensors from one of the experiments in which the average temperature difference is 0.68 °C.

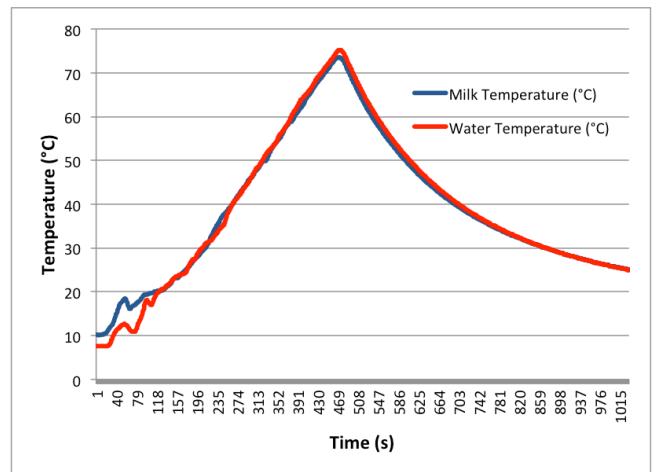


Figure 8: A graph showing the temperature curve of water control (red) and milk (blue). We observed that when milk reached 72° C, water's temperature was in the 71° C to 73° C range. Based on this we set the high temperature threshold of our system to 73° C.

As mentioned earlier, rather than placing the temperature probe in milk jars, we place a probe in a jar containing water. The temperature of the water jar is used to control the pasteurization process. This is done to eliminate any chances of the temperature probe (if it were placed in milk) contaminating the milk that is being pasteurized. Additionally, this also affords the practical benefit of eliminating the need to sterilize the temperature probe before each procedure. In this approach we leverage the fact that milk and water have very similar specific heat capacities i.e., given equal volumes and the same amount of heat – their temperature rise will be similar. We ensure that all jars in the stand get the same amount of heat by placing the stand in a water-bath that is heated on a stove. Additionally, we require that the volumes of milk and water in all the jars be the same. In our setup this volume is 120mL. With this volume and the jars used in our system, the liquid reaches the upper lip of the jars. While jars of some other capacity can also be used in our system, with the jars that are currently being used, users can easily ensure that each jar has the same volume of liquid, by visual inspection, without the need for a measuring apparatus. We also require that the initial temperature of water and milk be approximately the same in order to correctly determine when milk reaches the high temperature threshold. If milk is thawed and cold, users are required to use refrigerated water, otherwise, for freshly expressed breast milk, tap water at room temperature is required.

The goal of our system is to ensure that milk reaches the target temperature of 72° C in each procedure. Given that we are monitoring the temperature of the water jar only, we ran experiments in which we monitored the temperatures of both the water and milk jars while they were being heated. Over 20 runs we found that when milk's temperature reached 72° C, water's temperature was in the 71° C to 73° C range. Based on this, we set the high temperature threshold in our system to 73° C. This ensures that milk always reaches at least 72° C, a temperature high enough to deactivate pathogens. Figure 8 shows the temperature curves of milk and water from one of our experiments. In this experiment water achieved a peak temperature of 75.2° C while milk achieved a peak temperature of 73.5° C. Our system errs towards slightly overheating milk (by 1-2° C for a few seconds) because it's safer than the prospect of under-heating, and potentially not completely inactivating HIV or other pathogens. According to our project partners who are experts in infant nutrition and milk banking, the benefits of using a water jar to infer milk temperature and control pasteurization far outweigh the downside to overheating milk slightly. This is especially true for HIV-endemic areas such as KwaZulu-Natal (Durban comes under this province), where the benefit to prolonged heating of breast milk is preferable to the risk of under-heating the milk.

Before taking the system to Durban, we did a user trial in Seattle with eight subjects. All the subjects were employees at PATH, and were vaguely familiar with our project, although none of them had ever pasteurized milk or seen our system before. They were given verbal training about the pasteurization process and our system, and then asked to perform a procedure on their own. We did not provide intensive training on purpose as we wanted to understand the ease of use of our system. In order to identify any friction points that were possible stumbling blocks, we used the "Think-Aloud" method during trials where participants were encouraged to verbally communicate those points of friction, thus providing immediate feedback. This proved to be a helpful exercise as we saw that all but two subjects erroneously ended the procedure on the mobile phone before the process was actually complete. This caused the mobile application to upload

incomplete temperature curves to the server, while in reality the milk was cooling down. We addressed this problem immediately after the subject tests.

4. Durban Deployment

We travelled to Durban for a 3-week period in May-June of 2012 to deploy our pasteurization system. Our in-country partners - the Human Milk Banking Association of South Africa (HMBASA) and faculty at the Nelson Mandela School of Medicine at the University of KwaZulu-Natal (UKZN), facilitated this deployment. The UKZN medical school is co-located with the King Edward Hospital (KEH) that has a human milk bank in its Neonate Intensive Care Unit (NICU). Under the guidance of the HMBASA, this milk bank uses flash heat pasteurization to process donor breast milk for babies in the NICU. Our goal was to introduce the new pasteurization system at two locations: 1) the milk bank at KEH for doing routine pasteurizations, and 2) the pediatrics lab at the UKZN where researchers would pasteurize donor milk and send samples for microbial activity analysis to validate the safety of our system. In the early days of the trip we decided to set up our base at the pediatrics lab in UKZN, where we would demonstrate the system and train users. Since the milk bank at KEH already had a working system in place, we did not want to disrupt that until the milk bank technician was properly trained and comfortable with using our system.

4.1 Baseline Data Collection

During the first week of the deployment we visited a few milk banks (including the one at KEH) and conducted baseline interviews with key milk banking stakeholders. With these interviews we wanted to understand milk banking procedures, stakeholders' perception of these procedures and identify opportunities where appropriate technology could be introduced to address gaps. The stakeholders we interviewed included two milk bank supervisors (colleagues at UKZN), four milk bank technicians and a neonatologist. One of the supervisors is a pediatrician, while the other is a lactation consultant who has been practicing for over 10 years. The technicians are individuals who have been trained to perform breast milk pasteurization. In these early days, except for the two supervisors, none of the other stakeholders were aware of our new pasteurization system, and we kept this information from them until we completed all the baseline interviews and started user training.

All the interviewees indicated that it was a challenge to maintain a large enough, active pool of lactating donor mothers. The milk banks that use flash heat pasteurization typically pasteurize only when fresh donor milk is available. Depending on the availability of donor mothers, this translates to a few procedures per day. Pasteurized milk is then either fed to babies immediately or frozen for storage. One of the milk bank technicians works with a donated commercial pasteurizer that processes large volumes of milk at a time. Thus, this technician collects and freezes donor milk throughout the week, and pasteurizes a large batch of milk once a week. Even though she uses a commercial grade pasteurizer that automates much of the procedure, it is more labor intensive for her because she needs to thaw the frozen, unpasteurized milk bottles before putting them in the pasteurizer. Most of the milk bottles are frozen again after pasteurization because the large volume of milk cannot be consumed immediately. In addition to being labor intensive, we also learned from supervisors and doctors that repeated freezing and thawing causes fat decomposition in milk, which reduces the nutritional benefits of the milk. This indicates the need for a flexible

pasteurization system that can process lower volumes of milk at a time (e.g., the flash heat pasteurization system).

While trying to avoid getting biased answers, we asked stakeholders about their confidence-level with the end product of flash heat pasteurization. (Note: we did not ask FHP-specific questions to the neonatologist or the technician who used the commercial pasteurizer). Technicians indicated that they are careful when performing the procedure and make sure that it is performed correctly. They are confident that the pasteurized milk is safe to be fed to babies. However, they said that the water bath reaching a rolling boil wasn't a clear indicator of removing milk from the bath, so typically they wait for a short period of time after water starts to boil and then remove the milk. Supervisors had a similar concern with the water bath's rolling boil being used as a visual indicator to remove milk. They wanted a more definitive indicator to ensure that milk was heated appropriately.

We also asked if they would want anything about flash heat pasteurization to be changed or improved. Two of the technicians were concerned with contamination of milk during pasteurization. In FHP the milk jar does not have a lid (Figure 2), so the technicians expressed concern that they need to be extra cautious to prevent anything from falling into the milk while it is being pasteurized. In addition to wanting a more definitive indicator than rolling boil, supervisors had the same concern regarding contamination. Additionally, they were also concerned about post-pasteurization contamination. In FHP, milk is transferred to a smaller jar that has a lid for storage after pasteurization. This introduces the risk of post-pasteurization contamination. FHP currently processes only one milk jar (with 120 mL of milk) at a time and supervisors expressed the need for increasing the processing volumes (that being said, they already knew that our new system can pasteurize up to three bottles of milk at a time).

In addition to formal interviews, we also had informal conversations with supervisors to understand how they manage information about donors and records of milk pasteurization. Currently, all data is recorded on paper. Each milk bank maintains a donor registry that has information to identify each donor and a timeline of when milk was collected from each of them. There is a separate registry for recording pasteurization procedures. After pasteurization, milk bottles are labeled with the donor's ID, a batch ID and the date on which the pasteurization was performed. This system works well as currently milk banks operate in silos; however, during the deployment period we did observe that pasteurized milk bottles are exchanged between milk banks. This helped us realize that as milk banking is scaled up in South Africa, the exchange of milk between milk banks will increase and they would benefit from a digital information management system.

In order to collect baseline temperature data for FHP we had a technician and a supervisor perform two runs of milk pasteurization in which we had a temperature probe immersed in milk to passively record temperatures. They were asked to perform the procedure as they would normally. We told them that we are not evaluating their performance and needed this data only for our research. We found inconsistencies in the peak temperatures achieved by milk, which raised concern amongst supervisors. This highlighted the risk with the subjective interpretation of using the rolling boil of the water bath as a visual indicator to stop heating milk. The procedures took close to an hour in all the runs. While the water bath started boiling fairly quickly, usually within 10 minutes, cooling took a longer time. These experiments in the field confirmed results from earlier work

[1] where our lab experiments showed that water reaching a rolling boil is not a definitive indicator to stop heating milk, and that real-time temperature monitoring with clear feedback is needed to control the pasteurization process.

4.2 System Enhancements

We set up our system in the pediatrics lab at UKZN in parallel with visiting milk banks and collecting baseline data. After completing the baseline interviews with the supervisors, we demonstrated our system to them in order to get feedback and incorporate any changes. Looking at graphs from a few procedures on the server's web interface, they noticed that the cooling phase of the process was taking too long. They explained that in order to minimize nutritional and immunological degradation during pasteurization it is equally important to cool milk as quickly as possible, after the high temperature threshold is reached. So they helped us devise a more efficient cooling mechanism that shortened the procedure time to about 17 minutes. With this mechanism, after the high temperature threshold is reached, the jar holder is removed from the hot water bath and placed in a water basin at room temperature. After a minute ice packs are added to the water basin to speed up the cooling process. The gentle transition from hot water to water at room temperature to ice cold water ensures that jars do not break, but milk cools down much more quickly. We modified the mobile application to guide users through this 2-step cooling mechanism. Figure 9 shows step 2 of the cooling process along with the corresponding screenshot of the mobile app.



Figure 9: The 2nd step of the 2-step cooling process. In step 1 the jar holder is removed from the hot water bath and placed in a basin that has water at room temperature. After 1 minute the mobile app beeps to alert the user and the visual indicator changes (as shown in the inset). The user adds icepacks to the water basin to accelerate cooling.

During the baseline data collection we learned about the information management needs in human milk banking. It wasn't possible to implement a complete information management system during the short deployment period, however we made a start on it, in preparation for scale-up. We added a new screen to the mobile application to enter donor information (Figure 10).

In addition to archiving and tracking pasteurization procedures on the server, we saw an opportunity to provide tracking at milk bank facilities as well. We integrated a Bluetooth-enabled printer with our mobile application. This enables technicians to print pasteurization reports and labels for pasteurized milk jars. Figure

11 shows a screenshot of the Android activity used for printing. Figure 12 shows printouts of a bottle label and a pasteurization report. The pasteurization report has a summary of the procedure that includes the date, batch ID, donor IDs and temperatures achieved during pasteurization. The date and IDs are also encoded in a linear (one-D) barcode that is printed on the report. The labels for milk jars have the date, batch ID, donor ID and an expiration date. Similar to the pasteurization report, labels also have the date, batch ID and donor ID encoded in a one-D barcode that gets printed on each label. The barcodes also include the mobile phone's IMEI to uniquely identify the facility where the procedure was performed. As human milk banking scales up in South Africa and pasteurized milk jars are transferred between facilities, these barcodes will provide the capability to uniquely identify and track individual jars.



Figure 10: The system deployed at the Neonate ICU of King Edward Hospital. The Milk bank technician is entering donor information on the mobile app. Up to 3 donors can be entered on this screen (inset is a screenshot). Donor information includes a unique donor ID and a milk-type, which could be term or pre-term milk. This corresponds with the donor mother having delivered a term or a pre-term baby.

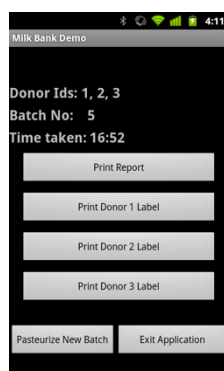


Figure 11: A screenshot of the Android activity that allows technicians to print pasteurization reports, and labels for pasteurized milk-jars at the end of each procedure. The mobile app uses a Bluetooth-enabled printer paired with the phone to accomplish this.

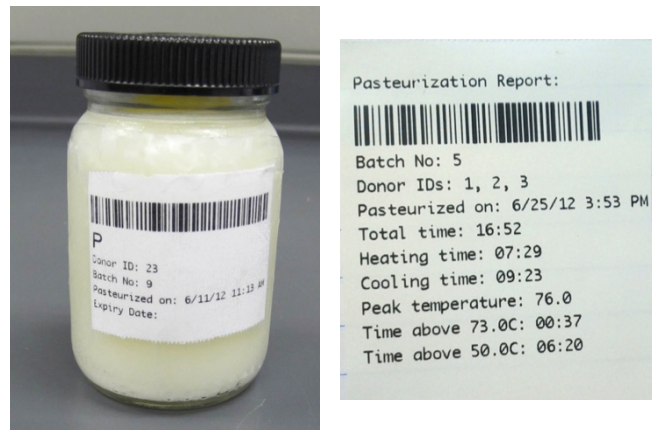


Figure 12: (Left) A pasteurized milk-jar with a label. The “P” on the label indicates that this milk is from a donor who delivered a preterm baby, and the donated milk is meant to be fed to a preterm baby. (Right) A pasteurization report summarizing a procedure. These reports become part of the registry maintained by technicians at milk banks. Each print out has a linear barcode that encodes information to uniquely identify a pasteurized milk jar or a pasteurization procedure.

4.3 User Training

We conducted training sessions with users to show them how to use and maintain the system. The user group included everyone from the baseline interviewee group excluding the neonatologist. We conducted three training sessions over three days in which first we demonstrated system set up that includes measuring the appropriate volumes of liquid for the glass jars, water bath and cooling water basin. We showed how the mobile phone is connected to the USB Bridge and how the Android application is started and used. We also covered common problems that could occur (e.g. the mobile app not being able to communicate with the temperature probe) and trouble shooting steps. After this we demonstrated the entire pasteurization procedure. Next, we had each user set up the system and perform a pasteurization procedure. Most users were unfamiliar with touch screen phones. However, they got comfortable with the Android application’s user interface by the end of the second training session. By the end of the third training session the users were able to perform procedures without any assistance from us. After this, we let the users tinker with the system independently while we were available to answer any questions. Figure 13 shows a training session in which milk bank technicians are working with our system. We have also created a user manual and a training video to help with scale-up efforts.

We were able to recruit local engineers to help maintain the system. This is critical for the long-term sustainability and scalability of the system. During the time we were in Durban the local engineers made enhancements to the mechanical aspects of the system and have continued to do so since we left. They are able to assemble the electronic components of the system as well (i.e., the components that go inside the enclosure that hosts the mobile phone and the USB Bridge).

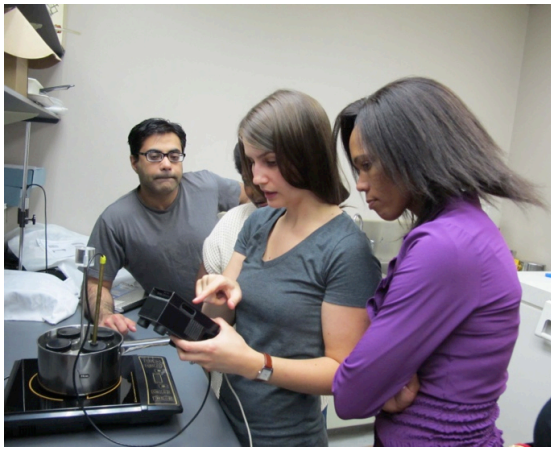


Figure 13: A user training session in the pediatrics lab at the UKZN. The 3 ladies (3rd lady is not quite visible) are technicians at milk banks in the Durban area. The equipment in this picture is similar to the equipment shown in Figure 6, with the exception of the black enclosure.

5. Results

We installed our system at two locations by the end of our deployment period in Durban. Our colleagues in the pediatrics lab at the UKZN use the system to pasteurize donor milk and perform microbial activity analysis on pre- and post-pasteurized samples. As of this writing they have processed 40 samples. 31 of the pre-pasteurized samples showed microbial growth but none of the post-pasteurized samples show any microbial activity. Their goal is to process 100 samples before concluding the research. We have also installed our system at the milk bank in King Edward Hospital. This system became operational after the UKZN researchers obtained microbial assay results from the first lot of 10 samples. It was important to wait for these results before using the system at KEH because the pasteurized milk is fed to babies at the NICU. 35 procedures have been performed at KEH to date, in which each procedure pasteurized one to three jars of milk. A total of three users are using the systems at these two locations – the milk bank technician at KEH and the two supervisors at the pediatrics lab. Temperature graphs accessible from the server show that the procedures are very consistent in terms of peak temperatures achieved and total time taken. Improved quality control as indicated by these results has significantly boosted the confidence of the staff performing the procedures. Supervisors have said that the sophistication added by the new system, especially the pasteurized milk jars with labels that have barcodes, adds to the perceived satisfaction of families who need donor milk for their babies, by reinforcing the perception that they are, in fact, receiving a medical grade product. HMBASA will install our system at two new milk banks located at hospitals in the coming months. They are also promoting the system with the South African Department of Health, and it is likely that the system will be adopted at lower-level healthcare facilities and community-level milk banks that are not affiliated with hospitals.

Our system makes several improvements to the existing flash heat pasteurization process. Continuous temperature monitoring, with clear audiovisual indicators for each stage of pasteurization, is very useful in producing repeatable, consistent results. Our system reduces the chances of contamination during or after pasteurization by monitoring the temperature of water to control

pasteurization and having milk in sealed jars with lids. Our system enables pasteurized milk jars to be tracked via the barcodes contained in labels printed by the mobile application. Finally, we have reduced the procedure time by a factor of three and increased the volume of milk processed per procedure by another factor of three.

Before traveling to Durban we were concerned that users might find it difficult to learn and maintain the new system. However, we were quite surprised at how quickly users learned it and were comfortable with using it after only three training sessions. It was encouraging to see that they could detect error scenarios and take the appropriate steps for resolution. We had not expected to identify and recruit local engineers for this project; however, having them on-board has been critical to the success of the project so far. They are maintaining the systems in Durban and continue to refine it. They will play an important role as HMBASA deploys our system at new milk banks.

In the current implementation, the mobile application running on the Android uploads temperature curves at the end of each procedure. The mobile phones being used at the UKZN and KEH use pre-paid, data-enabled SIM cards that need to be recharged every couple of months. During the deployment period we realized that supervisors do not need access to temperature curves in real-time. The need for having supervisory monitoring and documentation for each procedure is clear. However, it is acceptable to get this data weekly or even bi-weekly (similar to the way reporting is done in other domains such as immunization programs). In fact, requiring that each mobile phone have a data-enabled SIM card when the data is not needed in real-time would hinder the scaling up of the system in the real world. We will address this issue very soon and provide alternate mechanisms to upload data to the server. That being said, our partners continue to recharge the two SIM cards currently being used, given that this is the first deployment and having seamless and immediate access to the data is very helpful for research purposes.

6. Discussion and Future Work

The work presented in this paper is part of a larger project being led by PATH that aims to lower barriers for human milk banking in low resource environments. While the deployment in Durban and immediate next steps for South Africa will focus on milk banks affiliated with hospitals, our long-term vision is to facilitate milk banking at lower-level healthcare facilities and community-level banks that are not affiliated with hospitals (e.g. at infant transition homes). We also plan to take this technology to India for deployment in 2013.

We need to make some enhancements to our system so that it can scale well for varying deployment conditions. In the current implementation the Android mobile phone communicates with the temperature probe via a USB bridge that is not battery-powered. This is acceptable for deployments at NICUs where electricity is generally stable, however this is not suitable for environments with unreliable electricity. Additionally, communicating with a USB bridge requires that the mobile phone implement the Android Open Accessory protocol, which is typically available only on newer, higher-end Android devices – thus raising the cost of the solution. To address these issues, we are designing a battery-powered, Bluetooth-enabled interfacing board that will act as a bridge between the temperature probe and the mobile phone. Switching to Bluetooth for interfacing with the temperature probe will allow us to use any Bluetooth-enabled mobile phone (although we expect to continue using Android phones ourselves) and that will give us more flexibility, and lower the cost of the

technology. We have learned that community-level milk banks might not require extensive donor or milk jar tracking as provided by our current solution using a Bluetooth printer. The temperature monitoring and guiding system required for such milk banks could be made cheaper and simpler. Hence, we have added some audiovisual feedback capabilities to our new board, so that it can be packaged and programmed independently, and be used to monitor milk pasteurization and guide users through the process. The interfacing board will also support the different types of sensing applications described in [8].

During the deployment period we added printing capability into the Android application itself. However, since this is a general-purpose capability that would be useful to several other applications, we have now abstracted printer-specific functionality into a driver that leverages ODK Sensors to communicate with the Bluetooth-enabled printer. Applications are now able to simply send text that needs to be printed as strings or barcodes to the driver, and the driver encodes this text into printer-specific commands. This generalization also resulted in an enhancement to ODK Sensors that allows applications to actuate external devices. This enhancement, along-with the new battery-powered interfacing board, will enable a broad class of mobile sensing and actuator applications that communicate with external devices.

As mentioned in the previous section, the milk banking system does not require temperature curves to be uploaded to the server in real-time over the cellular network. The next iteration of our system will not require that the mobile phones being used have a SIM card. We will implement a delay tolerant protocol to transfer data in which the mobile phones at facilities will simply store temperature curves locally. Supervisors visiting facilities will be able to retrieve the stored data over Bluetooth using their own mobile phones. We will build additional tools that will run on supervisors' mobile phone to enable them to retrieve and visualize data from pasteurization procedures similar to those of some of our other projects [12]. We may also want to provide some data archival and visualization tools to run on supervisors' desktops.

The deployment in Durban has given us a better understanding of the milk-banking ecosystem. We have identified a huge opportunity to build a unified information management system for milk banking. Such a system will manage information for all stages of the milk banking process (discussed in Section 2) - from recruiting and screening donor mothers to feeding pasteurized milk to infants. We believe that this information system will play a critical role in the adoption of decentralized human milk banking in countries.

7. Related Work

The work presented in this paper is an example of a mobile cyber physical system (CPS) that is defined in [2] as computer systems that process and react to data from external stimuli from the physical world and make decisions that also impact the physical world. Our system is a mobile CPS with a human in the feedback loop (it doesn't control the heating element directly) because that helps keep costs/maintenance low in the settings in which we work. White et. al. discuss some R&D challenges inherent to mobile CPS in [9]. They identify interfacing with external sensors as one of the challenges, and propose to leverage a service-oriented device architecture [13] and the Device Profile for Web Services [3] to address it. Resource-constrained sensor platforms become part of IP-based cyber physical systems by implementing scaled-down web services protocols. Our work leverages the ODK Sensors Framework [7] that makes it easier for mobile applications to interface with external sensors over wired or

wireless communication channels. The framework shields application developers from communication channel-specific complexities, and provides sensor driver abstractions that encapsulate sensor-specific data processing. Sensor data is made available to IP-based cyber physical systems without requiring web services protocols to be implemented on sensor platforms. [7] and [8] compare ODK Sensors to related works in the general area of mobile device-centric sensing systems.

Commercial pasteurizers, like the one shown in Figure 1 [11], do provide temperature monitoring and archival capabilities. However, they require a temperature probe to be connected to a co-located computer, which might not always be practical for low-resource environments. Additionally, it is difficult to move the archived temperature data from the computer on which it is recorded, a requirement that will need to be addressed as milk banking scales up in countries. Our system is based on mobile phones, which lowers the infrastructure requirements. Capability to move temperature data is already built into the mobile application, and will be modified to incorporate our learnings from the deployment in Durban.

8. Conclusion

We have presented a low-cost system that leverages mobile and sensing technologies to monitor and control breast milk pasteurization. It enhances flash heat pasteurization by adding temperature monitoring and archival, and audiovisual feedback to guide technicians performing the procedure. The system is suitable for implementation at low-resource human milk banks. Continuous temperature monitoring and feedback helps ensure that pasteurization procedures are performed correctly. Archival of temperature data on a server accessible over a web browser enables supervisors to remotely monitor procedures and ensure procedural compliance. Additionally, the system enables technicians to print pasteurization reports and labels for pasteurized milk jars via a Bluetooth-enabled printer. The print outs have linear barcodes that encode information to uniquely identify individual milk jars and the pasteurization procedures they underwent. This capability will be useful as human milk banking is scaled up and milk jars are transferred between facilities. The total equipment-cost of our system is under \$800 USD. Our work to date is a start on creating information management tools that will enable governments to implement low-cost, decentralized human milk banking.

In collaboration with our in-country partners at the HMBASA and the UKZN, we have deployed our system at two locations in Durban, South Africa. One of the deployments is at the milk bank in the Neonate Intensive Care Unit of Kind Edward Hospital (KEH), where it is used to perform routine pasteurizations of donor breast milk. 35 procedures have been performed at KEH in which one to three jars of milk were pasteurized. The other deployment is at a pediatrics lab in the Nelson Mandela School of Medicine at the UKZN. Researchers are using our system to pasteurize breast milk and validating its safety. As of this writing they have processed microbial assays on 40 samples of donor milk. 31 of these samples showed microbial activity before pasteurization while there was no microbial growth in samples taken post-pasteurization. In the coming months HMBASA will deploy our system at two other facilities in the Durban area. They are also working with the South African Department of Health to implement the system at milk banks across the country.

The Durban deployments have given us a better understanding of the milk-banking ecosystem. We plan to build a unified information management system to address the information needs

of the entire milk banking process. We are also working on a new, battery-powered Bluetooth-enabled interfacing board to act as the bridge between the mobile phone and the temperature probe. This will enable the pasteurization monitoring/tracking application to be implemented on any Bluetooth-enabled mobile phone. With a completely battery-powered solution (board and mobile phone) our system will become suitable for environments that have transient electricity. We have also identified the need for a simpler and cheaper pasteurization-monitoring device that will be appropriate for community-level milk banks that are not affiliated with hospitals. For such milk banks we are integrating simple audiovisual feedback capabilities on the interfacing board so that it can be used (without a smartphone) to guide users through the pasteurization process. The deployment is an evaluation of the ODK Sensors Framework, and has helped evolve the framework to allow applications to actuate external devices. While our current and near-term scale-up plans focus on South Africa, we also plan to begin deployments of our system in India in 2013.

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