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.

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 caregivers 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) deductively 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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