PETiTE PLATFORM

Acceptability of Pediatric Oral Dissolving Film in a Clinical Study

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FAMCRU

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forward together
sonke siya phambili
saam vorentoe

DESMOND TUTU TB CENTRE · SENTRUM · IZIKO

Every breath counts

Unitaid
SAVE LIVES FASTER

Acceptability and preferences, and why it matters

Acceptability: The extent to which an intervention/treatment is considered to be *reasonable* among those *receiving, delivering or affected* by the intervention (WHO)

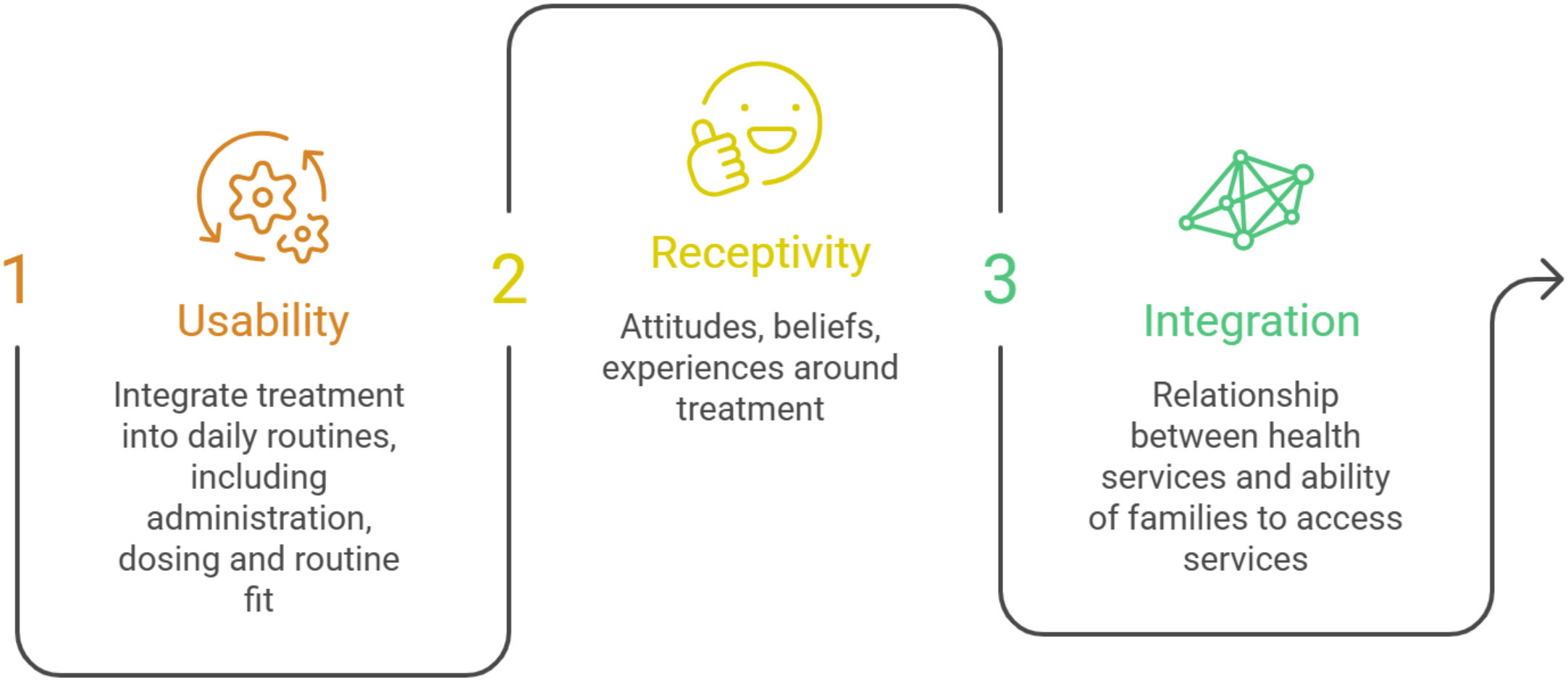
- When people think of a treatment as *fair, appropriate, and reasonable*, they are more likely to engage with it fully, leading to better outcomes.

- Considering patient preferences and acceptability is an *ethical imperative*, ensuring treatment is not just medically accurate and safe but also align with *patient values and circumstances*.

Acceptability in context

Catalyst Acceptability study, BENEFIT Kids (Unitaid). South Africa 2021.

Treatment acceptability framework (Wademan et al.)

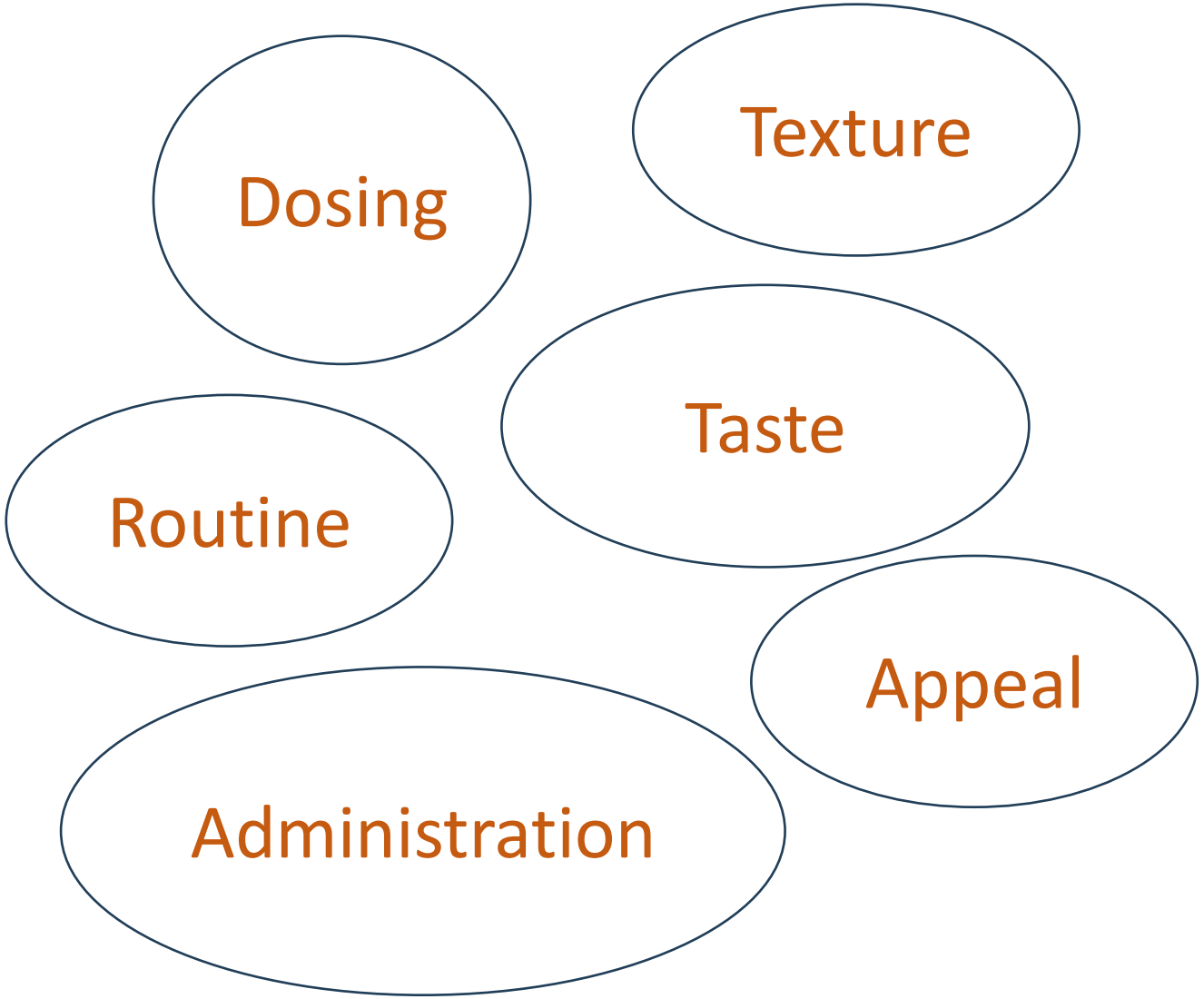


Wademan, D.T., 2022. Toward a conceptual framework of the acceptability of tuberculosis treatment in children using a theory generative approach. PLoS Global Public Health, 2(12)

1

Usability

Integrate treatment into daily routines, including administration, dosing and routine fit



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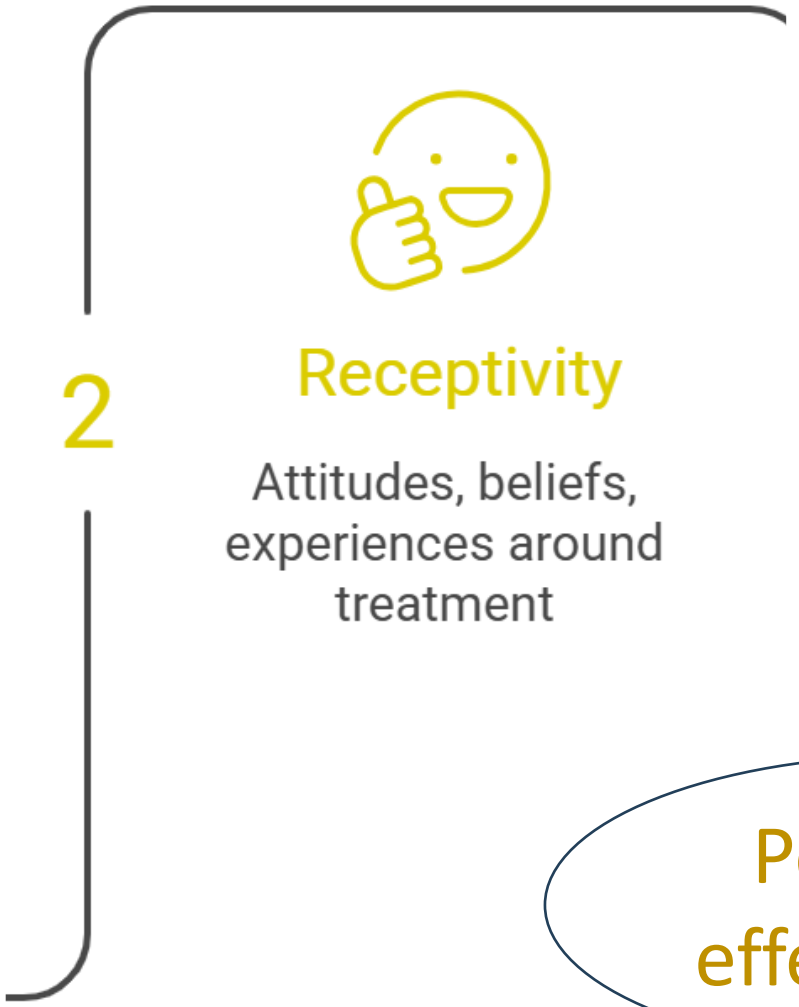


Health beliefs

Previous experience

Perceived effectiveness

Wademan, D.T., 2022. Toward a conceptual framework of the acceptability of tuberculosis treatment in children using a theory generative approach. PLoS Global Public Health, 2(12)

Structural support

Health system delivery

Household support

3

Integration

Relationship between health services and ability of families to access services

Wademan, D.T., 2022. Toward a conceptual framework of the acceptability of tuberculosis treatment in children using a theory generative approach. PLoS Global Public Health, 2(12)

PETITE ACCEPT Study: Aim and Objectives

Usability

Integration

Receptivity

Aim

To assess the acceptability of novel dolutegravir formulations.

Objectives

- Exploring the experiences of mothers
- Describing preferences for formulations
- Describing how context impacts care experiences
- Exploring perceptions of health workers
- Translate findings from study to practical recommendations

Study design and data collection

Health worker Cohort

Health workers involved in the trial

Interview 1: Assess first impressions of the medication, role in the health system

Interview 2: End of data collection period – reflection on experiences

Study design and data collection

Cohort of mothers living with HIV with infants receiving DTG

Infants receiving DTG-DT

Infants receiving DTG-Film

Interview 1: At enrollment

Interview 2: A follow-up interview at **Week 2**

Interview 3: A final data collection interaction at **~ 25 days after birth**

Findings

Participants

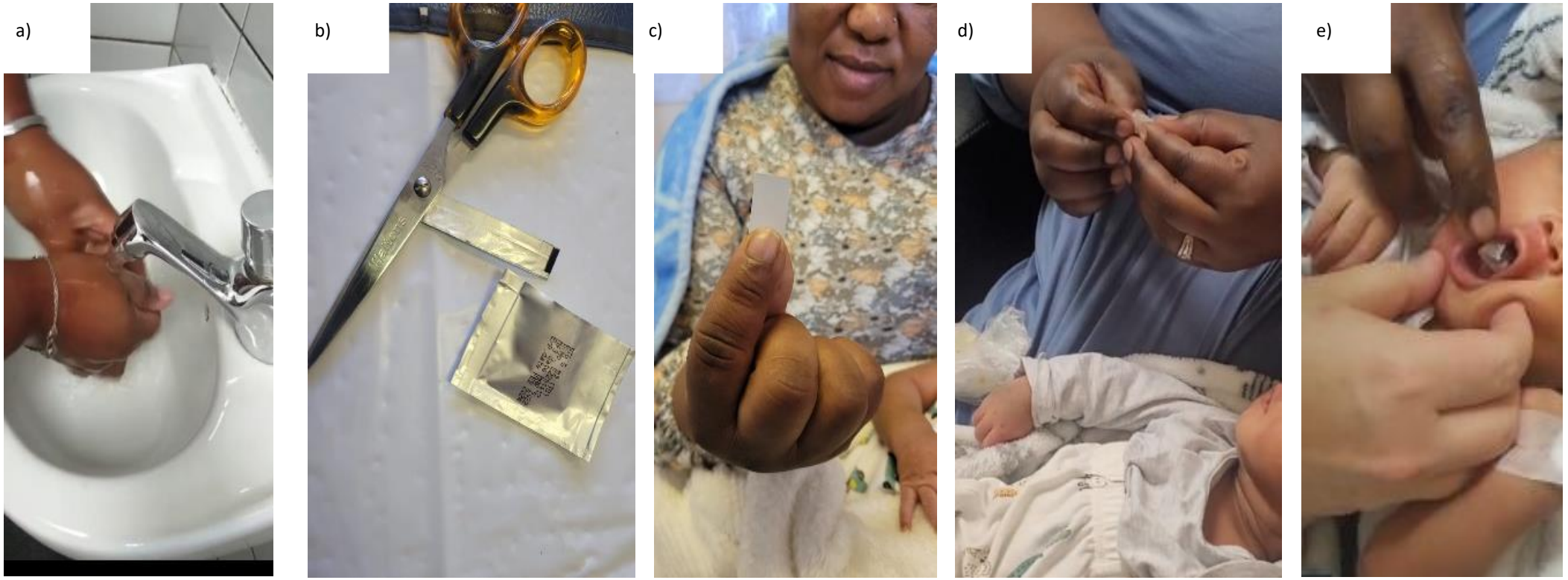
- 29 infant/mother pairs recruited (overall)
- Two mothers with twins
- 16 mothers with infants receiving DTG-Film
- High rates of disclosure to significant partners
- High rates of ART use during previous pregnancies
- 6 health workers:
  - Female
  - Pharmacist, adherence monitor, medical officer, nurse, and project manager

Table 1. Baseline characteristic of mother-infant dyads - receiving DTG-Film

Maternal Characteristics	Mothers with neonates - DTG-Film cohort (n=16) *	
Age (years)	Median (range)	38 (23-43)
Time since HIV diagnosis (years)	Median (range)	8.8 (2-15)
Time on DTG-based ART (months)	Median (range)	37.2 (3.0-88.9)
Disclosed HIV status to significant partner (yes)		12 (75%)
Number of children	Median (range)	2.9 (1.0-4.0)
Previous experience with using antiretroviral drugs for HIV prevention in their newborns (yes)		8 (50%)

DTG-Film

Figure 1. DTG-Film administration: a) Washing hands; b) cutting the sachet, c) mother holding the DTG-Film; d) folding the film, e) administering the DTG-Film to the neonate.



Administration of DTG Film to a Neonate

DTG-Film

5 mg film placed on tongue and allowed to dissolve

DTG-Film: Usability

Administration:

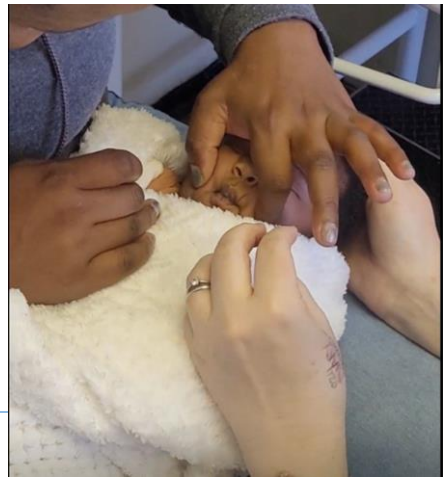
Simple, quick, and easy with minimal complications.

Washing and drying hands, opening the sachet with scissors, folding and inserting the film into the mouth of the neonate.

"*That thing [film] is easy, you bend it, and put it in [the mouth], he sucks it* [PID 24].

"*DTG-Film is much easier [than syrups], as long as you have scissors, you just cut [the sachet] and take it [film] and put it in the mouth" [HW 01]*

"I *wash my hands … make sure they are dry, and then I just cut the paper [DTG-Film sachet], fold it [film], and it is quick, so as soon as I put it onto his [infant's] tongue … it dissolves in a few seconds; he enjoys that one" [PID 35].*



DTG-Film: Usability

Administration:

The oral film is easy to dissolve, and easy for babies to swallow.

Caregivers and health workers: perceived whole dose administration.

"[My baby] did not spit it out, he did not vomit, he swallowed within two seconds, it dissolves fast, and it's gone in the mouth, it left nothing [PID 23].

"I am so proud of that film … every time I hear a patient gets the film, then … to me it feels like the patient gets the whole dose" [HW 04].

"The medicine (DTG-Film) it's easy to give the baby, you just put it inside the mouth, on top of the tongue, and it goes all in, the liquid one (ZDV), it's harder to give the baby, because maybe some of it messes, some of it even came out, but this one (DTG-Film), its perfect". [PID 08]

DTG-Film: Usability

Administration challenges:

One challenge identified by both mothers and health workers was that, when wet, the film would become sticky, and occasionally attach to either the caregiver's finger, or the lips or palate of the infants, leaving residue behind.

"[DTG-Film] was very easy to give and [the neonate] had no problem taking it, except one time she was sleeping, and it got stuck to the palate" [PID 38].

"[The film takes] maybe a minute because there is [some film] that is left on the finger and then now I noticed that it sticks, so you have to keep trying for the child to get that bit as well, but not more than a minute" [HW 02].

DTG-Film: Usability

Administration and dosing

Some caregivers commented on the dosing adjustment during the first month - once every second day for the first two weeks and then daily from day 14 onwards.

"Daily [administration], from the beginning would be much easier. As a mom, if I had to remember every second day I would have to have a calendar on the wall where I could mark it off and I would be constantly second guessing when it was administered. I don't think it's really ideal, especially not for a mom with a new baby" [HW 01].

DTG-Film: Usability

Usability

Packaging

Participants were also asked to reflect on the packaging and the impact on administration experiences. Some noted the challenge of current packaging but acknowledged that this is a challenge that could be easily addressed.

“One thing I am finding … the packaging is not great, but I am sure that is something that would be optimized if we are marketing it. You would have to have scissors in order to open it, this one doesn’t have a specific …tear or opening … the packaging itself it quite difficult to open." [HW 01]

“I mean, who walks around with scissors every day? You know, something that says, ‘tear here’ or ‘cut here’ [would be better]." [HW6].

DTG-Film: Receptivity

Receptivity

Conceptions of health and DTG-Film as medication

Oral dispersible films were novel to caregivers and health workers – which challenged existing understanding of medication or treatment. This also extended to broader households or support networks.

"I was scared at first, I don't want to lie. I was thinking 'films'; this is a paper what kind of a paper is this, it was my first time seeing it" [PID 38]

"My parents, with the [DTG] dispersible tablet they were watching me do it and they were like, 'oh okay', but with the film they were like, 'What is this? Why are you doing this? It looks like paper.' … My mom was worried that the baby might choke, but I showed her that it dissolves [so the baby won't choke]" [PID 35]

Hesitancies from those not receiving DTG-Film:

"I think with the film, a baby doesn't know about having [medicine] dissolved in their mouth. Then you still have to check the whole time if [the medication] dissolved. With the liquids, you just give it into their mouths and its done, you don't have to check the whole time, with the tablet I know when it's finished" [PID 01]

DTG-Film: Receptivity

Prior experience with ART for neonates

Half of caregivers have administered ART to infants after previous pregnancies. This facilitated trust, familiarity and helped shaped understanding of novel DTG formulations.

"Since [ART] has never disappointed me … I trust it" [PID 42]

"I am confident about the medication [my baby] receives because [my older daughter] also received medication and she is still HIV negative so [I] trust that even now it will be like that." [PID 29]

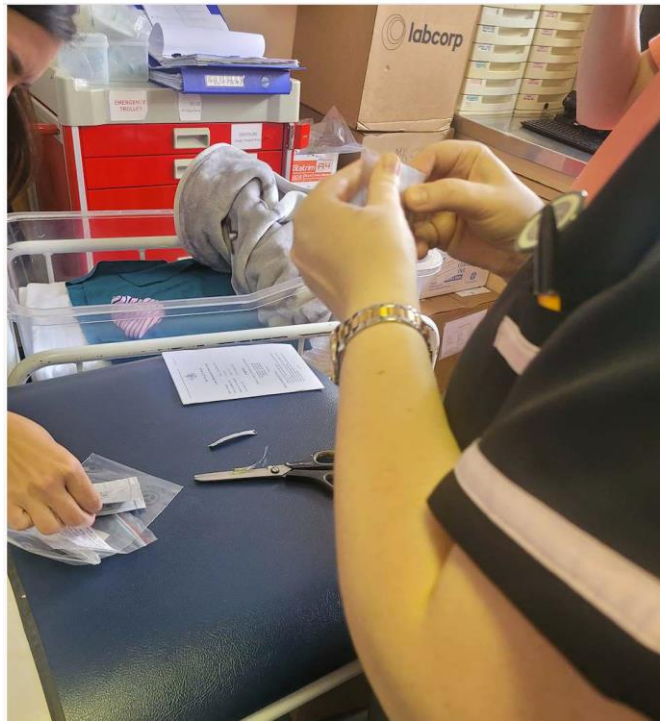
DTG-Film: Integration

Integration

Health system delivery

The film format of DTG was described as especially useful in a public health setting, where other formulations would need manipulation prior to administration:

"With pills, a pharmacist is not going to pop them out and break them for the mom, she would have to do that herself … the film, it's no fuss, no measurement, its accurate, you know exactly what is going in the baby … there is no spill, no fuss, you just give it and carry on with your life .. the syrup, it involves measurements which needs focus, you need to trust the mom gives the right volume." [HW 01]



DTG-Film: Integration

Integration

Household support and discretion

Participants emphasized the value of the film as a discrete form of medication, especially for those who have not yet discloses their HIV status to others. At the same time, many participants reported receiving household support to ensure that their infants received their medication.

"With people that one has not disclosed to, then the DTG-Film would be best … [I] can easily administer medication without fear of being seen" [PID 32].

"People in the household are very supportive and feel confident about the medication and oftentimes they would remind [me] about the medication" [PID 34].

"[My husband] is very supportive and helps to give the medications [to the neonate]" [PID27].

DTG-Film: Integration

Integration

Communication

Adequate communication is key to integration – in household and in health systems.

Also, the value of peer communication and word of mouth should be aknowledged

"That first day they helped me just to show me how it is done, they taught me and gave me this [film], there is a paper [pamphlet] that they gave me so that I can read it to know what to do, and they also helped me the first day showing me how it is done" [PID 23].

"Education … on the medicine, with instructions and explanations, it [DTG-Film] would be easily integrated." [HW 04]

"*I just give them this one (DTG-Film), because even when we talk there with other mothers [in the waiting room] we see that, there where we sit, we see that this is the one that is good/right for them.*" [PID 32]

Usability

Receptivity

Integration

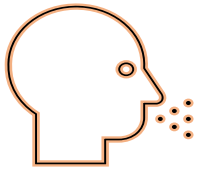
Acceptability of DTG-FILM

- We present a holistic approach to understanding of acceptability
- We demonstrate usability of the novel formulation, including packaging, ease of administration, dosing considerations are essential.
- But also: implications of the broader conceptualizations of what is ‘medication’, the integration of treatment into household contexts, and consideration of support and discretion
- Potential for health system integration

What does this mean?

- Formulation development is essential for improved care for neonates born to mothers living with HIV.
- For optimal uptake and use, novel formulations need to be acceptable to caregivers and health workers.
- Novel formulations need to align with the values and lifestyle of participants
- Trust-building and overcoming the unfamiliar/strange
- With appropriate messaging and education formulations can be integrated into paediatric care
- Beyond clinical metrics like lab results, patient (and family) centred outcomes should be prioritized.

Family-centered care



Quality of Life

Emotional health, cognitive function, and mental well-being (and the impact of caregiving)

Daily Functioning

The ability to perform daily tasks, maintain autonomy, and engage in social roles (and household functioning)

Symptom Burden

The management of pain, fatigue, and other side effects during treatment administration.

Care Experience

Accessibility, shared decision-making, and communication with the medical team when treatment is decided.

Family empowerment and support

Health professional empowerment and support

Togo, A. 2025. Person-and family-centred care in neonatology: a scoping review to identify existing definitions, models of care, and related categories of interventions. Journal of Global Health, 15, p.04263.

Acknowledgements

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Questions