Uptake of raltegravir granules in newborns diagnosed with HIV in Zimbabwe during the COVID-19 pandemic

EPB203

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BACKGROUND

- In 2020, Zimbabwe estimated 79,000 children <15 years living with HIV, with 5,100 new infections in children (1).
- In 2017, Zimbabwe introduced at birth point-of-care (POC) early infant diagnosis (EID) testing for earlier diagnosis and antiretroviral therapy (ART) initiation for infants living with HIV to reduce high mortality in untreated children (2,3), but newborn ART options were limited.
- In 2020, Zimbabwe adopted the World Health Organization's recommendation to use raltegravir (RAL) granule-based regimens as the preferred regimen in newborns living with HIV identified through birth testing (4).
- We describe implementation and lessons learned during roll-out of RAL granules during the COVID-19 pandemic.

METHODS

- RAL granules were introduced in 14 health facilities with capacity for POC HIV birth testing in Zimbabwe.
- Healthcare workers were trained on RAL use and caregiver counseling on preparation and administration of RAL to newborns living with HIV.
- Study population included all infants exposed to HIV born at project sites from June 2020-June 2021.
- From April-July 2021, trained research assistants retrospectively abstracted testing and ART outcome data from standard facility-based tools and registers.
- Research assistants received COVID-19 mitigation training and were provided with personal protective equipment.
- De-identified data was directly entered into a Microsoft Access database using a password-protected laptop.
- A waiver of consent was obtained for accessing and abstracting routinely collected de-identified patient-level data from health facility registers. There was no interaction with clients for extracting data.

Main Findings

Despite low coverage of birth testing and supply chain challenges of POC cartridges and neonatal antiretroviral (ARV) formulations, almost half of identified neonates diagnosed with HIV were initiated on RAL granule-based regimens, and 95% of those with documented follow-up were successfully transitioned to a non-RAL-based regimen at 28 days.

RESULTS

Figure 1: Point-of-care birth testing, ART initiation, and RAL treatment cascade; N=6989 neonates exposed to HIV in 14 health facilities in Zimbabwe.

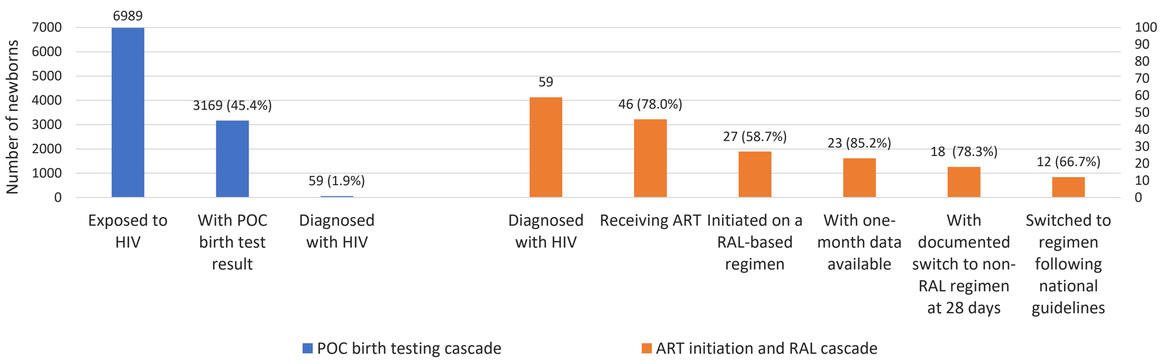
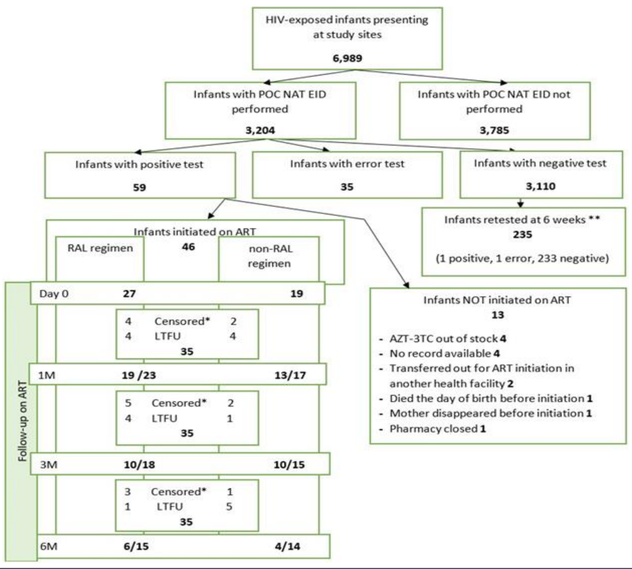


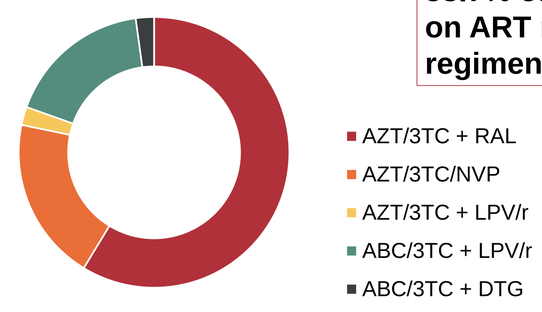
Figure 2: Flow-chart of outcomes for HIV-exposed and HIV-positive neonates



* Censored children are those who did not reach one, three, or six months on ART, respectively, at the end of the study period and are therefore not counted in the denominator. Children LTFU are those who were not censored and had no follow-up reported after each specific time point.
** 1,892 infants tested negative at birth were transferred out to another facility before six weeks.

- Infants initiated on RAL were initiated significantly earlier than those initiated on other ART regimens (median, four days vs. six days: p= 0.03).
- Data at 28 days of life was available for n=23 (85.2%): 18 (78.3%) switched to a non-RAL regimen.
  - national guideline-approved regimen (n=12)
  - AZT/3TC + LPV/r (n=6), not a recommended regimen
- Only two infants had a viral load (VL) result at six months, both collected from clinics with on-site POC VL.
  - Both had viral suppression (<1000 copies/mL)
- Number of children that received a weight check: 7 days: 10/27 (37%); 28 days: 6/19 (22%)
- Although one child died soon after birth before ART initiation, no child deaths were reported among the 46 on ART.
- No adverse drug events were documented.

Figure 3: ART regimen initiated in HIV-positive neonates.



58.7% of neonates initiated on ART received RAL-based regimens

CONCLUSIONS

Lower than expected birth testing uptake and RAL usage were observed. Main observed challenges were:

1. **Inconsistent supply chain** impacting availability of POC EID testing cartridges, RAL granules, and pediatric AZT/3TC.
   - Global and national COVID-19-related travel restrictions delayed manufacturer deliveries and in-country distribution.
2. **Shortage of trained healthcare workers due to strikes and high staff turnover**
   - Staff reassignment and facility space redistribution to support COVID-19-related activities impacted availability of trained staff.
   - COVID-19-related travel restrictions limited in-person mentorship and supervision visits.
   - High staff attrition led to work overload for remaining staff.
3. **Documentation gaps** of data points not recorded or not maintained in facility registers
   - This study was unable to assess accuracy of prescribed dose for weight
     - Dosage data was only documented in the client's take-home medical booklet
     - Weight was inconsistently recorded
   - Most infants did not have a documented six-month VL result due to long VL result turnaround time (5).

RECOMMENDATIONS

Addressing health systems gaps for supply chain, staffing (training, retention, mentorship, and supervision), and ability to track newborns living with HIV and maintain documentation of weight and RAL dosage at the facilities is needed to improve birth testing services and outcomes for HIV-exposed infants, timely ART initiation, and follow-up on optimized regimens.

ACKNOWLEDGMENTS

This research has been supported by the President's Emergency Plan for AIDS Relief through the United States Centers for Disease Control and Prevention under the terms of grants number: NU2GGH001463. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the funding agencies.

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