

# Community feedback on the JustMilk Nipple Shield Delivery System in the Vhembe District of Limpopo Province, South Africa

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**Background.** Infant medication administration is a major public-health challenge, especially in rural or low-resource areas. The JustMilk Nipple Shield Delivery System (NSDS) is a novel method of infant medication delivery designed to address some of these challenges.

**Objective.** To explore the acceptability of the JustMilk NSDS in selected communities in the Vhembe District of Limpopo, South Africa.

**Methods.** Data were collected through 39 semi-structured interviews and in five small groups (a total of 44 interviewees) with infant caretakers and health workers in the Vhembe District. Interviews were transcribed and coded into themes, which were verified by an independent coder.

**Results.** Four themes arose around the acceptability of the JustMilk NSDS: input on device design; perceived benefits of the device; perceived barriers to community acceptance; and suggested device applications. Participants expressed positivity about the NSDS concept. The potential for increased dosing accuracy was stated as the main positive attribute of the NSDS. Potential stigma was noted, and the need for an education programme on the device was discussed. No major community barriers to NSDS use were noted. Acetaminophen and deworming agents were suggested as potential applications for the device.

**Conclusion.** Participants were enthusiastic about the potential benefits of the NSDS, and were interested in using the device to deliver medication to infants. Design suggestions, especially to combat the potential stigma of device use, will be thoroughly considered by the researchers. This study was a positive step forward in developing the NSDS as a novel method of medication delivery to breastfeeding infants, particularly in rural or low-resource areas.

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The purpose of this study was to identify factors that might influence the user-acceptability of the JustMilk Nipple Shield Delivery System (NSDS), a novel platform for delivering drugs and nutrients to breastfeeding infants, in the Vhembe District of Limpopo, South Africa (SA). Paediatric medication delivery is a major public-health challenge. Most medications are designed for adults, often resulting in a lack of both dosage-appropriate formulations for infants, and suitable methods for delivering infant medications.<sup>[1]</sup> The most common infant drug-delivery devices are measuring spoons, dosing cups and oral syringes, all of which deliver liquid formulations and can lead to dosing errors.<sup>[1,2]</sup> Additionally, they have the following problems: cold chain and refrigerated storage requirements; unpalatability; and the potential presence of harmful excipients.<sup>[3]</sup> Alternatively, solid dispersible tablets must be dissolved in potable water in a clean container before being administered as above.<sup>[4]</sup> The development of safe, effective and affordable paediatric drug delivery devices is crucial to alleviate these problems.<sup>[1,5]</sup>

The JustMilk NSDS combines a modified nipple-shield with a dosage form such as a rapidly disintegrating tablet, and is currently in preclinical studies.<sup>[6-9]</sup> To use the NSDS, a mother places it over her breast, and as she breastfeeds, milk passes through the device, causing the active pharmaceutical ingredients (APIs) to be released directly from the tablet into the breast milk, which passes to the infant. The tablet is predosed with the infant medication and is designed to be rapidly delivered during feeding to minimise dosing concerns. Since the device utilises human milk as the tablet's dissolving agent, potable

water is not required to dissolve the tablet. The solid dispersible tablet may have a longer shelf life than liquid medication.

Limpopo is the northern-most province in SA, and has a population of 5.4 million. It is the most rural SA province, with 87% of the population considered rural, compared with the national average of 43%.<sup>[10]</sup> In this area, with limited access to health clinics, which often use liquid formulations, the long shelf-life of a dry NSDS tablet insert could be beneficial.<sup>[11]</sup> The generally higher range of temperature stability with tablets (compared with liquids) could also be of use during the area's exceptionally hot and rainy summer seasons. In addition, intermittent electricity in the region may compromise refrigeration options for liquid formulations.<sup>[12]</sup> Limited access to potable water suggests that the potentially disposable nature of the device might be useful, as there would be no need to hygienically clean the device for reuse.<sup>[13,14]</sup> Breastfeeding is extremely common in the Vhembe district, as is the early introduction of mixed feeding.<sup>[15]</sup>

## Methods

### Study setting

This study was conducted in the Mutale and Thulamela municipalities of the Vhembe district of Limpopo, SA. Table 1 lists the specific characteristics of each of these municipalities.<sup>[16,17]</sup> Interviews with infant caretakers (ICs) and health workers (HWs) were conducted at four rural government clinics and in five communities. The clinics were Thondo Tshivhase Clinic, Rambuda Clinic, Mutale Health

Centre and the University of Venda Campus Clinic. The communities were Tshilamba, Tshishivhe, Pile, Tshapasha and Tzhagwa.

### Participant recruitment

Participants were recruited through purposive sampling. A key informant helped identify participants using her knowledge as a local community resident, and as a past fieldworker for the Malnutrition and Enteric Diseases (MAL-ED) study.<sup>[18]</sup> Eligibility criteria centred on identifying with at least one of the following categories: (i) IC of a child  $\leq 5$  years; or (ii) HW employed at a local clinic. A total of 35 ICs (30 mothers and 5 women elders) and 9 HWs participated in the study, resulting in 44 total participants (Table 2). ICs and HWs agreed to participate via informed verbal consent before interviews. Only those who agreed to participate contributed to the findings of the study.

### Ethical considerations

Ethical approval was granted by the University of Venda (ref. no. CE/14/01/1605), the Vhembe District Municipality Department of Health and Social Development (ref. no. 10/1/1) and the Limpopo Department of Health (ref. no. 4/2/2).

### Data collection

Data collection occurred over 9 months in 2014, through 39 semi-structured interviews with 44 total participants. Five interviews were conducted in small groups and 34 interviews were one-on-one. Participants were asked open-ended questions relating to the potential acceptability of the NSDS. Topics included technology specifications, such as preferred device material, texture, shape, size and colour; the design of the tablet insert; packaging; acceptability within Venda culture and breastfeeding practices; possible stigma associated with device use; and potential applications of the technology.

Participants were shown a video simulation of the NSDS. To assess shape preferences, mothers were shown the NSDS prototypes as well as three other shapes of commercially available conventional nipple shields. To assess device material preferences, participants were presented with conventional nipple shields of varying thicknesses. To assess device colour preferences, two colours of NSDS prototypes, transparent and yellow (dyed with local materials), were shown as examples, and participants were informed that the device could be any colour. Tablet insert colour preferences were assessed by presenting NSDS prototypes each containing a single model tablet of a particular colour: white, yellow, green, blue or black.

Interviews with ICs were conducted at the homes of participants in the local Tshivenda language with a translator, or in English. All interviews with HWs were conducted at local health clinics, in English. Transcription and coding of the semi-structured interviews began during data collection. Participant recruitment and subsequent interviews were concluded when it was determined that data saturation was reached.

### Data analysis

This study used grounded theory to collect and analyse data.<sup>[19]</sup> Interviews were transcribed and coded into themes and subcategories, which were verified through an independent coder. Handwritten notes were coded in a similar fashion. The data analysis was modelled on Tesch's methods of qualitative data analysis.<sup>[20]</sup> Member checking was completed with selected participants at a later date, as an added measure of ensuring data saturation.

## Results

Four main themes emerged surrounding community acceptability of the JustMilk NSDS: input on device design; perceived benefits of the device; perceived barriers to community acceptance; and suggested device applications.

### Device design

#### Device material

A disposable, one-time-use device was preferred by a majority of participants. The main reasons for this were stated as ease of use and increased hygiene. Mothers considered that sterilising the device after every use might be inconvenient, time consuming, and difficult.

Some HWs and ICs noted cost and environmental impact as concerns with a disposable device, but these were secondary to prioritising hygienic medication-delivery practices. A concern over sufficient access to clean water was also brought up as a barrier to proper cleaning of the device.

Some ICs initially indicated a preference for a reusable device, expressing doubt that government clinics would be able to maintain a stock of the devices. However, after probing, it was revealed that these participants had a stronger preference for a disposable device for the same reasons as cited above.

A minority of participants, primarily ICs, strongly preferred a reusable device. One mother stated that a reusable NSDS would be more convenient because she would not need to travel to the clinic as frequently to acquire more devices. One grandmother

**Table 1. Characteristics of the study municipalities**

Feature	Mutale	Thulamela
Tribal/traditional area, %	96.8	85.4
Mean household size	3.8	3.9
Female-headed household, %	54.8	54.4
Highest education level, %		
No schooling	2.2	2.3
Some primary	45.5	42.7
Completed primary	7.0	6.4
Some secondary	36.7	36.0
Completed secondary	6.8	9.6
Higher education	1.1	1.9
Not applicable	0.7	1.1
Unemployment rate, %	48.8	43.8
Flush toilet connected to sewerage, %	3.8	10.7
Piped water inside dwelling, %	5.8	15.2
Electricity for lighting, %	83.3	87.2

**Table 2. Participant information (N=44)**

Feature	Infant caretakers (ICs)		
	Mothers	Grandmothers/elders	Health workers (HWs)
Participants, <i>n</i>	30	5	9
Mean age, years	27.9	-	46.4
Age range, years	19 - 45	62 - 84	24 - 60
Mean no. of children	1.6	-	-
No. of children range	1 - 4	-	-

noted that washing the device after each use would be similar to the current common practice of washing a spoon used to deliver infant medication, and liked this familiarity of practice.

Participants with either preference (disposable or reusable) expressed concern that a small child may find a used NSDS that had been improperly disposed of and play with it, causing disease in the child.

Most participants emphasised that the NSDS device should feel as similar to a breast as possible, while also maintaining a durable feel to ensure that it will not disintegrate or fall apart during use. ICs often preferred a material that they described as soft, but not too thin.

### Device shape, size and colour

The circular shape of the original NSDS prototype was preferred over alternative models with a reduced surface area (designed to increase skin-to-skin contact while breastfeeding). ICs, mothers in particular, expressed concern that an NSDS with a reduced surface area would fall off the breast during use. Many participants indicated a need for varying sizes of NSDS devices, stating that nipples are often different sizes, and the size of the current NSDS prototype would not fit all women's nipples. Most participants preferred a transparent device, the major reason being that it would clearly show dirt on the device, allowing a mother to know if it was contaminated. A few mothers preferred a transparent device specifically because it would enable them to observe the medication dissolving and entering the infant's mouth. One mother preferred a transparent device because she believed it to be the most discreet.

No participants preferred the yellow NSDS prototype to the transparent prototype. Some mothers did not have a strong preference between the two examples. Some mothers suggested making the device brown in colour to more accurately match skin tone, with a few stating that an infant might 'run away' or 'be scared' of a colour that did not match the breast. When probed about additional NSDS colours, most participants re-emphasised their original colour preference.

### Tablet colour

Most participants preferred a white tablet. Their reasons for this included that white was closest to the transparent colour of the sample prototypes, and white is the standard colour for many current medications in tablet form. Some ICs and HWs suggested coloured tablets resembling sweets to encourage the infant to come to the breast.

### Packaging

Participants were evenly split between preferring the pill prepackaged within the NSDS or requiring that an IC insert the tablet at home immediately before medication delivery. ICs who preferred receiving an NSDS with the pill already inside primarily cited hygiene as the reason for this preference, as it would require less direct handling of the device. Some ICs specifically expressed a concern that mothers might not wash their hands before inserting the tablet, with one mother warning that this could 'make a sickness to the child'. Some mothers also expressed

a fear that they might drop the tablet on the ground as they try to insert it into the NSDS. Convenience was also cited as a reason for this preference, but was not as heavily emphasised as hygiene.

Participants who preferred the notion of the mother or another IC inserting the tablet at home immediately prior to medication delivery often did not have a specific reason for this preference. Some mothers, however, expressed concern that they might receive an NSDS with the incorrect medication if they did not put it in themselves.

In the case of a disposable device, most mothers preferred that the device come prepackaged with the tablet insert already loaded inside. A small portion of ICs preferred a device, either disposable or reusable, where they would place the tablet in themselves because it would make them feel more personally empowered and capable in ensuring the health of their infant.

Both ICs and HWs preferred that instructions for the device include a verbal explanation in the clinic, accompanied by a demonstration by the nurse. One mother also suggested that written instructions be included as a method to remind mothers how to use the device when they are at home (Table 3).

### Perceived benefits of NSDS

All participants were enthusiastic about the NSDS, and most preferred the concept to current methods of infant medication delivery.

### Accuracy of dosing

The most popular aspect of the NSDS was that the medication is pre-dosed, eliminating the need to manually measure medication. Many infant medications in the Vhembe district are administered as syrups or liquid suspensions, and delivered with a measuring spoon provided by the clinic or with a household teaspoon, and these two instruments often differ in size. Additionally, most mothers mentioned challenges in ensuring that the infant swallows the full dose, stating that the medication often runs down the side of the infant's mouth during administration. Participants often mentioned that they were unsure if the baby was receiving the proper dose. These concerns included both under-dosing and over-dosing.

### Ease of delivery

Participants often stated that using the NSDS might increase the willingness of the infant to swallow medication. Many participants noted that infants do not like the taste of medication and do not want to swallow it. Several ICs mentioned squeezing the infant's mouth during administration to facilitate the process. The word 'force' came up several times when participants described their experiences in administering infant medication.

### Breastfeeding practices

Some participants brought up the fact that the NSDS could be easily incorporated into existing breastfeeding practices. A few participants

**Table 3. Interview quotes on NSDS design**

Sub-theme	Quote	Participant, age
Material	'If it's disposable ... it's going to be very clean. I think it's a good thing.'	IC: Grandmother, 65
	'I want to use it and throw it away. Because if I supposed to clean it, I will forget.'	IC: Mother, 45
Colour	'People cannot see while I am using this one [transparent device].'	IC: Mother, 29
Packaging	'Maybe they just made a mistake and put the wrong medicine. Then myself I take that medication and give it to my child, my child then get ill. The nurse is gone; I'm left alone with my child being ill.'	IC: Mother, 22
	'Even though they come together with the pills inside, myself I would take it out for me to learn to get experience of putting the pills myself.'	IC: Mother, 30
	'Okay, they can tell me there at the pharmacy. When I get [to] the road, I've got some other problem, then I forget. So on the paper is easy. When I get there at home, I will read it.'	IC: Mother, 21

NSDS = JustMilk Nipple Shield Delivery System; IC= infant caretaker; HW = health worker.

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mentioned that use of the device would encourage breastfeeding in the community. One mother mentioned that HWs especially recommend breastfeeding when an infant is ill, and explained that this device could act as a tool to encourage breastfeeding in the community (Table 4).

### Perceived barriers to community acceptance of NSDS

A concern noted by many participants was that the device can only be used by mother-infant dyads who are currently breastfeeding, and would not be effective in delivering medication to toddlers. An additional need to address medication administration for this age group was expressed. It was also noted that some mothers work or go to school during the day and therefore would not always be present in the home to deliver medication through breastfeeding. Some ICs stated that without proper education, other community members might think that a mother using the device has HIV, or that she has a condition that does not allow her to breastfeed normally or come into contact with her baby.

Many participants emphasised the idea that they would not associate any stigma with the device if they had prior knowledge about the device's function. Participants were highly encouraging about educating all members of the community on the purpose of the device. When probed on how they would feel if they saw someone else using the NSDS, participants mostly expressed thoughts of curiosity (Table 5).

### Potential applications of NSDS

The most common tablet insert suggestion from ICs was acetaminophen, given for common infant illnesses such as colds,

coughs and fevers. This is currently delivered to infants as a syrup using a medication spoon. HWs often suggested the deworming medication albendazole, since it is only provided to government clinics as solid tablets, and requires crushing and mixing in potable water before delivery as a liquid. Antibiotics were also suggested, as participants noted that the forms they currently used were oral suspensions requiring refrigeration that last for only up to 7 days.

### Discussion

All participant preferences for NSDS design, including disposability, a soft yet durable material, transparent colour and white API tablet will be carefully considered in future iterations of the NSDS design. The reasoning behind preferring a disposable or reusable NSDS highlights a strong community value of hygiene in the Vhembe district. Current limited access to infant medication-delivery devices, such as medicine spoons, seemed to occasionally sway an IC to favour a reusable device, for fear that the NSDS might also have a limited availability, especially if distributed by the government Department of Health. This mistrust of government health services seemed to be a factor in many responses, and should be thoroughly considered in the implementation of NSDS use.

An interest, particularly from mothers, in learning how to insert the tablet and to watch the medication dissolve, suggests that mothers greatly value a sense of ownership towards the health of their infant. Further community input on how to incorporate the concept of ownership into every step of NSDS use should be considered. It was clear that some participants did not trust the government clinic to insert the correct medication into the NSDS. Additional research into trust between patients and government

**Table 4. Interview quotes on perceived benefits of NSDS**

Subtheme	Quote	IC, age (years)
Preference over current medication delivery methods	'Ah, it is good. Not going to suffer to give medicine by using the spoon.'	Grandmother, 84
Dosing accuracy	'This is a perfect device because there is no way I can give overdose. I ... am quite certain that I have given the right amount at the right time because if it comes already packaged, I just take one and give. So this is good.'	Grandmother, 84
Ease of delivery	'It is good because I give one dose. I might overdose with teaspoon, but this has the whole dose.'	Mother, 34
	'The child cannot refuse to drink the medicine. She will always be drinking all the medicine.'	Mother, 37
Incorporating device into breastfeeding practices	'Even us who force the babies, there is no need to force now.'	Mother, 42
	'It's not like forcing the child, like squeezing. For this she will be breastfeeding, getting the medicine together.'	Mother, 30
	'Yeah it would influence us to give us our babies the breast rather than the bottle.'	Mother, 38

NSDS = JustMilk Nipple Shield Delivery System ; IC= infant caretaker; HW = health worker.

**Table 5. Interview quotes on perceived barriers to acceptance of NSDS**

Subtheme	Quote	IC, age (years)
Social stigma	'To me, there is not [a] problem, but I don't know about others because what will they think? ... If I have this one, some people maybe they don't know about it. They will think I have HIV.'	Mother, 20
Education programme	'There is a need for ... eh, education about the device. Because if in a household the mother just starts putting the shield and starts breastfeeding and has not explained that it is for administration of medication, people in the household, the in-laws would think oh, this mother has a really devastating disease ... that she is afraid to pass to the ... kid. Yeah. So, that part is very important that it's communicated ... before using it.'	Grandmother, 65
	'Yeah, people ... they won't know about it. So you have to tell them, show them, so that they can understand what is this.'	Mother, 21
Perception of others using the device	'I would have no problem because I will know that the mother is giving the child medicine.'	Mother, 38
	'I would ask the mother what are you doing with that, with that thing? And the mother will tell me, I'm giving the medicine to the child.'	Grandmother, 84

NSDS = JustMilk Nipple Shield Delivery System ; IC= infant caretaker; HW = health worker.



health services is recommended. As the literacy level of ICs can be limited, NSDS instructions should include a visual component, such as drawings or diagrams.

Comments suggesting that NSDS use could have a significant impact on improving dosing accuracy, and might increase the willingness of a child to swallow medication, will be considered in future clinical research.

A community education programme may be necessary to address the hygienic use of the NSDS and to reduce potential social stigma, especially in association with HIV. Efforts will also be made to make the device as discreet as possible, allowing mothers to feel comfortable using it in a variety of social situations. A breastfeeding education programme may also complement NSDS use.

The shared responsibility of infant care within the household may present a barrier to NSDS use, as only the mother can deliver the medication with this system.

APIs suggested by participants will be thoroughly considered. Specific emphasis will be placed on community preference, current infant-health needs in the region, and the feasibility of formulating the APIs into solid dispersible tablets.

The findings from these selected communities may be transferable to similar communities.

### Study limitations

Back-and-forth translation from Tshivenda to English occurred during interviews with participants who only spoke Tshivenda. The interviews were transcribed and coded in English, based on these translations. While the translator was fluent in both languages, some nuances of the responses may have been lost or misunderstood during data analysis. However, the researchers are confident that all data acquired were valid, and data saturation was reached.

Interview conditions were not standardised, as they occurred within the various selected communities at participant homes and clinic offices. However, this interview environment was more familiar to participants, and therefore most likely encouraged accurate and thoughtful responses.

Despite these limitations, the researchers are confident that the information gathered is truthful and represents the full range of participant responses.

### Conclusion

A qualitative research study was conducted in selected communities in the Vhembe district of Limpopo, SA, to assess the acceptability of the JustMilk Nipple Shield Delivery System (NSDS), a novel infant drug- and nutrient-delivery device. Data were collected through semi-structured interviews with 35 ICs and 9 HWs. A diversity of opinion was expressed within these interviews, which led to several suggestions on NSDS design and implementation. Four main themes arose addressing community acceptability of the JustMilk NSDS: input on device design; perceived benefits of the device; perceived barriers to community acceptance; and suggested device applications.

Participants had an overall positive reaction to the JustMilk NSDS, and did not cite any major cultural factors that would negatively affect community acceptance. Participants felt positive toward the current design and gave related suggestions, including that it more closely resemble the appearance and texture of a human breast. The most attractive features of the device appeared to be the potential for increased dosing accuracy compared with existing methods, and the possibility that infants will accept medication with greater ease. Participants also emphasised the potential to incorporate NSDS use into current breastfeeding practices. An education programme to accompany device use was stated to be very important, to inform community members about hygiene practices surrounding device

use, and to decrease any potential stigma. The NSDS and an associated education programme could provide an opportunity to encourage breastfeeding throughout the Venda community.

This study is a promising step in the design and implementation of the JustMilk NSDS. All suggestions by community members will be thoroughly considered, alongside feasibility of manufacturing. Additional acceptability studies will be planned to inform future device iterations. Clinical studies will also be necessary to understand additional aspects of device acceptability by mother-infant dyads, and to ensure that the device does not pose any unforeseen hazard to the mother or child.

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**Author contributions.** ADF designed and implemented this research, conducted the majority of participant interviews and performed data analysis and manuscript preparation. RLS conducted interviews and provided substantial contribution to study design and manuscript preparation. GG was critical in revising the content of the work for publication. SEG contributed to study design and manuscript review. VON provided substantial guidance on every step of study design, implementation, data analysis, and manuscript preparation.

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**Conflicts of interest.** ADF, RLS, GG and SEG were board members of JustMilk at the time of data collection. SEG and GG are listed inventors on US patent number 8357117, and ADF, RLS, GG and SEG are listed inventors on provisional US patent numbers 62/307,375; 62/337,805; and 62/424,006, all pertaining to the NSDS.

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