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Novel Device to Conduct Flash-Heat Treatment in Efforts to Reduce Mother-to-Child HIV Transmission in Low-Resource Areas

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Abstract - The objective of this design project was to create a device to prevent mother-to-child transmission (MTCT) of HIV through breast milk in preterm infants. Our team created a robust and intuitive device which utilizes Flash Heat Treatment (FHT), an established method to inactivate HIV. The FHT method heats jarred breast milk in boiling water for a short amount of time, enough to denature HIV reverse transcriptase while preserving the nutritional value of breast milk. [1] Thorough observation of users and available resources in Cape Town, South Africa enabled establishment of a design that can be used in urban/peri-urban areas. User research conveyed that low cost and effortless household adaptability were the most important elements of the design. As a result, a modified electric kettle was designed to function as a breast milk pasteurization device. Published data illustrating temperature curves during FHT with corresponding virology tests on the pasteurized milk were used to verify whether the device is likely to function effectively. [2] Experimental results indicate that the device matches the required temperature profile. After virology experimentation is complete, the new device may be incorporated into hospitals as well as households in the Cape Town area, and may be expanded to other low resource periurban/urban areas as well.

Key words: flash heat treatment, HIV, PMTCT, global health

I. INTRODUCTION

An estimated 20% of adults and 31% of pregnant women are HIV positive in South Africa, the country with the highest prevalence of HIV. [3] HIV/AIDS alone is a devastating illness. Mothers with the virus have the additional burden of avoiding mother-to-child transmission of HIV (MTCT). In South Africa, the rate of MTCT through breastfeeding is 44%. [4] Although formula feeding eliminates the risk of transmission, it lacks essential nutrients and antibodies found in breast milk. Additionally, formula that is reconstituted with contaminated water sources puts neonates at high risk for water borne illnesses such as diarrhea, which may actually lead to increased fatalities. For this reason, the World Health Organization (WHO) recommends that HIV positive mothers in low-resource areas breastfeed exclusively for 6 months. Afterwards, they may introduce other foods, but should continue breastfeeding for 12 months, ceasing only when a nutritionally adequate and safe diet can be provided. [5] Transmission is prevented primarily through maternal antiretroviral drugs (ARVs), with daily infant Nevirapine given as a prophylactic during the first six weeks of life. Although ARVs are very effective, resulting in a 1.1% transmission rate while breastfeeding, there is still a small risk of transmission. [6] As a result, mothers may not be completely comfortable with standard breastfeeding. Additionally, in low resource areas outside Cape Town, ARVs may not be readily available, and therefore a standardized pasteurization method is a valuable way to maintain breastfeeding as an option.

Breast milk flash-heat inactivation effectively inactivates the HIV virus to reduce MTCT while minimizing nutritional damage. [1] However, the heat treatment method has not been clinically proven on a large scale. Currently, it is recommended as an interim strategy by the WHO when infants are ill and unable to latch, mothers are unable to breastfeed, or when ARVs are temporarily unavailable. WHO guidelines do not specify treatment for pre-term infants. [5] Premature births can trigger numerous complications, and thus far, studies have not confirmed premature infants are fully protected by ARVs. Mowbray Maternity Hospital, mandates pasteurizing breast milk for premature infants in the Cape Town area. If mother's milk is unavailable, pasteurized donor milk is prescribed in preference to formula.[7]

The fact that breastfeeding improves infant survival rate in resource poor environments even if the mother is

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HIV positive is a recent finding. Until the late 1990s, formula was the recommended feeding method. As a result, public perception still maintains formula feeding as the correct feeding method. The South African government continues to provide free formula for newborns at all public hospitals. Although free formula is available for all infants, the program was started in order to lower HIV MTCT. Recent motions to end the program have been met with skepticism. Our intent is to encourage mothers to use breast milk by giving them confidence that pasteurized milk is safe for their infants, as well as a simple and efficient method to pasteurize.

II. USER ENVIRONMENT AND DESIGN REQUIREMENTS

A. Current Practice and User Environment: Mowbray Maternity Hospital, Cape Town, South Africa

Mowbray Maternity Hospital in Cape Town, South Africa has an established procedure for breast milk flash-heat treatment, which corresponds to the protocol published by Isreal-Ballard et al. with two modifications: 1) The milk jar is sealed instead of open due to issues of instability and agitation during treatment. 2) An electric stove is used as opposed to an open flame. Their method involves the following steps:

1. A 'Black Cat' peanut butter jar is autoclaved.
2. The mother expresses her milk into the jar, and seals the jar.
3. The jar is placed into an aluminum pan and water is poured into the pan until it reaches a level about two fingers above the level of the milk.
4. The user places the pot-jar combination onto an electric stove, and sets the intensity of the stove to its maximum level.
5. The jar is removed from the pot when the water reaches a rolling boil.
6. The milk is allowed to cool, and is then given to the baby in a sterilized receptacle.

The primary users of the Mowbray Maternity heat treatment protocol are HIV positive mothers in low resource environments. These women usually reside in periurban areas, where formula is not a safe option due to extreme disease burden and lack of sanitation. Four personal interviews with mothers indicated that they are satisfied with the current pasteurization system. However, user observation in the hospital setting illustrated significant deviations from the Mowbray flash-heat protocol. Improper water to milk ratios and insufficient water heating were among the mistakes observed, which could both allow for the virus to remain intact.

After preliminary user observation and interviews, requirements as well as specifications for the design were compiled. The following three factors were of highest importance: 1) Ready adaptability to household life 2) Presence of rolling boil indicator 3) Promotion of uniform milk temperature

III. DESIGN

Fig. 1: Photograph of Kettle Heat Treatment System

A. Uniform Milk Temperature

A simplified steady state 2D heat transfer analysis was performed to determine the temperature uniformity in the milk. Observation of particle motion in the milk indicated that a pure conductive model was sufficient to describe the system. A finite difference method was used to determine whether an agitation system was necessary, and to determine how jar geometry affected temperature distribution. This method consists of creating a mesh of "nodes", where the temperature at each node is dependent on the neighboring nodes. 50 mL of milk was used in the model, corresponding to studies conducted by Isreal-Ballard et al. [2] Boundary temperature conditions were experimentally determined through conducting the Mowbray flash-heat heat treatment protocol with each jar. The standard "Black Cat" peanut butter jar was modeled, along with a widely available jelly jar. During user interviews, all mothers mentioned that they only bought "Black Cat" peanut butter for heat treatment purposes, and it was not an item they would regularly purchase. As a result, we attempted to find a jar which would promote uniform heat conduction at the same, or lower cost (R17.85).

Heat transfer analysis indicated that the greatest disparity in temperature occurred between the middle of the jar, and bottom of the jar. Analysis results also revealed that the jelly jar had an increased number of similar node values, or a more uniform temperature during heat treatment. Experimental results (detailed in the next section) verified these preliminary findings.

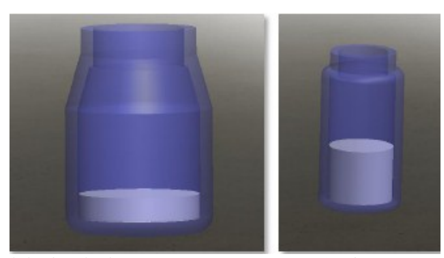

Fig. 2: Model of "Black Cat" Peanut Butter Jar (Left, 83x115mm) and Jelly Jar (Right, 50x95mm)

B. Rolling Boil indicator

In order to facilitate a “rolling boil” indicator, we began researching known, and affordable rolling boil indicators. The most obvious established indicator is a tea kettle whistle, which whistles once a liquid reaches boiling point. Although tea kettles are relatively inexpensive, a pan must be completely sealed in order for the whistle to function. Flash-heat heat treatment involves an open lid system, which keeps milk at about 72°C while the water reaches a rolling boil. A closed lid system causes the milk to reach considerably higher temperatures, which may jeopardize the integrity of important antibodies and protein in the milk. Initial personal interviews, as well as visits to homes in Cape Town townships, revealed that electric kettles are widely used, available, and affordable in urban and peri-urban areas. Conventional electric kettles (available in all major commercial super markets in South Africa) are able to quickly boil approximately 1.7 liters of water in 5-7 minutes. An audible switch on the kettle flips once the water reaches a boil, which provides both a visual and audio indicator of when to remove milk from the jar. Although electric kettles are closed systems, they are not completely sealed, and consequently the milk may follow an appropriate flash heat temperature profile.

C. Suspension System

The electric kettle requires slight modification to fully adapt to flash heat treatment. A frame was designed to suspend a milk jar from the lid of the electric kettle. A wire frame was chosen because wire and bead artistry is a significant aspect of Cape Town culture. This intricate form of craftmanship allows disadvantaged community members to be self-employed and empowered. Organizations such as “StreetWires” provide skills training as well as supplies to various townships. StreetWires provided a quote on the simple wire frame designed to encase the jelly jar: R8 (1 USD). It is designed to hook onto two rubber bands crossed on the lid of the electric kettle.

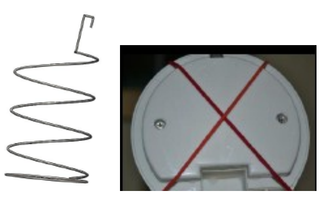

Fig. 3: Wire Frame (left) and lid modification to hold frame (right)

IV. EXPERIMENTAL RESULTS

To determine whether the design sufficiently adhered to flash-heat protocol, tests were run to establish whether the device followed a correct time-temperature profile, before proceeding to conduct virology testing. Israel-Ballard et al. published temperature profiles of milk and water during flash-heat treatment, with corresponding virology results indicating virus inactivation. [2] This temperature data was compared against kettle heat treatment temperature curves. Two thermistor probes continuously sampled both milk and water temperatures at 500 Hz. The signal was read through a National Instruments Data Acquisition system, and processed with a 10 Hz FIR low pass filter.

Following the protocol by Israel-Ballard et al., 50 mL of milk was placed in the jar. 1.6L of water was placed in the electric kettle, corresponding to “two finger widths” above the milk. The milk jar was removed from the kettle once the switch released, indicating a rolling boil.

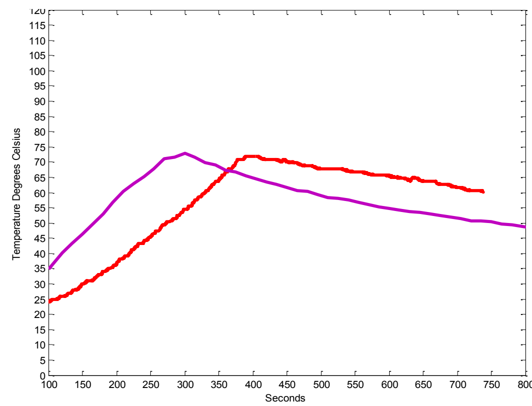

Fig. 4: Temperature Profile of Kettle Heat Treatment system and Israel-Ballard et al. conventional flash-heat system. Red: Kettle Heat Treatment milk temperature during heat treatment. Purple: Conventional flash-heat milk temperature during heat treatment.

Results (Fig. 4) suggest that the milk during kettle heat treatment follows an appropriate temperature profile, while compared to results published by Israel-Ballard et al. However, the milk does not decrease in temperature as quickly as conventional FHP. This may result in less preservation of nutrients and antibodies from the mother. Containing the milk in both the wire frame along with the jelly jar promotes continuous heat conduction even after the milk is removed from the boiling water. Further temperature testing may indicate that the milk must be released from the jelly jar after heat treatment into a different vessel to ensure proper cooling.

In order to test whether preliminary heat transfer analysis accurately identified the jelly jar dimensions as optimal for heat conduction, thermistor probes were placed at both the bottom of the milk jar, and the middle of the jar. Initial Heat transfer analysis indicated that these two areas of the jar had the greatest temperature difference, as specified earlier. Along with testing the kettle heat treatment system, the Mowbray Maternity FHP was also tested.

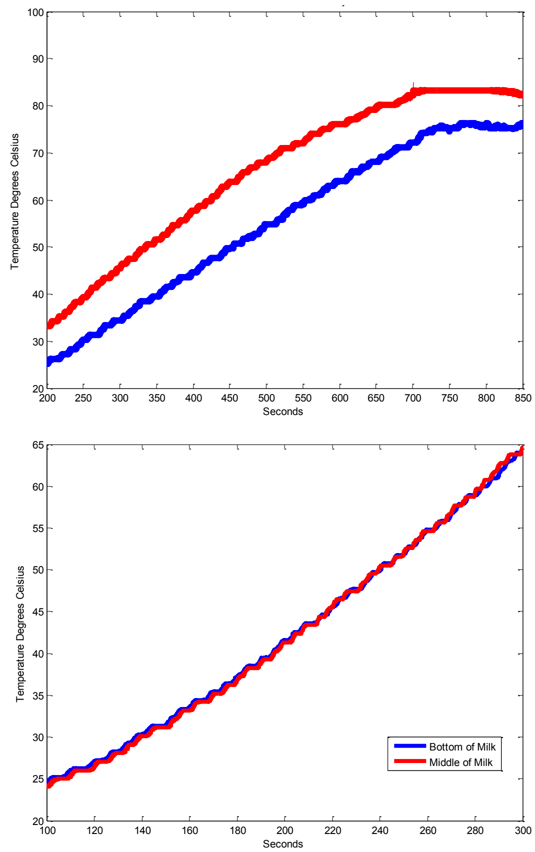

Fig. 5: Temperature Profile of bottom (blue) and middle (red) of milk jar. Top: Mowbray Maternity flash-heat treatment protocol, bottom: electric kettle flash-heat pasteruzation protocol.

Results (Fig. 5) confirmed predictions from our numerical heat transfer analysis, illustrating an approximately uniform milk temperature during heat treatment. Results from testing the Mowbray maternity protocol not only revealed a disparity between the temperature of the milk at the bottom of the jar and the middle of the jar, but a notably higher milk temperature during heat treatment. Milk at the bottom of the jar reached temperatures of approximately 80 degrees Celsius, which may lead to unnecessary damage of essential nutrients. Overall, these findings indicate that even if the protocol instituted at Mowbray Maternity hospital is carried out correctly by mothers, it may not be completely effective or optimal in terms of preserving compounds important to infant health.

V. CONCLUSION AND NEXT STEPS

This study presents preliminary results on a novel device to conduct a standardized method of flash-heat treatment in low-resource areas. The use of a modified electric kettle allows for simple integration into households. Additionally, adjustments to the kettle are so discreet, mothers concerned with the stigma of HIV will not be drawing unnecessary attention to the fact that they are pasteurizing breast milk. The modification simply consists of an addition of two rubber bands and a wire frame. The wire frame suspends the milk jar, and may also provide heat conduction along the length of the jar. Moreover, production of the wire frame benefits and involves local community members.

Overall our results indicate that the kettle heat treatment system follows an acceptable time-temperature curve. We expect that this will be confirmed by tests to measure the viability of the virus after heat treatment. After finalizing the kettle heat treatment system with further temperature and virology testing, we will identify partners to help with manufacturing and distribution to serve low-resource settings outside the Cape Town area. We hope that our efforts will both lower MTCT in premature infants, and at the same time give mothers a sense of security when feeding their infants breastmilk.

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