TEXT MESSAGE RESPONSE PREDICTS TENOFOVIR LEVELS IN MEN WHO HAVE SEX WITH MEN TAKING PRE-EXPOSURE PROPHYLAXIS

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Disclosures

- Gilead Educational Grant Recipient
- Study drug supplied by Gilead

Background

- Pre-exposure prophylaxis (PrEP) effectiveness is strongly linked to adherence
- Gold standard research method for tracking PrEP adherence is intracellular tenofovir-diphosphate (TFV-DP) concentrations
  - Expensive, not commercially available
- Text messaging has been shown to increase ART adherence among HIV+ individuals[a] and is being evaluated in several PrEP demonstrations projects[b]
- Response to daily, automated, SMS text messages to support adherence may be a good predictor of biological adherence measures and thus a non-biologic surrogate for PrEP adherence

[a]Moore et al., AIDS Care, 2012; [b]Marcus et al. HIV Med 2014.

iTab Intervention

- iTAB= Individualized Texting for Adherence Building
- Texting content developed via focus group
  - both health behavior and "factoid" messages
- Texts sent daily at participant-preferred time
  - two-way texts—participants asked to respond
- Participants go through text training and select content
  - 2 health behavior and 5 factoid messages per week

Objectives

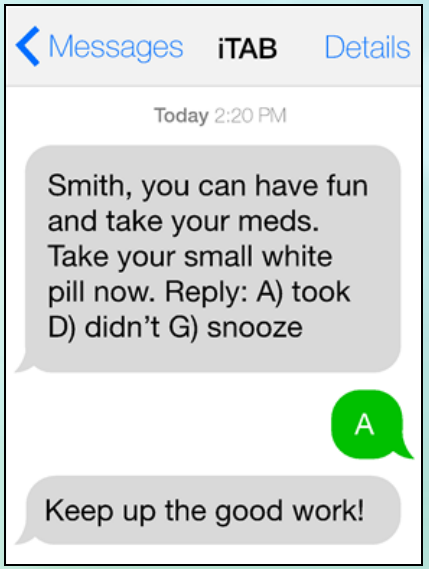
- To compare PrEP drug levels at weeks 12 and 48 with the proportion of daily reported pill taking by iTAB over 2 half-lives prior to study visit

- To establish the optimal level of adherence as determined by iTAB that best predicts PrEP drug level equivalent to taking ≥4 doses per week

Methods

- The TAPIR Study (RCT of Daily Text Messages **T**o Support **A**dherence to **P**rEP **I**n **A**t-Risk for HIV Individuals) is a 48-week study of 398 HIV-uninfected MSM and TGW randomized to iTAB versus SoC
- Analysis was performed on subjects on iTAB at weeks 12 and 48 with at least one TFV-DP level.
- TFV-DP concentrations were compared to the proportion of positive iTAB responses over 34 days prior to weeks 12 and 48 visit.
  - Positive iTAB response: ("A= Yes, I took my PrEP")

TVF-DP (fmol/ punch)	Adherence Interpretation
≥1250	7 doses/week
700-1249	4-6 doses/week
350-699	2-3 doses/week
<350	0-1 doses/week



Castillo-Mancilla *et al., AIDS Res Hum Retroviruses, 2013*

Statistical Analysis

- Wilcoxon rank sum test was used to compare proportions of positive iTAB response in adherence categories by TFV-DP levels
- Intraclass Correlation Coefficient (ICC) was used to assess the association between iTAB response and TFV-DP dosing levels
- ROC analyses were used to assess optimal iTAB response in predicting adequate adherence
  - Defined as TFV-DP > 719 fmol/punch (≥ 4 doses/wk)

Demographic Characteristics of Study Population (n=179)

Characteristic	Number (%)
Age, median (IQR)	33 (28-41)
Male	178 (99%)
Race	
White	131 (74%)
Black	23 (13%)
Hispanic Ethnicity	50 (28%)
Bachelor or advanced degree	90 (50%)
Income > $2000/month	105 (59%)

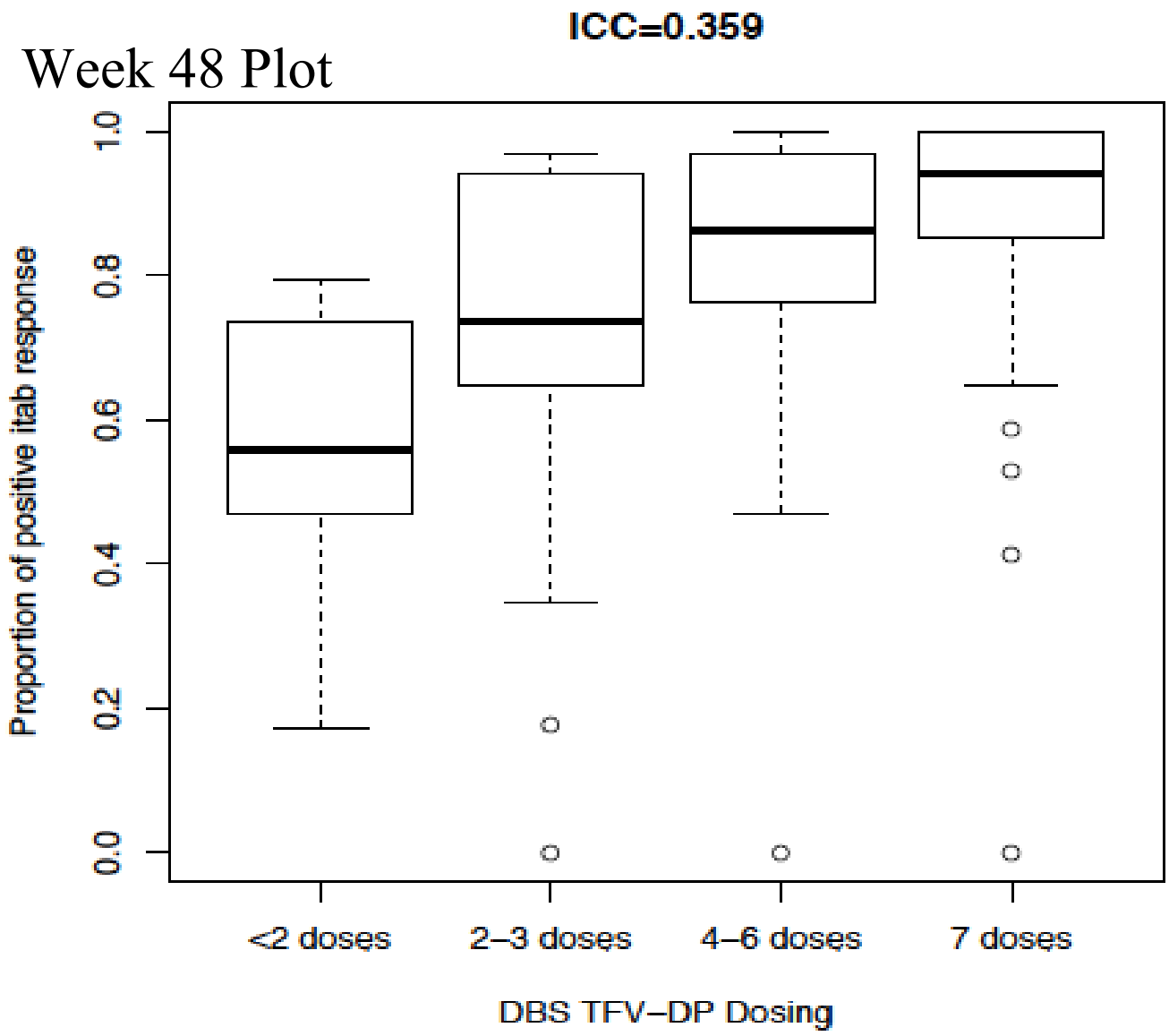
Results

	Week 12 Mean% (SD)	P-value	Week 48 Mean% (SD)	P-value
TFV-DP, mean level	1345 (± 577)	--	1259 (± 527)	--
Pos iTAB responses	87% ± 17%	--	84% ± 20%	--
Pos iTAB responses by doses/wk		**p=0.029**		**p<0.001**
<2 doses	61% ± 30%		56% ± 22%	
2-3 doses	69% ± 29%		68% ± 32%	
4-6 doses	88% ± 15%		83% ± 16%	
7 doses	89% ± 17%		84% ± 20%	

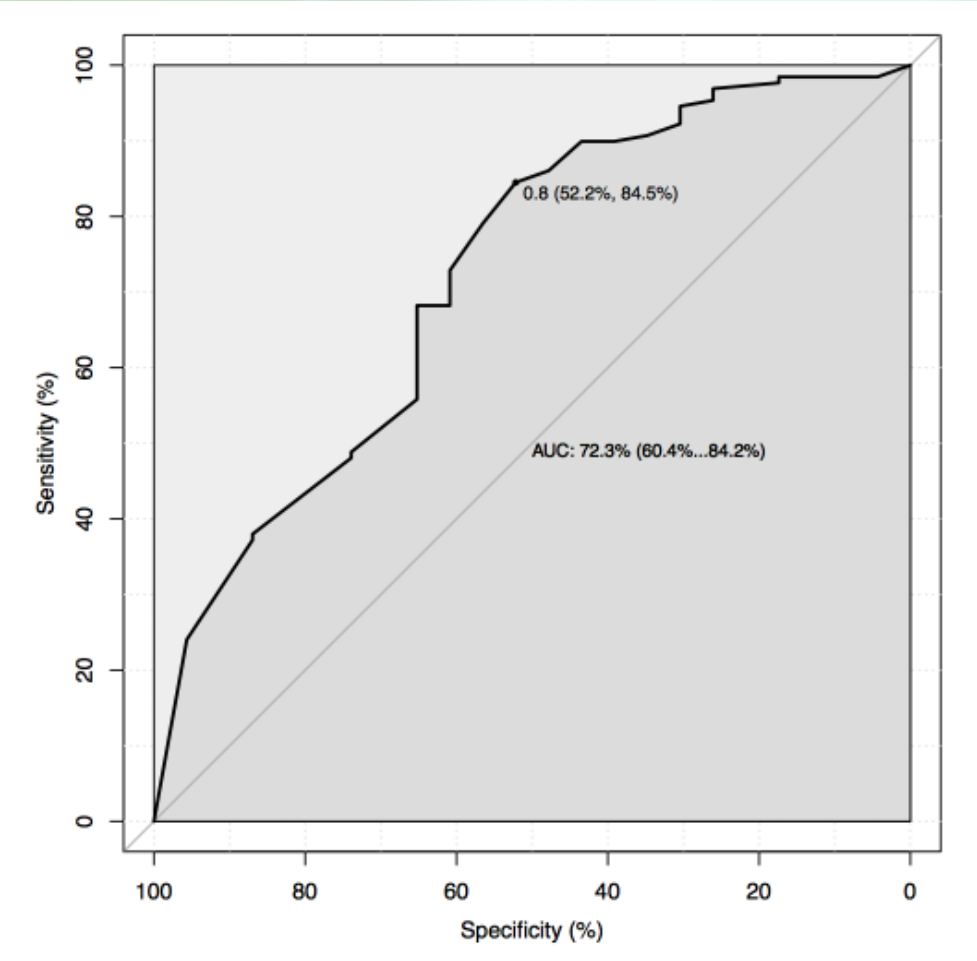
Mean%= proportion of positive iTAB responses

TFV-DP concentrations by dosing categories were associated with proportion of positive iTAB responses.

Week 48 Plot


ICC=0.359
Proportion of positive itab response
0.0
0.2
0.4
0.6
0.8
1.0
<2 doses
2–3 doses
4–6 doses
7 doses
DBS TFV–DP Dosing

Results



ROC analysis suggests that the optimal cut-score of proportion of positive iTAB responses to predict protective TFV-DP levels at week 48 was 75% (specificity 52%, sensitivity 85%, PPV 91%, NPV 38%).

iTAB >75%	TFV-DP >719	N (Proportion)
Yes	Yes	109 (71%)
No	No	12 (8%)
Yes	No	11 (7%)
No	Yes	20 (13%)

Limitations

- iTAB adherence is self-report, but daily and relates to biologic endpoint
- iTAB responses analyzed over 2 half-lives of intracellular TFV-DP thus iTAB data only ~1 month prior to study visit
- May be variance due to high biological variation

Conclusions and Future Directions

- Overall adherence to PrEP was high among iTAB users.
- Self-reported dosing by daily text messaging is associated with TFV-DP levels.
- In settings where PrEP drug level testing is not used, text message adherence reporting could be used to prompt and assess adherence.
- iTAB is currently being evaluated in settings where adherence may (1) be more challenging and (2) need to be higher (e.g., women, transgender individuals).

#ADHERENCE2017

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