Assessing acceptance and acceptability of an innovative pediatric antiretroviral lopinavir/ritonavir (LPV/r) pellet formulation

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Background

- WHO (2015) recommends the use of a LPV/r based regimen for all children < 3 years of age.
- LPV/r formulation for infants and young children most widely available is a syrup that requires refrigeration, contains 40% alcohol and tastes bitter.
- Cipla's LPV/r pellets have a new solid formulation which does not require refrigeration; they were tentatively approved by USFDA in 2015 for children from 2 weeks or above 5 kg.
- However, no acceptability data is available.

- The **LIVING clinical** trial evaluates the **effectiveness, pharmacokinetics** and **safety** of this new formulation in Uganda, Kenya and Tanzania.
- In order to scale up the use of these pellets at national program level, DND*i* commissioned a theory-driven realist evaluation **(RE-LIVING study)**.
- The **RE-LIVING study** aims to better understand **how the pellets** are used in real-life settings.

Objective

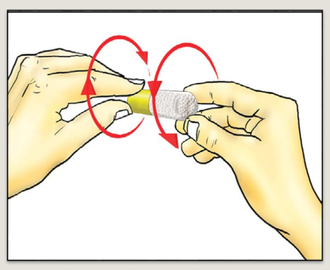
To assess the formulation's acceptability and adherence from the perspective of the child, caregiver, and healthcare providers, and to explore **which caregiver, organizational, and contextual factors** facilitate acceptance and adherence to this new formula.

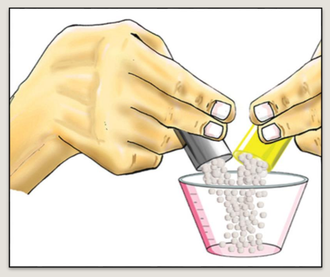
Methods

Qualitative research (participants and settings)
- Cases: dyad caregiver-infant (purposively selected)
- Three contrasting units of analysis (settings): Kenyatta National Hospital and Gertrude's Children's Hospital in Nairobi, and Lumumba clinic in Kisumu

Data collection (January – June 2017)
- 42 in-depth interviews with care-givers and 16 with health care providers
- 17 observations of pellet administration at home and 17 in clinical settings

Data analysis (June – November 2017)
- Primary analysis (qualitative descriptive) inductively conducted
- Secondary analysis (realist analytical) deductive-inductively conducted
- Data triangulation (theoretical, data sources, and investigator triangulation)

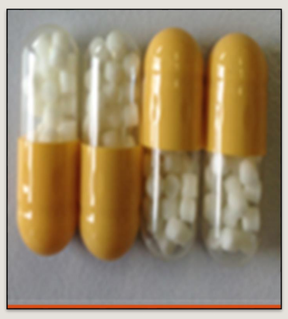




Results

Acceptability

Caregivers found the pellets highly acceptable due to
- the ease of storage (no refrigeration required)
- the packaging (discreet, secure closing, no spillage)
- administration with liquids
- taste: lack of bitterness



Children accepted the treatment pellets very well
- Easy to swallow when given with liquids or food

Adherence

- **Better acceptability** of the new formula contributes to **initiation of adherence.**
- **Visible positive outcomes** of giving the new formula (such as less viral load or gaining weight) stimulates **maintaining adherence.**
- **Easy administration** empowers caregivers and therefore supports their adherence to the treatment.
- **Adherence support** (counseling) delivered within the trial was highly appreciated, though instructions need to be adapted to the caregivers' level of understanding.

Conclusions

- The **acceptance of the new LPV/r pellet formulation** is high and ultimately may **contribute to long-term adherence.**
- Since food shortages were observed in some households, providing the medication with liquids (tea, water) was helpful in maintaining adherence.
- **Supportive caregiver-health care provider communication is essential** to convey correct instructions for administering the LPV/r pellets, while attention for contextual barriers is needed (HIV-related stigma, poverty-related challenges).
- The LIVING trial builds on positive organizational factors such as adherence support counseling, which is appreciated by the caregivers, and which contributed to an increased number of mother-child dyads being able to maintain adherence. The influence of structural-contextual factors need to be considered.

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