Feasibility of using Hemaspot™ dried blood spot kits for at-home collection of blood to quantify viral load among an online sample of U.S. HIV-positive MSM

Sabina Hirshfield, PhD [1], Richard A. Teran, MPH[2], Mary Ann Chiasson, DrPH[1,2], Martin J. Downing, PhD [1], Laura Dize, MS[3] and Charlotte A. Gaydos, MS, MPH, DrPH[3]

(1) Public Health Solutions, New York, NY , (2) Columbia University Medical Center, New York, NY, (3) Johns Hopkins University, Baltimore, MD

Author Contact Information: shirshfield@healthsolutions.org

BACKGROUND

- Suboptimal antiretroviral therapy (ART) adherence can impede viral suppression presenting a major public health challenge due to the probability of further HIV transmission. [1-4]
- HIV transmission risk among HIV-positive MSM is a challenge and can be attributed to a combination of sexual risk behavior and unsuppressed viral load (VL). In the U.S., an estimated 60% of HIV-positive MSM are virally unsuppressed. [5]
- Few studies in the U.S. have utilized dried blood spot (DBS) testing outside of a clinical setting; however, improved DBS collection materials have been developed, streamlining blood collection (e.g., no drying time, longer storage life) for non-clinical settings.
- The internet is an optimal platform to reach MSM not represented in traditional clinical research. Incorporating biomarker data improves the assessment of participant VL suppression status and self-reported data.
- We aimed to assess the (1) feasibility and acceptability of at-home DBS collection, and to (2) quantify HIV RNA among a sample of MSM recruited online.

METHODS

sexPOSITIVE! The M-Spot Study

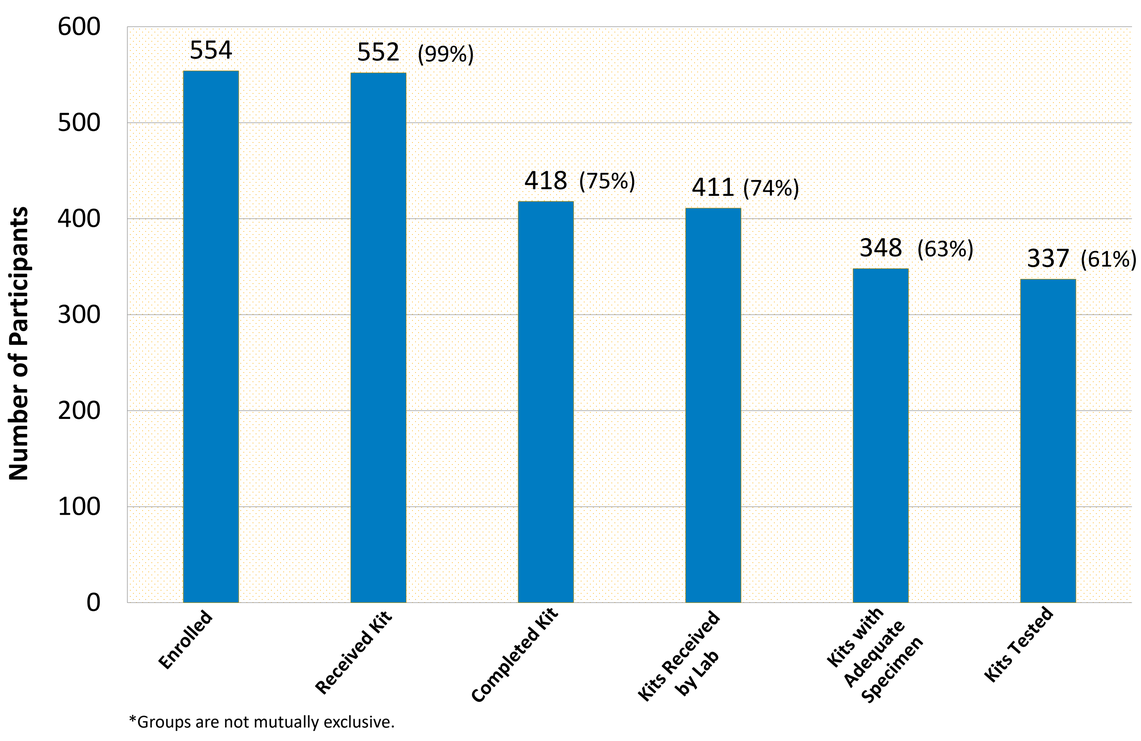
- From 09/01/2016-06/19/2017, HIV-positive MSM completing a 12-month follow-up survey for an online HIV risk reduction intervention (n=766) were invited to enroll in a study to collect an at-home DBS specimen. [6]
- Consenting participants (n=554 (72%)) were mailed a Hemaspot kit and instructed to return it directly to a laboratory for analysis.
- DBS samples were tested according to the Abbott RealTime HIV-1 package insert (Abbott Molecular Inc., Des Plaines, IL) for plasma samples.
- VL data was obtained using the “1.0mL HIV-1 RNA DBS IUO TT” open mode protocol on the Abbott m2000sp/rt system.
- VL results were reported as ‘Not Detected’, ‘≤2.92 log copies (832 copies/mL)’, and a quantifiable HIV-1 RNA reported from 2.93 log copies up to 7.00 log copies.

RESULTS

Table 1: Participant Characteristics by Kit Completion Status

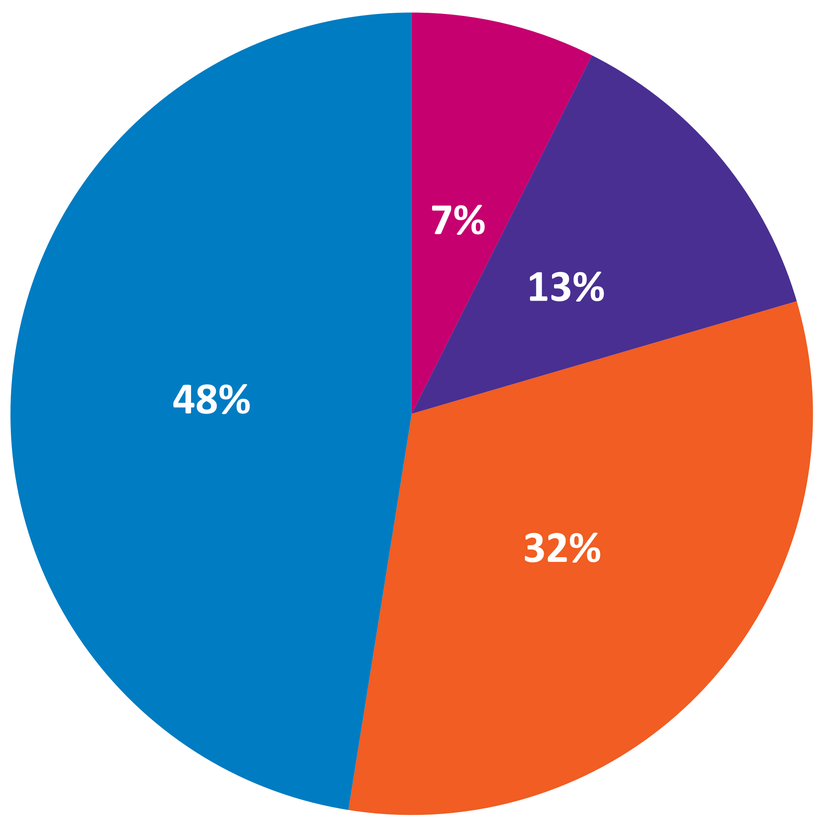
Variable	Total (n = 554) (means or n (%))	Completed kit (n=438) (means or n (%))	Did not complete kit (n = 116) (means or n (%))	p-value
AGE, n=553	39.6	39.5	40.0	0.69
WILSON ADHERENCE SCORE, n=515	84.6	85.4	81.4	**0.05**
RACE, n=554				0.69
Black	83 (15.0)	63 (14.4)	20 (17.2)	
Hispanic	90 (16.3)	73 (16.7)	17 (14.7)	
White	381 (68.8)	302 (69.0)	79 (68.1)	
EDUCATION, n=553				0.27
High school grad or less	54 (9.8)	44 (10.1)	10 (8.6)	
Some college	166 (30.0)	129 (29.5)	37 (31.9)	
College graduate	224 (40.5)	171 (39.1)	53 (45.7)	
Professional or Graduate Degree	109 (19.7)	93 (21.3)	16 (13.8)	
INSURED, n=551				0.77
Yes	516 (93.7)	409 (93.8)	107 (93.0)	
No	35 (6.4)	27 (6.2)	8 (7.0)	
RECRUITMENT SOURCE, n=553				0.57
Mobile Phone Application	170 (30.7)	139 (31.8)	31 (26.7)	
Bareback Website	332 (60.0)	258 (59.0)	74 (63.8)	
Other Sites	51 (9.2)	40 (9.1)	11 (9.5)	
PAST YEAR HIV DIAGNOSIS, n=551				0.77
Yes	105 (19.1)	84 (19.3)	21 (18.1)	
No	446 (80.9)	351 (80.7)	95 (81.9)	
SELF-REPORTED VIRAL LOAD RESULT, n=502				0.58
Undetectable (<=200 copies/ml)	456 (90.8)	361 (90.5)	95 (92.2)	
Detectable (>200 copies/ml)	46 (9.2)	38 (9.5)	8 (7.8)	
CURRENTLY ON ARV, n=553				0.75
Yes	516 (93.3)	407 (93.1)	109 (94.0)	
No	37 (6.7)	30 (6.9)	7 (6.0)	

Figure 1: Number of Participants Completing Each Study Step



*Groups are not mutually exclusive.

Figure 2: Participant Laboratory HIV-RNA Results



- No statistical differences were found among participants who enrolled in our study and those who did not enroll [data not shown]. Participants with a higher adherence score were more likely to complete the DBS kit ($P = 0.05$) (Table 1).
- Reasons for incomplete kits (Figure 1) include: 16 participants unable to collect their own blood sample, 111 participants lost to follow-up, and 7 withdrawals.
- Reasons for untested kits (Figure 1) include: 5 kits lost in the mail, 65 kits had inadequate amount of blood, 7 kits had an instrument error, and 4 kits had an internal control error.
- Over half (53%) of kits tested had detectable viremia.
- Among participants self-reporting an undetectable VL (n=284), 48% returned a DBS kit with detectable viremia.

CONCLUSIONS

- Enrollment in an at-home DBS collection study was found to be acceptable with 72% of participants recruited enrolling into the study.
- HIV-1 RNA quantification was feasible as 81% of kits received by our lab had adequate specimen and did not experience testing errors.
- Over half of all kits tested had detectable viremia. This is particularly concerning as nearly half of men who self-reported an undetectable VL had detectable viremia.
- Future studies should assess the feasibility of at-home DBS collection among other populations living with HIV, as well as collection at multiple time points.

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