A System for Safe Flash-Heat Pasteurization of Human Breast Milk

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ABSTRACT

We present ongoing development of a low-cost system to improve the flash-heat pasteurization process for human breast milk currently utilized in resource-constrained developing regions. Flash-heat was designed for low-resource environments, is simple to use and requires minimal infrastructure. It is currently used at a small-scale to provide safe breast milk to vulnerable infants with special needs. Safety concerns have limited the adoption of this method for use in human milk banks. The system presented in this paper improves the safety and procedural compliance of the flash-heat process by continuously monitoring the temperature of milk as it is being pasteurized, providing feedback to the user performing the procedure and bringing-in remotely-located quality assurance personnel into the process-approval loop. In partnership with PATH, a Seattle-based NGO, the system will be piloted at a human milk bank in South Africa later this year. The longer-term vision of the project is that the improved monitoring, feedback and reporting capabilities will help scale-up the adoption of cost-effective flash-heat pasteurization for establishing human milk banks in developing countries.

We present results from in-lab experiments that have helped us assess the feedback capabilities of our system and have validated the need for having a temperature monitoring and feedback system to enhance the safety of the flash-heat process.

INTRODUCTION

Breastfeeding is considered to be one of the pillars of child survival due to its well-documented immunological and nutritional properties. Infants in developing countries who are fed formula in lieu of breastfeeding are at increased risk of sickness and death since they are often exposed to potential pathogens through unsafe water and unhygienic conditions [12]. Specifically, many infants in developing countries are especially vulnerable and have increased risk of malnutrition, morbidity and mortality, such as those who are pre-term, low birth weight, severely malnourished, born to HIV-positive mothers, or orphaned. It is estimated that in Sub-Saharan Africa about 40% of the HIV-positive children get the infection from mother-to-child-transmission of the virus during breastfeeding [5]. For such infants with special needs, these risks are compounded when formula is fed instead of breast milk. Identifying a mechanism to provide safe breast milk to vulnerable infants could be of paramount importance to ensure their healthy growth, development and survival and thus could directly contribute towards achieving the Millennium Development Goal (MDG) #4 of reducing child mortality. South Africa has faced challenges meeting their MDG4 target [2] and has shown recent increases in deaths, indicating that innovative strategies to improve infant health, such as low-cost Human Milk Banking (HMB) systems to provide safe donor breast milk, are urgently needed.

Studies have shown that pasteurizing breast milk obtained from HIV-positive mothers effectively deactivates the virus and other contaminants in milk while retaining its immunological and nutritional properties [5] [11]. However, commercial-grade pasteurizers typically used in developed countries pose several barriers that make it difficult to adapt them for use in many resource-constrained contexts. Their cost tends to be high, typically in the USD$2000 to USD$12000 range. Being commercial-grade, they are more appropriate for pasteurizing high volumes of milk while HMBs often need to pasteurize very low volumes, e.g. a single 50 mL feeding for an infant. Additionally, the sophisticated equipment requires reliable infrastructure that often cannot be assumed to be available in low-resource settings. Although low-tech HMBs have been proposed for neonate wards in South Africa, lack of appropriate monitoring systems and quality assurance processes to

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ensure safety has been a major deterrent toward scale-up. Demonstrating that low-tech pasteurization of breast milk can be done safely is a critical step toward gaining advocacy and expanding HMB adoption to resource-poor communities and facilities.

Israel-Ballard et. al. have pioneered Flash-Heat Pasteurization (FHP), a low-cost, low-tech method to pasteurize breast milk in resource-poor settings [1][5][11]. This method was designed based on commercial-grade high temperature, short-time flash pasteurization methodology [3] [9], which involves heating breast milk to 72°C for 15 seconds; a process not possible in developing country settings without high-tech equipment. In the FHP procedure, breast milk is heated in a water-bath on an open flame; when the water reaches a "rolling boil", the milk is removed from the water-bath and allowed to cool at room temperature. Typically, when the water reached 100°C, the breast milk would reach a peak temperature of 72°C. Figure 1 (reproduced from [5]) shows the temperature curve of 50 mL of milk in a glass jar as it is heated in a pan containing 450 mL of water. The peak temperature of about 72°C is reached within 5 minutes and the jar is taken out of the water-bath immediately after that to cool the milk.

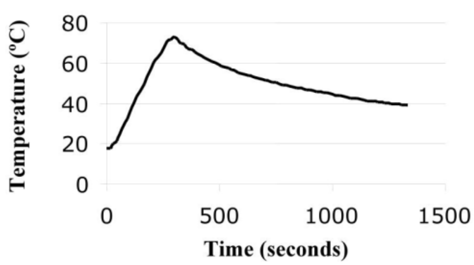

Figure 1: Typical temperature curve of milk during Flash-Heat Pasteurization (FHP). Milk is heated rapidly in a water bath, then cooled down.

The Flash-Heat method of pasteurizing milk is currently being used in homes in South Africa by HIV-positive mothers for their own milk as well as at a HMB for treating donor milk for use by vulnerable infants in a neonate ward [10]. PATH, a Seattle-based Non-Governmental Organization (NGO) that is our partner in this project, proposes to significantly scale-up HMBs that could utilize FHP in South Africa and other countries. This has created new system requirements to demonstrate that FHP can be performed safely and according to protocol:

- Temperature should be continuously monitored and the data stored for recordkeeping and report-generation. For organizations that have HMBs at different locations, this aggregation needs to be done at a central place. Hence data has to be moved from milk banks, where the procedures are performed, to a remote server.
- Quality assurance (QA) personnel should be in-the-loop and have access to temperature data in order to approve or reject procedures based on this data. They are not always co-located at the site where FHP procedures are performed and would typically be responsible for ensuring compliance at several different facilities.
- The system should provide feedback to staff performing the procedure in order to guide them through it. This is especially important for newly-hired staff as they learn the procedure.
- The system should have low initial cost, infrastructure, and maintenance requirements so that it is easy and practical to scale-up.

We are using FoneAstra [7] [8], a low-cost, networked sensing system, to address these new requirements. While previous work with FoneAstra has focused on remotely monitoring temperatures in vaccine cold-chains, milk pasteurization is a new application-domain where the same platform is being leveraged. This application furthers our research because humans are more closely involved in the sensing loop in milk pasteurization compared to the cold-chain monitoring application where there is little or no direct user interaction with FoneAstra deployed as a long-term temperature monitor. The FoneAstra-based system to enhance FHP milk pasteurization will be piloted in HMBs in South Africa later this year, starting with the HMB at a referral hospital in the KwaZulu-Natal province [10]. We expect the unit cost of the FoneAstra-based system to be approximately USD$100. It is worth mentioning that while a simple thermometer can be used to monitor FHP, FoneAstra's ability to easily move data to remote locations for recordkeeping or QA personnel's approval is critical for scaling up HMBs in the proposed countries.

The rest of the paper is structured as follows. We present a high-level overview of the FoneAstra platform in the next section. Experiments to assess the usability of the system are discussed next. We then analyze results obtained from in-lab experiments that simulate milk pasteurization at varying heat-intensities. We conclude the paper with a discussion of future work.

SYSTEM OVERVIEW

The work presented in this paper will explore the feasibility of improved safety processes for HMBs coupled with the simple, low-tech FHP method of pasteurization. The longer-term vision is that these processes become part of the strategy to provide safe breast milk to vulnerable infants at the clinic and community levels [13]. At a high-level the system will continuously monitor the temperature of milk as it is being pasteurized by staff, providing them with feedback to control the process and reliably know that the pasteurization was completed successfully. At the end of the procedure the monitored data will be sent to QA personnel for their approval and to a remote server for recordkeeping.

FoneAstra is an ideal platform to build a low-cost safety management system that can be implemented at HMBs. It is a programmable, embedded microcontroller-based accessory that is connected to a low-tier mobile phone over a serial link (Figure 2). The embedded microcontroller (based on ARM7) supports several I/O interfaces to which a variety of external sensors can be connected. Rather than relying on internet access, which is likely to be difficult to find in remote, rural or peri-urban regions, it leverages the connected mobile phone for SMS-based communications.

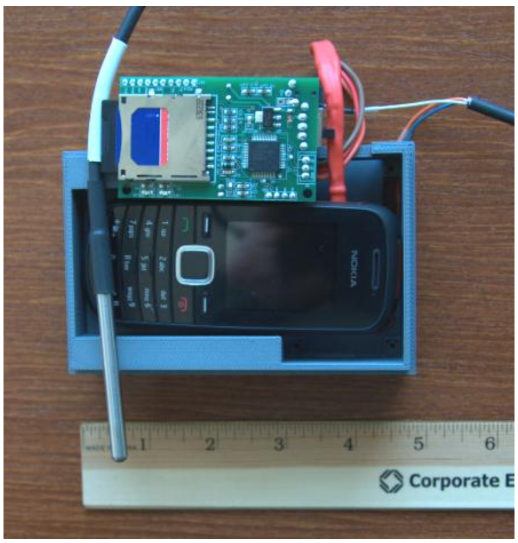

Figure 2: FoneAstra with a stainless steel, water-proof temperature probe connected to a Nokia 1661 mobile phone. The ensemble is packaged in a grey box visible around the phone (12cm X 8cm X 5cm).

For this application, a waterproof, food-grade temperature sensor probe [6] has been integrated with the board. Software running on FoneAstra continuously monitors temperature of the milk during the FHP procedure. Two LEDs and an LCD on the board provide feedback to the staff performing the procedure. The visual cues give clear indication when the high temperature condition has been achieved (72^{o}C for 15 seconds) and instruct the staff to cool the milk. When the milk has cooled down to about 40^{o}C, FoneAstra sends out an SMS message with the summarized temperature data to a QA person's mobile phone, requesting their approval. The QA person responds with an approval or rejection based on the data and this feedback is visually shown to the staff performing the pasteurization. An approval indicates that the milk is safe to be fed to an infant. The pasteurization procedure is considered complete at this point and an SMS message with the detailed temperature data is sent to a remote server for archival. Figure 3 depicts the feedback loop created by FoneAstra to assist in the pasteurization process. Audio modality for feedback is currently not implemented but will be available in a new version of the hardware.

USABILITY ASSESSMENT

Previous work on FoneAstra has focused mostly on the sensing and communication aspects of the system in which users do not have significant interactions with the device. However, users are more closely involved in the sensing loop in the milk pasteurization application and need to immediately act upon feedback from the device. This made it important for us to understand the contextual settings in which the device would be used and also evaluate the output modalities available so as to determine the most effective feedback mechanisms.

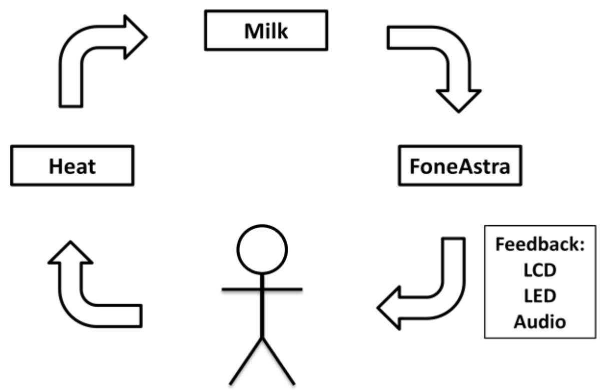

Figure 3: The feedback loop created by FoneAstra to assist in the FHP process.

	LIGHT	SOUND	TEXT
DEVICE ON AND READING TEMPS	....	No beep	Reading Temperature
REMOVE MILK FROM WATER	....	....	Remove Milk
QA PERSON IS LOOKING AT TEMPS	— — — —	No beep	Analyzing
APPROVED	———	No beep	Approved
DISAPPROVED	———	....	Disapproved

Figure 4: Results from a survey conducted to understand the effectiveness of various feedback modalities available on FoneAstra. A dotted-line under the LIGHT column indicates a blinking LED, while a solid line indicates that the LED is turned on, color of the line indicates color of the LED. A dotted-line under the SOUND column indicates a beeping sound.

Based on interviews conducted with PATH employees and HMB staff located in South Africa we learned that

FHP is done in relatively secluded rooms that will have ample space for mounting the FoneAstra-based temperature monitoring system. The HMB staff are either trained nurses or volunteers who receive some basic training to perform the procedure; this highlights the need to build a system that is very simple to use and gives clear indications to effectively guide users through the process.

FoneAstra currently uses a 16-character, 2-line LCD, a red LED and a green LED for visual output. Audio output capability is not currently available but is planned for the next revision of the hardware. We conducted online surveys with peers at the university to determine the most effective means to communicate output to the user performing pasteurization. Survey participants were shown 15 different tables (similar to Figure 4) in which each table lists the state of each output modality (table columns) at different stages of the process (table rows). For instance, cells with a dotted-line under the "LIGHT" column indicate a blinking LED while a solid line indicates that the LED is turned on. The color of the line indicates the type of LED (red or green). A dotted line in cells under the "SOUND" column indicates that the device is generating a beeping sound. We obtained responses from a total of 26 participants for this survey and Figure 4 represents the most popular choice of outputs amongst the participants. We will revalidate this with HMB staff in South Africa before implementing this feedback mechanism on the device.

Based on these survey results we conducted Wizard-of-Oz experiments in our lab where we had subjects perform the FHP process using whole milk. These experiments use a "low-fi" paper prototype of FoneAstra (shown in Figure 5). The paper prototype has 2 LEDs and an area mimicking a 2-line LCD. A strip of paper, with 2-line text strings (not shown in Figure 5) representing output for different stages of the process, is used to give textual feedback to the subject. The LEDs and textual display are controlled by the wizard during the experiment. Audio feedback has not been used in the experiments completed to date. FoneAstra's temperature probe used to monitor the temperature of the milk is connected to a laptop that is running software to sample the probe every second. The current temperature from the probe, visible to the wizard on a terminal window, is used to guide the subject through the pasteurization process. Subjects are given an overview of the pasteurization process and the visual cues they should expect before they start the procedure. As of this writing, we have done these experiments with 4 subjects and more are planned for the near-future. Observations made by the wizard and post-experiment interviews indicate that the visual feedback provided by LEDs and the paper strip are effective. However subjects feel overburdened by the need to continuously look for these visual cues. A preference for an additional audio cue has been indicated to alert them when heating should be stopped. Based on this feedback, adding support for audio beeps became a top-priority for us.

RESULTS

The goal of the FHP method is to get the milk to the high temperature condition (approximately 72°C) as fast as possible and then cool it down before use. In the current practice, it is preferred to use an open flame as the heat source since it provides heat at high intensity and does not require electricity. The water-bath reaching its boiling point (100°C), indicated by a "rolling boil", is used as the visual cue that the high temperature condition has been achieved and that milk be cooled down. While previous work has shown this indicator to be accurate in controlled environments, we expect that as operations are scaled-up, the type of heat source used and environmental conditions may vary, among other things. We wanted to understand the effect of varying intensities of heat on the FHP process. In this section, we discuss the results from our in-lab experiments in which we simulated FHP at varying heating intensities.

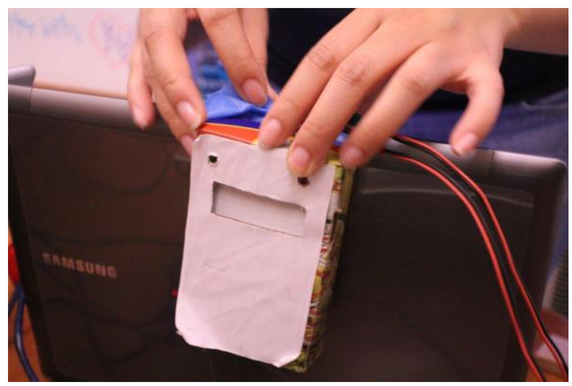

Figure 5: A paper prototype of FoneAstra used for Wizard-of-Oz experiments. LEDs are located in the two holes on the paper prototype.

Figure 6: Experimental setup. A glass jar with milk in it is placed in a water bath and heated on a stove. Two thermocouple probes connected to a DaqPRO data logger are used to monitor the temperature of milk and water respectively.

Our experimental setup, shown in Figure 6, is similar to the setup used in previous studies [5] [11]. An off-the-shelf propane gas stove was used as the heat source. A pan with 450 mL of water was used as the water-bath and 50 mL of whole milk in a glass jar was used in lieu of breast milk (since whole milk has properties closest to that of breast milk). Two thermocouple temperature sensors connected to a DaqPRO data logger [4] were used for monitoring the temperature of water and milk respectively. The data logger was configured to sample the sensor every second. The solid surface of the containers are at a higher temperature during the process than the liquids being heated, so we made sure that each sensor was completely immersed in the liquid and didn't have direct contact with its container.

Moderate Heat

Figure 7 shows the temperature curve of milk and water when a medium-intensity flame was used on the stove. In this setting we were able to replicate the results from previous studies. Milk reaches 72°C at about the time the water reaches its boiling point. The time period marked by the vertical, dotted lines represents the 15-second interval during which water was boiling and milk was in the 72°C temperature range. Milk was removed from the water-bath after this and allowed to cool down at room temperature (the sharp drop in water temperature is the removal of the probe from the water bath and its return to room temperature).

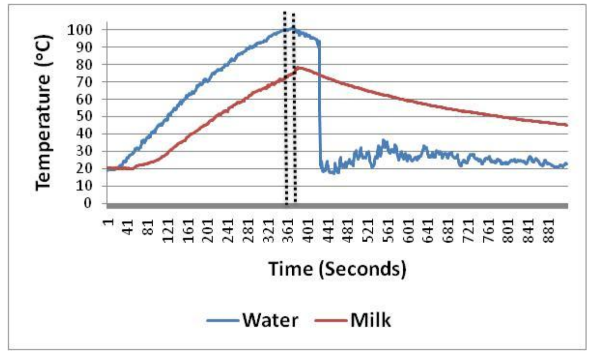

Figure 7: Temperature curve obtained on a medium intensity flame. Milk reaches 72°C at about the same time the water-bath reaches boiling point at 100°C. Milk is removed from the water-bath 15 seconds after it reaches 72°C. The 2 vertical dotted lines mark this 15-second period.

High Heat

Figure 8 shows the temperature curve of milk and water when a high-intensity flame was used on the stove. In this case water starts to boil at T=184 seconds, however milk reaches 72°C at T=250 seconds (indicated by the arrow). The vertical, dotted lines mark the 15-second interval during which water was at boiling point; milk was actually in the 55°C - 60°C range during this time. This experiment shows that milk might not have been completely pasteurized if water reaching its boiling point were used as the visual cue to remove milk from the water-bath. If milk is not heated sufficiently there is risk that the HIV virus and other contaminants might still be present and active at the end of the process. In this experiment milk was removed from the water bath 15 seconds after it reached 72°C.

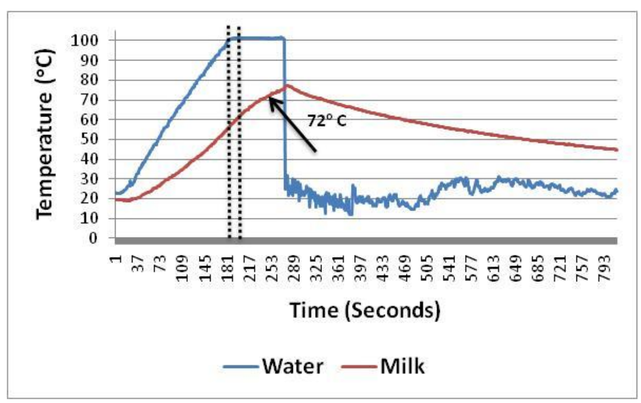

Figure 8: Temperature curve obtained on a high intensity flame. Water reaches boiling point very quickly (T=184) while milk reaches 72°C later (T=250, indicated by the arrow). This scenario shows that there is risk of not heating milk sufficiently if it is removed from the water-bath as soon as water reaches boiling point.

Low Heat

Figure 9 shows the temperature curve of milk and water when a low-intensity flame was used on the stove. In this case water never reaches its boiling point while milk reaches 72°C at T=1015 seconds (indicated by the arrow). Milk was eventually removed from the water-bath when the milk and water temperatures started to converge at around 80°C. So in this case there is risk of overheating the milk, which can lower its immunological and nutritional properties.

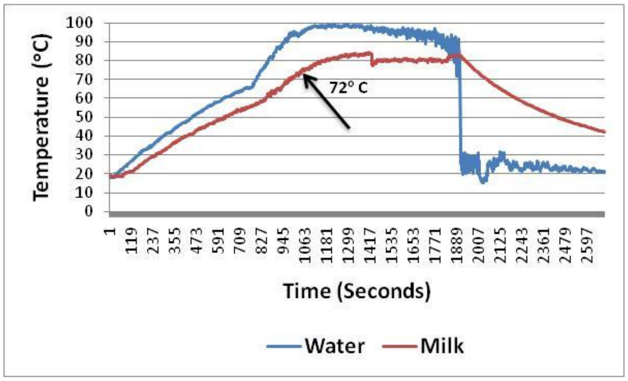

Figure 9: Temperature curve obtained on a low intensity flame. Water never reaches boiling point while the milk reaches 72°C at T=1015 (indicated by the arrow). This scenario shows that there is risk of overheating milk if the only cue available to the user is the visual indication of water reaching its boiling point. Milk was eventually removed from the water bath and cooled down.

We saw similar results when we performed experiments using electric and induction stoves as the heat source. Based on these experiments we conclude that additional recommendations must be in place to ensure that water reaching its boiling point is a reliable indicator in controlling the FHP process. Moreover, the properties of the vessel holding the milk could shift these curves to the left or right making it more difficult still to predict the outcome from visual observations alone. These results strengthen the case for providing more comprehensive protocol instructions, such as specifying the type of heating source, vessel, etc; as well as having the ability to monitor temperatures for quality assurance in low-tech pasteurization systems such as FHP.

CONCLUSION AND FUTURE WORK

We have presented a system that will be used to enhance an existing process currently prevalent in developing countries. Specifically, we are working on introducing low-cost technology to ensure the safety and procedural compliance of the flash-heat milk pasteurization process, especially when utilized by HMBs. FHP is appropriate for the resource-constrained environments of developing regions because of its simplicity and minimal infrastructure requirements. It has been shown to deactivate the HIV virus and other contaminants in human breast milk while retaining the invaluable nutritional and immunological properties of the milk. Such a method is urgently needed at the community and clinic levels to ensure that vulnerable infants with special needs get safe, healthy breast milk. FHP is currently done at small scales in homes and at a HMB in South Africa. Safety concerns have limited the method from being adopted at a larger scale.

In collaboration with PATH, we are building a system to monitor the FHP process in real-time as it is performed by HMB staff in clinics or mothers in their own homes. Our system is based on FoneAstra, a low-cost, remote monitoring system that has already been used to monitor cold-box temperatures in vaccine cold-chains. Continuous visual and audio feedback from FoneAstra, based on the direct sensing of the temperature of the milk being pasteurized, will help ensure that the procedure is performed reliably and safely for a variety of heating sources and vessels. Additionally, recorded temperature data will be sent via SMS to QA personnel for their approval. This data will also be sent to a remote server for recordkeeping and report-generation. The enhanced monitoring, feedback, and quality assurance enabled by FoneAstra will help to scale-up the adoption of Flash-Heat pasteurization at other HMBs in South Africa and other developing countries.

We have presented results from experiments and surveys conducted to understand the usability requirements of FoneAstra in the milk pasteurization application. These results will be incorporated in the implementation of the system that will be piloted later this year at a HMB in South Africa. We have already determined that audio output, currently not available on FoneAstra, will significantly improve the feedback given to users of the system. This capability will be added to the system before the pilot. Other in-lab experiments discussed in the paper simulated the pasteurization process at varying intensities of heat. Results from these experiments provide hard evidence to reinforce the need for a system that continuously monitors the temperature of milk throughout the FHP process.

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