Early Identification of ART missed doses: baseline data from the RETAIN study.

613

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BACKGROUND

We present baseline (visit 1) data from "Improving RETention and viral load outcomes for people taking Antiretroviral therapy through early IdentificatioN of missed doses (RETAIN)", a cohort study exploring detailed adherence metrics [viral load (VL), electronic adherence monitoring (EAM); tenofovir diphosphate (TFV-DP) concentrations and self-report (SR)] among people who start ART and are flagged for sub-optimal adherence in year 1.

METHODS

ART-naïve people from three Cape Town ART clinics had adherence monitored by:

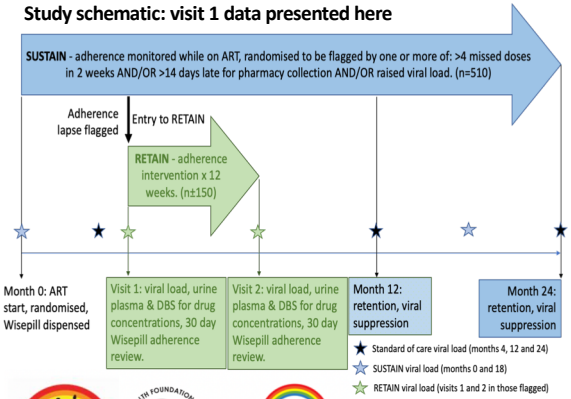
- missed doses (Wisepill EAM),
- missed clinic visits, or
- raised VL.



EAM

At the time of first flagging by any measure, participants received a scripted adherence support call, and were invited for blood draw for HIV-1 VL and TFV-DP (indicating dosing over 4-8 weeks); urine collected for tenofovir rapid assay (indicating dosing over 3-5 days). SR adherence and EAM data were collected for the prior 30 days. Initial adherence data at the time of first flagging for sub-optimal adherence are presented here.

Study schematic: visit 1 data presented here



Those flagged for sub-optimal adherence had poor adherence confirmed by objective measures (EAM and TFV-DP concentrations) despite self-reporting >90% dosing .

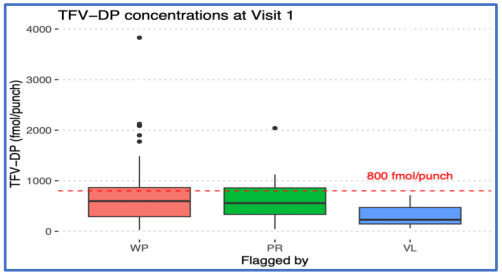
Flagged by:	n	Days to awareness of reduced adh: median (IQR)	SR - Self-reported 30-day adh (%): median (IQR)	UTRA - ppts with positive urine tenofovir: % (n)	EAM – electronic adh (%) over past 30 days: median (IQR)	TFV-DP - in DBS (fmol/ punch): median (IQR)	VL – ppts with viral load <50 copies/ml: % (n)
Missed doses (WP)	134	40 (22-90)	90 (83-97)	79 (n=106)	74 (60-83)	597 (288-894)	76 (n=102)
Missed visits (PR)	32	98 (59-127)	90 (83-93)	72 (n=23)	60 (10-88)	557 (326-866)	81 (n=26)
Raised viral load (VL)	3	134 (94-194)	100 (83-100)	100 (n=3)	0 (0-86)	229 (61-713)	66 (n=2)
Total	**170**	**42 (29-102)**	**90 (83-97)**	**77 (n=133/164)**	**73 (52-83)**	**579 (290-852)**	**77 (n=130)**

Reduced EAM adherence was seen across all groups (73%); as were **suboptimal TFV-DP** concentrations (<600fmol/ punch): normal range >800 fmol/punch.

Only 77% had **tenofovir in their urine (UTRA).**

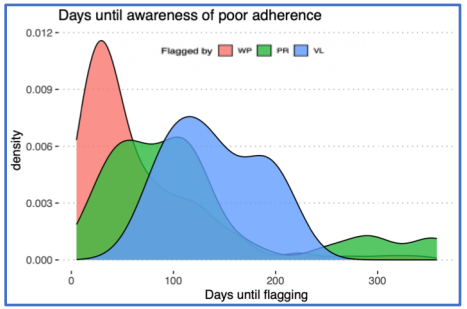


TFV-DP: dried blood spot collection (left), suboptimal TFV-DP concentrations at visit 1 (right).



RESULTS

Between July 2022 and February 2024, 170 of 505 (34%) people were flagged for poor ART adherence: 134 (79%) by missed doses, 32 (19%) by missed visits and 3 (1%) by raised viral load. 121/170 (71%) were women; mean (SD) age of 28.5 (±6.9) years.



Monitoring missed doses and missed visits allowed swifter detection of sub-optimal adherence (median (IQR) 40 (22-90) and 98 (58-127) days) compared to monitoring by viral load result: 134 (94-194) days.

CONCLUSIONS

- Poor adherence is prevalent early into antiretroviral therapy; a third of the cohort were viremic when poor adherence was noted.
- All those flagged for reduced adherence had poor adherence confirmed by objective measures, including EAM and TFV-DP concentrations, despite self-reporting near perfect dosing.
- Positive urine tenofovir reflects reasonable dosing near to the study visit (white-coat dosing).
- Poor adherence was noted most rapidly by detection of missed doses and missed visits; allowing time for adherence support before breakthrough viraemia occurs.

Acknowledgements: the fabulous BU & DCAT SUSTAIN/RETAIN teams and our participants.

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