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Emily J. Hamilton April 8, 2019

Agreement between ARV Adherence in self-report and lab data in Engagement

By

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Degree to be awarded: MPH

Department of Epidemiology

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B.S., Western Kentucky University, 2017

Emory University

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Abstract

Agreement between ARV Adherence in self-report and lab data in Engagement

By Emily Hamilton

Antiretroviral (ARV) adherence is critical in preventing the transmission of HIV. Among populations disproportionately affected by HIV, the Men who have Sex with Men (MSM) population accounts for most of the individuals living with HIV in the United States. Inconsistent ARV adherence presents a challenge for accurately measuring adherence through self-report measurements. This longitudinal cohort study compared self-reported ARV adherence to serum ARV detection among 400 MSM in Atlanta. Demographic characteristics and self-reported information on HIV medication use and continuity of HIV care was ascertained through structured questions on retention in care, HIV treatment, adherence, and HIV care services received via computer-assisted self-interviewing (CASI) surveys. Overall average agreement was highest for HIV treatment and lowest for retention in HIV care, with agreement ranging from kappa values of 0.08 (≥ 3 visits to outpatient HIV medical care in the past 12 months) to 0.65 (currently taking HIV medications). Participants who reported currently taking HIV medications had substantial agreement with corresponding laboratory data (K=0.65, 95% CI: 0.53, 0.77). Race, annual income, and currently receiving treatment for anxiety or depression were significantly associated with lab-reported non-adherence of HIV medications among participants who self-reported high adherence to HIV medications. Although our survey was specifically designed for MSM living with HIV, only one self-reported measurement of adherence substantially agreed with corresponding objective measures of ARV adherence, suggesting that relying solely on self-report may not be accurately representing ARV adherence among the MSM population and could increase the likelihood of overestimating ARV adherence levels. The results of this analysis show that self-reported adherence to ARV regimens was high when assessed by laboratory analysis.

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INTRODUCTION

Human Immunodeficiency Virus (HIV) continues to be a significant public health concern, with nearly 40,000 new HIV diagnoses reported in the United States in 2017 [1]. The men who have sex with men (MSM) are estimated to account for nearly two-thirds of HIV diagnoses in 2016 in the U.S., and are the most disproportionately affected population in terms of HIV acquisition [2]. Implementation of consistent HIV prevention and treatment among the MSM population continues to be challenging, as risk factors, health, and social stigmas surrounding HIV within this population give rise to health inequities [3].

Factors associated with increased risk of HIV acquisition among MSM include high-risk behaviors such as unprotected anal intercourse and substance use, as well as social and emotional stressors resulting from stigma and discrimination [2]. In the 2014 National HIV Behavioral Surveillance (NHBS) report for MSM, 65.2% of HIV-positive-unaware participants (participants who self-reported as having an unknown or negative HIV status, but when tested were found to be HIV-positive) reported having condomless anal sex within the previous twelve months; 28.6% of HIV-positive-unaware participants reported having condomless anal sex with a serodiscordant partner as their most recent sexual encounter [4]. Although the prevalence of high-risk sexual behaviors such as unprotected anal intercourse decreases once individuals become aware of their HIV-positive status, it is estimated that one in six HIV-positive individuals in the MSM population are unaware of their HIV status [2,5]. Substance use and frequent alcohol consumption among HIV-positive-aware MSM has been associated with an increased likelihood of engaging in high-risk sexual behaviors with serodiscordant partners, resulting in partners being more susceptible to HIV acquisition [6]. Stigmas surrounding HIV status and sexual orientation have also been associated with an increase in high-risk sexual behaviors; a study by

Radcliffe et al. surveyed 40 HIV-positive African American MSM and found that 78% of study participants reported experiencing stigma due to sexual minority status as well as stigma due to HIV status, which lead to an increase in high-risk sexual behaviors [7]. Implementing consistent strategies for preventing and treating HIV is critical for addressing risk factors and decreasing the burden of HIV among the MSM population.

The use of antiretroviral (ARV) therapies is one of the most effective strategies for treating HIV infection and preventing HIV transmission [1]. Consistent usage of combination ARV therapies can result in sustained CD4 cell counts and viral load suppression in HIV-positive individuals, serving as an effective treatment option and minimizing the risk of HIV transmission [8]. The introduction of ARV therapies for HIV treatment has greatly improved the life expectancy for individuals living with HIV [9,10]. Compared to an average life expectancy of 36.1 years in 2000, the life expectancy of HIV-positive individuals in the U.S. being treated with ARV treatments is now that of the general population [9]. Among serodiscordant heterosexual couples, the risk of HIV transmission was substantially reduced when seronegative or seropositive partners used pre-exposure prophylaxis (PrEP) as a preventative measure [11].

Adherence to antiretroviral treatments as well as consistent use of pre- and post-exposure prophylaxis greatly minimizes the impact of HIV on the MSM population. While the efficacy of ARV usage in non-MSM populations has been well-documented, reducing incidence of HIV infection among the MSM population through ARV adherence has limitations such as stigma surrounding HIV, homophobia, and limited access to HIV care [12]. According to the 2014 NHBS report for MSM, 78% of HIV-positive MSM between the ages of 18-24 years were currently taking anti-HIV medicines, although this figure did not appear to be corroborated by laboratory data [4]. This NHBS report additionally stated that 15% of HIV-negative and 28.6% of HIV-

positive-unaware MSM engaged in condomless anal intercourse within the last twelve months, yet only 3.5% of HIV-negative and 1.9% of HIV-positive-unaware MSM reported taking PrEP before sex within the last twelve months [4]. Reporting low rates of PrEP due to lack of awareness was supported in a study conducted by Bauermeister et al., which reported that only 27% of MSM age 18-24 years were aware of PrEP, with 1% reported ever using PrEP [13].

ARV therapies are most effective in reducing the transmission of HIV when taken consistently [8]. Measuring ARV adherence among the MSM population typically relies on self-reported measures of adherence, and while self-report data are typically congruent with viral load data, there are many limitations to relying primarily on self-report [14]. Lack of standardization among questionnaires, discrepancies in recall periods and questionnaire response, social desirability, and recall bias can be present in self-report adherence studies, which could result in a relatively poor assessment of objective ARV adherence [14]. Understanding discrepancies between self-report and lab adherence data among MSM can provide a more objective measure of ARV adherence by highlighting what psychosocial or biomedical factors may influence disparities between adherence reporting and allowing these discrepancies to be accounted for when developing self-report surveys. We aim to assess how well self-reported antiretroviral usage aligns with laboratory measurements among the MSM population, and how potential inconsistencies in self-reported adherence data change our understanding of ARV adherence among MSM.

METHODS

This study is a longitudinal cohort study of 400 HIV-positive black and white MSM aimed to assess factors contributing to discrepancies in HIV care and prevention. Inclusion criteria for participants at enrollment included self-reported positive HIV status, self-identification as male and male sex at birth, at least 16 years of age, self-reported race as black or white and non-Hispanic, English speaking, current and future residence in the Atlanta Metropolitan Statistical Area (MSA), and at least one male sex partner in the 12 months before the baseline interview. Participants were excluded at enrollment if the participants were determined to not be living with HIV or were currently enrolled in another HIV prevention or treatment clinical trial.

Computer-assisted self-interviewing (CASI) surveys were conducted between June 2016 and July 2017. Baseline surveys collected demographic information as well as information on HIV care participation, HCV and STIs, drug use, HIV disclosure and condom use with anal sex partners, access to HIV healthcare, history of mental health, and influencing psychosocial factors. Self-reported information on HIV medication use and continuity of HIV care was ascertained through structured questions on retention in care, HIV treatment, adherence, and HIV care services received. Serum samples were collected to determine the presence of ARVs and were qualitatively tested using a validated mass spectrometry approach that can detect all but the most recently approved ARV medications, with testing conducted by laboratories at the Johns Hopkins Medical Institute.

Kappa coefficients (κ) were calculated to assess agreement between lab-reported HIV medication adherence and survey reports of retention, treatment, and adherence of HIV care. Kappa values of 0.4 or less were considered poor to fair agreement, values between 0.41 and 0.6

to be moderate agreement, values between 0.61 and 0.8 to be substantial agreement, and values greater than 0.8 to indicate near perfect agreement. Sensitivity and specificity values with corresponding 95% confidence intervals were used to evaluate the validity of self-reported data.

Logistic regression was used to compare demographic characteristics and risk factors associated with lab-reported non-adherence to HIV medications among participants who reported taking ≥80% of prescribed HIV medications within the last 30 days. Factors included in the regression model were: age in years at baseline (18-34, 35-54, ≥55), education level (did not finish high school, high school or GED, some college/associate degree/technical school, college/post-graduate/professional school), annual income in US dollars (0-14999, 15000-29999, 30000-49999, 50000-74999, ≥75000), race (white, black), current health insurance (yes, no), time since HIV diagnosis (≤ 90 days, >90 days), current treatment for anxiety or depression (yes, no), and exposure to HIV stigma (mild, moderate, severe). Adjusted risk ratios and corresponding 95% confidence intervals were reported to assess for potential significant associations ($p<0.05$). Data were analyzed using SAS 9.4.

RESULTS

Engage[men]t enrolled 400 survey participants, 391 (97.8%) of these have corresponding laboratory data on current HIV medication use. Characteristics of survey participants are categorized in Table 1. 74% of participants reported taking prescribed HIV medications 80% of the time or greater in the 30 days prior to the survey. The majority of participants who reported taking at least 80% of prescribed HIV medications had current health insurance coverage, had at least some college education, were diagnosed with HIV greater than 90 days prior to the survey, and received outpatient HIV medical care 1 to 4 times in the previous 12 months. 80.3% of survey participants had lab-reported detection of at least one HIV medication compared to 94.6% of survey participants who reported taking at least 80% of prescribed HIV medications.

Table 2 compares measures of agreement as well as measurements of sensitivity and specificity between lab-reported HIV medication adherence and participant reports of retention, treatment, and adherence of HIV care. Overall average agreement was highest for HIV treatment and lowest for retention in HIV care, and agreement ranged from kappa values of 0.08 (≥ 3 visits to outpatient HIV medical care in the past 12 months) to 0.65 (currently taking HIV medications). Participants who reported currently taking HIV medications had substantial agreement with corresponding laboratory data (K=0.65, 95% CI: 0.53, 0.77). Survey reports of retention in HIV care and HIV medication adherence displayed poor to fair agreement with laboratory data. Sensitivity measurements in table 2 were high and specificity measurements were generally low and varied. Sensitivity ranged from 85 to 99%, while specificity ranged from 18 to 99%. High sensitivity and specificity values were observed for participants who reported receiving care from an outpatient HIV medical care provider within the past 12 months (Se: 90, Sp: 78), having a personal history of taking HIV medications (Se: 85, Sp: 99), currently taking

HIV medications (Se:93, Sp:89), and taking ≥80% of prescribed HIV medications within 2 hours of the correct time within the past 30 days (Se: 97, Sp: 83).

Table 3 compared characteristics associated with lab-reported non-adherence to HIV medications among participants who reported taking ≥80% of prescribed HIV medications in the past 30 days. Age, education level, current health insurance, time since HIV diagnosis, frequency of alcohol consumption, and exposure to HIV stigma were not significantly associated with lab-reported non-adherence among participants who reported high adherence. Race, annual income, and currently receiving treatment for anxiety and depression were significantly associated with lab-reported non-adherence of HIV medications among participants who self-reported high adherence to HIV medications. African American participants were 4.06 times more likely to have lab-reported non-adherence even though they self-reported adherence compared to white or Caucasian participants (95% CI: 1.43, 11.56). Participants who reported current treatment of anxiety or depression were 4.45 times more likely to have lab-reported non-adherence compared to participants who were not currently being treated for anxiety or depression (95% CI: 1.67, 11.86). Participants who reported an annual income of ≥75,000 dollars were 0.02 times more likely to have lab-reported non-adherence compared to the referent income group, suggesting that this income range is protective against non-adherence (95% CI: 0.01, 0.30). The goodness-of-fit for the logistic model was not significant ($p > 0.05$), suggesting that the fitted logistic model used to obtain the risk ratio values was adequate.

DISCUSSION

We assessed the agreement between self-reported antiretroviral usage and laboratory measurements among the MSM population. Self-reported questions about retention in HIV care were not well correlated to lab data showing recent ARV use. Substantial agreement was found between survey participants who self-reported currently taking HIV medications and corresponding laboratory data on ARV adherence while self-report questions pertaining to retention in HIV care and consistent adherence to ARV regimen guidelines displayed poor to fair agreement with laboratory data. Demographic characteristics including race, annual income, and current treatment of anxiety or depression were significantly associated with lab-reported non-adherence of HIV medications among participants who self-reported high adherence to HIV medications. Although self-report is one of the most commonly used methodologies for reporting ARV adherence, few studies have examined the extent to which self-reported measures of adherence accurately reflect objective measurements of adherence [14].

Our results reported that, of the self-report survey responses that would suggest high ARV adherence, survey participants that reported currently taking ARV medications had substantial agreement with laboratory data. Aspects of the agreement data evaluated in this study deviates from a previous study aimed at assessing the efficacy of using standardized medication adherence reports as a measurement of ARV adherence in HIV-infected individuals. Results from a 2015 study conducted by Duong et al. reported a strong relationship between participants self-reporting ARV adherence within the previous 4 days and objective measurements of adherence, including HIV RNA levels and plasma levels of ARVs [15]. The results of the Duong et al. study were inconsistent with the results of our study, as our survey participants who reported adherence to ARV medications within the previous 4 days displayed poor to fair

agreement with objective measurements of ARV adherence (Table 2). A possible explanation for the inconsistency in study results could be due to differences in survey content as well as the degree to which surveys were specific to HIV-infected individuals, as the Duong et al. study measured self-report using a standardized Patient Medication Adherence Questionnaire [15].

African American participants whose reported current treatment for anxiety or depression were significantly more likely to report ARV adherence but have lab values that did not show recent ARV use. Those with an annual income of 75,000 USD or greater were significantly less likely to have discordance between ARV adherence measurements. Racial disparities among MSM and risk of non-adherence to ARV medications has been documented in previous studies, with psychosocial factors such as racial discrimination, medical mistrust, social stigmas, and reduced access to consistent HIV care contributing to increased ARV non-adherence among black MSM when compared to white MSM [16,17]. Higher rates of depression or anxiety among MSM has also been associated with increased risk of non-adherence to ARV medications, which are also consistent with our findings [18,19]. Although other studies do not explicitly state the potential protective effect of high annual income on ARV non-adherence, low socioeconomic status and inconsistent source of income has been associated with increased likelihood of ARV non-adherence [20]. Sociodemographic factors found to be significantly associated with discordance between self-report and lab-reported measures of ARV adherence are reflective of previously established factors associated with ARV non-adherence. Although our results did not show a significant association between age, education level, health insurance coverage, time since HIV diagnosis, alcohol consumption, or exposure to HIV stigma and discordance of ARV adherence measurements, other studies report variable associations between these factors and ARV adherence [21,22].

There are several limitations with this study. Participants were recruited in the Atlanta Metropolitan Area and may have increased linkages to HIV care and increased likelihood of HIV care retention, which has been associated with increased ARV adherence when compared to non-metropolitan and rural areas [23]. Self-reported measurements of ARV adherence assessed for agreement to laboratory data on ARV adherence were based on questions concerning current HIV care, retention in HIV care, and HIV medication adherence, but agreement was not assessed for self-reported psychological factors, personal attributes, or institutional resources, and may also be valid self-reported measurements of ARV adherence [24]. Through our regression model, we aimed to address the association of certain demographic, psychosocial, and personal attributing factors to discordance between self-report and lab-report ARV adherence, although it would be difficult to include all factors which could potentially influence discordance in reported measurements of adherence. Lastly, our study population consisted of black and white MSM, and the results of this study may differ from other populations and demographics that are vulnerable to HIV acquisition, such as Latinos, women, and adolescents.

The findings of this study could have direct implications within the field of HIV research concerning medication adherence, as self-report is the most widely used measurement of ARV adherence [14]. Numerous studies have been published on adequately addressing the influence of risk factors associated with inconsistent ARV adherence within study design, improving ARV intervention strategies, and developing self-report surveys tailored to certain populations living with HIV [25]. Furthermore, the University of California San Francisco provides a database of surveys and scales specific to populations either vulnerable to HIV or living with HIV and tested by the California Association of Professional Scientists for use by HIV researchers [26]. Previously published information on addressing factors associated with inconsistent ARV usage

as well as available resources dedicated to structuring valid self-report surveys for HIV study populations should result in high agreement between self-reported and lab-reported measurements of recent ARV use. Although our survey was specifically designed for MSM living with HIV, only one self-reported measurement of adherence substantially agreed with corresponding objective measures of ARV adherence, suggesting that relying solely on self-report may not be accurately representing ARV adherence among the MSM population and could increase the likelihood of overestimating ARV adherence levels. These results foster questions concerning what behavioral factors are not being adequately addressed among the MSM population, what factors contribute to continued inaccuracy in self-report data even when surveys are specific to MSM individuals living with HIV, and whether or not future research involving HIV medication adherence should move towards a more objective standard of measuring adherence.

ARV adherence will continue to remain a concern for MSM population if factors that contribute to inconsistencies in self-reporting adherence are not adequately addressed. Without addressing restrictions leading to ARV non-adherence, the United States will not meet the 90-90-90 program initiative set forth by the United Nations Programme on HIV/AIDS (UNAIDS), which aims to have 90% of all individuals living with HIV to know their HIV status, 90% of all individuals with an HIV diagnosis to adhere to ARV therapies, and 90% of individuals adhering to ARV therapies to have suppressed viral loads by the year 2020 [27]. The results of our study have highlighted the need to revisit the design and implementation of self-report surveys catered for the MSM population to discourage discordance between self-report and objective measurements of adherence. In addition, future research should consider implementing the use of a more objective measurement to limit the effects of overestimating ARV adherence. Current

progress on increasing access to ARV and sustainable quality HIV care, working with health care providers to increase health literacy and positive impacts surrounding ARV treatments, and working with the MSM population to address social and psychological factors influencing non-adherence will continue to provide useful insight into how to remove barriers to ARV adherence and increase the impact of future studies on ARV adherence.

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Table 1. Comparison of Total Study Participants to Participants Who Reported taking ≥80% of Prescribed HIV Medication in the Last 30 Days by Certain Demographic and HIV Care Characteristics

Characteristic	N	%	% Reporting ≥80% Medication Adherence
Total Sample	400	100.0	74.0
Age at Interview (years)			
18-24	31	7.7	67.7
25-34	104	26.0	62.5
35-44	109	27.3	71.6
45-54	109	27.3	82.6
55-64	42	10.5	88.1
≥ 65	5	1.2	100.0
Race			
White/Caucasian	193	48.3	85.5
Black/African American	207	51.7	63.3
Education			
Did Not Graduate High School	10	2.5	60.0
High School Graduate or GED	59	14.7	62.7
Some College or Associate Degree	169	42.3	69.2
College or Post-Graduate	162	40.5	84.0
Current Health Insurance Coverage			
Yes	284	71.0	81.7
No	106	26.5	55.7
Unknown	8	2.0	50.0
Not Reported	2	0.5	50.0
Annual Income (US Dollars)			
0-14,999	116	29.0	63.8
15,000-29,999	92	23.0	72.8
30,000-49,999	74	18.5	77.0
50,000-74,999	39	9.7	82.1
≥ 75,000	65	16.3	89.2
Unknown	10	2.5	60.0
Not Reported	4	1.0	50.0
Time Since HIV Diagnosis			
≤ 90 Days	14	3.5	50.0
> 90 Days	386	96.5	74.9
Visits to Outpatient HIV Medical Care in Past 12 Months			
0	20	5.0	50.0
1-4	267	66.7	80.9
5-9	64	16.0	78.1

≥10	10	2.5	70.0
Not Reported	39	9.8	33.3
History of Taking Any HIV Medications			
Yes	383	95.7	77.3
No	16	4.0	0
Not Reported	1	0.3	0
Currently Taking HIV Medication			
Yes	348	87.0	85.1
No	35	8.7	0
Not Reported	17	4.3	0
HIV Antiretroviral Analyte Detected			
Yes	321	80.3	87.2
No	70	17.5	11.4
Not Reported	9	2.2	88.9

Table 2. Agreement between Lab-Reported ARV Adherence and Participant Reports of Retention, Treatment, and Adherence of HIV Care

Item	Total N	Agreement K (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)
Retention in HIV Care				
≥ 3 visits to outpatient HIV medical care*	352	0.08(-0.01,0.17)	89(84,93)	18(12,25)
Have not missed a scheduled appointment for HIV care*	360	0.30(0.17,0.43)	91(88,94)	38(25,50)
Have seen an outpatient HIV medical care provider*	135	0.15(-0.04,0.33)	90(85,96)	78(64,92)
HIV Treatment				
Personal History of Taking ARVs	390	0.31(0.19,0.43)	85(82,89)	99(78,100)
Currently taking ARVs	375	0.65(0.53,0.77)	93(90,96)	89(78,99)
HIV Medication Adherence				
Have not missed ARV dose in last 4 days	340	0.28(0.17,0.38)	99(98,100)	23(14,31)
Have missed 3 or less ARV doses**	340	0.35(0.22,0.49)	98(96,99)	29(18,40)
Reported ‘very good’ or ‘excellent’ at correctly taking ARVs**	337	0.27(0.17,0.37)	99(97,100)	22(14,30)
Reported ‘almost always’ or ‘always’ for how often ARVs taken correctly**	339	0.38(0.24,0.52)	97(96,99)	32(20,44)
Reported taking ≥ 80% of prescribed ARVs**	328	0.37(0.20,0.54)	97(95,99)	32(17,47)
Reported taking ≥ 80% of prescribed ARVs within 2 hours of correct time**	322	0.20(0.09,0.31)	97(96,99)	83(74,91)
Intentionally stopped taking all ARVs for 3 consecutive days or less*	310	0.16(-0.03,0.36)	95(92.97)	27(06,61)

*In past 12 months
**In past 30 days

Table 3. Characteristics Associated with Lab Reported Non-Adherence to HIV Medications among Participants who reported taking ≥80% of Prescribed HIV Medications in the Past 30 Days

Variable	Adjusted RR	95% CI
Age at Baseline (years)		
35-54	1.00	
18-34	1.04	0.40, 2.67
≥55	0.69	0.13, 3.53
Education Level		
College, Post-Graduate, or Professional School	1.00	
Did not Finish High School	0.61	0.03, 11.15
High School or GED	2.41	0.61, 9.50
Some College, Associate Degree or Technical School	1.49	0.55, 4.10
Annual Income (US Dollars)		
30,000-49,999	1.00	
0-14,999	0.55	0.18, 1.70
15,000-29,999	0.68	0.21, 2.19
50,000-74,999	0.48	0.08, 2.71
≥75,000*	0.02	0.01, 0.30
Race		
White/Caucasian	1.00	
Black/African American*	4.06	1.43, 11.56
Current Health Insurance		
Yes	1.00	
No	1.23	0.49, 3.09
Time Since HIV Diagnosis		
>90 days	1.00	
≤90 days	0.27	0.01, 5.40
Current Treatment for Anxiety or Depression		
No	1.00	
Yes*	4.45	1.67, 11.86
Frequency of Alcohol Consumption		
Once a month or less	1.00	
Weekly or bi-weekly	1.02	0.37, 2.84
Nearly daily or daily	0.73	0.23, 2.28
Exposure to HIV Stigma		
Mild	1.00	
Moderate	1.15	0.46, 2.87
Severe	0.30	0.06, 1.58

*$p<0.05$