

CCTG 595: Text messaging responses correlate with tenofovir-diphosphate dried blood spot concentrations among men who have sex with men on pre-exposure prophylaxis

Jill Blumenthal*¹, Sheldon Morris¹, Sonia Jain¹, Katya Corado², Jason Young¹, Xiaoying Sun¹, Peter Anderson⁴, Michael Dube², Richard Haubrich¹, David Moore¹
¹UCSD, ²Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, ³USC Keck School of Medicine, ⁴University of Colorado

BACKGROUND

- Pre-exposure prophylaxis (PrEP) effectiveness is strongly linked to adherence.
- We sought to validate a daily texting adherence metric, individualized Texting for Adherence Building (iTAB), using a biologic marker, tenofovir diphosphate (TFV-DF) levels in dried blood spots (DBS)

METHODS

- CCTG 595 is a 48-week RCT testing iTAB to promote PrEP adherence in HIV-uninfected MSM.
- Analysis was performed on subjects randomized to iTAB with week 12 DBS TFV-DP levels and iTAB data available.
- TFV-DP levels were compared to proportion of messages responded to positively and adherence patterns over 34 days (two TFV-DP half-lives) prior to week 12.
- Baseline risk factors and demographics were explored as covariates of adherence.
- Methods for statistical analysis included correlation test and Wilcoxon rank sum test for association, and heatmap and Ward Hierarchical Clustering for adherence patterns.

DEMOGRAPHICS and RISK FACTORS

- 152 subjects were included in the analysis
- Mean age was 35 years old; 82% were White, 11% Black, 31% Hispanic; >90% had at least a college education
- 29% had an STI in the last 3 months, 66% had a serodiscordant partner

RESULTS

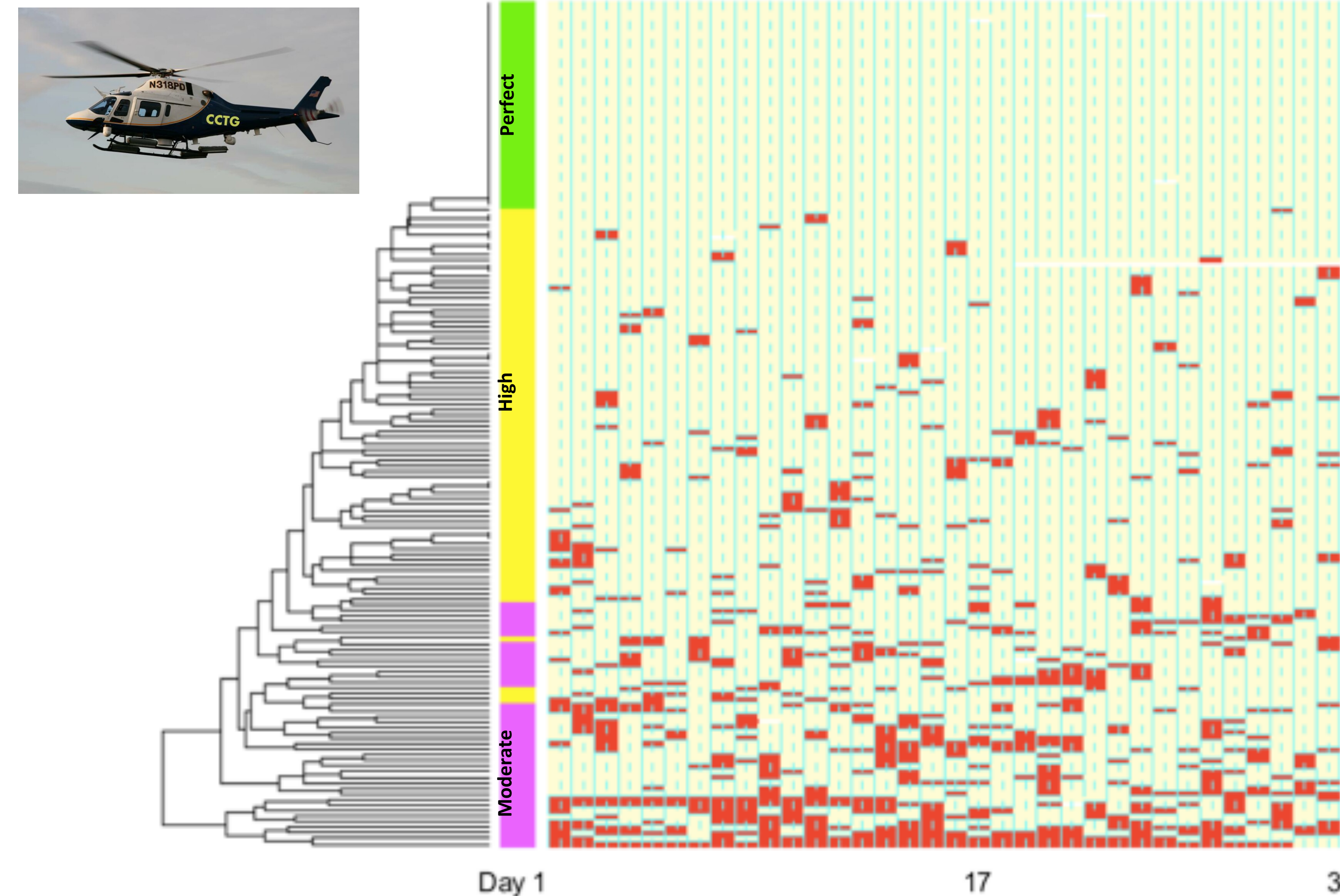
- Mean TFV-DP concentration was 1353 ± 558 fmol/punch.
- Participants reported taking a mean of 87% of doses as measured by positive iTAB responses.
- We found a significant correlation between TFV-DP concentrations and proportions of positive iTAB responses ($r=0.26$, $p=0.001$).
- Subjects with TFV-DP > 891 (~>5 doses/week) had a higher proportion of positive iTAB responses (89 versus 76%, $p=0.003$).
- Subjects statistically clustered into 3 groups based on Ward Hierarchical Clustering representing adherence (mean TFV-DP in fmol/punch):

Perfect (Green) = 37; 1547 ± 694

High (Yellow) = 75; 1356 ± 484

Moderate (Magenta) = 40; 1167 ± 495

Heat Map of iTAB Responses by Adherence Cluster



Based on iTAB data over 34 days (x-axis). Light green boxes indicate days a subject reported taking the dose; red days a subject reported missing the dose; white are missing data. Subjects (y-axis) are clustered into 3 groups based on Ward Hierarchical Clustering representing perfect (green), high (yellow) and moderate (magenta) adherence

RESULTS (Continued)

- Perfect/high adherers had significantly higher TFV-DP concentrations than moderate adherers ($p=0.037$).
- Baseline variables associated with better adherence cluster included older age, non-Hispanic ethnicity and less drug use.

CONCLUSIONS

- Early adherence to PrEP was high among those receiving text message adherence reminders
- Subjects with a higher proportion of positive iTAB responses had significantly higher TFV-DP levels and were more likely to have TFV-DP levels consistent with taking at least 5 doses/week.
- As iTAB response data correlates with a biologically confirmed adherence marker, iTAB might be useful to monitor adherence for PrEP

Baseline Characteristics by Adherence Cluster

	Moderate	Perfect/High	P-value
Median Age (IQR)	31 (23-27)	36 (29-42)	0.002
Race			0.14
White	28 (76%)	94 (74%)	--
Black	6 (16%)	56 (5%)	--
Other	3 (8%)	11 (10%)	--
Ethnicity			0.027
Hispanic/Latino	18 (46%)	29 (26%)	--
Education			0.083
High school diploma or less	6 (15%)	7 (6%)	--
College	30 (75%)	79 (71%)	--
Post-graduate	4 (10%)	26 (23%)	--
STI (gonorrhea, chlamydia, syphilis)	12 (30%)	33 (29%)	>0.999
Serodiscordant partner	27 (71%)	71 (65%)	0.55
Drug use- DAST10 score, max 10 (IQR)	3 (1-4)	2 (0-3)	0.005
Alcohol use- AUDIT score, max 40 (IQR)	6 (2-9)	5 (2-8)	0.6

*All categorical assessments are depicted as n (%) and continuous variables as median (Interquartile Range).

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Corresponding author:
Jill Blumenthal, MD
UCSD Medical Center
Email: jblumenthal@ucsd.edu