

Acceptability of a Modified Nipple Shield Device to Reduce Breast Milk Transmission of HIV in Developing Countries: A Qualitative Study

Introduction

In low-resource settings, breastfeeding is protective against infant morbidity and mortality, yet can be a significant source of mother-to-child transmission of HIV. The current WHO-recommended method to prevent HIV transmission via breast milk is with the use of antiretrovirals (ARVs) given to either the mother or the infant.¹ Heat treatment of expressed breast milk has been endorsed by WHO as an interim strategy under certain circumstances, but has not yet been widely implemented.² Alternative options that are both feasible and viable are urgently needed to make breastfeeding safe for HIV-positive breastfeeding mothers.

As a potential solution, FHI has developed a novel, low-cost, Modified Nipple Shield Device (MNSD) based upon a conventional nipple shield that could be used discreetly by HIV-positive mothers for prevention of mother-to-child transmission (PMTCT) during breastfeeding. During or shortly after the passage of breast milk through the shield, HIV is killed when it comes in contact with a non-woven textile disk containing sodium dodecyl sulfate (SDS), a virucide that has been shown in vitro to kill HIV at concentrations as low as 0.025% without affecting breast milk’s immunological and nutritional factors.³ PATH and FHI collaborated to explore the hypothetical acceptability of the MNSD in the Western Province of Kenya.

Modified Nipple Shield Device Prototype



Breast shield with replaceable filter inserted



"Drug loaded" filter



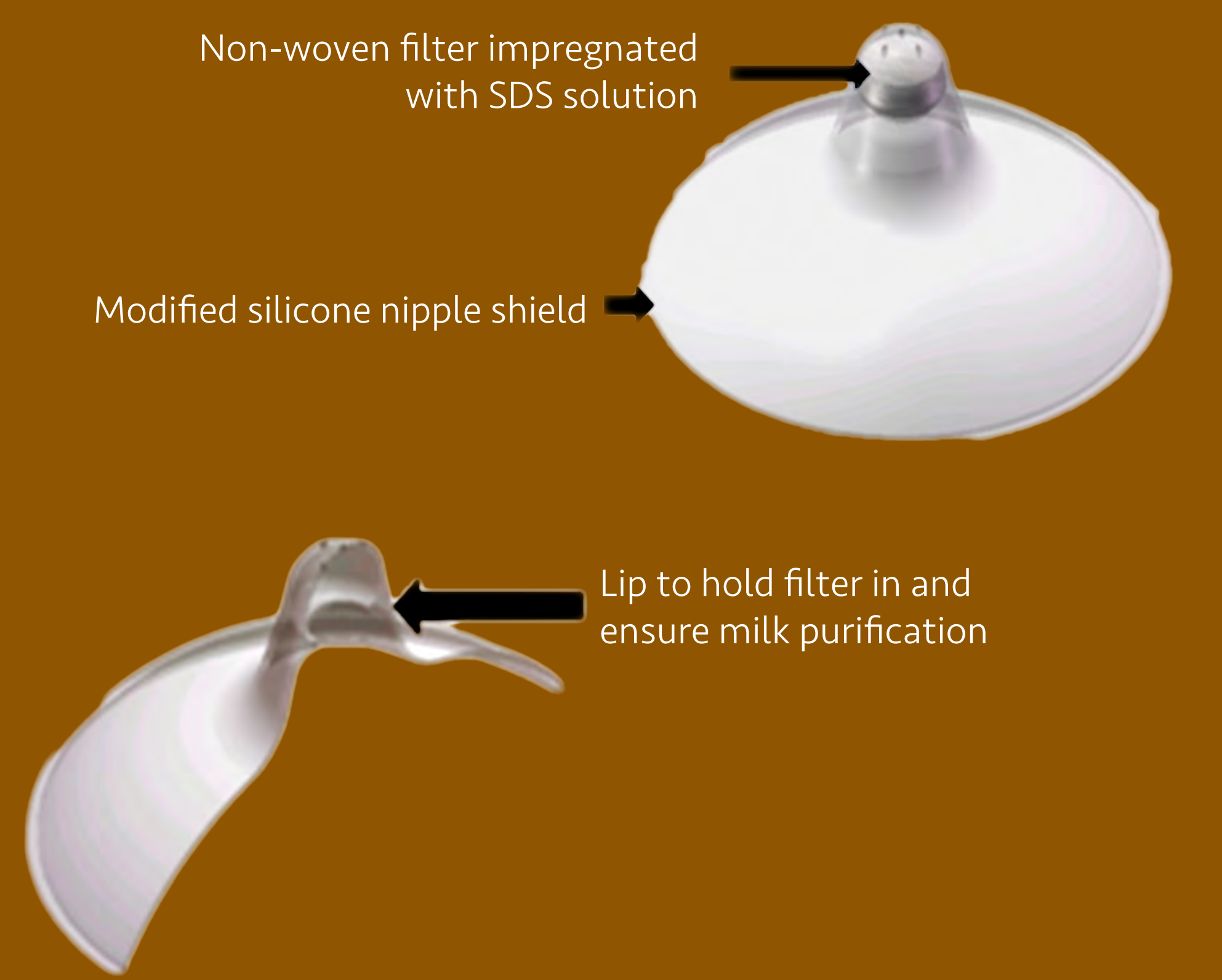
Filters stored in blister pack

Study Objective

The primary objective of this study was to determine the acceptability of using the MNSD as a strategy to reduce postnatal transmission of HIV and to make breastfeeding safe in low-resource settings. Secondary objectives included the following: (1) to assess mothers’ understanding of how mother-to-child transmission of HIV occurs; (2) to examine the cultural context that might affect acceptance of a device like the MNSD; (3) to identify potential disadvantages and challenges of using, cleaning, and storing the MNSD; and, (4) to identify potential design and implementation issues for the MNSD.



Schematic drawing of FHI's Modified Nipple Shield Device (patent pending).



Methods

Qualitative data collection occurred in Nairobi and Western Province in Kenya. Eleven focus group discussions (FGDs) were held separately with HIV-positive mothers who were breastfeeding at the time of the FGD (n=69), grandmothers/mothers-in-law (n=16), and fathers/husbands (n=18). The topics discussed during the FGDs included HIV and infant feeding, stigma, community perceptions, cultural beliefs, the MNSD concept, how the device kills HIV, and its potential acceptability in the respondents’ communities. In addition, ten in-depth individual interviews were conducted with local maternal and child healthcare providers. The topics discussed during the in-depth individual interviews were similar to those in the FGDs, but also included broader discussions about future implementation strategies and what would be needed for the MNSD to be considered a feasible and safe option for PMTCT when breastfeeding. MNSD prototypes were used to facilitate discussions. The transcripts were uploaded into NVivo Version 8.0 and then structurally and content coded.

Results

The FGD respondents and healthcare stakeholders identified four primary themes during their discussions about the MNSD: (1) stigma; (2) hygiene; (3) efficacy and safety; and, (4) access.

1. Stigma

For most FGD respondents and healthcare stakeholders, their greatest concern regarding the MNSD is countering potential stigmatization of mothers as HIV positive. They discussed the following factors:

- Designing the device to ensure a mother’s privacy.
- Disclosure of HIV status to relatives and neighbors.
- Overcoming the fear of HIV testing and being treated at a healthcare facility.
- Education and sensitization of the community.

“For me, the challenge is how one would be able to keep the HIV status a secret when using this thing. I would not like to give birth again. My HIV status was my secret, because I had not yet disclosed it even to my husband, so when breastfeeding, I would have to hide. I am thinking about those who want to have children, if they breastfeed using in the presence of their relatives, they will ask why you are breastfeeding through the Nipple Shield. That will be a question that she may not be able to answer.” (Mother, Kibera)

“...Stigma is a major challenge even in HIV management. So whatever we do we need to de-stigmatize HIV within the urban set-up...we have had people not wanting to go for HIV tests and treatments...sometime back there were reports that some people would rather share their (HIV) medicines than go to the clinic. What was causing that? Stigma issues within the urban set-up. It’s not just within the rural areas. Stigma cuts across urban and rural. And so the acceptability and usability will depend on how well the product is marketed and it will also depend upon the individual’s own initiative.” (Healthcare stakeholder, Nairobi)

2. Hygiene

Most FGD respondents and the healthcare stakeholders agreed that maintaining the cleanliness of the MNSD, although challenging, was possible and considered similar to safe bottle feeding. They offered the following solutions for cleaning and reducing potential contamination:

- Discard the MNSD and/or the replacement disks after each use.
- Use hot or boiling water.
- Store in a clean container that is washable and safe.
- Wash and/or store in disinfectant.

“So if you are going to re-use that you are introducing another aspect to the whole scenario. You are introducing infection. So how will you control for that infection? So personally, if it can be discarded...use once, discard, that would be the ideal. If it’s not possible, then you may...the shield itself you can re-use, but the disk you have to discard.” (Healthcare stakeholder, Nairobi)

“We should have something like a bottle for storing the Nipple Shield. This bottle should have water and then we should have some disinfectant put in that water so that if there are any germs they will be killed. I know that cleaning will be a problem for many mothers because boiling water will take their time. With this disinfectant, even if she washes with cold water, it will be okay.” (Father, Kakamega)

3. Efficacy and Safety

The majority of FGD respondents and healthcare stakeholders agreed that mothers would trust that the MNSD destroys HIV in breast milk and could be a mechanism of providing safe breast milk to their infants for the following reasons:

- If mothers receive education about the MNSD.
- If mothers see one another using the MNSD successfully (i.e., their babies are testing negative for HIV).
- If doctors and scientists advise its use.
- If using the MNSD is part of the PMTCT package (similar to ARVs).



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Results, cont.

“You see, when ARVs were introduced, it took time for some people to trust them. But now, they are never late for their appointments to get their dose of ARVs. We are shining with ARVs. Why would we refuse to shine with this one?” (Mother, Bungoma)

“[Mothers] will not trust it if they see it not working for those who have used it. But if they see them in good health, and they have accepted their HIV status and go to the doctor for advice and now are okay, they will trust it. I don’t think that there is any who would say that they do not want. It is just like ARVs. They will trust it as long as they are educated about it.” (Grandmother, Kakamega)

4. Access

Most FGD respondents and healthcare stakeholders agreed that any infant feeding options for PMTCT should be AFASS: affordable, feasible, acceptable, sustainable and safe.

The MNSD “must be something that is AFASS. That means it must be something a mother can easily buy even if the program comes to an end.” (Healthcare stakeholder, Kakamega)

“It is better not to know about that thing that can save my child’s life than to know about it and not be able to buy it. That will be very painful.” (Mother, Bungoma)

Conclusions

Respondents felt the MNSD was a promising approach for reducing MTCT in their communities. The following would need to be addressed to ensure effective and safe implementation:

- Development of an easy and standardized method for cleaning the MNSD.
- Studies to confirm safety and efficacy.
- Reduction or elimination of costs for purchasing MNSD and replacement disks.
- Sensitization of communities to reduce HIV-related stigma.
- Promotion by healthcare professionals beginning at the national level with the Ministry of Health.

References

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