Breast Milk HIV Shield

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Abstract

Our work provides the foundation for what we hope might become a possible solution for reducing the transmission of HIV from mother to child via breast milk. This report summarizes some of the current research aimed at reducing this transmission and develops several novel approaches to the problem. Sodium Dodecyl Sulfate is identified as a promising compound to deactivate HIV in breast milk, though copper filtration and flash heating are also considered. The team is currently working to identify laboratories to test the efficacy of the nipple shield and thus the next step depends on these initial results.

For further information, send us an email: team@justmilk.org.

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Background and Need

Of the almost 25 Million people living with HIV in Sub-Saharan Africa, about 60% are women, leading to roughly 10 million HIV-infected potential mothers living in the region. 700,000 children are then born each year to HIV-positive mothers [1]

Without any intervention, 30-35% of mother-to-child transmission (MTCT) cases are due to breastfeeding. The

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remaining portion of MTCT cases occur in utero and at childbirth. This is called perinatal transmission. As the total percentage of MTCT ranges from between 15-45% by region, it's expected that a child born to an HIV-positive mother has a 5-10% chance of acquiring the virus via breastfeeding [2]. Therefore, 50,000 babies each year will acquire HIV via breastfeeding.

Several studies suggest that treatment with ARV's can be effective at reducing the risk of perinatal transmission. For example, a 2004 study showed that taking antiretroviral therapy and giving birth by cesarean section leads to a transmission rate of only 1% [3]. Unfortunately, the implementation of programs to prevent perinatal transmission has been slow. So even though the percentage of HIV-positive pregnant women in low- and middle-income countries that have access to ARV's has increased from 10% in 2004 to 23% in 2006, coverage varies significantly by country, with, for example, only 7% coverage in West and Central Africa in 2006 [4]. Indeed, Dr. Arletty Pinel, the Chief of UNFPA Reproductive Health Branch said in 2006 that, "these programmes (to prevent perinatal transmission) have been a failure. Despite the fact that the global HIV response is now awash in funding, pregnant women still don't have access to the drugs that will prevent them from passing the virus on to their children." So although progress has been made since 2006, programs in most countries still have to work to increase coverage.

However, programs to prevent post-natal transmission of HIV through breast feeding have not been evaluated as widely as the programs to prevent perinatal transmission, and the latest WHO recommendations leave the majority of women in low-resource settings with difficult choices and some uncertainty as what is best to do, since formula feeding is not a realistic option for most women.

The WHO policy states that, "when replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended. Otherwise, exclusive breastfeeding is recommended during the first months of life." [5]. This is because using formula in low-resource settings has been shown to decrease infant survival due to increased numbers of deaths from diarrhea and malnutrition [6]. In terms of specific breast-feeding recommendations, the situation is also ambiguous. Some of the most recent published data from a study of exclusive breast feeding followed by rapid weaning in Zambia [7] has shown no benefit for the intervention group compared to a control group that followed traditional breast feeding practices. About 7% of infants in both groups became HIV infected via breast milk between four and 24 months of age.

So, given the difficulties and lack of certainty regarding prevention methods for MTCT through breastfeeding, we've identified a definite and significant need for an appropriate breast milk treatment system.

Methods of Breast Milk Deactivation

Flash Heating

Flash heating, as well as pretoria pasteurization (longer duration heating), have been shown to effectively remove HIV from milk. Procedurally, using the flash-heating method, a mother first expresses 75-150 mL of breast milk into a glass jar. The jar is then placed in a pot of water, which is brought to a boil. At this point the milk can be removed, and fed to the baby once it cools to an acceptable temperature [8].

Flash heating utilizes materials that are already found around the home, which could put the mother's

upfront cost of the device at virtually zero. Furthermore, daily cooking is done by most families, so that the boiling of the milk might be incorporated into everyday life. Again, both the flash heating and pretoria pasteurization methods have been proven to effectively remove HIV from milk [9]. Additional research has also been conducted into the degree to which these methods damage the vitamin content of breast milk. Broadly speaking, no significant damage to the nutritional content of the milk was detected, though flash heating seemed slightly more nutritionally preservative [10].

However, the flash heating method could require more boiling than is typical for a mother's routine, which might require increased time, effort, and money to acquire the extra fuel. Even if the heating were somehow incorporated entirely into the daily cooking, performing the acts of manually expressing enough milk (often 600mL/day), storing the milk, and finally delivering the milk to the child are simply not practical for many women. Furthermore, by blatantly not breastfeeding a child, a woman is often subject to the stigma of being HIV+, a reality that many women and their families are reluctant to admit. Acceptability studies looking into the heat treatment of breast milk in Zimbabwean society have been performed [11]. The results indicate that it would be acceptable if correctly introduced and understood, however this acknowledgment required a resource intensive small-group discussion even in the study. Many people were hesitant of the method’s effectiveness and the inconveniences of having to boil water on a frequent basis.

Copper

Research has shown that impregnating fibers and/or polypropylene filters with a copper-oxide mixture (70% Cu2O and 30% CuO, >99% purity [12]) can be used as a biocidal method of removing HIV-1. Work has not yet been done in putting this into a user-oriented device for a breastfeeding application.

Copper, along with copper impregnated fibers, is very cheap [12] We also suspect that copper-based filters might be more easily marketed ("all-natural") than chemical microbicide based ones. However,

possible effects of copper on breast milk constituents have not been well researched. Indeed, neither in-vivo nor even comprehensive in-vitro studies have been carried out. However, copper filtration does look promising, and if proven effective and appropriate, our final design could easily incorporate a copper-based filter.

Sodium Dodecyl Sulfate (SDS)

Sodium dodecyl sulfate (SDS), also known as Sodium lauryl sulfate (SLS), is a surfactant commonly found in toothpaste, shampoo, etc. Recent in-vitro work has shown that SDS, in concentrations as low as .1%, is highly effective at eliminating HIV-1 [13]. An in-vivo study involving goats is ongoing. SDS is also extremely inexpensive.

However, similar to copper, possible nutritional side effects of infant SDS intake via breast milk have not been extensively researched. In this case though, nutritional in-vitro studies have been carried out, and in-vivo research is further along. SDS can also cause skin irritation, depending on the concentration and duration of contact. There are also concerns of SDS affecting taste. Similar to drinking orange juice after brushing your teeth, SDS has been shown to temporarily decrease the reception of sweet tastes.

Contextual Considerations

Time constraints dictated that we could not undertake formal studies of our potential market; in addition the innovative nature of our device means that no context specific studies have taken place in the past by other parties. We therefore sought to analyze our market by contacting representative authorities in affected regions and gathering testimonials that would provide an indication of the desirability and viability of the project. The anecdotal evidence gathered was from various regions in Sub-Saharan Africa, including Malawi, Tanzania and Zimbabwe.

Our primary contact in Malawi, Mrs. Stella Chiphangwi, a senior matron at Open Arms Malawi (a care home for children affected by HIV) informed us that the official Government line for HIV positive mothers was strictly no breast-feeding, to prevent MTCT. This means that mothers are forced to source formula from either hospitals or NGO's, if they are financially incapable of purchasing their own. This introduces a variety of problems, including that many babies die after contracting diarrhea and malnutrition, due to insufficient formula and use of contaminated water for mixing. On a more personal level, if a mother is visibly not breastfeeding her new-born, a very natural and culturally open practice in Malawi, this has the effect of drawing unwanted attention to the mother for not following the norm, and results in some stigmatization if it is revealed that she is HIV positive. More crucially, the mothers are highly concerned about not being able to provide enough nutrition for their child. It was from this perspective that Mrs. Chipangwe added that these mothers would indeed love to breastfeed their children, and that a proposed discreet device such as the nipple shield would be highly desirable. However, she emphasized that the role of education on the effectiveness and practicality of the device would be crucial on the uptake and acceptance, should the device be disseminated.

Mrs. Gloria Sangiwa, the Senior Technical Adviser for HIV/AIDS care and treatment for FHI (Family Health International), provided us with insight for the current status of HIV and breastfeeding in Tanzania. In contrast to Malawi, the official government policy is exclusive breastfeeding for six months followed by non-abrupt weaning. She encouraged us to explore the feasibility of different systems such as the maternity bra and breast-shield concept in different settings, as uptake would vary from region to region, considering the cultural and customary practice differences present. She also underlined that currently nobody in Tanzania was using the flash-heating method for de-activating HIV, and she considers that it is 'culturally impossible' to adopt this method as the main approach for preventing MTCT. On the other hand, she was very optimistic of the viability of the nipple-shield concept, and recommended that this was an avenue we should continue to explore.

Mrs. Ruth Mufute of Africare provided us with input more specific to Zimbabwe. According to her, most mothers in rural settings often breastfeed for up to a year or more because they can't afford formula and

breastmilk is their best source of nutrition. She also informed us that the whole community was involved in decisions where breast-feeding was concerned, indicating that like Malawi it is not considered a private practice at all. Due to this public nature she recommended that it might be convenient if the mother is wearing the treatment device all day, to prevent the drawing of unnecessary attention to her if she is required to apply and remove it during every feed. Regarding how we might consider disseminating the proposed technology, she suggested the use of midwives to distribute the technology, as well using them as agents to advise, promote and inform the HIV mothers about the efficacy and value of using such a device. In addition, she added that we may choose to market the nipple shield as a tool to be used by both HIV negative and HIV positive mothers, making the concept more acceptable and less alienating.

Design Requirements

With the above considerations, we need something that fulfills the following requirements:

Low cost

- The device should (after possible subsidization) be of sufficiently low cost to be affordable to be bought by the mother (or family) without detrimental effects to the mother's livelihood or health.

Convenient and acceptable for the mother to use

- The device should be quick and relatively unobtrusive for use by the mother. It must be able to be used outside the home environment. There is a need to minimize the display of the device to avoid the mother being identified as having HIV. This will be community specific depending on the stigma of HIV in specific regions.

Acceptable by the baby

- The device must in a form so that intake is readily accepted by the baby. Mimicking the breast feeding experience as closely as possible is ideal.

Easy to clean/maintain

- The device must be quick and easy to clean. It should have as little an effect as possible on the daily routine of the mother.

Fast

- The time that the process of treating the HIV takes must be minimized; it cannot take up a large proportion of the mother's time during the day which may be spent working.

No nutritional side effects

Initial Concept Devices

Flash Heating

- Integrated bottle/heater (wire mesh around outside)
- Thermal storage heating
- Phase changing materials/gels
- Bottle/heater that hooks around cooking pot
- Low cost breast pump to ease what would have to be manual expression

Filtering Device

- Filtering column/straw that increases contact time of milk to Copper/SDS. Might require extra pressure (hand pump, etc.)
- A reservoir for storing SDS, drip into another reservoir for mixing SDS and milk, etc. Might be incorporated into "super bra". Such a two-stage system could also be used with copper particulates, as opposed to fiber-impregnated SDS or copper.
- Small filter (multi-stage or single stage) incorporated directly into nipple shield.

Final Concept Device

Given our research regarding the gravity of some of the contextual challenges that devices which required significant amounts of time or effort to operate would face, we decided that the small nipple-shield filter device is the only design which could possibly be successfully implemented.

Our intention is to prototype several different designs in this general fashion, which we expect will have different flow rates, requisite suction power, SDS impregnation statistics, etc. Below are renderings of some possibilities (coming soon).

Testing of Devices

- SDS at 20% concentration and 99%+ purity was available.
- Measuring concentration of SDS.

- Refractive Index

- Conductivity

- Viscosity?

- pH?

- Surface tension

- Flash point?

Team Information

- Tombo Banda, Mechanical Engineering, Imperial College, UK
- Geoff Galgon, Mathematics and Economics, California Institute of Technology, USA
- Stephen Gerrard, Chemical Engineering, Cambridge University, UK
- Ryan Hubbard, Systems Engineering, Olin College, USA
- Elizabeth Kneen, Mechanical Engineering, Olin College, USA
- David Sokal MD, Scientist, Behavioral and Biomedical Research, Family Health International, USA

Media and Publications

- Engineers Without Borders (UK) [5] (http://www.ewb-uk.org/node/3843)

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* The Engineer Online (UK) [6] (http://www.theengineer.co.uk/Articles/308081/Blocking+trar
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