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Acceptability of Self-Collected Rectal Swabs for HIV Exposure Testing among MSM/TGW

Hong Van Tieu[1], Maria Lemos[2], Michele Andrasik[2], Ira Fleming[2], Vijay Nandi[3], Geneva Ortiz[1], Debbie Lucy[1], Martin Musuruana[4], Julie McElrath[2], Beryl A Koblin[1]

[1]Laboratory of Infectious Disease Prevention, New York Blood Center, New York, NY, [2]Fred Hutchinson Cancer Research Center, Seattle, WA, [3]Laboratory of Data Analytics, New York Blood Center, New York, NY, [4]University of Illinois School of Medicine, Peoria, IL

Correspondence:
Hong Van Tieu, MD, MS
Lab of Infectious Disease Prevention
New York Blood Center
310 East 67th Street #3-110
New York, NY 10065 USA
Email: htieu@nybc.org
Phone: (212) 570-3081
Fax: (212) 861-5873

Updated Abstract

Background: HIV biomedical prevention trials lack a reliable, sensitive method to measure HIV exposure and condomless sex. A pilot, prospective cohort study assessed the acceptability of self-collected rectal swabs and feasibility of testing for HIV-1 RNA and Y chromosome short tandem repeats (STRs) as biomarkers for HIV exposure and condomless receptive anal sex among MSM and transgender women (TGW) in NYC. Data on acceptability of and adherence to self-administered rectal swab collections for detection of HIV exposure biomarkers are presented here.
Methods: Eligibility criteria were assigned male at birth, age 18-50 years, HIV-negative, ≥2 male anal sex partners of HIV+/unknown status and receptive anal sex without condoms ≥3 times in last month, reside in NYC. 30 participants (ppts) were recruited via websites and referrals. They were randomized to daily vs. sex act-based self-administered rectal swab collection for 2 months. Self-administered online surveys on risk behaviors and acceptability (based on Likert scale 1 to 5), HIV testing, and blood sample collections were performed at baseline and month 2 visits. Ppts were asked to complete daily mobile app-based sex diaries. Presence of human and Y chromosome DNA (Quantifiler Duo PCR) was used to distinguish successful collections from empty rectal swabs.
Results: Of 29 MSM and 1 TGW enrolled, 37% were 18-29 years, 30% Black and 23% Latino. Ppts reported median 6 sex partners and median 8 receptive anal sex acts in the last 60 days. The proportion of swab returns vs. expected was 59.7% in the daily arm and 49.7% in the sex act- based arm (p=0.27). Acceptability measures based on comfort level (mean Likert score=4.4 [SD 0.8] for both groups) and ease (mean 4.3 [SD 0.8] for both groups) in self-collecting rectal swabs were high. In comparing human and Y chromosome DNA results from rectal swabs to matching mobile app self-reported data on anal sex and condom use, adherence in swab collection was higher in the sex act-based arm compared with daily arm (89.2% vs. 72.7%, p<0.0021).
Conclusion: Self-administered rectal swab collection for testing of biomarkers for HIV exposure and condomless anal sex was acceptable among MSM/TGW, with higher adherence in the sex act-based arm. Methods to improve adherence to rectal swab collection and return should be explored.

Introduction

- The U.S. HIV epidemic continues to disproportionately affect men who have sex with men (MSM), with MSM constituting 63% of new HIV infections.
- Condomless receptive anal sex (anal sex as a bottom without condom use) confers highest HIV acquisition risk among MSM.
- HIV biomedical prevention trials lack a reliable, sensitive method to measure HIV exposure and condomless sex. Self-reported sexual risk behaviors can be biased and inaccurate. A biomarker that supplements self-reported sexual behavior would advance field of HIV vaccine and other biomedical prevention research
- There has been emerging research on use of biomarkers in genital mucosal specimens as surrogates for HIV exposure and condomless sex in clinical trials.
- This is a pilot, prospective cohort study among MSM and transgender women (TGW) in NYC to assess: (1) Acceptability of daily vs. after sex self-collection of rectal swabs, (2) Feasibility of testing of rectal swabs for HIV-1 RNA and Y chromosome short tandem repeats (STRs) as biomarkers for HIV exposure and condomless receptive anal sex.

Methods

- **Study inclusion criteria:** (1) assigned male sex at birth, (2) age 18-50 years, (3) HIV-negative by HIV testing at month 0 study visit, (4) ≥2 male anal sex partners of HIV+/unknown status and receptive anal sex without condoms ≥3 times in last month, (5) reside in New York City area, (6) own Android or iPhone smartphone with data plan.
- **Exclusion criteria:** (1) HIV-positive by HIV testing at month 0 study visit, (2) report history of bleeding hemorrhoids or bleeding anal warts.
- **Recruitment:** social media (Facebook page, Craigslist ads, etc.) and referral letters to past study participants
- Participants completed an online prescreener questionnaire to assess eligibility. Eligible participants were contacted by phone and scheduled on-site study visit within 4 weeks.
- **Month 0 study visit procedures:** (1) informed consent, (2) HIV rapid testing using Orasure (HIV Western Blot confirmatory testing if positive), (3) 17 mL whole blood collection for Y chromosome DNA sequencing, (4) HIV risk reduction counseling , (5) self-administered online survey, (6) random assignment to either daily or after sex self-collection of rectal swabs (N=15 in each arm), (7) instructions on rectal swab self-collection, (8) downloading and testing of smartphone app-based sex diary, (9) $50 reimbursement.
- **Month 2 study visit procedures:** (1) HIV rapid testing with Orasure (with HIV Western Blot confirmatory testing if positive), (2) HIV risk reduction counseling, (3) self-administered online survey, (4) smartphone app uninstalled, (5) $50 reimbursement.
- **Smartphone app diary** questions include whether participant had anal sex (top or bottom) with a man or transwoman in the past 24 hours
- **Self-collected rectal swabs:** Self-collect 2 rectal swabs (1 swab for HIV-1 RNA and Y chromosome DNA detection, 1 swab as backup for reruns) daily vs. after sex for 2 months; return swabs to study site every 2 weeks ($50 reimbursement for each return visit); daily arm: collect swabs in mornings, after sex arm: collect swabs within 8 hours of last receptive anal sex act (with or without condoms); instructed to place swabs in rectum for at least 15 seconds to ensure adequate collection of material/secretions; collected rectal swabs are stored frozen and shipped to HVTN Laboratory every 1-2 months
- **Laboratory testing:** (1) detection of Human RPPH1 Ribonuclease P and Male SRY DNA using Quantifiler Duo PCR kit, (2) detection of Human Y chromosome mixtures on DNA rectal swab specimens using commercially available AmpFLSTR Yfiler PCR kit or a more sensitive custom-Illumina assay (pending, not presented here), (3) detection of HIV-1 RNA on rectal swab specimens from condomless and protected sex/abstinent receptive anal sex episodes with known HIV-positive partners using HVTN Viral Diagnostics HIV-1 RNA PCR assay (Robert Coombs Laboratory) (not presented here).

Results

- 30 participants enrolled in the study. Retention at Month 2 was 86.7%.
- **Table 1** shows the baseline sociodemographic characteristics of the participants obtained from the online survey at month 0.
- **Table 2** shows the risk behavior and PrEP/PEP use characteristics of the participants obtained from the online survey at month 2.

Table 1: Baseline Sociodemographic Characteristics at Month 0, N=30

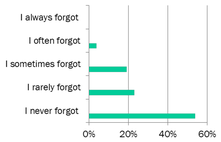
	Total	Daily rectal swab	After sex rectal swab
	N (%)	N (%)	N (%)
Age, years			
18-24	6 (20.0)	3 (20.0)	3 (20.0)
25-29	5 (16.7)	3 (20.0)	2 (13.3)
30-35	12 (40.0)	6 (40.0)	6 (40.0)
36+	7 (23.3)	3 (20.0)	4 (26.7)
Gender			
Male	29 (96.7)	14 (93.3)	15 (100.0)
Transwoman	1 (3.3)	1 (6.7)	0 (0.0)
Race/ethnicity			
White	9 (30.0)	3 (20.0)	6 (40.0)
Hispanic	7 (23.3)	3 (20.0)	4 (26.7)
Black/African-American	9 (30.0)	5 (33.3)	4 (26.7)
Other	5 (16.7)	4 (26.6)	1 (6.7)
Education			
Less than high school graduate	1 (3.3)	0 (0.0)	1 (6.7)
High school graduate/GED	2 (6.7)	2 (13.3)	0 (0.0)
Some college	8 (26.7)	4 (26.7)	4 (26.7)
College graduate or more	19 (63.3)	9 (30.0)	10 (33.3)
Employment status			
Working full-time	19 (63.3)	8 (53.3)	11 (73.3)
Working part-time	5 (16.7)	4 (26.7)	1 (6.7)
Other/Not working	6 (20.0)	3 (20.0)	3 (20.0)
Total annual personal income			
Less than $10,000	6 (20.0)	4 (26.7)	2 (13.3)
$10,000 – 19,999	6 (20.0)	3 (20.0)	3 (20.0)
$20,000 – 39,999	5 (16.7)	2 (13.3)	3 (20.0)
$40,000 – 59,999	5 (16.7)	2 (13.3)	3 (20.0)
$60,000 – 79,999	4 (13.3)	1 (6.7)	3 (20.0)
$80,000+	4 (13.3)	3 (20.0)	1 (6.7)

Table 2: Risk Behavior and PrEP/PEP Use Characteristics at Month 2, N=30

	Total	Daily rectal swab	After sex rectal swab
	N (%)	N (%)	N (%)
In the past 60 days, how many men or transwomen partners did you have anal sex with (top or bottom)?			
0	1 (4.0)	0 (0.0)	1 (7.1)
1 - 2	3 (12.0)	2 (18.2)	1 (7.1)
3 - 5	6 (24.0)	2 (18.2)	4 (28.6)
6 - 8	8 (32.0)	4 (36.4)	4 (28.6)
9+	7 (28.0)	3 (27.3)	4 (28.6)
In the past 60 days, how many of the men or transwomen partners you had anal sex with (top or bottom) are HIV+?			
0	15 (60.0)	5 (41.7)	10 (76.9)
1	6 (24.0)	5 (41.7)	1 (7.7)
2+	4 (16.0)	2 (16.7)	2 (15.4)
In the past 60 days, how many times did you have anal sex as a bottom?			
1 - 2			
3 - 7	5 (25.0)	4 (36.4)	1 (11.1)
8 - 11	4 (20.0)	3 (27.3)	1 (11.1)
12+	5 (25.0)	2 (18.2)	3 (33.3)
	6 (30.0)	2 (18.2)	4 (44.4)
In the past 60 days, of the times you had anal sex as a bottom, how many times was a condom not used?			
0	2 (8.7)	1 (8.3)	1 (9.1)
1 - 2	3 (13.0)	3 (25.0)	0 (0.0)
3 - 5	5 (21.7)	2 (16.7)	3 (27.3)
6 - 7	5 (21.7)	2 (16.7)	3 (27.3)
8+	8 (34.8)	4 (33.3)	4 (36.4)
In the past 60 days, have you used HIV pre-exposure prophylaxis (PrEP)?			
Yes	14 (46.7)	6 (40.0)	8 (53.3)
No	16 (53.3)	9 (60.0)	7 (46.7)
In the past 60 days, have you used HIV post-exposure prophylaxis (PEP)?			
Yes	0 (0.0)	0 (0.0)	0 (0.0)
No	30 (100.0)	15 (50.0)	15 (50.0)

- **Proportion of swab returns vs. expected** was 59.7% in daily arm and 49.7% in after sex arm (p=0.27) (caveat in comparison: different denominators).
- **Acceptability measures** in self-collecting rectal swabs were high:
  - On a scale of 1-5 (with 1 being very uncomfortable and 5 being very comfortable), how comfortable are you about collecting the rectal swabs on your own? *Mean Likert score 4.4 (SD 0.8) (N=26)*
  - On a scale of 1-5 (with 1 being difficult and 5 being easy), how would you describe the ease or difficulty in collecting the rectal swabs on your own? *Mean Likert score 4.3 (SD 0.8) (N=26)*
- **Self-reported adherence** in self-collecting rectal swabs:

How often did you forget to collect the rectal swabs according to your randomization schedule (daily vs. after sex)? (N=26)
**higher proportion of forgetting in daily arm (p=0.04)*



How often did you collect the rectal swabs by placing the swab inside your rectum for at least 15 seconds as instructed? (N=26)

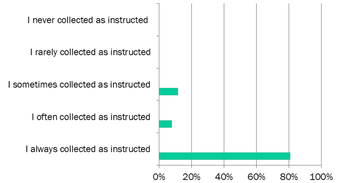


Figure 1: Testing Schema for Y Chromosome DNA and HIV-1 RNA Testing

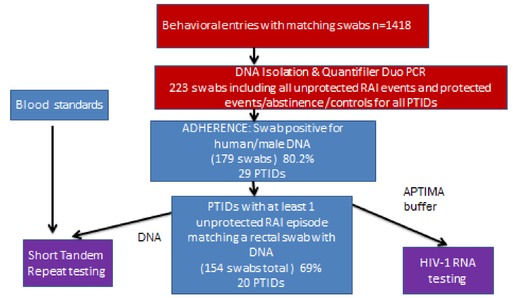


Table 3: Adherence to Rectal Swabbing Based on Human and Y Chromosome DNA Testing

Human RPPH1 Ribonuclease P and Male SRY DNA	Positive	Negative	Total
Daily	88 (72.7%)	33	121
After Sex	91 (89.2%)	11	102
All	179 (80.2%)	47	223

Human and Y Chromosome DNA Positivity on rectal swabs is higher in after sex arm compared to daily arm (89.2% vs. 72.7%, Chi Squared test p<0.0021).

Summary and Conclusions

- Self-administered rectal swab collection for testing of biomarkers for HIV exposure and condomless anal sex was acceptable among MSM/TGW.
- There was no significant difference in adherence of rectal swab collection based on returned swabs; however, adherence was higher in after sex arm compared with daily arm based on swabs containing human/Yc DNA.
- Participants in daily arm reported forgetting to self-collect swabs more often and also returned more empty swabs without human/Yc DNA detection.
- Methods to improve adherence to rectal swab self-collection and return should be explored.
- Next steps: HIV-1 RNA detection on self-collected rectal samples, complete laboratory analyses to assess condomless sex using Short Tandem Repeat Analysis.

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