

# A Self-Reported Adherence Measure to Screen for Elevated HIV Viral Load in Pregnant and Postpartum Women on Antiretroviral Therapy

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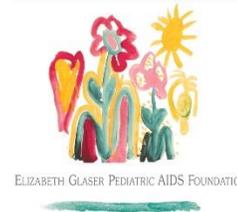
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# Conflict of interest disclosure

The authors have no real or apparent conflicts of interest to report.

# Background

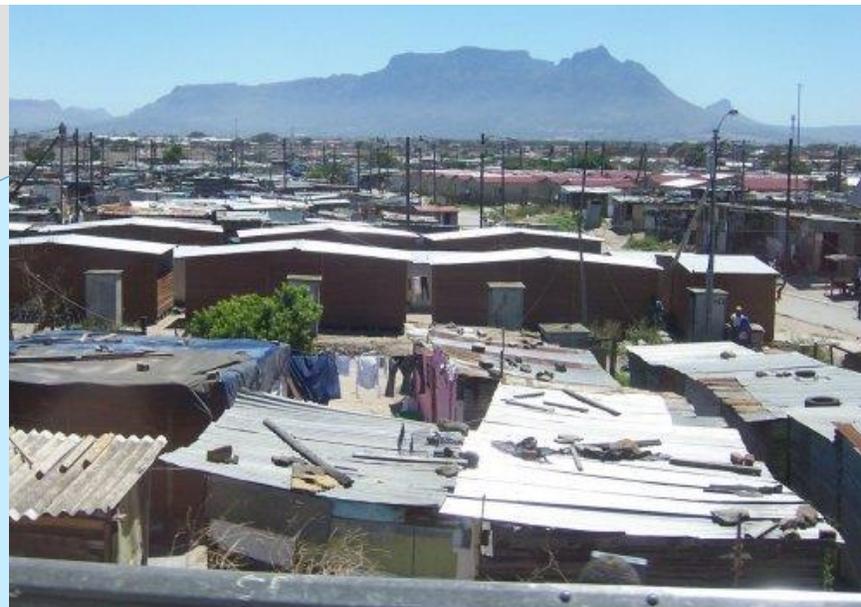
- There has been rapid global implementation of universal antiretroviral therapy (ART) for all pregnant and breastfeeding women
- Maternal ART adherence is a concern with implications for vertical transmission and maternal health
- Measuring and monitoring ART adherence is very challenging
  - Viral load(VL) invaluable for treatment monitoring - does not directly measure adherence, expensive and often infrequent
  - Scepticism about self-report measures but often one of the few if not only practical methods in low resource settings
- There is need for adherence measures which can be conducted frequently with limited resources, both in clinical and research settings

# Study aims

- To investigate the association between a new three-item self-reported adherence measure and elevated HIV VL in HIV-infected pregnant and postpartum women
- To assess differences in reported adherence across sociodemographic subgroups

# Setting

- Gugulethu, Cape Town
- High levels of poverty and unemployment
- Large primary care clinic with integrated antenatal ART services
- Antenatal HIV prevalence 33% in 2014 (Myer *et al*, 2015)



# Background – three-item scale

- Developed and field tested in the US (Wilson *et al*, 2014)
  - Literature review of all commonly used self-report items used
  - Four rounds of cognitive testing to identify which items were most consistently understood
  - Narrowed down to three items which had excellent internal consistency in field testing ( $\alpha=0.86$ )
- Performed well in validation against electronic drug monitoring in the US (Wilson *et al*, 2016)
- Scale has never been assessed outside of the US

# Three-item scale

1. Days missed the last 30 days: On how many days did you miss at least one dose of any of your HIV medicines? (0–30 days)
2. Frequency: In the last 30 days, how often did you take your HIV medicines in the way you were supposed to?  
(never/rarely/sometimes/usually/almost always/always)
3. Rating: In the last 30 days, how good a job did you do at taking your HIV medicines in the way you were supposed to?  
(very poor/poor/fair/good/very good/excellent)

## Aggregate scale score:

- Item 1 reverse coded into “days taken”
- Each item linearly transformed to a 0-100 scale with 0 being the worst and 100 representing the best adherence
- The mean of the three scores taken to get an equally weighted aggregate scale score

# Methods

- Participants enrolled into the MCH-ART study from April 2013 -June 2014
- MCH-ART eligibility:
  - Aged 18 and older
  - Newly initiating ART in pregnancy
- Initiated a fixed dose combination of EFV+FTC/3TC+TDF
- Questionnaires translated into isiXhosa
- Up to three study visits from ART initiation to six weeks postpartum
- At each visit
  - In person study visits with questionnaires administered isiXhosa
    - Demographics
    - Three-item self-reported adherence scale (Wilson *et al*, 2014 & 2016)
  - HIV RNA VL (Abbott RealTime HIV-1)
    - VL  $\geq 1000$  copies/mL to indicate elevated VL



# Methods

- The first study visit with both adherence and VL measure for each woman after 16 weeks on ART was included
  - to ensure all women had the opportunity to reach viral suppression

## Analyses

- Internal consistency
  - Cronbach's alpha
- Association between VL and adherence assessed
  - Logistic regression
  - Receiver Operating Characteristics (ROC) curve analysis

# Results

- 628 women enrolled in MCHART
  - 176 were excluded (169 insufficient time on ART, 7 missed essential measures)
  - Women excluded were more likely to present later for antenatal care
  - No other differences at baseline between women included or excluded
- 452 women included

## Description of 452 women included

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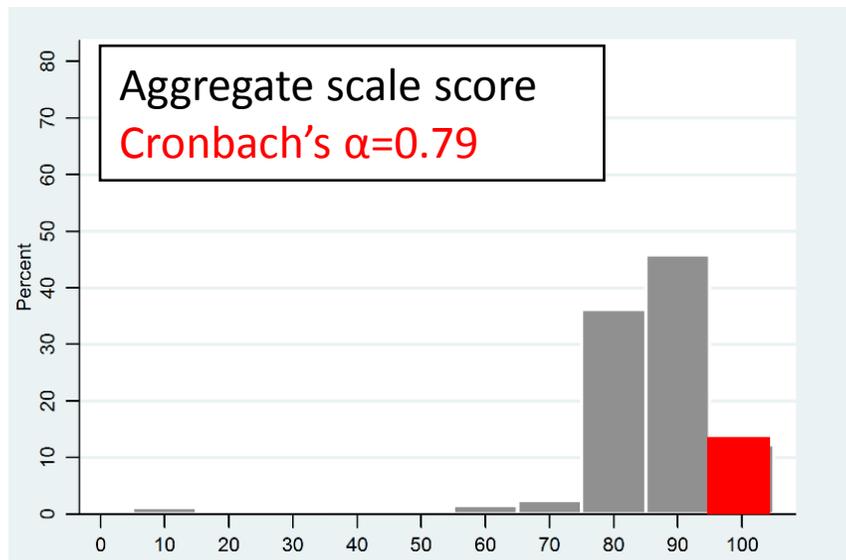
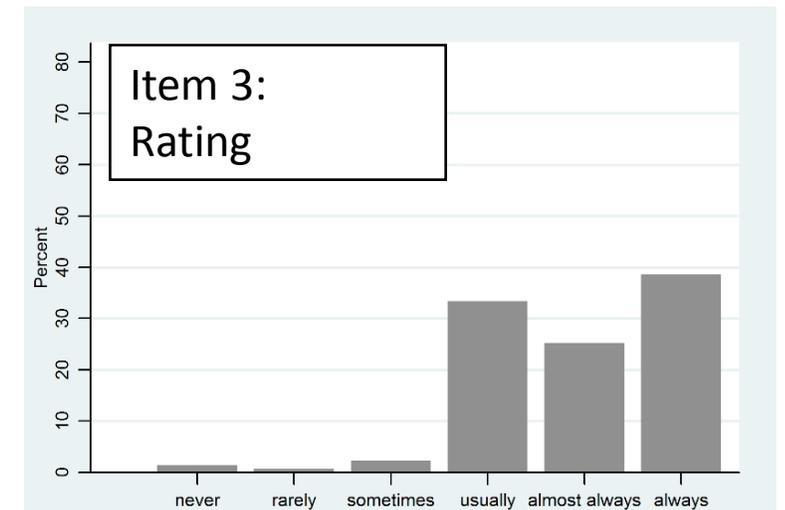
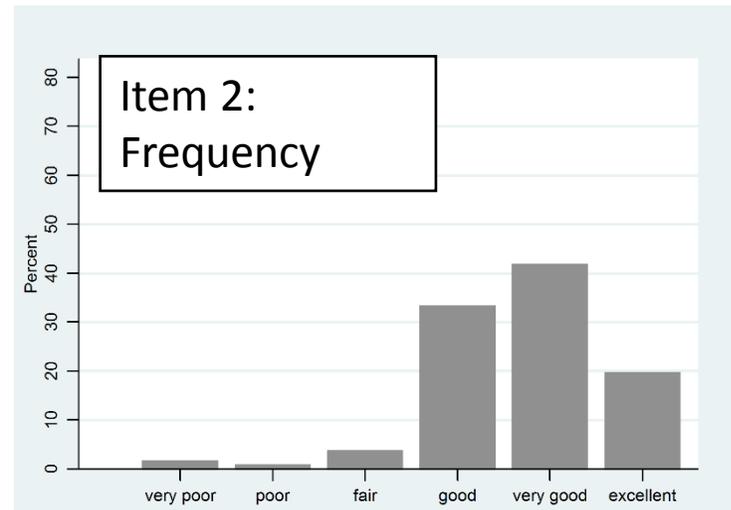
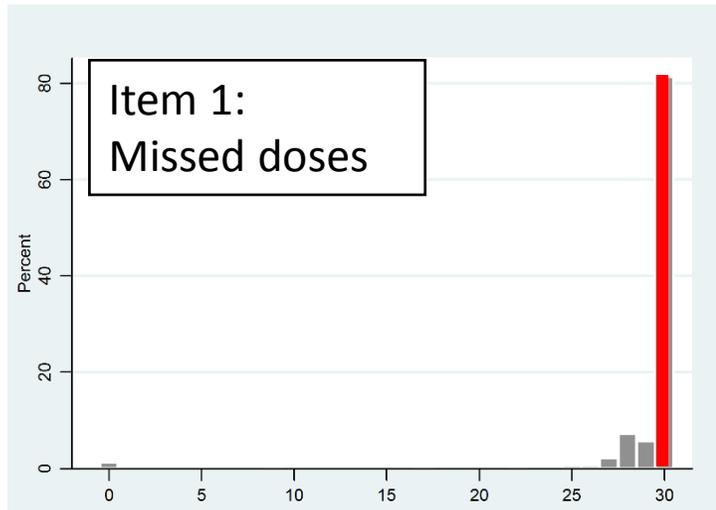
<b>At the time of booking for antenatal care</b>	<b>Median (IQR) or N (%)</b>
Years of age	28(25-32)
Completed secondary school	117(26)
Married/ Cohabiting	187(41)
Diagnosed in this pregnancy	241(53)
Primigravida	80(18)
Pre-ART HIV VL $\geq$ 1000 copies/mL	382(85)

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<b>At the time of adherence assessment</b>	
Pregnant at time of sampling	147(33)
Weeks on ART	19(18-21)
VL <1000 copies/mL at the time of assessment	404(92)
Aggregate three-item scale score	89 (78-94)

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# Histogram showing distribution of individual items and the combined three-item scale score



- All items and scale left-skewed
- Prominent ceiling effect in missed dose item
- Ceiling effect reduced on aggregate scale
  - Only 12% reaching perfect score on all items compared to 80% when only considering missed doses

## Distribution of scale responses by participant subgroups

Presented as median (IQR) of aggregate score and AUC predicting VL $\geq$ 1000

		Median three-item scale score (IQR)		ROC analysis
		VL<1000 (n=414)	VL $\geq$ 1000 (n=38)	AUC
All women		89(78-94)	81.1(76-89)	<b>0.656</b>
Education	Completed secondary school	<b>92(83-94)</b>	<b>88.9(81-89)</b>	0.735
	Did not complete secondary school	<b>89(78-94)</b>	<b>78.9(76-94)</b>	0.643
Pregnancy	Pregnant	89(78-94)	81(78-89)	0.677
	Postpartum	89(81-94)	78(71-89)	0.655
ART duration	16-20 weeks	89(78-94)	81(76-94)	0.639
	20.1-24 weeks	89(79-94)	82(79-89)	0.646
	>24 weeks	93(81-94)	78(11-89)	0.719

- Elevated VL consistently associated with lower adherence scores
- AUC was 0.656 using a VL cut-off of  $\geq$ 1000 copies/mL
- No difference by subgroups other than education ( $p<0.001$ )

## Sensitivity, specificity and predictive values for three-item scale scores to predict VL $\geq$ 1000 copies/mL

Three-item scale score	Viral load		Sensitivity	Specificity	Positive predictive value	Negative predictive value
	$\geq$ 1000	<1000				
Non-adherent (<80)	17	108	45%	74%	14%	94%
Adherent ( $\geq$ 80)	21	306				
Non-adherent (<90)	29	253	76%	39%	10%	95%
Adherent ( $\geq$ 90)	9	161				
Non-adherent (<100)	37	360	97%	13%	9%	98%
Adherent (100)	1	54				

- Using any non-perfect score (<100) detected 97% of women with VL $\geq$ 1000
- Very high negative predictive values - those scoring above threshold on the scale had a very low probability of have a raised VL

# Discussion

- First use of this new three-item scale in a non-English speaking setting
  - Performed well after translation
- Simple self-report adherence scale showed reduced ceiling effect
- Potential as a first-stage ART adherence screener in HIV-infected pregnant and postpartum women



# Limitations & further research

- Very adherent population
  - limited our ability to show relationships between adherence scale scores and VL
- All women newly initiated and persisted on treatment to the time of assessment
  - Performance in treatment experienced populations and repeatedly over time requires further investigation
- Administered by trained research interviewers outside of routine care
  - Reduced social desirability bias
  - Generalizability to routine care setting not known
- Not able to compare to other adherence measures used in routine care
  - Shows promise compared to missed doses alone
  - Further research needed to compare to measures such as pharmacy refill and pill counts commonly used in routine care

# Conclusion

- In the era of universal ART, critical need to focus attention on maternal adherence monitoring in low resource settings
- Simple self-report adherence scale showed potential as a first-stage adherence screener in HIV-infected pregnant and postpartum women
- With further validation within routine care, this simple scale may add value to adherence monitoring, both for this vulnerable group and more generally in ART programmes

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