Substantial Missingness of Electronic Adherence Monitoring Data in a Randomized Clinical Trial among Young Black MSM

Kara Herrera[1], Casey M. Luc[1], Sierra Upton[1], Jeb Jones[2], Mark Dworkin[1]
[1]University of Illinois at Chicago, Chicago, IL, USA, [2]Emory University, Atlanta, GA, USA

Continuum 2024 • June 9-11, 2024 • Puerto Rico

#CONTINUUM2024

Background

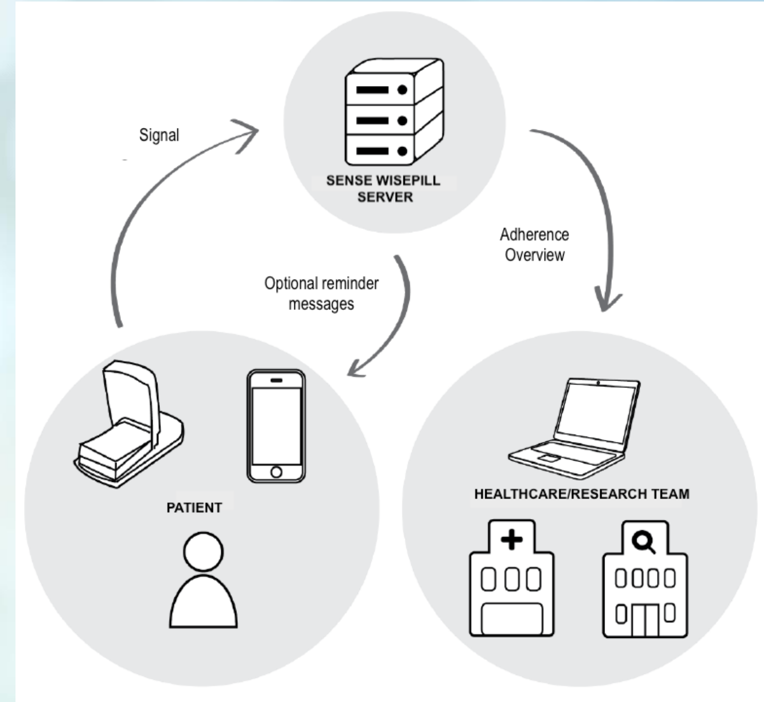
Diagnoses of HIV Infection among Men Who Have Sex With Men, by Age Group and Race/Ethnicity, 2018—United States and 6 Dependent Areas

Race/Ethnicity	13-24 years old (N=6,353) Diagnosis, %	>24 years old (N=18,581) Diagnosis, %
Multiple Races	3%	2%
White	16%	29%
Native Hawaiian/Other Pacific Islander	<1%	<1%
Hispanic/Latino	27%	32%
Black/African American	52%	33%
Asian	2%	3%
American Indian/Alaska Native	<1%	<1%

CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2021. HIV Surveillance Supplemental Report 2023;28(4).

Background

- Real-time electronic adherence monitoring (EAM) with wireless devices has been used in several studies internationally. However, there is less experience with EAM among YBMSM living with HIV
- In a pilot study of EAM among 40 YBMSM living with HIV in Chicago, the participants generally found the EAM devices acceptable and useful and 79% had at least one of three months with <80% adherence
- Based on prior EAM studies, we included EAM as a method to monitor adherence in a randomized clinical trial of a mobile health application designed to improve adherence
- Here we share our experience with this method of monitoring in a population of YBMSM living with HIV in the United States



Dworkin MS, Panchal P, Wiebel W, Garofalo R, Jimenez A, Haberer JE. Experience with antiretroviral electronic adherence monitoring among young African American men who have sex with men living with HIV: findings to inform a triaged real-time alert intervention. AIDS Care. 2020;32(9):1092-1101. doi:10.1080/09540121.2020.1713975

#CONTINUUM2024

Objective

- To determine the frequency of months with missing EAM data for 30 consecutive days and to explore factors associated with missing EAM data
- We hypothesized that EAM data would not have substantial missingness

Methods

- YBMSM were recruited throughout the United States into a digital health multisite RCT, “A mobile phone intervention using a relational human talking Avatar to promote multiple stages of the HIV Care Continuum in African American MSM,” (R01MH116721)
- Those who were eligible self-reported as Black, had at least one male sexual partner in their lifetime, were 18-34 years old, English speaking, owned a smartphone, initiated or prescribed ART, and had a detectable viral load in the previous 4 weeks or self-reported being non-optimally ART adhering or were referred by a provider due to adherence or retention in care concerns
- Study participants completed questionnaires on a wide range of items, including socio-demographics, depression, substance use, and ART adherence

#CONTINUUM2024

Methods

- The participants' ART adherence was electronically monitored with a Wisepill device (Wisepill Technologies, Capetown, South Africa) for 7 consecutive months and adherence was calculated at 30-day intervals
  - The number of openings was dichotomized into missing $\geq$1 months of EAM (0 openings) vs. $<$1 months of missing EAM data (at least 1 out of 30 openings).
  - We defined substantial missingness of EAM data as missing $\geq$1 months over the 7 months of monitoring
- In addition to EAM, self-reported adherence for ART was collected at 30-day intervals using Wilson’s three-item adherence self-report scale to delineate Wisepill device use from ART adherence
- We determined the frequency of months with no EAM data and explored unadjusted prevalence ratios (PRs) and 95% confidence intervals (CIs) for factors associated with missing EAM data

#CONTINUUM2024

Results

Table 1. Participant Characteristics of YBMSM enrolled in a Digital Health RCT (N=249)

	N	%
Age, years		
18-24	32	12.9
25-34	217	87.1
Patient Health Questionnaire for Depression (PHQ-9)		
≥10 (moderate, moderately severe, severe)	65	26.1
<10 (none, minimal, mild)	184	73.9
REALM-SF		
Below high school literacy (At least one word wrong)	93	37.4
High school literacy or above (No words wrong)	156	62.6
Any substance use in prior two weeks		
Yes	210	84.3
No	39	15.7
Current or previous homelessness		
Yes	56	22.5
No	193	77.5
Education		
Less than college	85	34.1
Some college or more	164	65.9
Randomization		
Intervention	111	44.6
Control	112	45.0
Loss to follow-up	26	10.4
Loss to follow-up at 6-months		
Yes	91	36.5
No	158	63.5

#CONTINUUM2024

Proportion of Participants Missing EAM Data by Month Among YBMSM Enrolled in a Digital Health RCT (N=249)

Month	Proportion missing
Month 1	7%
Month 2	27%
Month 3	35%
Month 4	43%
Month 5	46%
Month 6	49%
Month 7	54%

Unadjusted Prevalence Ratios of Selected Factors and Missing EAM Data Among YBMSM Enrolled in a Digital Health RCT (N=249)

Age (<25 vs. 25+)
Depression (PHQ-9 10+ vs. <10)
REALM-SF (At least one word wrong vs. not)
Any substance use in prior two weeks (Yes vs. no)
Previous or current homelessness (Yes vs. no)
Education (Some college or more vs. less than college)
Randomization (Intervention vs. control)

0 0.5 1 1.5 2

Issues Reported with EAM Device Among YBMSM Enrolled in a Digital Health RCT (N=158)

30%
Forgot

10%
Lost

1%
Damage

3%
Other

14%
Battery

9%
Did not use

30%
Travel

3%
Stolen

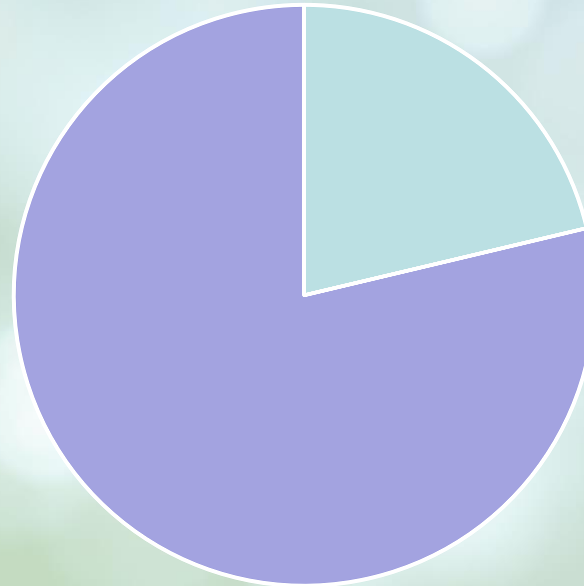
#CONTINUUM2024

Opinions on the EAM Device Among YBMSM Enrolled in a Digital Health RCT (N=158)

	Yes	No
Was the device convenient to use?	142	16
Would you participate in a research study in the future that used this device?	153	5
Did you have any concerns about the size of the device?	57	101
Did you have any concerns about the shape of the device?	22	136
Did the device attract any attention?	31	127

#CONTINUUM2024

Proportion of ≥1 Months of Missing EAM Data Among YBMSM Enrolled in a Digital Health RCT Who Reported ART Use (N=576 Follow-Up Months)



Discussion

- There was substantial missingness of EAM data among YBMSM in this nationally recruited predominantly remote RCT, with those aged <25 having a significantly greater prevalence of having $\geq$1 months of EAM data
- The large proportion of missing one or more months of EAM data raises questions about feasibility of EAM for long-term follow-up of adherence monitoring in this key population
- Issues related to the size, shape, and concerns over privacy may be considered when designing future interventions
- An emerging area of research using EAM involves EAM-triggered real-time alerts that may overcome issues like forgetting. This active EAM approach is currently being studied in BMSM (R34MH132432)

Limitations

- EAM reliably records device openings but does not determine if medication was taken
- High proportion of LTFU of YBMSM limited ability to collect information on device issues at the end of the study
- The results may not be generalizable to all YBMSM or other priority populations

Strengths

- This is the first analysis of use of an electronic adherence monitoring device in a large sample of YBMSM living with HIV in the United States
- Collecting multiple measures of adherence allowed us to understand whether those who completed follow-up reported taking ART during months that EAM had no openings

Recommendations

#CONTINUUM2024

- Since adherence is a critical outcome measure, future studies of adherence in YBMSM should consider feasibility of electronic adherence monitoring when long-term follow-up is planned
- Long-term studies of YBMSM that involve electronic adherence monitoring should consider including an additional adherence measure

Acknowledgements

- We would like to thank the study participants for their time
- We would like to acknowledge Li Lui, PhD, Antonio Jimenez, PhD, Autumn Smith, MPH and Corina Wagner, M.Ed., MBA, of University of Illinois at Chicago, Lisa Chung, MPH and Meaghan Woody, MPH, of Emory University, Robert Garofalo, MD of Lurie Children's Hospital, and Leandro Mena, MD and Paul Burns, PhD of the University of Mississippi Medical Center
- We would like to acknowledge the National Institute of Mental Health (R01MH116721) for funding this research