EWH Design Competition Proposal for:
Kifua Pampu: Breast Pump to Help Reduce Mother to Child HIV Infections

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1. Problem definition:

Transmission of HIV through breast milk is a major concern in low-resource settings where alternatives are not readily available. In 2016, 110,000 children aged 0 to 14 were living with HIV in Tanzania and ~40% of them contracted HIV through breastfeeding. The Tanzania Food and Nutrition Center reported that 57% of babies are not exclusively breastfed for 6 months, and a major reason for this is the fear of HIV transmission. There are also many side effects of not exclusively breastfeeding an infant for 6 months. For example, infants who are given cow's milk in the first 6 months are more susceptible to iron deficiency and gastrointestinal tract infections [1]. Unfortunately, over 40% of children in Tanzania remain malnourished and increasing the percentage of mothers breastfeeding their children can have a substantial impact. While in most cases getting antiretroviral treatment is the best option, it is not widely available and it must be taken consistently to be effective. Over the last 10 years in Tanzania, the percent of antiretroviral treatment coverage has increased significantly, but as of 2017 according to UNAIDS only 66% of people HIV positive were receiving antiretroviral treatment [2].

Therefore, we are developing a breast pump that can discreetly scrub HIV from the breast milk while also seeking to lower malnutrition rates. Regardless of the mother's HIV status, our pump is a low-cost system affordable and robust enough that it can be used in all environments. The design of our pump will allow it to be switched from manual to automatic, providing easy use for all mothers. Incorporated into this pump will be a filter to inactivate HIV and provide antimicrobial properties.

2. Impact in developing world

In rural settings without access to antiretroviral treatment, the only way for a mother to ensure she does not pass HIV onto her child is by not breastfeeding. Our goal is to eliminate this need of sacrifice and promote breastfeeding of infants so they are less susceptible to illness and infections. Currently there is a significant social stigma surrounding HIV which makes it less likely for mothers affected to seek help due to fear of being identified as HIV positive. Therefore, this unit will be marketed as a consumer product rather than a medical device. The description will be set as a “breast pump with antimicrobial effects” in order to appeal to women both affected and unaffected by HIV. Though the main attractive point of the product is the filter which acts as an inactivator of HIV, we want to be able to provide the product to women in need without publicly announcing that they are a carrier of the infection. This allows customers to discreetly use the breast pump without fear of wearing the social stigma that typically comes with HIV. In doing this, the market will also be expanded from those infected to anyone who requires a breast pump. Without the limiting label of a medical device, customers from all areas will be able to access the product and allows for a wider span of adoption opportunities. The potential accepted use of a breast pump can also serve as an empowerment tool for women. This can encourage women to pursue a work life and not be limited by child care.

3. Required performance specifications

We will be using silver nanoparticles that have previously shown to inactivate HIV from multiple cell lines. It has been previously reported that silver nanoparticle coated condoms were effective in inactivating HIV in C8166 T cells [3]. This same study also looked at the antimicrobial properties and cytotoxicity of silver nanoparticles, and they reported a significant decrease in bacterial growth and limited cytotoxicity to HeLa cells [3]. Silver nanoparticles have also been used to prevent transmission of HIV in human cervical cells with no significant cytotoxicity [4].

While we cannot test this in our current labs at Clemson, the goal is for the silver to leech off of the filter, come in contact with the milk, and inactivate the virus to undetectable levels. We also want our device to act as an antimicrobial agent and increase the shelf life of breastmilk. We can test this by identifying common bacteria that causes breast milk to spoil and perform tests to determine the efficacy of our filter as an antimicrobial agent.

The breast pump that the filter will be placed in is simply a modification of an existing breast pump, and it will be tested to ensure it can work efficiently as before. Flow rate of milk from mothers typically ranges from 0 to 4.6 grams per 5 second period, but is dependent on the frequency at which mothers pump.

From research on developing countries, and from personal experience in Tanzania, breast pumps are not widely used and available in rural areas. Part of the problem is sterilization of the pump without access to clean water. It has also come to our attention that this product would be shared by mothers in rural areas and therefore would need to be easily shared between mothers with HIV and those without HIV.

4. Implementation of prototype

We have designed a prototype of our breast pump that is able to convert a manual pump to an electrically powered pump. This was done by retrofitting an existing manual breast pump with a 3D printed cap that created an airtight seal. This can then be attached to a power source with a motor and pump to make an electrically powered breast pump. Switching from manual to automatic is simple and fast, allowing for easy use from mothers with or without access to power. (Figure 1 of flow diagram of breast pump design)

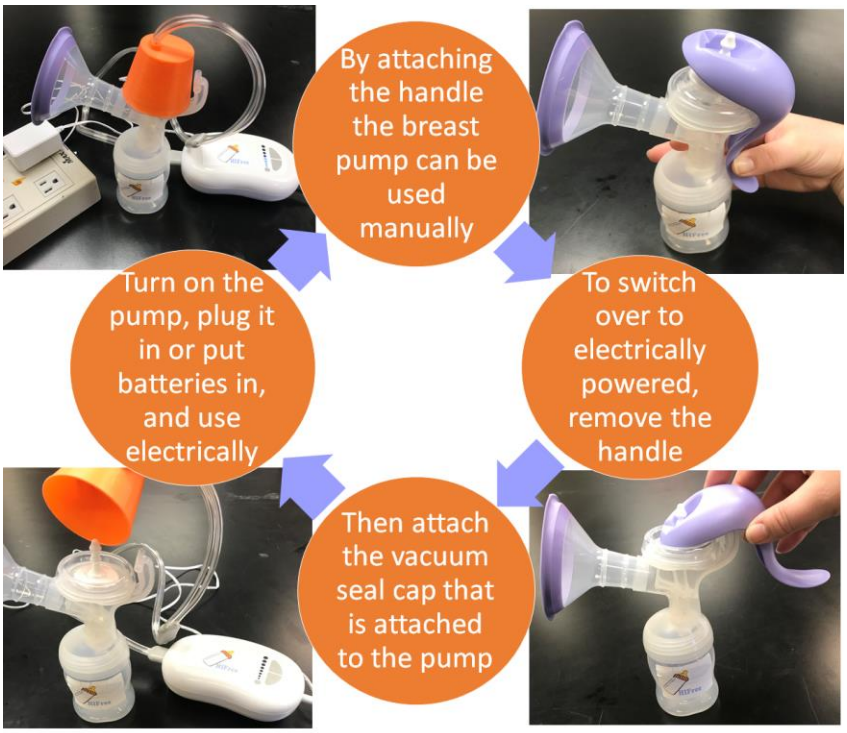

Figure 1. Prototype breast pump showing manual and electrical pumping mechanism and how to convert between the two modes. Below is picture showing the location of the filter assembly in the neck of the pump.

As far as prototyping the filter component of this device, we are currently in progress of optimizing the filter design. Our current prototype is a woven polymer into a knitted polymer material with silver nanoparticles absorbed into the polymer surface of the filter (Figure 2). The weaving of the polymer allows for control of the filter pore size, which will maximize contact of the milk with the surface while not impeding the flow greatly. Surface adhesion of the silver nanoparticles will allow diffusion of these nanoparticles into the milk to increase the efficacy of this device by increasing contact time of the silver nanoparticles into the milk while keeping the silver concentration in the milk at a safe level to ingest.

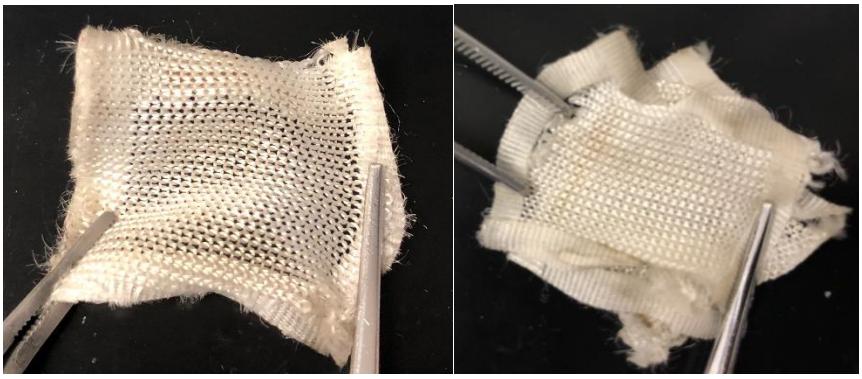

Figure 2. Preliminary filter design used in Proof of Performance tests. Left image shows one layer of knitted polymer mesh. The layers can be stacked to create a multilayered woven filter (right image). The individual polymer fibers are pulled and then coated with silver nanoparticles. The weaving of the strands for each layer controls the pore size for an individual mesh layers.

5. Proof of performance

Because our breast pump prototype is a modification of an existing on market breast pump (Figure 1), it would meet the same performance specifications as any commercial pump. The modification would allow our breast pump to exceed most breast pumps on the market because of its easy conversion from manual to automatic.

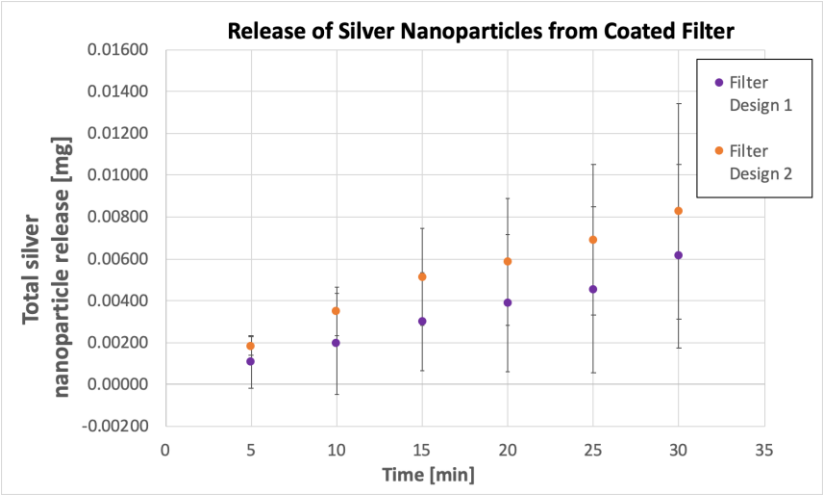

Figure 3. Release of silver nanoparticles from the prototype (single layer) woven mesh filters.

As a preliminary test we absorbed silver nanoparticles into a woven polymer mesh square (Figure 2) and measured the leaching of silver nanoparticles from the filter over a period of 30 minutes (Figure 3). There was a linear trend of total silver nanoparticle release from the filter over the 30min test (Figure 3). In this preliminary test, the silver release from our new filter material was similar to that from silver-coated condoms [3] and was at concentrations similar to what was found to be effective at inhibiting HIV in vitro while staying well below levels known

to be cytotoxic [4]. While this is simply a preliminary test, in continuing tests, we will perform this experiment again with longer times and with higher flow rates to determine how much total silver can be released over the lifetime of the filter. With this data, we will be able to determine the number of uses that a filter could be used in the field. It is recommended that a mother exclusively breastfeeds for 6 months [1], so ideally this device would include enough filters to at least reach the minimum time of 6 months.

6. Business plan for manufacture and distribution of the technology

The plan for the initial funding for this project is to apply for grants relevant to the prevention of the transmission of HIV. The National Institute of Health has a library of grants to support the 90/90/90 prevention and treatment goal of achieving 90% of HIV infected people knowing their status, 90% of diagnosed patients being treated with antiretrovirals, and 90% of those treated to have viral suppression. The Funding Opportunity Announcement (FOA) we plan to submit to is **PA-18-780.** This solicitation is specifically focused on *"feasibility, tolerability, acceptability and safety of novel or adapted interventions that target HIV prevention, treatment or services research"* [5]. The grant can provide us with up to $450,000 over a 3 year period to support research, prototype production, and testing to prove safety and efficacy.

The pump and bottle portion of our product will need to be injection molded for mass production. In order to produce our product we will initially have to partner with contract manufacturers who specialize in injection molding of medical grade plastics. We will work with them to make the design simple to drive costs down and make it easier for mothers in Tanzania to clean. A company we have looked into partnering with is PTI Engineered Plastics. They specialize in injection molding for medical products as well as other sectors. This company would also be ideal, because they do contract manufacturing and have explicitly stated they work closely with the designers to come up with the most optimal design for manufacturing. Once we have determined the optimal method of making it and the polymer to use, we also will partner with a contract manufacture to produce our filters. We have looked into partnering with PolyMed due to their experience in making medical grade polymeric materials and their close proximity to us. After manufacturing we will partner with a packaging company in order to prepare it for distribution. Since breast pumps are a consumer product and not something that has to be sterilized in its packaging, this will allow us a quicker path to consumers.

Our breast pump will be a consumer product, sold directly to stores for distribution. Since the primary way we will market our product is a breast pump used to lengthen the overall shelf life of the milk, this will broaden our market further to any working mother who wishes to pump for her baby to be fed at a later time. We believe our product will be a class II device under FDA regulations. This is because even though a breast pump is a class I device, the addition of our filter moves it up a regulatory classification. We believe we can prove substantial equivalence to other products on the market that use silver as an antimicrobial agent and silver condoms that have been used to prevent HIV transmission. After clearance we hope to partner with a non-

profit organization to help bring our pump to Tanzania. After piloting it in Tanzania, we hope for it to spread to other low resource regions.

References:

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