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A Self-Powered Foot Mapping Trail Using Piezoelectric Effect

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HIV DISCLOSURE, RETENTION IN HIV CARE, AND VIRAL LOAD SUPPRESSION: A STUDY AMONG NEW TO HIV CARE PATIENTS

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HIV DISCLOSURE, RETENTION IN HIV CARE, VL SUPPRESSION: A STUDY AMONG NEW TO HIV CARE PATIENTS

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EPIDEMIOLOGY

ABSTRACT

HIV remains a major ongoing public health problem globally and in the United States (US). Despite the advances in the antiretroviral therapy (ART), new HIV cases continue to occur. Hence, understanding the factors that influence patient's decision to HIV treatment and prevention is of paramount. HIV disclosure, an important modifiable behavior, is a barrier to linkage and engagement in HIV care. Thus far, studies examining HIV disclosure and its impact on HIV related outcomes, retention in care (RIC) and viral load (VL) suppression among HIV patients newly initiating care are scant. While these studies provide insights on risk factors of HIV disclosure and its impact of HIV related outcomes to some extent, they are limited to examining few risk factors of HIV disclosure and different ascertainment of HIV disclosure generating inconsistent results. Additionally, the majority of the studies conducted have HIV cohorts with enrollment not restricted to couple of weeks from initiating care. The aim of this dissertation was to assess factors associated with HIV disclosure/patterns of HIV disclosure and its impact on RIC and VL suppression. Using new to HIV care integrating ENGagement and Adherence Goals upon Entry (iENGAGE) data, we observed that Black race, emotional support, and unmet needs predicted any HIV and broad disclosure, whereas males, emotional support, active coping and acceptance were associated with selective disclosure. We observed that HIV disclosure and patterns of disclosure did not significantly improve RIC and 48-week VL suppression. However, any disclosure, broad

and selective disclosure groups were significantly less likely to achieve VL suppression over time. Finally, we did not observe effect modification by HIV disclosure and patterns of HIV disclosure on the relationship of iENGAGE intervention with 48-week VL suppression. In conclusion, this dissertation contributes to the existing knowledge of early HIV disclosure and HIV related outcomes among patients initiating care.

Keywords: HIV disclosure, patterns of HIV disclosure, viral load suppression, retention in care, new to care, iENGAGE, effect modifier

DEDICATION

To my mother:

Pramodini Arvind Modi

&

In loving memory of:

My Father

Arvind Jamnadas Modi

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IMPACT OF HIV DISCLOSURE ON RETENTION IN CARE AND VIRAL LOAD SUPPRESSION AMONG NEW TO HIV CARE PATIENTS

LIST OF ABBREVIATIONS

AIDS	acquired immune deficiency syndrome or acquired immunodeficiency syndrome
ART	anti-retroviral therapy
AUDIT-C	alcohol use disorders identification test
ASSIST	alcohol, smoking and substance involvement screening test
CASI	computer administered self-interview
CDC	Centers for Disease Control and Prevention
CNICS	CFAR Network of Integrated Clinical Systems
CFAR	Centers for AIDS Research
CI	confidence interval
EMR	electronic medical record
JHU	Johns Hopkins University at Baltimore
HR	hazards ratio
HRAP	HIV risk assessment for positives
HIV-ASES	HIV adherence self-efficacy scale
iENGAGE	integrating ENGagement and Adherence Goals upon Entry
IDU	intravenous drug user
IRB	institutional review board
MOS-4	medical outcomes study social support survey-4

MSM	men who have sex with men
OR	odds ratio
PHQ	patient health questionnaire
PLWH	people living with HIV
SD	standard deviation
UAB	University of Alabama at Birmingham
UNC	University of North Carolina at Chapel Hill
UW	University of Washington at Seattle
VL	viral load
WHO	World Health Organization

INTRODUCTION

In 2016, about 36.7 million people were living with HIV and 1.8 million were newly infected worldwide [1]. HIV is a global public health epidemic which not only affects individuals but their social network and communities [2, 3]. In the US, more than 1.2 million people are living with HIV. The success of Anti-Retroviral Therapy (ART) has significantly improved the life expectancy of people living with HIV (PLWH) [4]. Once considered a life-threatening illness, HIV infection is now perceived as a multifaceted chronic illness [5, 6]. The importance of engagement and retention in HIV care is emphasized by the US National HIV/AIDS Strategy [7]. The HIV treatment cascade projects that about 86% diagnosed with HIV, 40% are engaged in HIV care, 37% prescribed ART and 30% achieved viral load (VL) suppression [8-10].

Inconsistent HIV care has negative implications at individual and population level. At individual level, there is lower ART adherence, development of resistant virus, sustained viremia, and poor health outcomes [11, 12]. At a population level, continuous HIV transmission adds to the HIV epidemic. Alternatively, virally suppressed state improves the overall health and reduces the risk of HIV transmission [13]. This underscores the importance of the continuous efforts required to curb transmission ad reduce the occurrence of new infections. Regardless of decline in new HIV cases, about 40,000 new HIV infections occur annually in the US and still remains a major challenge for government organizations to scale up prevention efforts [4].

The first year of HIV diagnosis is stressful where newly diagnosed HIV infected individuals adjust to the new diagnosis [5, 14] and simultaneously learn behavioral skills to engage and retain in HIV care. During this initial year, HIV disclosure plays a critical role [14, 15] supporting patients to develop coping strategies to reduce stress from the new diagnosis [16], link and retain in HIV care to achieve VL suppression for better health related outcomes [17, 18].

HIV Disclosure and Patterns of HIV Disclosure

HIV disclosure is an important HIV behavior of talking about one's HIV serostatus to individual(s) or organization(s) [19]. From public health perspective, role of HIV disclosure to HIV treatment and prevention is noteworthy [20-22]. Patients who disclose prior to ART initiation have better ART adherence and achieve VL suppression which improves the overall quality of life among PLWH [23]. Timing of HIV disclosure after HIV diagnosis is equally important [24]. Early HIV disclosure to sexual partners reduces the spread of HIV infection with individuals choosing less risky sexual behaviors and adopting HIV testing and counselling [25]. Disclosure to family, friends, co-workers or religious leaders may provide opportunities to gain social support [26-28] to link to HIV care in timely manner, initiate ART and achieve virally suppressed state [29] to prevent transmission of the virus to sex partners [30, 31].

Potential benefits of HIV disclosure include gaining social support to cope with the new diagnosis, reduced mental health problems, engagement and retention in HIV care, ART initiation and adherence and overall good quality of life [17, 25-28, 30, 32-36]. Risks include stigma, discrimination, rejection, blame, violence and loss of financial support [22, 25, 37-40]. Addressing negative implications associated with HIV disclosure

is beyond the scope of this dissertation. Despite the benefits, the rates of HIV disclosure range from 42-100% in developed countries [25]. In the US, CDC estimated disclosure rates to be 72% [41]. If HIV disclosure rates were 100%, the HIV transmission risk would reduce to 32.5-74% [42, 43]. However, a cross sectional survey conducted by Marks (2002) among active HIV patients across six clinics in California reported only 50% participants were asked about HIV disclosure by health care providers [44].

HIV disclosure is a complicated process and PLWH may evaluate benefits and risks of disclosure [26, 27]. Depending on the choice, an individual may choose to disclose to no one resulting in non-disclosure; may selectively disclose to a specific group like family, friends, religious leaders or broadly disclose to more than one group [39]. Several studies so far have examined role of HIV disclosure but the focus has been on patients established in HIV care [5, 45], men who have sex with men (MSM) population [18, 46-49], intravenous drug users (IDU), alcohol users [50] or women [33, 51-53]. However, literature is scant on early HIV disclosure [24, 54] among patients newly initiating HIV care [23, 35, 39, 46, 47, 55-57]. Additionally the ascertainment of HIV disclosure varies across studies [51, 58, 59].

Crossby (2017) conducted study on association of disclosure and condom use among young black MSM aged 15-29 years and found that about 70% disclosed their HIV status to initial male partner but only 9% reported using condom while having sex [47]. Elopre (2016) showed that 87% of the participants disclosed their HIV status to someone before initiating care and of those 58% were selective disclosers among adults 19 years and older, new to HIV care. The same study showed that Blacks were 4 times more likely to non-disclosure (OR = 4.0; 95% CI = 1.8, 8.9) and about 2 times more

likely to selective disclosure (OR = 1.7; 95% CI = 1.0, 2.7) compared to whites. CD4 count <200cells/ml of blood at initial HIV care appointment was associated with non-disclosure and selective disclosure but the results were not statistically significant [39]. Trinh (2016) conducted a retrospective cohort study among ART naïve patients and found that among participants 38 years of age and younger, disclosure was associated with higher CD4 recovery compared to who did not disclose 6 months' post ART initiation [60]. Abler (2015) assessed the association of depression with HIV disclosure to sex partners among newly diagnosed MSM, 18 years and older, found that higher the depression (score of ≥16 on Beck depression inventory), lesser was early disclosure to sexual partners [46]. Skunodom (2006) focused on association of non-disclosure among pregnant women and found that almost 70% women disclosed their HIV status within a month of pregnancy and additional 24% disclosed by 4months. This study showed that not having HIV positive partner or not knowing if partner was tested for HIV before, learning of HIV status during delivery and having more than one sexual partner was associated with non-disclosure [57]. Olley (2004) found that among HIV patients with less than 1 year of HIV diagnosis, non-disclosure was significantly associated with males, alcohol abuse prior to sex, no condom use during last sexual encounter, and having multiple sexual encounters in last 6 months [56].

To our knowledge, no study has been conducted so far to examine the factors associated with disclosure among new to HIV care patients within 14 days of their primary HIV care appointment across geographically diverse urban HIV clinics.

HIV disclosure, Retention in Care (RIC) and Viral Load (VL) Suppression

Early HIV disclosure is an important modifiable factor to promote RIC and achieve VL suppression. Among patients initiating care, RIC is inconsistent with negative implications on VL suppression [12, 61-64]. PLWH who disclose their HIV status may gain required mental support, transportation help and reminders to regularly attend clinic visit appointments, reassurance to cope with the diagnosis and initiate ART, reminders and financial assistance to start medications for better survival outcomes [23, 65-68].

Few studies have assessed role of HIV disclosure and HIV related outcomes. Breger (2017) reported among ART naïve patients in Cameroon, HIV disclosure to at least one person prior to ART initiation was associated with a marginal increase in chances of patients retained in HIV care measured as one clinical visit within 180 days of baseline visit (RR = 1.14; 95%CI = 0.94, 1.38) [69]. Elopre (2015) showed that among adult HIV patients establishing care, non-disclosure was found to be associated with poor RIC measured as no HIV care appointments missed in at least 6 months [70]. The same authors showed that participants who chose selective disclosure to friends or family had almost double the odds of detectable viral load (≥200 copies/ml of blood). The limitation of the study was differential missing viral loads among disclosure groups [71]. Halperin (2013) reported that among newly diagnosed (within 6 months of HIV diagnosis) early disclosure to at least one person was significantly associated with RIC measured as having 2 or more appointments at least 3 months apart during 1 year time frame [72]. The authors also reported that among patients who disclosed 66.7% had a visit constancy of 80% or greater compared to 22.2% among those who did not disclose [72]. Buma (2015)

showed that 80% of ART naïve patients who disclosed their HIV status achieved VL suppression compared to 19% who did not disclose. The same study showed almost 97% of early disclosers (disclosure prior to ART) and 81% of late disclosers (disclosure post ART) achieved VL suppression (<400 copies/ml of blood) [23]. Conversely, Daskalopoulou (2017) conducted a study among HIV patients in care and showed that non-disclosure was not associated with detectable VL [5].

Few studies were done so far to explain the impact of HIV disclosure on RIC and VL suppression especially among new to care patients. These studies ascertain RIC measures differently and results vary. RIC and VL suppression being important components predicting favorable survival outcomes among patients initiating care, delineating the association of HIV disclosure with RIC and VL suppression is critical.

Aims and Implications

The Joint United Nations Programme on HIV and AIDS (UNAIDS) proposed a 90-90-90 initiative to scale up efforts to end AIDS epidemic [31]. HIV disclosure is key component of HIV prevention strategies and it is important to address the existing gaps in the literature about factors associated with HIV disclosure and its impact on HIV related outcomes, especially among new to HIV care patients. Therefore, this dissertation aimed to 1) determine the factors associated with HIV disclosure status and patterns of HIV disclosure among new to care patients 2) examine the association of HIV disclosure status and patterns of disclosure with 48-week VL suppression, time to VL suppression and RIC measures 3) evaluate if HIV disclosure is an effect modifier of association of behavioral intervention with 48-week VL suppression.

Overall, the findings of this dissertation contribute to the understanding of role of HIV disclosure among new to HIV care patients. Identifying risk factors for HIV disclosure is the initial step to identify patients at risk of non-disclosure allowing health care team to initiate a dialogue to promote disclosure. Furthermore, examining relationship of HIV disclosure with RIC and VL suppression provides insight on development of interventions targeted to patients initiating care to promote disclosure at initial visit.

FACTORS ASSOCIATED WITH HIV DISCLOSURE STATUS AMONG PATIENTS NEW TO HIV CARE IN URBAN US HIV CLINICS

by

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In Preparation for 'AIDS and Behavior'

Format adapted for dissertation

ABSTRACT

Introduction: HIV disclosure is an important behavior with implications for HIV treatment and prevention but understudied among new to HIV care patients who face unique challenges adjusting to a new diagnosis. This study evaluated the factors associated with HIV disclosure status and patterns of HIV disclosure among new to HIV care patients.

Methods: A cross-sectional study was conducted evaluating the integrating ENGagement and Adherence Goals upon Entry (iENGAGE) participant cohort. The primary and secondary outcomes included HIV disclosure status (Yes/No) and patterns of disclosure (Broad, Selective and Non-disclosure) respectively. Logistic and Multinomial Logistic Regression were used to evaluate the association of participant factors with HIV disclosure and patterns of HIV disclosure respectively.

Results: Of 371 participants, the average age was 37 (±12) years, 79.3% were males, and 62.3% were African Americans. A majority of participants (78.4%) disclosed their HIV status at baseline, 63.1% were broad disclosers and 15.2% were selective disclosers. Blacks demonstrated lower odds of any HIV (OR = 0.28; 95%CI = 0.13, 0.58) and broad disclosure (OR = 0.23; 95%CI = 0.10, 0.53). Need for substance use treatment or counseling services was associated with higher odds of any HIV (OR = 2.07; 95%CI = 1.05, 4.07) and broad disclosure (OR = 2.47; 95%CI = 1.12, 5.51). One unit increase in the use of emotional support was associated with higher log odds of any HIV (OR = 1.62; 95%CI = 1.39, 1.89) and broad disclosure (OR = 1.75; 95%CI = 1.45, 2.12). Males were associated with lower odds of selective disclosure (OR = 0.28; 95%CI = 0.09, 0.85). The log odds of selective disclosure increased with one unit in emotional support (OR = 1.42;

95%CI = 1.13, 1.79), active coping (OR = 1.43; 95%CI = 1.07, 1.90) and decreased with one unit increase in acceptance (OR = 0.73; 95%CI = 0.55, 0.96).

Conclusion: Black race, emotional support, and unmet needs predicted any HIV and broad disclosure, whereas males, emotional support, active coping and acceptance were associated with selective disclosure. Interventions to promote early HIV disclosure among new to HIV care patients should focus on coping strategies and unmet needs.

Keywords: HIV disclosure and patterns, new to HIV care, coping, unmet needs, multisite, iENGAGE.

INTRODUCTION

Informing other individual(s) or organization(s) about one's HIV infection status is defined as the process of HIV disclosure [1-4]. HIV disclosure is an important behavior with implications for HIV prevention strategies and health outcomes in the lives of people living with HIV (PLWH) [5]. The benefits of HIV disclosure[6] include increased opportunities for social support [7-9], improved engagement [10] and retention in HIV care [11], earlier ART initiation [12-14], and better ART adherence [10, 15]. HIV disclosure is also associated with decreased mental illnesses [15]. However, there are chances of undesirable outcomes like discrimination, rejection, stigma [16-18] and hence the rates of disclosure vary considerably across settings [3]. The average rate of disclosure in developed countries varies from 42-100% [11, 19] and is about 72% in the US [20].

HIV disclosure is identified as a complex selective process [21] and the choice of disclosure ranges from nondisclosure (disclosed to no one) to selective/partial disclosure (disclosed to one person or group) to broad disclosure (more than one person or group) [22-24]. Disclosure was reported utmost to mothers [25] and non-family members [26, 27] and lowest among past or causal sex partners [19]. A study conducted among newly diagnosed HIV individuals in the US showed that about 13% of participants chose non-disclosure [17].

Several factors that have been associated with HIV disclosure and patterns of disclosure. Age, gender, race, ethnicity, education, marital status, education, time since HIV diagnosis, number of sexual partners, sexual orientation are known to be correlated with HIV disclosure [7, 23, 28, 29]. However, results vary across studies contingent on

study design, population and outcome ascertainment [7, 21, 30-36]. The majority of prior studies on HIV disclosure focus on patients established in HIV care [35, 37], men who have sex with men (MSM) population [38-42], injection drug users (IDU), alcohol users [43] or women [13, 25, 44, 45]; few studies have focused on HIV patients who were not established in care [17, 34, 38, 39, 46-49]. These studies were specific to populations such as ART naïve patients [34], patients initiating ART [50], those diagnosed who had less than 1 year of HIV infection [46, 47], which were either focused on specific populations like MSM [38, 39], new mothers [48]. Also, the focus was on only a few specific factors and their relationship with HIV disclosure like condom use [39], depression [38], stress and coping during disclosure process [46], CD4 response [50]. A study conducted by Elopre, et.al., among new to care HIV patients was limited to evaluating socio-demographic factors, church attendance, and living arrangement [17]. The association of specific coping behaviors, supportive services needed, HIV treatment self-efficacy with HIV disclosure remains unmapped among new to care HIV cohort.

Additional studies are required to identify factors associated with disclosure [19] especially among new to HIV care patients to achieve better HIV related outcomes [17]. To address these gaps, we evaluated the factors associated with HIV disclosure status and patterns among new to outpatient HIV care patients enrolled in iENGAGE (integrating ENGagement and Adherence Goals upon Entry) study.

METHODS

Study Design

We conducted a cross-sectional study evaluating the iENGAGE cohort. Participants were enrolled in this randomized behavioral trial from Dec 2013 to June 2016.

Setting

iENGAGE is an NIAID funded randomized controlled behavioral intervention trial evaluating the impact of a 4-session counselor-delivered semi-tailored intervention implemented in a clinic setting (R01 AI 103661 and clinical trials.gov NCT01900236). New to outpatient HIV care patients were enrolled within 14 days of their initial primary HIV care provider appointment at four US HIV clinics: the University of Alabama at Birmingham (UAB), the University of North Carolina at Chapel Hill (UNC), John Hopkins University (JHU), and the University of Washington at Seattle (UW). Clinic patients were eligible for study inclusion if they were adults 18 years and older, with documented HIV infection, who were initiating care at one of the four participating sites. Only English speaking, those not planning to move in the next 12 months and able/willing to provide informed consent patients were enrolled. Patients who received prior outpatient HIV care at any other facility or site were excluded. Institutional Review Board (IRB) approvals were obtained at each site for this study. Details of the iENGAGE study can be found elsewhere [51].

As a part of the iENGAGE study, participants completed a study assessment at baseline (questionnaires) and at 48 weeks (questionnaire plus blood draw). Questionnaires were completed using CASI (computer-administered self-interview) that asked questions about mental health, alcohol use, substance use, sexual risk assessment,

disclosure, social support, unmet needs, coping, and stigma using standardized, validated instruments.

All data were extracted from the iENGAGE database and Centers for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS) through electronic data queries. CNICS is a clinic-based cohort of HIV infected patients across 8 US HIV clinics and collects comprehensive clinical data using electronic medical records (EMR) and other established sources at each clinic [52].

Participant cohort

Of the 941 patients screened, 372 new to HIV care participants were enrolled in the iENGAGE study across sites (Figure 1). One participant was found to be not new to care after being randomized to the intervention arm and was withdrawn from the study due to protocol violation, resulting in a sample size of 371.

Outcomes

For the current study, the primary dependent variable of interest was HIV disclosure status (Yes/No) and the secondary dependent variable was patterns of HIV disclosure (non-disclosure, selective disclosure, broad disclosure).

Participants completed a 3-item HIV disclosure questionnaire as a part of the baseline CASI assessment. The following questions were asked to assess if participants disclosed HIV status: Q1) 'Have you told anyone about your HIV status, not including your health provider?' (Responses: Yes/No/No response). If the participants responded 'Yes' to Q1 they were asked two follow up questions: Q2) 'Have you told more than 1 person about your HIV status?' (Responses: Yes/No) and Q3) 'Who have you told about your HIV status?' [Responses: Spouse/significant other, current sexual partner(s), past

sexual partner(s), family member(s), friend(s), religious leader(s) (e.g., priest, rabbi, pastor/ No response/ NA - skip question)].

HIV disclosure status

HIV disclosure was defined as disclosure of HIV status to someone other than health care provider i.e. if participants responded 'Yes' to Q1. For data analysis, HIV disclosure status was dichotomized as Yes/No variable.

Patterns of Disclosure

Patterns of disclosure was categorized as non-disclosure, selective disclosure, and broad disclosure. Non-disclosure was defined as participants who did not disclose their HIV status to anyone other than healthcare provider. Participants who responded 'No" to question 1 were categorized as non-disclosers. Selective disclosure was defined as disclosed to only one group from the categorical response items. Participants who responded 'No' to Q2 (did not disclose to more than one person and disclosed HIV status to only one group on Q3 (Spouse/significant other only, current sexual partner(s) only, past sexual partner(s) only, family member(s) only, friend(s) only, or religious leader(s) only) were categorized as selective disclosers. Broad disclosure was defined as disclosed to more than one group. Participants who responded 'Yes' to Q 2 and selected more than 1 group on Q3 were categorized as broad disclosers.

Independent variables

Socio-demographic variables

Socio-demographic variables included age (years), gender (Male, Female/Transgender), race (White, Black, Other (Native American, Asian), ethnicity (Hispanic, Non-Hispanic) were collected at the time of screening.

ART use

ART use at enrollment (Yes/No) was obtained from the CNICS data repository for participants across sites. Participants started ART prior to or on the date of enrollment were grouped as 'Yes'.

Baseline VL value

Baseline laboratory value for plasma VL was obtained from the CNICS data repository for participants across sites. The closest value to the enrollment date was recorded (preferably -90days, +14 days). In instances where more than 2 values were available, the highest value was selected.

Baseline CD4 count

Baseline CD4 count at the time of entering HIV care was obtained using CNICS data repository for participants across sites. The closest value to study enrollment date was recorded (-90days and +14 days). For data analysis CD4 count was categorized as <200 and ≥200 cells/μL of blood.

Psychosocial factors

At enrollment visit participants, completed questionnaires on psychosocial factors using CASI [51].

Depression

The 8-item Patient Health Questionnaire (PHQ-8) was used to assess how often the depressive symptoms bothered participants over the past 2 weeks [53, 54]. A 4-point Likert-like scale ('not at all'= 0 to 'nearly every day'= 3) was used to rate each question and scores ranged from 0-24. A score of <10 was considered no depressive disorder, ≥10 was considered major depression and ≥20 was considered severe major depression. For analysis purposes, we dichotomized as depression yes/no variable, consistent with prior use in the literature.

Anxiety

The 5-item PHQ-5 questionnaire was used to assess if participants experienced anxiety (sudden fear or panic) in the past 4 weeks [55]. The response options were yes (score of 1)/no (score of 0). The composite score ranged from 0-5. Anxiety scores were categorized as no anxiety (score = 0), panic symptoms (score ≤4) and panic syndrome (score =5). For analysis purposes, we dichotomized as anxiety yes/no variable.

Social support

The 4-item abbreviated Medical Outcomes Study Social Support Survey (MOS-4) was used to measure perceived social support [56, 57]. Each question measures a different type of perceived support (informational, tangible, positive social interaction, affectionate). Items were rated on a 5-point scale ranging from "none of the time" (1) to "all of the time" (5). For data analysis, we will use a composite score which ranges from 0-100 [58]. The higher the composite score, the greater the support received.

HIV stigma

HIV stigma was measured using Bunn and Earnshaw instruments [59, 60]. The domains assessed were enacted stigma, disclosure concerns, negative self-image or internalized stigma, and concerns with public attitudes about PLWH or public stigma [59]. A 4-point Likert-like scale ranging from 'strongly agree' (1) to 'strongly disagree' (4) was used for rating. A composite score was calculated summing responses to all questions [59]. Anticipated stigma to family, friends and healthcare providers was measured. The responses ranged from 'very unlikely' (1) to 'very likely' (5) [60]. The higher the composite scores, the higher the stigma [59, 60].

Coping

Participant's coping skills were measured using an adapted brief cope questionnaire to assess 9 of the 14 domains: active coping, positive reframing, acceptance, religion, using emotional support, denial, substance use, behavioral disengagement, and self-blame. Each domain was measured using 2 items [61, 62]. Using emotional support, positive reframing, acceptance, and religion were perceived as adaptive coping strategies and denial, substance use, behavioral disengagement, and self-blame were perceived as maladaptive coping strategies [63]. Items were rated on a 4-point Likert scale ranging from 'not doing this at all' (1), to 'doing this all the time' (4) and an average score was used for each domain.

Supportive services

Supportive services needed in the last 6 months was assessed using an instrument previously used in the CDC Retention in Care (RiC) trial [64]. Supportive services included counseling, substance use treatment, housing, emergency financial assistance,

employment assistance, transportation, food, groceries or meals, benefits assistance and childcare. For analysis purposes, services were classified in 3 categories: counseling/substance abuse treatment; housing expenditure (housing, transportation, food, groceries, meals, and childcare) and financial assistance (financial, employment, and benefits assistance).

Quality of life

EuroQOL-5D was used to measure the five health-related quality of life: mobility, self-care, usual activities, pain/discomfort, anxiety/depression. Each quality was measured using a single question. Response for each question ranged from 'no problems' (1) to 'severe problems' (3) [65].

Self-Efficacy

The 12-item HIV Adherence Self-Efficacy Scale (HIV-ASES) was used to measure self-efficacy in HIV treatment adherence. This questionnaire assessed patient's confidence to carry out important treatment-related behaviors [66]. Answer choice ranged from 'cannot do it at all' (0) to 'certain can do it' (10). In addition, participants had option to select 'refuse to answer' or 'don't know'. Composite scores were calculated and the higher the score, greater is the adherence self-efficacy. [66].

Sexual risk factors

Participants completed questionnaires on alcohol use, substance use and sexual behavior at the enrollment visit and HIV transmission risk factor was obtained using the CNICS data repository.

HIV Transmission risk factor

HIV Transmission risk factor was recorded as either MSM, IDU, or heterosexuals. For participants who reported multiple risk factors, IDU was given the priority followed by MSM and then heterosexual in the CNICS database.

Alcohol use

The 3-item Alcohol Use Disorders Identification Test (AUDIT–C) questionnaire was used to measure alcohol consumption during the past year among participants. AUDIT-C scores were categorized as no risk (score of 0-2 for men (M), 0-1 for women (W)), low risk (score of 3 for M, 2 for W) and high risk (score of 4 for M, 3 for W) [67]. The transgender patients were treated as females for AUDIT-C scores for analysis.

Substance use

The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) was used to measure substance use (cocaine/crack, amphetamines, opiates, injection drug use) [68]. For data analysis substance use was categorized as Never (responded 'no' to drug use), Prior (responded 'never' used drugs in past 3 months) and Current (responded used drugs once or twice, weekly, monthly or daily in last 3 months) [69].

Sexual behavior

HIV Risk Assessment for Positives (HRAP) was used to assess the number of sexual partners in the past 6 months. For data analysis, the number of sexual partners was categorized as 0, 1, 2, 3, 4-5, ≥6 partners.

Statistical Analysis

Descriptive statistics were calculated as means and standard deviation for continuous variables and counts and percentages for categorical variables. Q-Q plots were used to determine normality of continuous variables.

Logistic regression was used to estimate odds ratios (ORs) and their respective 95% confidence intervals (CIs) to evaluate the association of risk factors with HIV disclosure status (Yes/No). To assess the association of risk factors with patterns of disclosure (non-disclosure, selective disclosure, broad disclosure) multinomial logistic regression was used to calculate ORs and their respective CIs.

The variables included in the adjusted models were based on the evidence from the literature, recommendations from expert clinicians and statistical significance (<0.10) in unadjusted models. We further employed a stepwise method to generate the parsimonious models. A two-sided p-value of <0.05 was considered significant for this analysis.

RESULTS

The average age of participants was 37 (± 12) years, 79.3% were males, 62.3% were African Americans, and 94.6% Non-Hispanics (Table 1). Overall, 78.4% of the participants disclosed their HIV status at baseline, 63.1% were broad disclosers and 15.2% were selective disclosers. Among participants who disclosed, 30.8% reported depression and the percentage was similar for broad disclosers (28.7%) compared to selective disclosers (34%) or non-disclosers (34.6%). However, a higher percentage of participants who disclosed their HIV status reported anxiety symptoms (33.2%) compared to participants who did not disclose (25%). Current substance use was

reported by a lower percentage of participants who disclosed (16.9%) compared to participants who did not disclose (21.1%). The higher average score indicative of better active coping was reported by broad disclosers (score =6.8) compared to selective disclosers (score =7) and non-disclosers (score=6). Detectable baseline VL value (≥200) was reported by 93.8% and 69.3% reported no baseline ART use.

HIV disclosure status

In the final parsimonious logistic regression model, Blacks had significantly lower odds of disclosure compared to Whites (OR = 0.28; 95%CI = 0.13, 0.58). One unit increase in using emotional support as coping behavior was associated with significantly higher log odds of disclosure (OR = 1.62; 95%CI = 1.39, 1.89). The odds of disclosure was double among participants receiving substance use or counseling services in last 6 months (OR = 2.07; 95%CI = 1.05, 4.07) compared to those who did not.

Patterns of disclosure

In the final parsimonious multinomial logistic regression model, Blacks had significantly lower odds of broad disclosure (OR = 0.23; 95%CI = 0.10, 0.53) compared to Whites. Participants who reported use of emotional support as coping behavior (OR = 1.75; 95%CI = 1.45, 2.12) and need for substance use treatment or counseling in past 6 months (OR = 2.47; 95%CI = 1.12, 5.51) had significantly higher odds of broad disclosure. The log odds of selective disclosure increased with one unit increase in use of emotional support (OR = 1.42; 95%CI = 1.13, 1.79) and active coping behaviors (OR = 1.43; 95%CI = 1.07, 1.90). Males (OR = 0.28; 95%CI = 0.09, 0.85) were associated with lower odds of selective disclosure. With one unit increase in acceptance as coping behavior (OR = 0.73; 95%CI = 0.55, 0.96), lower was the log odds of selective disclosure.

DISCUSSION

Early disclosure is an important HIV prevention and treatment strategy [70, 71] but little is known about factors associated with early HIV disclosure among new to care PLWH [17, 19]. In this cross-sectional study among new to HIV care patients enrolled within 14 days of their HIV primary care appointment across 4 US HIV clinics, we found that males had 72% lower odds of selective disclosure and about half the odds for broad disclosure compared to females. Black race was associated with 70% lower odds of disclosure to anyone and broad disclosure and 34% lower odds of selective disclosure compared to the White race. Substance use or counseling services need in the last 6 months was associated with more than double the odds of disclosure to anyone and broad disclosure. Coping behaviors were found to be associated with all types of disclosure, and may represent a modifiable factor for behavioral interventions to enhance disclosure among new to care PLWH. One unit increase in the use of emotional support was associated with almost double the increase in log odds of disclosure to anyone, broad and selective disclosure. One unit increase in active coping resulted in the increase in log odds of selective disclosure.

We observed that men were 46% less likely to broadly disclose and 72% less likely to selectively disclose their HIV status compared to females after adjusting for other variables in the analysis. Males generally have poor at medical attending services compared to females who disclose to gain support to seek the medical help needed [34, 72-75]. Our results are consistent with prior studies among new patients seeking HIV care [17, 47]. Furthermore, the fear of being perceived as a homosexual which may not be accepted culturally may result in non-disclosure [7]. A study conducted among

patients within 6 months of HIV diagnosis showed that about 55.6% of males did not disclose their HIV status [76]. Buma (2015) showed that only 15% of males disclosed their HIV status before prior to starting ART [34]. Our results contradict the findings of another cross-sectional study conducted among HIV patients enrolled within a year of diagnosis where there was no difference in the odds of disclosure among males and females [77]. The difference in results is likely due to the study conducted in the Nigerian population and the lower overall disclosure rates. Additionally, in the unadjusted analysis, we examined transmission risk factors and found that MSM were more likely to disclose their HIV status compared to the heterosexual group, though the results were not significant. These results may suggest that males who are MSM were more likely to disclose as suggested by another prior study [17].

Black race was associated with lower odds of HIV disclosure to anyone (72%), broad (77%) and selective disclosure (34%). Results from a prior study showed that Blacks were 4 times more likely to non-disclose and about 2 times more likely to selective disclosure compared to broad disclosure[17]. Blacks are more susceptible to stigma from cultural context [46] resulting in non-disclosure. In addition, Blacks have increased depressive symptoms from the stress of the new diagnosis and adjustment disorder resulting in non-disclosure and social isolation [38]. Our results were in a similar direction with other studies except for some differences in the magnitude of results, which could be attributed to diverse geographic HIV clinic data used in our study, which was the single site for the prior study.

To our knowledge, this is the first study to assess the association of need for supportive services in the last 6 months and HIV disclosure among new to HIV care

patients. The initial year of HIV care is challenging and it is important to address unmet needs in this cohort. In this study, the need for substance use treatment or counseling services in the last 6 months was significantly associated with almost 2 times the odds of disclosure to anyone and broad disclosure. PLWH face significant challenges related to substance use [78] and mental health issues [79-81]. Further among new to care patients, these challenges are exaggerated with the added stress of coming to frequent medical appointments, taking regular medications and learning the skills to navigate through the diagnosis during this initial year. Hence, they may choose to disclose to more people to gain social support and help with other necessities. Our results suggest that addressing unmet needs during initial HIV primary care appointment is important. Conversely, the odds of selective disclosure was almost halved with the need for the same. The reason for this finding was not clear but is possible due to the smaller sample size of selective disclosure group. It is possible that HIV infected individuals in need of substance use or counseling services may be dealing with multiple health-related issues and disclosed to the social network broadly rather being selective to be able to get all the help required to address different issues. Future studies among the larger cohort of new to HIV care patients may provide more insight on the role of unmet needs and its association with the early disclosure; if addressing these needs during the initial visit would be beneficial and if unmet needs be a focus for intervention targeted for new to HIV care patients.

Interestingly, the trends for one unit increase in different adaptive coping strategies was towards higher log odds of disclosure. There was significant increase in log odds of disclosure to anyone, broad and selective disclosure compared to non-disclosure for every unit increase in active coping and the use of emotional support in

unadjusted analysis. In adjusted analysis, the results remained statistically significant for use of emotional support for all disclosures and for active coping and selective disclosure. It is probably because patient actively trying to cope with the diagnosis seek support by disclosing. We found that the higher the acceptance, the lower the disclosure. One possible explanation is participants who may have accepted their HIV diagnosis may not have felt the need to disclose their HIV status to gain support. Based on the unadjusted and adjusted results of this study focusing on adaptive and maladaptive coping strategies may motivate newly diagnosed patients to disclose their serostatus early and achieve better HIV related outcomes. Use of different coping strategies may depend on the outcomes of disclosure. One prior study which looked at the relationship coping perspective and found that non-disclosure actually became a coping strategy after experiencing negative outcomes from initial disclosure [46]. Nevertheless, our results are supportive of using coping strategies as a part of the intervention for early HIV disclosure for patients new to HIV to aid disclosure. We recommend future studies explore the relationship of type and magnitude of each coping strategy and early HIV disclosure among new to HIV care patients.

Strengths

Our study provides an understanding of the association of several factors with HIV disclosure status and patterns of disclosure and adds to the existing literature among new to HIV care patients. The results of our study add to the future efforts to build HIV disclosure specific interventions for new to HIV care patients. We have a geographically diverse sample population and a geographically diverse cohort of individuals who have never received outpatient HIV care before.

Limitations

The cross-sectional design of this study did not allow for assessment of temporal relationship and no inferences on causality can be made. However, our associations can gauge the strength of effect and possibility of potential factors to consider. Results of the study may not be generalized beyond the geographic areas covered by the iENGAGE study but the sites used for study implementation are representative of national estimates. Data collected during the iENGAGE study is self-reported and there is a possibility of recall bias or information bias. Prior studies have shown that self-reported data are acceptable for capturing HIV behaviors.

CONCLUSION

Our study found that Black race, emotional support, and unmet needs were associated with any HIV and broad disclosure, whereas males, emotional support, active coping and acceptance were associated with selective disclosure. Interventions of early HIV disclosure targeted for new to HIV care patients may require a multifaceted approach and focus on coping strategies and unmet needs as intervention components. Future studies on early HIV disclosure in larger cohorts of PLWH may provide insight on evidence-based intervention recommendations for new to HIV care patients.

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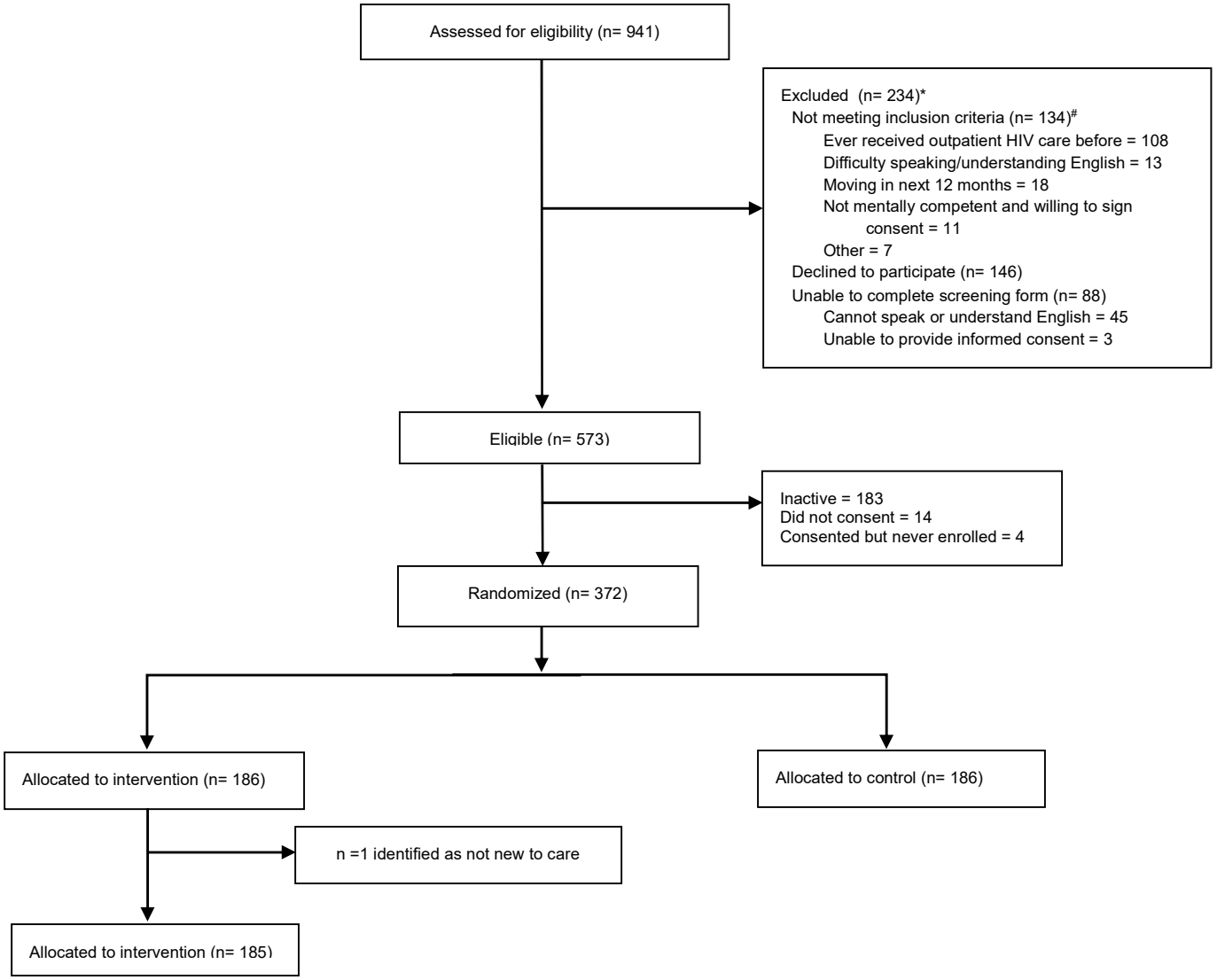
Figure 1. Participant flow diagram for all new to care patients across 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016.



*93 of the 234 were not new to care participants; # There were 5 questions for participants to meet the inclusion criteria and participants can choose multiple reasons.

Table 1. Baseline patient characteristics by HIV disclosure status and patterns of HIV disclosure at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016 (n = 371).

Variables	Overall n=371	HIV Disclosure n=370		Disclosure patterns n=369		
		Yes n = 290	No n = 80	Non-disclosure n = 80	Selective Disclosure n = 56	Broad Disclosure n = 233
Socio-demographic factors						
Age (years)	37.1 (±12)	36.8(±12)	38.4(±12.1)	38.4 (±12.1)	37.2 (±13)	36.6 (±11.7)
Sex						
Male	294 (79.3)	227 (78.3)	66 (82.5)	66 (82.5)	39 (69.6)	188 (80.7)
Female	71 (19.1)	57 (19.7)	14 (17.5)	14 (17.5)	15 (26.8)	41 (17.6)
Transgender	6 (1.6)	6 (2.1)	0	0	2 (3.6)	4 (1.7)
Race						
Black	231 (62.3)	163 (56.2)	67 (83.8)	67 (83.8)	41 (73.2)	121 (52.9)
White	109 (29.4)	98 (33.8)	11 (13.8)	11 (13.8)	10 (17.9)	88 (37.8)
Other	31 (8.4)	29 (10.0)	2 (2.5)	2 (2.5)	5 (8.9)	24 (10.3)
Ethnicity						
Hispanic	20 (5.4)	19 (6.6)	1 (1.3)	1 (1.3)	3 (5.4)	16 (6.9)
Non-Hispanic	351 (94.6)	271 (93.5)	79 (98.8)	79 (98.8)	53 (94.6)	217 (92.1)
Insurance						
None	87 (23.6)	71 (24.7)	15 (19)	15 (19)	13 (23.2)	58 (25.1)
Private	107 (29.1)	87 (30.2)	20 (25.3)	20 (25.3)	19 (33.9)	68 (29.4)
Public	174 (47.3)	130 (45.1)	44 (55.7)	44 (55.7)	24 (42.9)	105 (45.5)
ART[1]						
Yes	114 (30.7)	88 (30.3)	25 (31.3)	25 (31.3)	18 (32.1)	70 (30)

No	257 (69.3)	202 (69.7)	55 (68.8)	55 (68.8)	38 (67.9)	163 (70)
Baseline CD4 count, cells/ml of blood						
<200	85 (24.3)	65 (24.4)	20 (26.7)	20 (26.7)	10 (18.9)	55 (25.9)
200-300	83 (24.9)	60 (22.6)	23 (30.7)	23 (30.7)	11 (20.8)	49 (23.1)
≥350	174 (50.9)	141 (53.0)	32 (42.7)	32 (42.7)	32 (60.4)	108 (50.9)
Baseline VL value[2] , copies/ml of blood						
<200	16 (4.3)	15 (5.2)	1 (1.3)	1 (1.3)	2 (3.6)	13 (5.6)
>=200	348(93.8)	269 (92.8)	78 (97.5)	78 (97.5)	53 (94.6)	215 (92.3)
Missing	7 (1.9)	6 (2.1)	1 (1.3)	1 (1.3)	1 (1.8)	5 (2.2)
Psychosocial factors						
Depression						
No	241(69.3)	189 (70.3)	51 (65.4)	51 (65.4)	35 (66)	154 (71.3)
Yes	107 (30.8)	80 (29.7)	27 (34.6)	27 (34.6)	18 (34)	62 (28.7)
Anxiety						
Yes	113 (31.4)	94 (33.2)	19 (25)	19 (25)	15 (27.3)	78 (34.4)
No	247 (68.6)	189 (66.8)	57 (75)	57 (75)	40 (72.7)	149 (65.6)
Social support score	57 (±29.1)	59.4 (±29.3)	48.5 (±26.9)	48.5 (±26.9)	54.8 (±27.6)	60.5 (±29.6)
Quality of life						
No Mobility	317(85.9)	250 (86.5)	66 (83.5)	66 (83.5)	45 (80.4)	205 (88.4)
No Self-Care	358 (97.3)	280 (97.2)	77 (97.5)	77 (97.5)	54 (98.2)	225 (97)
No Usual activities	300 (81.1)	236 (81.7)	63 (78.8)	63 (78.8)	47 (83.9)	188 (81)
No Pain	209 (57)	165 (57.7)	43 (53.8)	43 (53.8)	30 (54.6)	135 (58.7)
No Depression / Anxiety	163 (44.7)	129 (44.8)	35 (43.8)	35 (43.8)	27 (49.1)	101 (43.5)
Stigma						
Enacted stigma	2.2 (±0.7)	2.2 (±0.7)	2.3 (±0.7)	2.3 (±0.7)	2.4 (±0.8)	2.1 (±0.7)
Disclosure concerns	3.1 (±0.6)	3.0 (±0.6)	3.2 (±0.5)	3.2 (±0.5)	3.3 (±0.5)	3.0 (±0.6)
Internalized stigma	2.3 (±0.7)	2.3 (±0.7)	2.4 (±0.8)	2.4 (±0.8)	2.5 (±0.7)	2.2 (±0.7)

Public stigma	2.7 (±0.7)	2.7 (±0.7)	2.8 (±0.7)	2.8 (±0.7)	2.9 (±0.7)	2.6 (±0.7)
Anticipated stigma						
Family	2.7 (±1.4)	2.7 (±1.4)	2.8 (±1.3)	2.8 (±1.3)	2.9 (±1.4)	2.6 (±1.4)
Friends	2.8 (±1.3)	2.7 (±1.2)	3.1 (±1.3)	3.1 (±1.3)	3.0 (±1.3)	2.6 (±1.2)
Healthcare provider	1.8 (±0.9)	1.8 (±0.9)	1.7 (±0.9)	1.7 (±0.9)	2.0 (±1.1)	1.8 (±0.9)
Coping Behavior						
Active coping	6.7 (±1.7)	6.9 (±1.6)	6 (±2.2)	6 (±2.2)	7 (±1.3)	6.8 (±1.6)
Denial	3.6 (±1.9)	3.5 (±1.9)	3.7 (±1.9)	3.7 (±1.9)	4 (±1.9)	3.4 (±1.9)
Substance use	3.1 (±1.8)	3.2 (±19)	2.9 (±1.5)	2.9 (±1.5)	3.0 (±2.0)	3.2 (±1.8)
Emotional support	5.2 (±2.2)	5.6 (±2.0)	3.6 (±1.9)	3.6 (±1.9)	4.7 (±2.1)	5.8 (±2)
Behavioral disengagement	2.7 (±1.2)	2.7 (±1.3)	2.6 (±1.2)	2.6 (±1.2)	2.5 (±1.2)	2.7 (±1.3)
Positive reframing	5.7 (±2)	5.8 (±1.9)	5.3 (±2.0)	5.3 (±2.0)	5.5 (±2.0)	5.9 (±1.9)
Acceptance	6.8 (±1.5)	6.9 (±1.4)	6.5 (±1.8)	6.5 (±1.8)	6.5 (±1.7)	7 (±1.4)
Religion	5.5 (±2.2)	5.5 (±2.2)	5.3 (±2.3)	5.3 (±2.3)	6.1 (±2.1)	5.3 (±2.2)
Self-blame	4.7 (±2.1)	4.7 (±2.1)	4.7 (±2.2)	4.7 (±2.2)	4.6 (±2.2)	4.7 (±2.1)
HIV treatment self-efficacy	9 (±1.5)	9 (±1.5)	9 (±1.3)	9 (±1.3)	8.9 (±1.8)	9 (±1.4)
Supportive services needed in last 6 months						
Financial assistance[3]	179(49.2)	137 (48.2)	42 (52.5)	42 (52.5)	22 (40)	114 (50)
Household expenditure[4]	194 (52.9)	145 (50.5)	49 (61.3)	49 (61.3)	22 (40.7)	122 (52.6)
Substance use treatment or counseling	125 (34)	109 (37.9)	16 (20)	16 (20)	11 (19.6)	98 (42.3)
Sexual risk factors						
Transmission risk[5]						
MSM	219 (60)	175 (61.4)	43 (54.4)	43 (54.4)	35 (62.5)	218 (60.1)
Heterosexual	117 (32.1)	87 (30.5)	30 (38)	30 (38)	20 (35.7)	66 (29)
IDU	29 (8)	23 (8.1)	6 (7.6)	6 (7.6)	1 (1.8)	22 (9.7)

Sex partners						
0	76 (20.5)	59 (20.3)	17 (21.25)	17 (21.3)	11 (19.6)	48 (20.6)
1	100 (27)	74 (25.5)	26 (32.50)	26 (32.5)	19 (33.9)	55 (23.6)
2	55 (14.8)	38 (13.1)	17 (21.25)	17 (21.3)	5 (8.9)	32 (13.7)
3	38 (10.2)	31 (10.7)	7 (8.75)	7 (8.8)	9 (16.1)	22 (9.4)
4-5	40 (10.8)	33 (11. 4)	6 (7.50)	6 (7.5)	8 (14.3)	25 (10.7)
≥6	62 (16.8)	55 (19)	7 (8.75)	7 (8.8)	4 (7.1)	51 (21.9)
Alcohol use						
No risk	191 (52.3)	143 (50.2)	48 (61.5)	48 (61.5)	33 (60)	110 (48)
Low risk	46 (12.6)	35 (12.3)	11 (14.10)	11 (14.1)	7 (12.7)	28 (12.2)
High risk	127 (34.9)	107 (37.5)	19 (24.4)	19 (24.4)	15 (27.3)	91 (39. 7)
Substance use						
Never	198 (55.8)	148 (53.2)	50 (65.8)	50 (65.8)	38 (69.1)	110 (49.3)
Prior	93 (26.2)	83 (29.9)	10 (13.2)	10 (13.2)	10 (18.2)	73 (32.7)
Current	64 (18)	47 (16.9)	16 (21.1)	16 (21.1)	7 (12.7)	40 (17.9)
Other factors						
Site						
UAB	153 (41.2)	111 (38.3)	42 (52.5)	42 (52.5)	21 (37.5)	90 (38.6)
UNC	76 (20.5)	62 (21.4)	13 (16.3)	13 (16.3)	13 (23.2)	49 (21)
JHU	78 (21)	63 (21.7)	15 (18.8)	15 (18.8)	17 (30.4)	45 (19.3)
UW	64 (17.3)	54 (18. 6)	10 (12.5)	10 (12.5)	5 (8.9)	49 (21)
Study arm						
Control	186 (50.1)	146 (50.3)	40 (50)	40 (50)	28 (50)	118 (50.6)
Intervention	185 (49.9)	144 (49.7)	40 (50)	40 (50)	28 (50)	115 (49.4)

Numbers in the table represent n (%) for categorical variables and means (±Standard Deviation) for continuous variables

[1]ART – antiretroviral therapy

[2]VL value – viral load value

[3]Financial assistance category includes financial, employment, benefits assistance

[4]Household expenditure category includes housing, transportation, food, groceries, meals and childcare

[5]Transmission risk – MSM – men who have sex with men, IDU – injection drug users

[6] Site - UAB – University of Alabama at Birmingham; UNC – University of North Carolina at Chapel Hill; JHU – Johns Hopkins University at Baltimore; UW – University of Washington at Seattle

Table 2: Unadjusted logistic and multinomial logistic regression models for HIV disclosure status and patterns of HIV disclosure at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016.

Variables	HIV Disclosure (n=370)	HIV disclosure patterns (n=369)	
	Yes OR (95%CI)	Selective Disclosure OR (95%CI)	Broad Disclosure OR (95%CI)
Socio-demographic factors			
Age (years) 10 unit change	0.90 (0.73, 1.10)	0.99 (0.97, 1.02)	0.99 (0.97, 1.01)
Gender			
Male	0.76 (0.40, 1.45)	0.49 (0.22, 1.10)	0.89 (0.46,1.72)
Female/Transgender	Ref	Ref	Ref
Race			
Black	0.28 (0.14 0.54)	0.67 (0.26, 1.72)	0.23 (0.11, 0.45)
Other	1.63 (0.34, 7.77)	2.75 (0.43, 17.49)	1.5 (0.31, 7.23)
White	Ref	Ref	Ref
Ethnicity			
Hispanic	5.54 (0.73, 42.02)	4.47 (0.45, 44.14)	5.83 (0.76, 44.64)
Non-Hispanic	Ref	Ref	Ref
Insurance			
None	1.09 (0.52, 2.28)	0.91 (0.35, 2.41)	1.14 (0.53, 2.42)
Public	0.68 (0.38, 1.23)	0.57 (0.26, 1.28)	0.70 (0.38, 1.29)
Private	Ref	Ref	Ref
ART[1]			
Yes	0.96 (0.56, 1.64)	1.04 (0.50, 2.17)	0.95 (0.55, 1.64)
No	Ref	Ref	Ref
Baseline CD4 count, cells/ml of blood			
200-350	0.80 (0.40, 1.60)	0.96 (0.34, 2.72)	0.78 (0.38, 1.58)

≥350	1.36 (0.72, 2.55)	2.00 (0.81, 4.93)	1.23 (0.64, 2.34)
<200	Ref	Ref)	Ref
Baseline VL value, copies/ml of blood[2]			
≥200	0.23 (0.03, 1.77)	0.34 (0.03, 3.84)	0.21 (0.03, 1.65)
Missing	0.40 (0.02, 7.48)	0.50 (0.01, 19.56)	0.39 (0.02, 7.40)
<200	Ref	Ref	Ref
Psychosocial factors			
Depression			
Yes	0.80 (0.47, 1.37)	0.97 (0.47, 2.03)	0.76 (0.44,1.32)
No	Ref	Ref	Ref
Anxiety			
Yes	1.49 (0.84, 2.65)	1.13 (0.51, 2.48)	1.57 (0.87,2.8)
No	Ref	Ref	Ref
Social support score	1.01 (1.00, 1.02)	1.01 (1.00, 1.02)	1.02 (1.01, 1.02)
Quality of life			
No mobility	1.26 (0.64, 2.51)	0.81 (0.33, 1.96)	1.50 (0.73, 3.07)
No Self-Care	0.91 (0.19, 4.37)	1.40 (0.12, 15.81)	0.84 (0.17, 4.11)
No Usual activities	1.20 (0.65, 2.22)	1.41 (0.58, 3.44)	1.15 (0.62, 2.16)
No Pain	1.17 (0.71,1.93)	1.03 (0.52, 2.06)	1.22 (0.73, 2.04)
No Depression/Anxiety	1.04 (0.63, 1.72)	1.24 (0.62, 2.47)	0.99 (0.59, 1.66)
Stigma			
Enacted stigma	0.81 (0.56, 1.17)	1.23 (0.74, 2.05)	0.74 (0.50, 1.08)
Disclosure concerns	0.68 (0.44, 1.07)	1.52 (0.79, 2.94)	0.57 (0.36, 0.92)
Internalized stigma	0.82 (0.58, 1.16)	1.33 (0.82, 2.16)	0.73 (0.51, 1.05)
Public stigma	0.85 (0.58, 1.23)	1.36 (0.80, 2.33)	0.75 (0.51, 1.11)
Anticipated stigma			
Family	0.92 (0.76, 1.10)	1.01 (0.79, 1.31)	0.89 (0.74, 1.08)
Friends	0.79 (0.65, 0.97)	0.98 (0.74, 1.30)	0.76 (0.62, 0.93)
Healthcare provider	1.10 (0.83, 1.45)	1.29 (0.90, 1.84)	1.05 (0.79, 1.39)
Coping			

Active coping	1.29 (1.11, 1.49)	1.35 (1.07, 1.70)	1.27 (1.10, 1.48)
Denial	0.97 (0.84, 1.11)	1.09 (0.90, 1.31)	0.94 (0.81, 1.08)
Substance use	1.10 (0.95, 1.29)	1.06 (0.86, 1.30)	1.12 (0.95, 1.32)
Emotional support	1.62 (1.40, 1.88)	1.33 (1.10, 1.61)	1.71 (1.47, 2.00)
Behavioral disengagement	1.09 (0.87, 1.36)	0.96 (0.69, 1.34)	1.12 (0.89, 1.40)
Positive reframing	1.17 (1.02, 1.33)	1.06 (0.88, 1.28)	1.19 (1.04, 1.36)
Acceptance	1.19 (1.02, 1.39)	1.01 (0.82, 1.26)	1.25 (1.06, 1.47)
Religion	1.03 (0.92, 1.16)	1.18 (1.00, 1.39)	1.00 (0.89, 1.12)
Self-blame	1.00 (0.89, 1.13)	0.98 (0.83, 1.15)	1.00 (0.89, 1.13)
HIV treatment self-efficacy	0.99 (0.84, 1.18)	0.95 (0.76, 1.19)	1.01 (0.85, 1.21)
Supportive service needs in last 6 months			
Financial assistance[3]	1.03 (0.68, 1.56)	0.60 (0.30, 1.21)	0.91 (0.54, 1.51)
Household expenditure[4]	0.65 (0.39, 1.07)	0.44 (0.22, 0.88)	0.70 (0.42, 1.18)
Substance use treatment or counseling	2.44 (1.34, 4.43)	0.98 (0.42, 2.30)	2.93 (1.60, 5.37)
Sexual risk factors			
Transmission risk[5]			
MSM	1.40 (0.82, 2.39)	1.22 (0.59, 2.51)	1.48 (0.85, 2.57)
IDU	1.32 (0.49, 3.56)	0.25 (0.03, 2.24)	1.67 (0.61, 4.53)
Heterosexual	Ref	Ref	Ref
Sex partners			
1	0.82 (0.41, 1.65)	1.13 (0.43, 2.96)	`0.75 (0.36, 1.55)
2	0.64 (0.29, 1.41)	0.46 (0.13, 1.59)	0.67 (0.30, 1.50)
3	1.28 (0.48, 3.41)	1.99 (0.57, 6.90)	1.11 (0.40, 3.07)
4-5	1.59 (0.57, 4.41)	2.06 (0.56, 7.58)	1.48 (0.52, 4.21)
≥6	2.26 (0.87, 5.88)	0.88 (0.21, 3.74)	2.58 (0.98, 6.77)
0	Ref	Ref	Ref
Alcohol use			
Low risk	1.07 (0.50, 2.27)	0.93 (0.33, 2.64)	1.11 (0.51, 2.41)
High risk	1.89 (1.05, 3.40)	1.15 (0.51, 2.58)	2.09 (1.15, 3.81)

No Risk	Ref	Ref	Ref
Substance use			
Prior	2.80 (1.35, 5.82)	1.32 (0.50, 3.48)	3.31 (1.58, 6.96)
Current	0.99 (0.52,1.90)	0.58 (0.22, 1.54)	1.14 (0.58, 2.22)
Never	Ref	Ref	Ref
Other factors			
Site[6]			
UAB	0.49 (0.23, 1.05)	1.00 (0.30, 3.30)	0.44 (0.20, 0.95)
UNC	0.88 (0.36, 2.18)	2.00 (0.53, 7.49)	0.77 (0.31, 1.92)
JHU	0.78 (0.32, 1.87)	2.27 (0.63, 8.14)	0.61 (0.25, 1.50)
UW	Ref	Ref	Ref
Study arm			
Intervention	0.99 (0.60, 1.62)	1.0 (0.51, 1.98)	0.98 (0.59, 1.62)
Control	Ref	Ref	Ref

OR = odds ratio; CI = confidence interval

[1]ART – antiretroviral therapy

[2]VL value – viral load value

[3]Financial assistance category includes financial, employment, benefits assistance

[4]Household expenditure category includes housing, transportation, food, groceries, meals and childcare

[5]Transmission risk – MSM – men who have sex with men, IDU – injection drug users

[6] Site: UAB – University of Alabama at Birmingham; UNC – University of North Carolina at Chapel Hill; JHU – Johns Hopkins University at Baltimore; UW – University of Washington at Seattle

Table 3: Adjusted logistic regression models for HIV disclosure status at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016.

Variables	HIV Disclosure (Yes/No) Adjusted Model n=223	HIV Disclosure (Yes/No) Parsimonious Model n=348
	OR (95%CI)	**OR (95%CI)**
Age	0.98 (0.94, 1.02)	
Gender		
Male	**0.14 (0.03, 0.75)**	
Female	Ref	
Race		
Black	0.46 (0.15, 1.43)	**0.28 (0.13, 0.58)**
Other[1]	1.24 (0.15, 9.96)	1.77 (0.35, 9.01)
White	Ref	Ref
Ethnicity		
Hispanic	3.43 (0.24, 49.16)	
Non-Hispanic	Ref	
Substance use		
Prior	4.07 (1.02, 16.14)	
Current	0.30 (0.07 1.33)	
Never	Ref	
Alcohol use		
Low risk	1.18 (0.28, 4.98)	
High risk	2.31 (0.79, 6.72)	
No risk	Ref	
Depression		
Yes	0.83 (0.26, 2.65)	
No	Ref	
Anxiety		
Yes	1.21 (0.41, 3.53)	
No	Ref	
Supportive services in last 6 months		
Substance use treatment or counseling	2.59 (0.91, 7.40)	**2.07 (1.05, 4.07)**
Housing expenditure[2]	0.71 (0.27, 1.82)	
Baseline CD4 count, cells/ml of blood		
200-350	0.69 (0.19, 2.59)	
>350	0.79 (0.24 2.66)	
<200	Ref	
Coping behavior		

Active coping	**1.37 (1.04, 1.82)**	
Use of emotional support	**1.61 (1.22, 2.11)**	**1.62 (1.39, 1.89)**
Acceptance	0.89 (0.64, 1.23)	
Positive Reframing	0.78 (0.57, 1.07)	
Anticipated Stigma from friends	1.01 (0.67, 1.50)	
Social support score	1.01 (0.99, 1.02)	
Transmission risk[3]		
MSM	1.80 (0.50, 6.44)	
IDU	3.45 (0.44, 27.08)	
Heterosexual	Ref	
Sex partners		
1	0.30 (0.06, 1.40)	
2	0.38 (0.08, 1.89)	
3	0.40 (0.06, 2.62)	
4-5	0.68 (0.12, 3.93)	
≥6	0.39 (0.07, 2.27)	
0	Ref	
Site[4]		
UAB	0.77 (0.20, 3.03)	
UNC	3.27 (0.64, 16.55)	
JHU	2.07 (0.42, 10.24)	
UW	Ref	

OR = odds ratio; CI = confidence interval

[1]Other race category includes Native American, Asian or other

[2]Household expenditure category includes housing, transportation, food, groceries, meals and childcare

[3] Transmission risk – MSM – men who have sex with men, IDU – injection drug users

[4] Site: UAB – University of Alabama at Birmingham; UNC – University of North Carolina at Chapel Hill; JHU – Johns Hopkins University at Baltimore; UW – University of Washington at Seattle

Table 4: Adjusted multinomial logistic regression models for patterns of HIV disclosure at the 4 US HIV clinics enrolled in the IENGAGE study during 2013-2016.

Variables	Patterns of HIV disclosure Adjusted Model n = 234		Patterns of HIV disclosure Parsimonious Model n = 300	
	Selective disclosure OR (95%CI)	Broad disclosure OR (95%CI)	Selective disclosure OR (95%CI)	Broad disclosure OR (95%CI)
Age	0.98 (0.93, 1.03)	0.98 (0.95, 1.02)		
Gender				
Male	0.27 (0.05, 1.43)	0.39 (0.12, 1.60)	**0.28 (0.09, 0.85)**	0.54 (0.21, 1.42)
Female	Ref	Ref	Ref	Ref
Race				
Black	0.62 (0.13, 3.05)	**0.30 (0.10, 0.94)**	0.66 (0.22, 2.03)	**0.23 (0.10, 0.53)**
Other[1]	3.21 (0.26, 40.19)	1.21 (0.15, 10.15)	4.75 (0.67, 33.61)	1.74 (0.32, 9.30)
White	Ref	Ref	Ref	Ref
Ethnicity				
Hispanic	0.70 (0.02, 23.16)	3.40 (0.25, 46.75)		
Non-Hispanic	Ref	Ref		
Social support score	1.01 (0.99, 1.04)	1.00 (0.98, 1.02)		
Alcohol use				
Low risk	0.78 (0.13, 4.72)	0.79 (0.20, 3.18)		
High risk	1.16 (0.34, 3.95)	1.74 (0.68, 4.43)		
Supportive services needed in last 6 months				
Substance use treatment or counseling	0.48 (0.11, 2.08)	2.49 (0.95, 6.53)	0.58 (0.19, 1.84)	**2.47 (1.12, 5.51)**

Household expenditure[2]	0.69 (0.21, 2.24)	0.92 (0.37, 2.30)		
Baseline CD4 count (cells/ml of blood)				
200-350	0.64 (0.10, 4.05)	0.75 (0.22, 2.49)		
>350	2.92 (0.65, 13.14)	0.73 (0.24, 2.22)		
<200	Ref	Ref		
Coping				
Active coping	1.34 (0.90, 1.99)	1.19 (0.91, 1.55)	**1.43 (1.07, 1.90)**	1.07 (0.88, 1.32)
Use of emotional support	1.36 (0.97, 1.89)	**1.73 (1.34, 2.23)**	**1.42 (1.13, 1.79)**	**1.75 (1.45, 2.12)**
Behavioral disengagement	0.94 (0.32, 2.76)	1.62 (0.79, 3.31)		
Acceptance	**0.59 (0.37, 0.92)**	0.80 (0.56, 1.13)	**0.73 (0.55, 0.96)**	0.95 (0.75, 1.19)
Positive Reframing	0.82 (0.55, 1.21)	0.88 (0.66, 1.18)		
Religion	1.88 (0.9, 3.64)	1.01 (0.64, 1.60)		
Anticipated Stigma from friends	1.10 (0.57, 2.12)	0.92 (0.58, 1.46)		
Site[3]				
UAB	0.41(0.05, 3.18)	0.83 (0.22, 3.15)		
UNC	1.32 (0.16, 11.32)	2.99 (0.63, 14.15)		
JHU	0.78 (0.10, 6.10)	0.90 (0.21, 3.87)		
UW	Ref	Ref		
Stigma				
Disclosure concerns	2.10 (0.57, 7.69)	0.89 (0.35, 2.26)		

Negative self-image	0.97 (0.38, 2.48)	0.58 (0.27, 1.24)

OR = odds ratio; CI = confidence interval

[1]Other includes Native American, Asian and other race

[2]Household expenditure category includes housing, transportation, food, groceries, meals and childcare

[3]Site: UAB – University of Alabama at Birmingham; UNC – University of North Carolina at Chapel Hill; JHU – Johns Hopkins University at Baltimore; UW – University of Washington at Seattle

IMPACT OF HIV DISCLOSURE ON RETENTION IN CARE AND VIRAL LOAD SUPPRESSION AMONG NEW TO HIV CARE PATIENTS

by

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ABSTRACT

Introduction: Viral load (VL) suppression plays an important role in achieving better survival outcomes and HIV prevention. HIV disclosure is identified as a barrier to engage and retain patients early in HIV care to achieve VL suppression. We aimed to evaluate the impact of any HIV disclosure and patterns of HIV disclosure on 48-week VL suppression, time to VL suppression, visit adherence and 4-month visit constancy among patients enrolled in iENGAGE (integrating ENGagement and Adherence Goals upon Entry) study.

Methods: We conducted a retrospective cohort study using iENGAGE participants where HIV disclosure was recorded at the enrollment visit. The primary outcome was 48 week VL suppression (<200 copies per ml of blood). Secondary outcomes were time to VL suppression, during 48 weeks, visit adherence (100% versus not) and 4-month visit constancy. Logistic Regression, Ordinal Logistic Regression, and Cox Proportional Hazards models were used to evaluate the appropriate associations.

Results: In the adjusted analysis, the odds of 48-week VL suppression for any disclosure (OR = 0.97; 95%CI = 0.28, 3.39), selective (OR = 1.26; 95%CI = 0.20, 7.85) and broad (OR = 0.92; 95%CI = 0.26, 3.30) disclosure were similar and non-significant. Any disclosure (HR = 0.65; 95%CI = 0.44, 0.94), selective (HR = 0.77; 95%CI = 0.45, 1.32) and broad disclosure (HR = 0.63; 95%CI = 0.43, 0.92) groups were less likely to achieve VL suppression over time compared to non-disclosure group. The estimates for perfect visit adherence and 4-month visit constancy were similar for any and broad disclosure. Among selective disclosers the estimates for perfect visit adherence were higher (OR = 1.85; 95%CI = 0.57, 6.02)

and for 4-month visit constancy were minimally lower (OR = 0.65; 95%CI = 0.30, 1.42) compared to nondisclosure but were statistically non-significant

Conclusion: HIV disclosure did not improve retention in care (RIC) and VL suppression among new to HIV care patients. Nevertheless, adding a component for disclosure counseling to existing counseling services at initial appointment may be beneficial for new diagnosis adjustment and HIV prevention. Developing a new instrument for disclosure to capture intimacy of participants with their social network in future studies may be beneficial.

Keywords: HIV disclosure, VL suppression, RIC, 4-month constancy, visit adherence, new to HIV care

INTRODUCTION

People living with HIV (PLWH) continue to grow and survive longer with the availability of advanced antiretroviral therapy (ART) combinations. [1, 2]. According to CDC, of the 1.2 million PLWH about 50% are retained in care, and 28% are achieving viral load (VL) suppression [3]. The US National HIV/AIDS Strategy emphasizes the importance of engagement and retention in HIV care (RIC) [4] which ultimately helps lower the cumulative VL burden [5] and improve survival outcomes [6, 7]. Longitudinal VL suppression measure has been shown to have important consequences on health outcomes and the spread of HIV infection [5]. HIV disclosure remains one of the major psycho-social barriers to engage and retain patients early in HIV care to achieve VL suppression [8].

Few studies have evaluated the relationship of HIV disclosure with RIC and VL suppression. However, the participant selection criteria for duration of HIV and results vary. Breger (2017) showed marginal likelihood of RIC associated with HIV disclosure prior to ART initiation among ART naïve patients [9]. Elopre (2015) showed that the new to care patients who did not disclose their HIV status were 2 times more likely to be poorly retained in care during the initial year [10] and have detectable viral load values (≥200 copies/ml of blood) [11]. Conversely, other studies among patients already in HIV care, showed no association between non-disclosure and detectable VL (>50 copies /ml of blood after 6 months of ART) [1]. Prior studies suggest during the first year of HIV care, non-disclosure in HIV patients is associated with higher risk of missed appointments resulting in poor retention [10, 12] which is associated in turn with double the risk of mortality compared to those who are attended all appointments and were

retained in care [13]. A study conducted among HIV patients diagnosed in the initial 6 months of care showed that 66.7% of those who disclosed their HIV serostatus were retained in HIV care at year 1 and 2 compared to 33.3% at year 1 and 11.1% at year 2 among those who did not disclose [14]. The same study demonstrated that 66.7% of those who disclosed had visit constancy of 80% or more compared to 22.2% who chose non-disclosure [14].

HIV disclosure has been shown to be associated with components of HIV care continuum like linkage to HIV care and ART adherence [8, 9, 15] but no clear relationship has been demonstrated for other critical components like RIC and VL suppression [9] especially among new to care patients. Addressing this gap in the literature is important to achieve better HIV related health outcomes. To our knowledge, no study has examined the role of early HIV disclosure status and time to VL suppression and suitable RIC measures (visit adherence and 4-month visit constancy) among new to care patients using a multisite data. Hence, in this study we evaluated 1) the association of HIV disclosure status and patterns of disclosure with 48-week VL suppression 2) the association of HIV disclosure status and patterns of disclosure with time to VL suppression and RIC measured using visit adherence and 4-month visit constancy among new to HIV care patients enrolled within 14 days of their HIV primary care visit across 4 urban HIV clinics. We believe that gauging this relationship will delineate the role of early HIV disclosure and may improve rates of VL suppression and RIC.

METHODS

Study Design and Setting

We conducted a retrospective cohort study using iENGAGE (integrating ENGagement and Adherence Goals upon Entry) study funded by the National Institute of Allery and Infectious Diseases (NIAID) - R01 AI 103661and clinical trials.gov NCT01900236. The iENGAGE randomized behavioral intervention trial was implemented at the 4 US HIV clinics: the University of Alabama at Birmingham (UAB), the University of North Carolina at Chapel Hill (UNC), the John Hopkins University (JHU) and the University of Washington at Seattle (UW). Institutional Review Board (IRB) approved study protocol and recruitment activities at each site and participants went through the informed consented process prior to enrollment. iENGAGE enrollment criteria included age ≥ 18 years with confirmed HIV infection, no prior outpatient HIV care, English speaking, not moving in next one year and willing to provide informed consent. Rationale and design of the iENGAGE study are available elsewhere [16].

Participant Cohort

All participant data was collected electronically using a customized web application designed for the study and stored at UAB [17].

Overall, 941 new to HIV care patients were screened, 372 participants were enrolled across sites from Dec 2013-Apr 2016 and followed for the next 48 weeks. One participant was later found to have had prior HIV care and was withdrawn resulting in a final sample of 371. At baseline and at 48-week final visits participants completed a set of questionnaires on mental health variables (depression, anxiety), alcohol use, substance use, quality of life, sexual risk assessment, coping, social support, HIV stigma, HIV

disclosure, HIV related self-efficacy, and unmet needs. At the final 48-week visit patient completed additional questionnaires on HIV visit adherence and ART adherence questions and a blood draw for VL values.

Outcomes

The primary dependent variable of the study was 48-week plasma VL suppression defined as a VL value of <200copies/ml of blood [18]. As defined by the iENGAGE study protocol 48-week VL value was collected between 46-72 weeks from date of randomization. The VL values were obtained from the central electronic database designed for the iENGAGE study [17] and Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS) [19].

The secondary dependent variables of the study were: 1) time to VL suppression 2) RIC measures – visit adherence and 4-month visit constancy.

Time to VL suppression: We calculated the time to VL suppression (defined as <200 copies/ml) as the time in days from the randomization date to the first date with VL suppression during the study period. Participants were administratively censored at 48 weeks from date of randomization. We conducted sensitivity analysis for time to VL suppression using 72 weeks as the censoring time.

RIC measures: Measuring retention in care is complex and there is no gold standard established [20]. We used visit adherence and 4-month visit constancy measures. Visit adherence was used as a dichotomous variable as perfect adherence (100%) vs. not perfect (<100%). Visit constancy evaluates the proportion of pre-specified time intervals with at least one attended clinic visit during an observation period of interest [20]. As per the treatment guidelines, the time intervals ranged between 3 and 6 months [13, 21-23].

We used a 4-month interval for this study as patients newly initiating HIV outpatient HIV medical care have more frequent scheduled visits than established HIV patients.

Independent Variables

Disclosure and Disclosure patterns

To assess HIV disclosure participants answered a 3-item HIV disclosure questionnaire. The first question captured disclosure to anyone: 'Have you told anyone about your HIV status, not including your health provider?' If participants responded 'yes' to the first question, the next 2 follow up questions captured information on patterns of disclosure: 'Have you told more than 1 person about your HIV status?' and 'Who have you told about your HIV status?' [choices: Spouse/ significant other, current sexual partner(s), past sexual partner(s), family member(s), friend(s), religious leader(s) (e.g., priest, rabbi, pastor/ No response/ NA - skip question)]. For data analysis, we have used HIV disclosure as dichotomous (non-disclosure and any HIV disclosure and non-disclosure) and 3-level variable [patterns of HIV disclosure – non-disclosure (disclosed to no one), selective (disclosure to only 1 group) and broad disclosure (disclosed to > 1 group)]

Other covariates

Information on covariates was obtained using the iENGAGE screening form, questionnaires completed at enrollment visits and using the CFAR (Centers for AIDS Research) Network of Integrated Clinical Systems (CNICS) database.

Socio-demographic variables

Socio-demographic variables included age (years), gender (Male, Female/Transgender), race (White, Black, Other (Native American, Asian), ethnicity (Hispanic, Non-Hispanic) and insurance (Yes/No).

HIV related risk factors

ART use at enrollment (Yes (started ART prior to or on the date of enrollment)/No), baseline CD4 count (<200, 200-350cells, >350cells), and baseline VL values (<200 cells/ml of blood, ≥200 cells/ml of blood and missing values) were captured for all participants using CNICS repository. Baseline laboratory value for plasma VL value and CD4 values were obtained closest to enrollment (timeframe: -90days, +14 days). In instances where multiple baseline VL values were available, the greater value was selected.

Sexual risk factors

HIV transmission risk factors [men who have sex with men (MSM), intravenous drug user (IDU), heterosexuals)] were captured for all participants using the CNICS database. If multiple transmission risk factors were reported, precedence was given to IDU followed by MSM and then heterosexuals. Substance use (cocaine/crack, amphetamines, opiates, injection drug use) was measured using the Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) [24] and was categorized as never (no drug use ever), prior (no drug use in past 3 months) and current (drug use once or twice, weekly, monthly or daily in last 3 months) [25]. Alcohol consumption in the past year was measured using a 3-item Alcohol Use Disorders Identification Test (AUDIT–C) questionnaire and was categorized as no risk [score=0-2 for men (M), 0-1 for women (W)], low risk [score = 3 (M), 2 (W)] and high risk [score = 4 (M), 3 (W)] [26]. The number of sexual partners in past 6 months was assessed using The HIV Risk Assessment for Positives (HRAP) and was categorized as 0, 1, 2, 3, 4-5, ≥ 6 partners.

Psychosocial factors

Depression experienced in last 2 weeks was assessed using an 8-item Patient Health Questionnaire (PHQ)-8; rated using a 4-point Likert-like scale ('not at all'= 0 to 'nearly every day'= 3) with a score range of 0-24 and interpreted as a score ≥10 - depression and <10 - no depression [27, 28]. Anxiety experienced in the last 4 weeks was captured using a 5-item PHQ-5 questionnaire [29] with an overall score range of 0-5. Scores were categorized as no anxiety (overall score = 0) and anxiety (overall score 1-5). Perceived social support (informational, tangible, positive social interaction, and affectionate) was assessed using a 4-item abbreviated Medical Outcomes Study Social Support Survey (MOS-4) [30, 31]. A 5-point Likert scale ('none of the time' = 1 to 'all of the time' = 5). A composite score ranged from 0-100 [32]. Higher composite score, greater the perceived support. Participant's coping skills were measured using an adapted brief cope questionnaire to assess 9/14 domains: active coping, positive reframing, acceptance, religion, using emotional support, denial, substance use, behavioral disengagement, and self-blame. Each domain was measured using 2 items [33-35] and score using a 4-point Likert scale ('not doing this at all' = 1, to 'doing this all the time' = 4). An average score was recorded for each domain. Supportive services needed in last 6 months was assessed with 'unmet needs' instrument used in CDC RIC trial [15] and were categorized into 3 broad categories: counseling/substance abuse treatment; housing expenditure (housing, transportation, food, groceries, meals and childcare) and financial assistance (financial, employment, and benefits assistance). EuroQoL (EQ)-5D was used to measure the five health-related quality of life: mobility, self-care, usual activities, pain/discomfort, anxiety/depression, and responses ranged from 'no problems' = 1 to 'severe problems' =

3 [36]. Each domain was dichotomized as 'Yes' (moderate or severe problems) 'No' (no problems). A 12-item HIV Adherence Self-Efficacy Scale (HIV-ASES) was used to measure patient's confidence to accomplish treatment-related behaviors [37] with responses ranging from 'cannot do it at all' = 0 to 'certain can do it' = 10. Higher composite score, greater the adherence self-efficacy [37].

Other factors

UAB, UNC, UW, and JHU consisted of the 4 sites and participants were randomized to either intervention arm or control arm in the study.

Statistical Analysis

Descriptive statistics were presented as means and standard deviation for continuous variables and numbers and percentages for categorical variables. Normality of continuous variables was tested using Q-Q plots. Variance Inflation Factor was not >5 for any of the variables included in the models and hence multi-collinearity was not an issue [38, 39]. In addition, we avoided variables if the condition index was ≥ 30 [40] and checked correlation estimates for variables to ensure correct estimates. Supportive services needed in last 6 months for housing expenditure and financial assistance showed moderate correlation (R = 0.5) and hence we added only one of the variables in the model [41].

48-week VL suppression

Logistic regression Model was used to estimate odds ratios (ORs) and their respective 95% confidence intervals (CIs) to examine the association of any disclosure and patterns of disclosure with 48-week VL suppression.

Time to VL suppression

Cox Proportional Hazards Model was used to evaluate the association of HIV disclosure status and patterns of HIV disclosure with time to VL suppression for a study period of 48 weeks. Proportional Hazards assumption was checked using log (-log) survival plots which was further tested using an interaction term between independent variables and time (natural log) and was met. The interaction term was further excluded from the analysis. We generated Kaplan-Meier curves to visually present time to VL suppression among disclosed anyone vs. non-disclosed group and among selective, broad disclosers vs non-disclosers. We conducted sensitivity analysis where participants were followed for a study period of 72 weeks.

4-month visit constancy

Ordinal Logistic regression model was used to calculate OR and 95%CI to estimate the association of disclosure and patterns of disclosure with the 4-month visit constancy where the 48 weeks' study period was divided into 3 intervals each of 4 months each. If participants had no arrived visits in all three intervals, then score = 0%; had at least 1 arrived visit in just one interval, then score = 33%; at least 1 arrived visit in exactly two intervals, then score = 67%; and at least 1 arrived visit in each of the three intervals, then score = 100%.

Visit adherence

Logistic regression model was used to obtain ORs and corresponding CIs to assess the relationship of any disclosure and patterns of disclosure with visit adherence (100%t adherence vs. <100% adherence).

Adjusted models were generated to account for potential confounders which were selected based on clinical significance, prior literature and statistical significance (p-value <0.10) from unadjusted models. A two-sided p-value of 0.05 was considered statistically significant for all adjusted analysis.

RESULTS

Baseline participant characteristics by 48-week VL suppression and RIC measures are described in Tables 1 and 2 respectively. Among 371 participants, overall 78.4% disclosed their HIV status. Percentages of 48-week VL suppression were similar among non-disclosure (84.9%), any HIV disclosure (86.6%), selective (83.3%) and broad disclosure (87.2%) (Table 1). Among participants who disclosed to anyone, 57% displayed perfect (100%) visit adherence and 50% scored 100% on 4-month constancy. The results were similar among non-disclosure, selective and broad disclosure.

48-week VL suppression

The odds of 48-week VL suppression were similar and statistically non-significant for any disclosure (OR = 0.97; 95%CI = 0.28, 3.39), selective disclosure (OR = 1.26; 95%CI = 0.20, 7.85) broad disclosure (OR = 0.92; 95%CI = 0.26, 3.30) compared to non-disclosure in the adjusted analysis (Table 3).

Time to VL suppression

The final analytical sample for time to VL suppression was 333. Participants who were virally suppressed at baseline (n = 25) and had no follow-up data (n = 13) were excluded from the analysis. Participants were censored at death date if deceased during the study

period (n = 2), on withdrawal dates (n = 2) and administratively censored at 48 weeks from date of randomization into the study. The median follow up time was 72 days. There were 285 total VL suppression events. In the adjusted model, any disclosure (HR = 0.66; 95%CI = 0.46, 0.96), selective disclosure (HR = 0.82; 95%CI = 0.49, 1.37) and broad disclosure (HR = 0.64; 95%CI = 0.44, 0.93) groups were less likely to achieve VL suppression over time compared to non-disclosure group. Results were statistically significant for any HIV disclosure and broad disclosure but not for selective disclosure (Table 4). The Kaplan Meir curves demonstrated no real difference with insignificant log rank p –values between any HIV disclosure vs. non-disclosure groups (p = 0.71) and selective, broad and non-disclosure groups (p = 0.57) (Figures 1 and 2).

In the sensitivity analysis, we censored participants at 72 weeks and the results were similar for all models (data not presented).

4-month visit constancy

In the adjusted analysis, the odds of 4-month visit constancy similar among any disclosure compared to non-disclosure (OR = 0.85; 95%CI = 0.47, 1.53) and broad disclosure compared to selective and non-disclosure (OR = 0.92; 95%CI = 0.50, 1.69). The odds of the same was minimally lower among selective disclosure compared to broad and non-disclosure (OR = 0.65; 95%CI = 0.30, 1.42) but statistically non-significant (Table 5).

Visit adherence

Similarly, in the adjusted analysis, the odds of perfect visit adherence were similar for any (OR = 1.12; 95%CI = 0.50, 2.55) and broad disclosure (OR = 0.96; 95%CI = 0.42, 2.22) compared to non-disclosure. The odds of the same were slightly higher among selective disclosure compared to non-disclosure (OR = 1.85; 95%CI = 0.57, 6.02) (Table 6).

DISCUSSION

In the present study among patients initiating outpatient HIV care, disclosure did not significantly improve 48-week VL suppression, visit adherence and 4-month visit constancy when adjusted for sociodemographic factors, HIV related risk factors, psychosocial and other factors. Any HIV disclosure, selective and broad disclosure groups were significantly less likely to achieve VL suppression over time compared to non-disclosure in the adjusted analysis. The odds of visit adherence was higher among selective disclosers whereas the odds of 4-month constancy was lower among selective disclosers compared to non-disclosers but results were not statistically significant and lack precision with wide CIs.

Our results from the adjusted analysis showed nearly no association of 48-week VL suppression with any HIV disclosure and broad disclosure. Our findings are consistent with prior studies where non-disclosure was not associated with VL suppression [1, 11]. With the newer one pill ART regimens with fewer side effects, ART adherence is better resulting in VL suppression [42, 43]. In this study, new to care participants were in good health with 75% of those had a baseline VL value <200 copies/ml of blood and 88% had CD4 counts >350 cells/ml of blood and waning the

necessity to disclose HIV serostatus with disease progression [11, 44]. Additionally, lack of association in this study could be due to the modest sample size. The odds of the 48-week VL suppression was a little higher among selective disclosers but statistically non-significant. One possible explanation is individuals who selectively disclose may strategically select confidants to gain the emotional support required and have favorable outcomes [1, 45]. Our results differ from Elopre (2015) who reported selective disclosure to family was associated with detectable VL[11]. One possible explanation for inconsistent results could be patients in the study had disease progressed enough necessitating disclosure to family. Also, there was differential missing of VL values among disclosure categories as noted by the authors. Future studies with larger new to HIV care cohort, capturing the extent of disclosure in each disclosure category and further clarify this association. Future qualitative studies to understand barriers to VL suppression among new to care patients who disclosed and understanding cultural frameworks around HIV disclosure among new to care patients would help clarify the unexpected findings of the study. In addition, developing a new instrument for disclosure to capture the intimacy of participants with their social network in future studies may be beneficial.

To our knowledge, this is the first study to evaluate the association of disclosure with time to VL suppression. Interestingly, our results showed that the hazard of time to VL suppression over 48 weeks' study period was less likely among any HIV disclosure, selective and broad disclosure. Results were paradoxical to what we initially hypothesized. The results could be attributed to inconsistent HIV care during the initial year. Inconsistent care has been shown to be associated with detectable VL over time [5].

Especially among new to care patients, coming to appointments at regular intervals to initiate ART or to make changes to the ART regimen to achieve sustained VL suppression is critical. Another possible explanation could be social desirability bias where having disclosed HIV serostatus was overstated by patients [46]. In this study, any disclosure and broad disclosure groups, there was nearly no association with 4-month constancy and the estimates little lower among selective disclosers. Modest sample size of the study and residual confounding due to unknown behavioral factors not controlled for could be another reasons contentious results. Future studies with larger sample size and longer follow up periods, capturing the number of people patients disclosed to and change of disclosure over time may provide further insights into this association.

Our results showed HIV disclosure did not significantly improve visit adherence and 4-month constancy among any HIV disclosure and broad disclosure group. About 78.2% participants reported having disclosed their HIV status at enrollment visit which could have concealed the difference between the disclosure and non-disclosure groups [9]. Our results were nearly similar to Breger (2017) study among ART naïve patients where authors reported a weak but not statistically significant association of HIV disclosure with RIC [9]. The observed difference could be because the study was based in sub-Sahara region which included a different cohort of HIV population and use of different retention measure (at least one arrived visit within 180 days of initial visit). Our results were inconsistent with other prior studies [10, 14, 47]. Elopre (2015) reported non-disclosure was associated with poor RIC among patients initiating HIV care [10]. Wohl (2011) reported disclosure as a major predictor of RIC among Latino and African American patients established in care [47]. Our results possibly differ due to controlling

for potential confounders (coping behaviors, need for supportive services, stigma, and substance use) in the analysis which were not controlled for in prior results. The odds of visit adherence were higher among selective disclosers as shown by another prior study [11]. However, our results lack precision with wide CIs and statistical non-significance. Additionally, in this study, we used visit adherence and 4-month constancy as measures of RIC whereas prior studies measured RIC as more than 180 days' gap between arrived HIV care visits. Halperin (2013) showed that patients who disclosed were significantly more likely to have a visit constancy (80% or higher) [14]. Visit constancy was measured at 6-months interval for five intervals over 2.5 years in this study, which is different from the 4-month constancy that we used in our study considered more appropriate for new to HIV care patients.

Strengths

The strengths of the study include a geographically diverse cohort of new to HIV outpatient care patients from across four US HIV clinics. Next, our results quantify the association of HIV disclosure status and patterns of HIV disclosure with sustainable VL measure (time to VL suppression) which has not been studied before in addition to single 48-week VL suppression. Finally, our study is the first to gauge the relationship of HIV disclosure and patterns of disclosure with appropriate measures of retention for the new to care population which contributes to the gaps identified in the literature.

Limitations

HIV disclosure may have been over-reported due to social desirability bias. However, our rates were comparable to US national estimates. The iENGAGE participants may have moved from the area and retained in care someplace elsewhere which we may have

missed resulting in exaggerated percentage on PLWH not retained in care and a possible misclassification. However, we anticipate there were only a handful of participants across each site. During the screening process for the iENGAGE study participants were asked if they had plans to move in the next 12 months and if they responded yes, they were not enrolled in the study. Every attempt was made to be in touch with the enrolled participants if they moved to help them complete study activities and obtain 48-week VL value. Information bias may have been imposed due to missing data. However, we used CNICS data in addition to iENGAGE study data for participants across sites to obtain the VL values throughout the year including the 48-week VL values. There are rigorous data standards for data collection and storage for quality control at CNICS sites and central CNICS data repository to minimize information bias. Study findings may not be generalized to other HIV patient populations. However, the demographics are largely consistent with national figures.

CONCLUSION

HIV disclosure may play an important role in overall HIV care and prevention, however, it did not significantly improve RIC and VL suppression. Our results suggest that adding a component of HIV disclosure counseling for HIV prevention along with other counseling services may be sufficient at the initial appointment. Future studies with larger sample size and longer follow up periods among new to HIV patients looking at the extent of disclosure to the social network may provide further insight in the understanding association of HIV disclosure and HIV related outcomes. Future qualitative studies to understand barriers of RIC and VL suppression among new to care patients who disclosed their HIV serostatus may be beneficial.

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TABLES

Table 1. Baseline patient characteristics by 48-week VL suppression at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016 (n = 371).

Variables	Overall n = 371	48-week VL suppression	
		Yes (<200 copies/ml of blood) n = 269	No (≥200 copies/ml of blood) n = 43
Socio-demographic factors			
Age (years)	37.1 (±12)	37.5 (±12.4)	34.2 (±10.8)
Sex			
Male	294 (79.3)	217 (87.2)	32 (12.9)
Female	71 (19.1)	47 (82.5)	10 (17.5)
Transgender	6 (1.6)	5 (83.3)	1 (16.7)
Race			
Black	231 (62.3)	160 (82.9)	33 (17.1)
White	109 (29.4)	84 (91.3)	8 (8.7)
Other	31 (8.4)	25 (92.6)	2 (7.4)
Ethnicity			
Hispanic	20 (5.4)	17 (100)	0
Non-Hispanic	351 (94.6)	252 (85.4)	43 (14.9)
Insurance			
None	87 (23.6)	71 (92.2)	6 (7.8)
Private	107 (29.1)	83 (90.2)	9 (9.9)
Public	174 (47.3)	113 (80.1)	28 (19.9)
HIV Related Risk Factors			
HIV disclosure status			
Yes	290 (78.4)	213 (86.6)	33 (13.4)
No	80 (21.6)	56 (84.9)	10 (15.2)
Patterns of disclosure			
Non-disclosure	80 (21.7)	56 (84.9)	10 (15.2)
Selective disclosure	56 (15.2)	35 (83.3)	7 (16.7)
Broad disclosure	233 (63.1)	177 (87.2)	26 (12.8)
ART[1]			
Yes	114 (30.7)	83 (88.3)	11 (11.7)
No	257 (69.3)	186 (85.3)	32 (14.7)
CD4 count			
<200	85 (24.9)	60 (84.5)	11 (15.5)
200-300	83 (24.3)	65 (89)	8 (11)
>350	174 (50.9)	125 (88)	17 (12)
VL value[2]			
<200	16 (4.3)	6 (75)	2 (25)
>=200	348 (93.8)	260 (87.3)	38 (12.8)

Missing	7 (1.9)	3 (50)	3(50)
Sexual risk factors			
Transmission risk[3]			
MSM	219 (60)	164 (85.9)	27 (14.1)
Heterosexual	117 (32.1)	83 (87.4)	12 (12.6)
IDU	29 (8)	18 (81.8)	4 (18.2)
Sex behavior			
0	76 (20.5)	62 (91.2)	6 (8.8)
1	100 (27)	63 (81.8)	14 (18.2)
2	55 (14.8)	39 (83)	8 (17)
3	38 (10.2)	26 (86.7)	4 (13.3)
4-5	40 (10.8)	29 (85.3)	5 (14.7)
≥6	62 (16.7)	50 (89.3)	6 (10.7)
Alcohol use			
No risk	191 (52.5)	133 (83.7)	26 (16.4)
Low risk	46 (12.6)	36 (90)	4 (10)
High risk	127 (34.9)	95 (88)	13 (12)
Substance use			
Never	198 (55.8)	152 (85.9)	25 (14.1)
Prior	93 (26.2)	73 (94.8)	4 (5.2)
Current	64 (18)	33 (75)	11 (25)
Psychosocial factors			
Social support score	57 (±29.1)	59.4 (±28.5)	47 (±28.5)
Quality of life			
No Mobility	317 (85.9)	228 (85.7)	38 (14.3)
No Self-Care	358 (97.3)	258 (86)	42 (14)
No Usual activities	300 (81.1)	216 (86.4)	34 (13.6)
No Pain	209 (57)	159 (88.8)	20 (11.2)
No Depression / Anxiety	165 (44.7)	127 (87.6)	18 (12.4)
Stigma			
Enacted stigma	2.2 (±0.7)	2.1 (±0.7)	2.2 (±0.8)
Disclosure concerns	3.1 (±0.6)	3.1 (±0.6)	3.0 (±0.6)
Internalized stigma	2.3 (±0.7)	2.3 (±0.7)	2.3 (±0.8)
Public stigma	2.7 (±0.7)	2.7 (±0.7)	2.8 (±0.7)
Anticipated stigma			
Family	2.7 (±1.4)	2.7 (±1.4)	2.8 (±1.4)
Friends	2.8 (±1.3)	2.7 (±1.3)	2.8 (±1.3)
Healthcare provider	1.8 (±0.9)	1.8 (±0.9)	1.8 (±0.7)
Coping			
Active coping	6.7 (±1.7)	6.9 (±1.6)	6.2 (±1.9)
Denial	3.6 (±1.9)	3.5 (±1.9)	3.5 (±1.7)
Substance use	3.1 (±1.8)	3 (±1.7)	3.4 (±2.1)
Emotional support	5.2 (±2.2)	5.3(±2.2)	5 (±2.1)
Behavioral disengagement	2.7 (±1.2)	2.6 (±1.2)	2.7 (±1.2)
Positive reframing	5.7 (±2)	5.8 (±1.9)	5.6 (±1.8)
Acceptance	6.8 (±1.5)	7 (±1.5)	6.3 (±1.7)

Religion	5.5 (±2.2)	5.5 (±2.3)	5.6 (±2.2)
Self-blame	4.7 (±2.1)	4.6 (±2.1)	4.7 (±2.1)
HIV treatment self-efficacy score	9 (±1.5)	9.1 (±1.4)	8.4 (±1.9)
Supportive service needs in last 6 months			
Financial assistance[4]	179 (49.2)	117 (79.1)	31 (21)
Housing expenditure[5]	194 (52.9)	125 (78.6)	34 (21.4)
Substance use treatment and counseling	125 (34)	89 (84)	17 (16)
Depression			
Yes	107 (30.8)	73 (84.9)	13 (15.1)
No	241(69.3)	180 (87)	27 (13)
Anxiety			
Yes	113 (31.4)	77 (86.5)	12 (13.5)
No	247 (68.6)	185 (86.5)	29 (13.6)
Other factors			
Site[6]			
UAB	153 (41.2)	106 (83.5)	21 (16.5)
UNC	76 (20.5)	58 (90.6)	6 (9.4)
JHU	78 (21)	49 (77.8)	14 (22.2)
UW	64 (17.3)	56 (96.6)	2 (3.5)
Study arm			
Control	186 (50.1)	136 (86.6)	21 (13.4)
Intervention	185 (49.9)	133 (85.8)	22 (14.2)

[1]ART – antiretroviral therapy
[2]VL value – viral load value
[3]Transmission risk – MSM – men who have sex with men, IDU – injection drug users
[4]Financial assistance category includes financial, employment, benefits assistance
[5]Household expenditure category includes housing, transportation, food, groceries, meals and childcare
[6] Site - UAB – University of Alabama at Birmingham; UNC – University of North Carolina at Chapel Hill; JHU – Johns Hopkins University at Baltimore; UW – University of Washington at Seattle

Table 2: Baseline patient characteristics by visit adherence and 4-month visit constancy at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016.

Variables	Visit adherence		4-month visit constancy*			
	100% adherence n = 206	<100% adherence n = 160	0%score n = 15	33%score n = 50	66%score n = 120	100%score n = 186
Socio-demographic factors						
Age (years)	38.4 (±12.2)	35.3 (±11.5)	34.9 (±12.4)	35.9 (±11.5)	35.3 (±10.8)	38.8 (±12.7)
Sex						
Male	166 (57)	125 (43)	12 (4.1)	37 (12.6)	101 (34.3)	144 (49)
Female	36 (52.2)	33 (47.8)	3 (4.2)	12 (16.9)	16 (22.5)	40 (56.3)
Transgender	4 (66.7)	2 (33.3)	0	1 (16.7)	3 (50)	2 (33.3)
Race						
Black	116 (50.9)	112 (49.1)	10 (4.3)	36 (15.6)	72 (31.2)	113 (48.9)
White	72 (67.3)	35 (32.7)	3 (2.8)	13 (11.9)	38 (34.9)	55 (50.5)
Other	18 (58.1)	13 (41.9)	2 (6.5)	1 (3.2)	10 (32.3)	18 (58.1)
Ethnicity						
Hispanic	12 (60)	8 (40)	1 (5)	0	11 (55)	8 (40)
Non-Hispanic	194 (56.1)	152 (43.9)	14 (4)	50 (14.3)	109 (31.1)	178 (50.7)
Insurance						
None	70 (81.4)	16 (18.6)	1 (1.2)	11 (12.6)	22 (25.3)	53 (60.9)
Private	64 (60.4)	42 (39.6)	3 (2.8)	12 (11.2)	49 (45.8)	43 (40.2)
Public	70 (40.7)	102 (59.3)	10 (5.8)	26 (14.9)	49 (28.2)	89 (51.2)
HIV related risk factors						
HIV disclosure status						
Yes	163 (57)	123 (43)	11 (3.8)	40 (13.8)	95 (32.8)	144 (50)

No	42 (53.2)	37 (46.8)	4 (5)	9 (11.3)	25 (31.3)	42 (52.5)
Patterns of disclosure						
Non-disclosure	42 (53.2)	37 (46.8)	4 (5)	9 (11.3)	25 (31.3)	42 (52.5)
Selective disclosure	32 (59.3)	22 (40.7)	3 (5.4)	10 (17.9)	18 (32.1)	25 (44.6)
Broad disclosure	131 (56.5)	101 (43.5)	7 (3)	30 (12.9)	77 (33.1)	119 (51.1)
ART[1]						
Yes	49 (43)	65 (57)	0	17 (14.9)	43 (37.7)	54 (47.4)
No	111 (44.1)	141 (56)	15 (5.8)	33 (12.8)	77 (30)	132 (51.4)
CD4 count						
<200	50 (58.8)	35 (41.2)	0	11 (12.9)	24 (28.2)	50 (58.8)
200-300	49 (59)	34 (41)	3 (3.6)	8 (9.6)	31 (37.4)	41 (49.4)
>350	94 (55)	77 (45)	10 (5.8)	29 (16.7)	57 (32.8)	78 (44.8)
VL value[2]						
<200	7 (46.7)	8 (53.3)	2 (12.5)	6 (37.5)	6 (37.5)	2 (12.5)
>=200	199 (57.8)	145 (42.2)	13 (3.7)	44 (12.6)	111 (31.9)	180 (51.7)
Missing	0	7 (100)	0	0	3 (42.9)	4 (57.1)
Sexual risk factors						
Transmission risk[3]						
MSM	131 (60.1)	87 (39.9)	6 (2.7)	24 (11)	81 (37)	108 (49.3)
Heterosexual	61 (53)	54 (47)	5 (4.3)	20 (17.1)	29 (24.8)	63 (53.9)
IVDU	11 (39.3)	17 (60.7)	3 (10.3)	5 (17.2)	9 (31)	12 (41.4)
Sex behavior						
0	47 (61.8)	29 (38.2)	1 (1.3)	7 (9.2)	18 (23.7)	50 (65.8)
1	51 (52.6)	46 (47.4)	5 (5)	16 (16)	30 (30)	49 (49)
2	29 (54.7)	24 (45.3)	4 (7.3)	7 (12.7)	20 (36.4)	24 (43.6)
3	21 (55.3)	17 (44.7)	1 (2.6)	6 (15.8)	14 (36.8)	17 (44.7)

4-5	27 (67.5)	13 (32.5)	1 (2.5)	7 (17.5)	14 (35)	18 (45)
≥6	31 (50)	31 (50)	3 (4.8)	7 (11.3)	24 (38.7)	28 (45.2)
Alcohol use						
No risk	110 (58.2)	79 (41.8)	8 (4.2)	21 (11)	65 (34)	97 (50.8)
Low risk	30 (65.2)	16 (34.8)	1 (2.2)	7 (15.2)	16 (34.8)	22 (47.8)
High risk	64 (71.4)	60 (38.7)	6 (4.7)	20 (15.8)	36 (28.4)	65 (51.2)
Substance use						
Never	121 (61.1)	77 (39)	6 (3)	19 (9.6)	69 (34.9)	104 (52.5)
Prior	54 (60)	36 (40)	5 (5.4)	17 (18.3)	23 (24.7)	48 (51.6)
Current	22 (34.9)	41 (65.1)	3 (4.7)	12 (18.8)	25 (39.1)	24 (37.5)
Psychosocial factors						
Social support score	60.5 (±28.8)	52.6 (±29.2)	47.3 (±30.5)	53.5 (±29.5)	58.6 (±27.7)	57.7 (±29.7)
Quality of life						
No Mobility	181 (57.8)	132 (42.2)	13 (4.1)	41 (12.9)	104 (32.8)	159 (50.2)
No Self-Care	200 (56.7)	153 (43.3)	15 (4.2)	49 (13.7)	116 (32.4)	178 (49.7)
No Usual activities	166 (56.3)	129 (43.7)	15 (5)	42 (14)	97 (32.3)	146 (48.7)
No Pain	125 (60.7)	81 (39.3)	10 (4.8)	26 (12.4)	68 (32.5)	105 (50.2)
No Depression / Anxiety	102 (63.4)	59 (36.7)	8 (4.9)	16 (9.7)	58 (35.2)	83 (50.3)
Stigma						
Enacted stigma	2.2 (±0.7)	2.2 (±0.7)	2.4 (±0.7)	2.3 (±0.7)	2 (±0.6)	2.2 (±0.7)
Disclosure concerns	3.1 (±0.6)	3 (±0.6)	3 (±0.6)	3 (±0.6)	3 (±0.6)	3.1 (±0.6)
Internalized stigma	2.3 (±0.7)	2.3 (±0.7)	2.2 (±0.6)	2.3 (±0.7)	2.3 (±0.7)	2.3 (±0.8)
Public stigma	2.7 (±0.7)	2.7 (±0.7)	2.6 (±0.8)	2.8 (±0.8)	2.6 (±0.6)	2.7 (±0.7)
Anticipated stigma						

Family	2.7 (±1.4)	2.7 (±1.4)	2.8 (±1.5)	2.7 (±1.5)	2.7 (±1.4)	2.7 (±1.4)
Friends	2.8 (±1.3)	2.7 (±1.3)	2.9 (±1.1)	2.8 (±1.4)	2.7 (±1.3)	2.8 (±1.3)
Healthcare provider	1.8 (±1)	1.8 (±0.9)	2.0 (±1.2)	1.9 (±1)	1.7 (±0.8)	1.8 (±0.9)
Coping						
Active coping	6.9 (±1.6)	6.5 (±1.9)	5.9 (±2.2)	6.4 (±1.8)	6.7 (±1.8)	6.8 (±1.6)
Denial	3.5 (±1.9)	3.6 (±1.9)	3.5 (±2.3)	3.4 (±1.7)	3.5 (±1.7)	3.6 (±2)
Substance use	3.0 (±1.8)	3.2 (±1.8)	3.8 (±2)	3.2 (±1.9)	3 (±1.7)	3.1 (±1.8)
Emotional support	5.3 (±2.1)	5.0 (±2.2)	4.5 (±2.1)	5.3 (±2.1)	5.2 (±2)	5.2 (±2.3)
Behavioral disengagement	2.6 (±1.3)	2.7 (±1.2)	3.5 (±2.4)	2.7 (±1.3)	2.7 (±1.2)	2.6 (±1.2)
Positive reframing	5.9 (±1.9)	5.5 (±2)	5.1 (±2.1)	5.8 (±2.1)	5.7 (±1.8)	5.7 (±2)
Acceptance	6.9 (±1.6)	6.8 (±1.5)	6.5 (±1.6)	6.8 (±1.8)	6.8 (±1.6)	6.9 (±1.5)
Religion	5.6 (±2.2)	5.3 (±2.3)	5.6(±2.3)	5.7 (±2.1)	5.2 (±2.2)	5.6 (±2.3)
Self-blame	4.7 (±2.1)	4.7 (±2.1)	5.9 (±2.4)	4.8 (±2.2)	4.7 (±2)	4.5(±2.2)
HIV treatment self-efficacy score	9.3 (±1.2)	8.7 (±1.7)	8.7 (±1.8)	9 (±1.3)	8.9 (±1.7)	9.1 (±1.3)
Supportive service needs in last 6 months						
Financial assistance[4]	86 (48.6)	91 (51.4)	9 (5)	30 (16.7)	57 (31.8)	83 (46.4)
Housing expenditure[5]	87 (45.3)	105 (54.7)	9 (4.6)	34 (17.5)	60 (30.9)	91 (46.9)
Substance use treatment or counseling	63 (50.8)	61 (49.2)	5 (4)	18 (14.4)	45 (36)	57 (45.6)
Depression						

Yes	51 (48.1)	55 (51.9)	5 (4.7)	18 (16.8)	31 (29)	53 (49.5)
No	146 (61.3)	92 (38.7)	8 (3.3)	28 (11.6)	82 (34)	123 (51)
Anxiety						
Yes	57 (51.8)	53 (48.2)	6 (5.3)	21 (18.6)	29 (25.7)	57 (50.4)
No	145 (59.2)	100 (40.8)	9 (3.6)	28 (11.3)	89 (36)	121 (49)
Other factors						
Site[6]						
UAB	84 (55.6)	67 (44.4)	6 (3.9)	22 (14.4)	57 (37.3)	68 (44.4)
UNC	57 (77)	17 (23)	2 (2.6)	13 (17.1)	17 (22.4)	44 (57.9)
JHU	28 (36.4)	49 (63.6)	5 (6.4)	13 (16.7)	26 (33.3)	34 (43.6)
UW	37 (57.8)	27 (42.2)	2 (3.1)	2 (3.1)	20 (31.3)	40 (62.5)
Study arm						
Control	99 (53.8)	85 (46.2)	6 (3.2)	24 (12.9)	68 (36.6)	88 (47.3)
Intervention	107 (58.8)	75 (41.2)	9 (4.9)	26 (14.1)	52 (28.1)	98 (53)

[*]Score = 0% – no arrived visits in all three intervals; score =33% – at least 1 arrived visit in just one interval, score = 67% – at least 1 arrived visit in exactly two intervals; and score = 100% – at least 1 arrived visit in each of the three intervals

[1]ART – antiretroviral therapy

[2]VL value – viral load value

[3]Transmission risk – MSM – men who have sex with men, IDU – injection drug users

[4]Financial assistance category includes financial, employment, benefits assistance

[5]Household expenditure category includes housing, transportation, food, groceries, meals and childcare

[6] Site - UAB – University of Alabama at Birmingham; UNC – University of North Carolina at Chapel Hill; JHU – Johns Hopkins University at Baltimore; UW – University of Washington at Seattle

Table 3: Logistic Regression models for association between 48-week viral load (VL) suppression and HIV disclosure status/ patterns of HIV disclosure among new to HIV care patients at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016

	HIV disclosure status (Yes)		Patterns of HIV Disclosure			
	Any disclosure vs. Nondisclosure		Selective disclosure vs. Nondisclosure		Broad disclosure vs. Nondisclosure	
	OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value
Unadjusted model[a]	1.15 (0.54, 2.48)	0.72	0.89 (0.31, 2.56)	0.83	1.22 (0.55, 2.68)	0.63
Adjusted model[b]	0.97 (0.28, 3.39)	0.96	1.26 (0.20, 7.85)	0.80	0.92 (0.26, 3.30)	0.90

[a]Unadjusted model n = 312 for HIV disclosure status (Yes); n = 311 for Patterns of HIV disclosure

[b] Adjusted model 2 = Adjusted for socio-demographic factors (age, gender, race, insurance) + HIV related and sexual risk factors (ART use, baseline CD4 count, transmission risk, substance use) + psychosocial and other factors (active coping and acceptance, social support score, HIV related self-efficacy score, supportive services for housing expenditure and site); n = 227

Table 4: Cox Proportional Hazards models for association between time to VL suppression censored at 48 weeks and HIV disclosure status/patterns of HIV disclosure among new to HIV care patients at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016

	HIV disclosure status (Yes)	Patterns of HIV Disclosure	
	Any disclosure vs. Nondisclosure	Selective disclosure vs. Nondisclosure	Broad disclosure vs. Nondisclosure

	HR (95%CI)	p-value	HR (95%CI)	p-value	HR (95%CI)	p-value
Unadjusted model[a]	1.05 (0.80, 1.39)	0.72	1.21 (0.82, 1.78)	0.34	1.03 (0.77, 1.36)	0.87
Adjusted model[b]	0.66 (0.46, 0.96)	0.03	0.82 (0.49, 1.37)	0.45	0.64 (0.44, 0.93)	0.02

[a]Unadjusted model n = 333 for HIV disclosure status (Yes); n = 332 for Patterns of HIV disclosure
[b]Adjusted model = Adjusted for socio-demographic factors (age, gender, race, ethnicity, insurance) + HIV related and sexual risk factors (ART use, baseline CD4 count, transmission risk, substance use, number of sexual partners) + psychosocial and other factors (religion and acceptance, supportive services for housing expenditure, qualify of life indicators for pain and mobility, enacted stigma, anticipated stigma from friends and site); n = 236

Table 5: Logistic Regression models for association between visit adherence (Yes vs. No) and HIV disclosure status/patterns of HIV disclosure among new to HIV care patients at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016

	HIV disclosure status (Yes)		Patterns of HIV Disclosure			
	Any disclosure vs. Nondisclosure		Selective disclosure vs. Nondisclosure		Broad disclosure vs. Nondisclosure	
	OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value
Unadjusted model[a]	1.17 (0.71, 1.93)	0.54	1.28 (0.64, 2.58)	0.49	1.14 (0.68, 1.91)	0.61
Adjusted model[b]	1.12 (0.50, 2.55)	0.78	1.85 (0.57, 6.02)	0.30	0.96 (0.42, 2.22)	0.93

[a]Unadjusted model n = 365;

[b]Adjusted model = Adjusted for socio-demographic factors (age, gender, race, insurance)
+ HIV related and sexual risk factors (ART use, baseline CD4, substance use, transmission risk) + psychosocial and other risk factors (active coping, positive reframing, social support score, supportive service for housing expenditure, stigma associated with disclosure concerns, quality of life measures - pain, anxiety/depression, depression and site); n = 240 for HIV disclosure status and n = 242 for patterns of disclosure.

Table 6: Ordinal Logistic Regression models for association between 4-month visit constancy and HIV disclosure status/patterns of HIV disclosure among new to HIV care patients at the 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016

	HIV disclosure status (Yes)		**Patterns of HIV disclosure**			
	Any disclosure vs. Nondisclosure		**Selective disclosure vs. Nondisclosure**		**Broad disclosure vs. Nondisclosure**	
	OR (95%CI)	**p-value**	**OR (95%CI)**	**p-value**	**OR (95%CI)**	**p-value**
Unadjusted model[a]	0.91 (0.57, 1.45)	0.68	0.70 (0.37, 1.34)	0.28	0.98 (0.60, 1.58)	0.92
Adjusted model[b]	0.85 (0.47, 1.53)	0.76	0.65 (0.30, 1.42)	0.28	0.92 (0.50, 1.69)	0.78

[a]Unadjusted model 1 n = 370 for HIV disclosure status; n =369 for patterns of HIV disclosure
[b]Adjusted model = Adjusted for socio-demographic factors (age, gender, race, insurance (Yes/No) + HIV related and sexual risk factors (baseline CD4 count, substance use, transmission risk factor, sexual behavior) + psychosocial and other risk factors (supportive services for housing expenditure, stigma associated with disclosure concerns and site); n =301

FIGURES

Figure1. Kaplan Meier survival curves for days to 48-week viral load (VL) suppression for new to HIV care patients across 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016 for any HIV disclosure vs. non-disclosure group

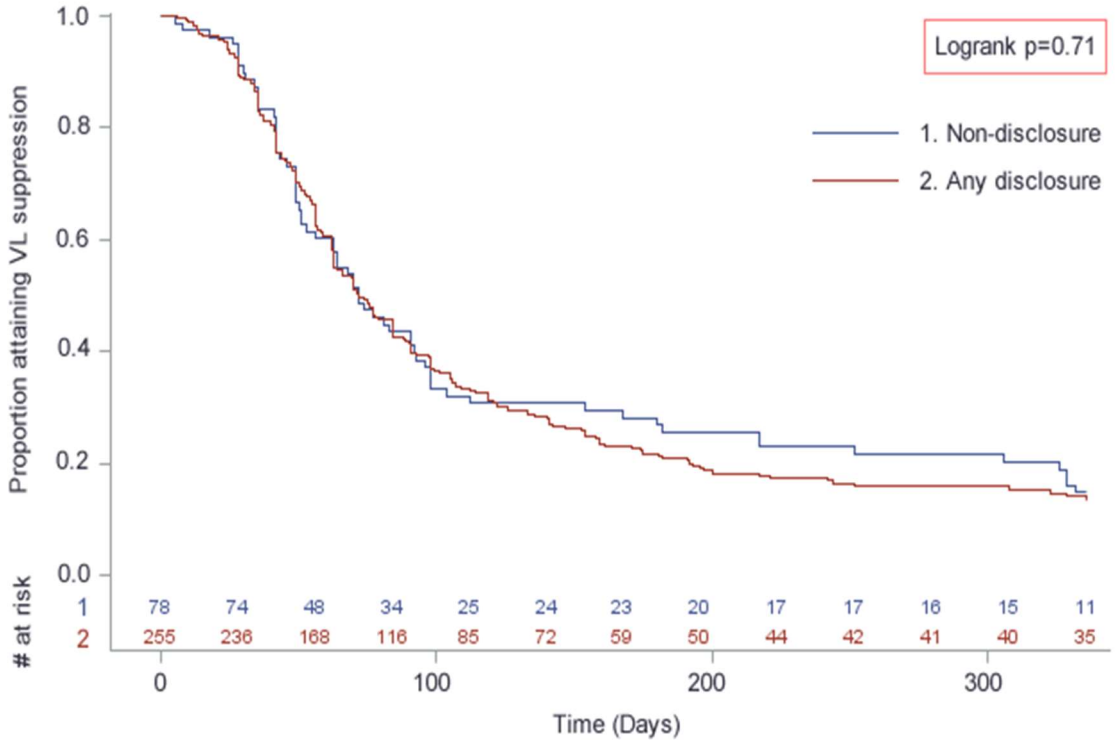
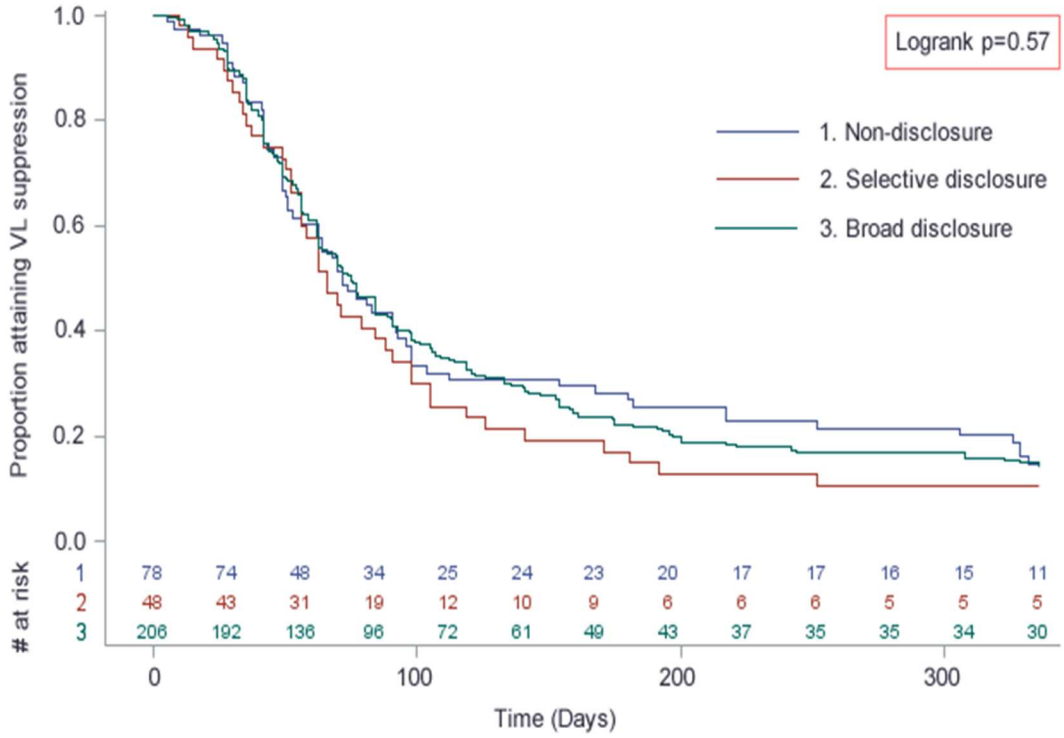


Figure 2. Kaplan Meier survival curves for days to 48-week viral load (VL) suppression for new to HIV care patients across 4 US HIV clinics enrolled in the iENGAGE study during 2013-2016 for any broad, selective and non-disclosure groups



HIV DISCLOSURE: A POTENTIAL EFFECT MODIFIER OF THE ASSOCIATION BETWEEN THE iENGAGE INTERVENTION COMPONENT AND HIV VIRAL LOAD SUPPRESSION

by

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ABSTRACT

Introduction: Early HIV disclosure is an important behavior among newly diagnosed HIV patients, which may impact viral load (VL) suppression. The mechanisms through which HIV disclosure impact VL suppression is unclear. The aim of this study is to evaluate if HIV disclosure if an effect modifier of the association of integrating ENGagement and Adherence Goals upon Entry (iENGAGE) intervention with 48-week VL suppression among patients newly initiating HIV care.

Methods: We obtained information on iENGAGE study arm and HIV disclosure from enrollment visit**.** The primary outcome was 48-week VL suppression (<200 copies/ml of blood). The relationship of iENGAGE intervention with 48-week VL suppression was obtained using Logistic Regression analysis. Stratified analysis was conducted to obtain stratum-specific odds ratios (ORs) and 95% confidence intervals (CIs) to evaluate potential effect modification.

Results: There was nearly no association between iENGAGE intervention arm and 48 week VL suppression (OR = 0.93; 95%CI = 0.49, 1.78). Stratified analysis with HIV disclosure status variable showed that the odds of 48-week VL suppression for the stratum specific OR were similar between any HIV disclosure group (OR = 0.92; 95%CI = 0.44, 1.91) and non-disclosure group (OR = 1.00; 95%CI = 0.26, 3.84) suggesting no evidence of effect modification.

Stratified analysis by patterns of HIV disclosure variable also showed no effect modification. The stratum-specific OR for 48-week VL suppression differed a little for selective disclosure group (OR = 0.71; 95%CI = 0.14, 3.64) compared to broad disclosure (OR = 0.97; 95%CI = 0.42, 2.20) and non-disclosure (OR = 1.00; 95%CI = 0.26, 3.84) but lack precision

Conclusion: Achieving VL suppression at 48 weeks in iENGAGE intervention participants did not differ between HIV disclosed and non-disclosed groups suggesting no effect modification. We recommend future studies with larger sample size and longer follow up periods to clarify the direct and indirect role of disclosure with VL suppression.
Keywords: HIV disclosure, effect modifier, iENGAGE, new to HIV care, VL suppression, stratified analysis

INTRODUCTION

Despite the advances in antiretroviral therapy (ART) regimens, not all people living with HIV (PLWH) achieve viral load (VL) suppression. Sustained VL suppression has important implications at the individual and population level [1]. At the individual level, virally suppressed state improves the overall quality of life [1] by reducing morbidity and mortality [2]. At the population level, virally suppressed individuals do not spread HIV infection [1-4] and prevent new HIV infections [5]. According to CDC, in the US, only about half of the PLWH have undetectable viral loads [6] and new HIV cases continue to occur with about 37,600 new HIV infections were estimated in the USA in 2014 [7] which is a public health problem. For newly diagnosed HIV patients, early retention is associated with attaining virally suppressed state and lower cumulative VL [8]. Missed clinic appointments among new to care are common resulting in unfavorable health related outcomes [9]. Behavioral intervention strategies have been shown to have positive implications on linkage and retention in care (RIC).

Randomized nGage (Network Supported HIV Care Engagement for Younger Black Men Who Have Sex with Men and Transgender Persons) trial among young black men who have sex with men (YMSM) implemented intervention comprising of identifying a friend to support and receiving 4 intervention sessions delivered by social worker showed that intervention participants were 3 times more likely to attend 3 clinic appointments over a year [10, 11]. RIC behavioral intervention which incorporated personal contact to participants by case managers showed fewer gaps in HIV care [12] and enhance RIC to achieve VL suppression. Participating and Communicating Together (PACT), an ART adherence intervention showed 2.8 times statistically significant higher

odds of achieving >95% ART adherence in the intervention group compared to controls [13]. A brief strength-based case management intervention encouraged patients to identify and use their own skills to arrive at a clinic appointment have helped link patients to HIV care [14, 15]. However, the impact of evidence-based intervention on achieving timely VL suppression among patients newly initiating care is lacking [12]. Hence, integrating ENGagement and Adherence Goals upon Entry (iENGAGE) behavioral intervention trial focused on offering support through personal contact and phone reminders through study interventionists to new to outpatient HIV care patients to retain in care for better HIV related outcomes [16].

In addition to intervention strategies, important determinants to achieve VL suppression include missed clinic appointments, poor ART adherence, low CD4 count, substance use suggesting diverse mechanisms influencing achieving VL suppression [17, 18]. Existing literature suggests that patient-level factor, HIV disclosure may affect VL suppression [19]. Implications of the HIV disclosure on RIC have been reported [20-22] but the literature is scant on the association of HIV disclosure with VL suppression [19]. Further, the role of HIV disclosure as an effect modifier remains unknown. The causality of the same is uncertain with varying findings across studies [23-28]. It is likely that patients, who did not disclose their HIV status during the initial year of diagnosis may be burdened with the HIV diagnosis, not come to HIV care clinic for primary care appointments or to intervention visits with study interventionists with fear of being seen and distanced from the family or local community with HIV associated stigma. Conversely, it remains unclear whether among HIV disclosed patients the magnitude of

intervention effect would be higher to eventually achieve greater VL suppression. This pathway seems plausible but remains unexplored.

To address this gap, we investigated whether the magnitude of iENGAGE intervention on 48-week VL suppression was modified by HIV disclosure/patterns of disclosure among patients newly initiating HIV care. We hypothesized that HIV disclosure will modify the association between the iENGAGE intervention and VL suppression.

METHODS

Setting

The iENGAGE study is a randomized controlled behavioral intervention trial implemented at four academically affiliated HIV clinical sites: the University of Alabama at Birmingham (UAB), the University of North Carolina at Chapel Hill (UNC), the John Hopkins University (JHU), and the University of Washington at Seattle (UW). Patients ≥18 years, with documented HIV infection, initiating HIV care at one of the four sites, English speaking, with no plan to move in next year and able/willing to provide informed consent were enrolled in the study. Patients with prior HIV primary care, non-English speaking or understanding and unable to complete informed consent process were excluded. Each site obtained the Institutional Review Board (IRB) approvals for this study.

Study assessments included completing a set of questionnaires at baseline and at 48 weeks from enrollment using CASI (computer-administered self-interview). Questions regarding mental health, alcohol use, substance use, sexual risk, HIV disclosure, social support, supportive services needed, coping, and stigma were asked at both the visits.

Additionally, at 48-week visit patients also responded to questions regarding visit adherence, ART adherence and completed a blood draw to obtain VL values. Additional details for the iENGAGE study were published separately [16].

Participant cohort

Overall, 372 participants were recruited across all sites and of those 186 participants were assigned to the intervention arm. One participant after being enrolled and randomized to intervention arm was identified to be not new to HIV care and was withdrawn. The final analytical sample size was 371 with 185 participants in the intervention arm of the study.

iENGAGE intervention component

iENGAGE used several intervention strategies from CDC RIC [29] and Participating and Communicating Together (PACT) ART adherence [13] interventions to provide opportunities to build participant knowledge, motivation, and skills for dynamic self-care demands (entry into care, adjustment to a new HIV diagnosis, initiation of ART, retention in care over time, early and on-going ART adherence). The iENGAGE intervention offered support to participants through face-to-face counseling visits and phone reminders. Face-to-face sessions were usually in line with clinic appointments and were scheduled at enrollment or between 0-2 weeks, between 2-12 weeks, 12-24 weeks and 24-48 weeks after randomization. Phone call component included appointment reminder calls (7-day and 2-day reminders), interim phone contacts (at about 2 weeks after each session) and missed visit calls (within 1-2days of missed visit). Ad-hoc calls were allowed as appropriate from the participants. We will categorize the intervention component as a dichotomous variable (Yes/No) for this secondary analyses.

Outcome

The primary outcome of the study is 48-week plasma VL suppression. A VL value of <200copies/ml of blood was considered as undetectable VL or virally suppressed state [30] and ≥200copies/ml was considered as detectable VL. The ideal window period to obtain 48-week VL was 46-52 weeks from date of randomization and extending up to 72 weeks from date of randomization as needed.

Effect modifier

HIV disclosure was measured using a 3–item questionnaire during the enrollment visit for all participants. The first question asked if participant disclosed HIV status to anyone besides health care provider and the answer choices were yes/no/no response. If the participant answered 'yes' to Q1; the next two questions asked if participant chose to disclose their HIV status to more than 1 person (choices: yes/no/no response) followed by to whom did the participant disclosed to (choices: Spouse/ significant other, current sexual partner(s), past sexual partner(s), family member(s), friend(s), religious leader(s) (e.g., priest, rabbi, pastor/ No response/ NA - skip question). HIV disclosure was used as a dichotomous variable (Yes/No) and a 3-level patterns of HIV disclosure variable (broad disclosure, selective disclosure, non-disclosure) for data analysis.

Statistical analysis

Descriptive statistics are shown as numbers and percentages. Logistic regression analysis was used to present the odds ratios (ORs) and corresponding 95% confidence intervals (CIs) to examine the association of primary exposure of interest iENGAGE intervention

with the outcome 48-week VL suppression. Stratified logistic regression analysis was conducted to examine potential effect modification by 2-level HIV disclosure (any HIV disclosure vs. non-disclosure) and 3-level patterns of HIV disclosure (selective disclosure vs. non-disclosure, broad disclosure vs. non-disclosure) variables.

RESULTS

There was nearly no association between iENGAGE intervention arm and 48 week VL suppression (OR = 0.93; 95%CI = 0.49, 1.78) (Table 2). Stratified analysis with a two level HIV disclosure status variable showed that the odds of 48-week VL suppression for the stratum specific OR were similar between any HIV disclosure group (OR = 0.92; 95%CI = 0.44, 1.91) and non-disclosure group (OR = 1.00; 95%CI = 0.26, 3.84) and to the crude estimate (OR = 1.15; 95%CI = 0.54, 2.48) suggesting no evidence of effect modification (Table 2 and 3).

Stratified analysis by patterns of HIV disclosure variable also showed no effect modification. The stratum specific OR for 48-week VL suppression differed a little for selective disclosure group (OR = 0.71; 95%CI = 0.14, 3.64) compared to broad disclosure (OR = 0.97; 95%CI = 0.42, 2.20) and non-disclosure (OR = 1.00; 95%CI = 0.26, 3.84) but were statistically non-significant and lack precision (Table 4).

DISCUSSION

Although evidence-based behavioral interventions have been shown to have a positive impact on key components of HIV care continuum related outcomes [11-13], it remains unknown if new to HIV care patients with disclosed HIV serostatus benefit greater from these interventions. To our knowledge, this is the first study to evaluate the role of HIV disclosure and patterns of HIV disclosure as a potential effect modifier on the association

of the iEGAGE intervention with 48-week VL suppression. In this study, among patients newly initiating HIV care enrolled in the iENGAGE study, we found nearly no independent effect of the iENGAGE intervention on 48-week VL suppression. The stratum-specific ORs did not differ between any HIV disclosure group and non-disclosure group suggesting on effect modification by 2-level HIV disclosure variable. Similarly, there was no effect modification observed with 3-level HIV disclosure variable. The stratum-specific ORs for selective disclosure differed marginally compared to broad and non-disclosure but lack precision with wide confidence intervals and statistical non-significance.

Despite the fact that there was no association between the iENGAGE intervention and 48-week VL suppression, the iENGAGE data shows that approximately 73% of the intervention arm participants came to the clinic to receive all 4-intervention sessions during the study period. This finding suggests that evidence-based interventions are critical during the initial year of HIV care. The emphasis on tailored behavioral interventions like iENGAGE should continue as the burden of new HIV infections continue. The components of the iENGAGE intervention based on motivational interviewing (MI) strategies would still be beneficial in educating new to care patients on HIV, address barriers to HIV care and ART adherence and impart skills for self-care [16]. This tailored client-centered intervention would equip patients with the skills to collaborate with healthcare providers and effectively participate in treatment management [16]. The interventions targeted to new to HIV care patients were relatively new and we recommend future research to evaluate the effect evidence-based interventions on VL suppression among larger new to HIV care cohorts, with extended follow-up time for

more reliable results. Knowing the uptake of specific components by participants at each session during the study period may help further improve the overall intervention to have positive implications on VL suppression.

We initially hypothesized among any HIV disclosers, selective and broad disclosers, iENGAGE intervention participants will have higher odds of VL suppression compared to non-disclosers. However, the results were paradoxical. With advances in HIV treatment, HIV disclosure may not be a necessity due to disease progression for individuals. Other possible explanation could be social desirability bias and in order to respond favorably, participants reported disclosure over non-disclosure while self-reporting. We suggest interpreting results cautiously owing to the small sample size of the study and low power to detect the difference. It is not precisely clear what may have led to these findings in the study but we recommend future studies with larger sample size and longer follow-up periods to clarify the direct and indirect role of disclosure on VL suppression.

Strengths

Contrast to other studies, our study explored an alternative dimension of HIV disclosure and patterns of HIV disclosure on the association of 48-week VL suppression among new to HIV care patients.

Limitations

This is a secondary data analysis of the original iENGAGE behavioral intervention trial which was not designed to test the effect modification of the variables we report. Despite the limitations, we believe our study provides insight on the plausible mechanism through which HIV disclosure may impact VL suppression. We used self-reported data for this

analysis, which may be subject to social desirability bias due to under or over reporting of study variables. Prior research has shown that the HIV behaviors captured using the self-report were acceptable. Results of the study may not be generalized beyond the geographic areas covered but the sites were representative of national estimates.

CONCLUSION

In summary, we found no statistically significant effect modification by HIV disclosure or patterns of HIV disclosure on the association between the iENGAGE intervention and 48-week VL suppression. With modest sample size, results of the study should be interpreted cautiously. As the occurrence of new HIV infections still continue it is important to recognize the importance of early HIV disclosure and its role in HIV prevention.

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TABLES

Table 1. The iENGAGE study arm and HIV disclosure status/patterns of HIV disclosure patient demographics

Variables	HIV disclosure status (n =370) n (%)		Patterns of HIV disclosure (n = 369) n (%)		
	Any HIV disclosure	Non-disclosure	Non-disclosure	Selective disclosure	Broad disclosure
Intervention	144 (78.3)	40 (21.7)	40 (21.9)	28 (15.3)	115 (62.8)
Control	146 (78.5)	40 (21.5)	40 (21.5)	28 (15.1)	118 (63.4)

*Percentages were rounded

iENGAGE = integrating ENGagement and Adherence Goals upon Entry

Table 2. Logistic regression model to examine the independent association study arm, HIV disclosure status and patterns of disclosure with 48-week viral load (VL) suppression

Variables	48 week VL suppression	
	OR (95%CI)	p-value
Intervention vs. control	0.93 (0.49, 1.78)	0.83
Any HIV disclosure vs. nondisclosure	1.15 (0.54, 2.48)	0.72
Selective disclosure vs. nondisclosure	0.89 (0.31, 2.56)	0.83
Broad disclosure vs. nondisclosure	1.22 (0.55, 2.68)	0.63

Table 3. Stratified analysis by HIV disclosure status to generate stratum specific odds ratios (ORs) and 95% confidence intervals (CIs) for iENGAGE study arm and 48- week viral load (VL) suppression

Study arm	Any HIV disclosure		Non-disclosure	
	OR (95%CI)	p-value	OR (95%CI)	p-value
Intervention	0.92 (0.44, 1.91)	0.81	1.00 (0.26, 3.84)	1.00
Control	Ref		Ref	

Table 4. Stratified analysis by patterns of HIV disclosure to generate stratum specific odds ratios (ORs) and 95% confidence intervals (CIs) for iENGAGE study arm and 48- week viral load (VL) suppression

Study arm	Non-disclosure		Selective disclosure		Broad disclosure	
	OR (95%CI)	p-value	OR (95%CI)	p-value	OR (95%CI)	p-value
Intervention	1.00 (0.26, 3.84)	1.00	0.71 (0.14, 3.64)	0.68	0.97 (0.42, 2.20)	0.94
Control	Ref		Ref		Ref	

SUMMARY

Regardless of advances in ART treatment, new HIV cases continue to occur. Early HIV disclosure has been identified as an important barrier to HIV treatment and prevention. The goal of this dissertation was to determine predictors of HIV disclosure status and patterns of disclosure and impact of these variables on RIC and VL suppression among new to HIV care patients.

In cross-sectional analysis, using iENGAGE data on patients newly initiating HIV care enrolled from Dec 2013- Jun 2016 across 4 US HIV clinics, we reported that Black race, emotional support, and unmet needs predicted any HIV and broad disclosure, whereas males, emotional support, active coping and acceptance were associated with selective disclosure. Our results suggest interventions to promote early HIV disclosure among new to HIV care patients should focus on coping strategies and unmet needs as intervention components.

Using a retrospective cohort study, we evaluated the impact of HIV disclosure on RIC and VL suppression. We found that HIV disclosure did not significantly improve 48-week VL suppression, visit adherence and 4-month visit constancy in the adjusted analysis. Additionally, in the adjusted analysis, any HIV disclosure, selective and broad disclosure groups were significantly less likely to achieve VL suppression over time compared to non-disclosure. Our results suggest that adding a component of HIV disclosure counseling for HIV prevention along with other counseling services may be

sufficient at the initial appointment. Future studies among new to HIV patients looking at the extent of disclosure to social network and longer follow-up study periods may provide further insight in understanding the association of between HIV disclosure and HIV related outcomes. Designing a new instrument for disclosure to capture intimacy of participants with their social network in future studies may be beneficial. Additionally, qualitative studies to determine barriers to 48 week VL suppression among those who disclosed HIV status and understanding societal and cultural frameworks around HIV disclosure among new to HIV patients may provide further clarification.

Finally, among patients newly initiating HIV care enrolled in the iENGAGE study, we found nearly no independent effect of the iENGAGE intervention on 48-week VL suppression. Our results showed that there was no effect modification by HIV disclosure or patterns of HIV disclosure on the association of iENGAGE intervention with 48-week VL suppression. With modest sample size, results of the study should be interpreted cautiously. Also, the iENGAGE behavioral intervention trial was not specifically designed to evaluate effect modifier role of HIV disclosure. Future studies with larger HIV new to care cohorts specifically designed to evaluate the direct and indirect role of HIV disclosure would contribute to the literature of HIV disclosure among new to care patients.

Our findings have clinical and public health relevance. From clinical standpoint, the risk factors identified may be used to identify at risk of non-disclosure patients to initiate timely discussion on HIV disclosure. The results provide information to HIV health care providers that disclosure may impact other critical components of HIV care continuum, adjustment to new diagnosis and HIV prevention efforts but did not have

significant positive implications on RIC and 48-week VL suppression. From public health standpoint, our results suggest that unmet needs and coping behaviors should be the components interventions targeted new to HIV care population to promote HIV disclosure to reduce HIV transmission by embracing safe sex behaviors. Public health efforts and resources should be allocated to develop evidence-based interventions like iENGAGE are important to help patients embrace the new HIV diagnosis, navigate through HIV care and ART adherence barriers and develop self-care skills.

In conclusion, our findings report risk factors of HIV disclosure and patterns of HIV disclosure among new to HIV care patients and its impact on HIV related outcomes. We recommend future quantitative and qualitative studies among new to HIV care patient cohorts to further explore the direct and indirect role of HIV disclosure with HIV related outcomes.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD

Project Revision/Amendment Form

Form version: June 26, 2012

In MS Word, click in the white boxes and type your text; double-click checkboxes to check/uncheck.

- Federal regulations require IRB approval before implementing proposed changes. See Section 14 of the IRB Guidebook for Investigators for additional information.
- Change means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the investigator's Brochure, questionnaires, surveys, advertisements, etc.). See Item 4 for more examples.

MAY 08 2017

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1. Today's Date 5/4/2017

2. Principal Investigator (PI)

Name (with degree)	Michael J. Mugavero, MD,	Blazer ID	mmugavero
Department	Medicine	Division (if applicable)	Infectious Diseases
Office Address	BBRB 206H	Office Phone	6-5822
E-mail	mmugavero@uabmc.edu	Fax Number	4-5600

Contact person who should receive copies of IRB correspondence (Optional)

Name	Riddhi Modi	E-Mail	rmodi@uabmc.edu
Phone	4-1284	Fax Number	4-5600
Office Address (if different from PI)	BBRB 206 A2		

3. UAB IRB Protocol Identification

3.a. Protocol Number: X120501005

3.b. Protocol Title: Integrating ENGagement and Adherence Goals upon Entry: iENGAGE to Control HIV

3.c. Current Status of Protocol—Check ONE box at left; provide numbers and dates where applicable

- ☐ Study has not yet begun — No participants, data, or specimens have been entered.
- ☐ In progress, open to accrual — Number of participants, data, or specimens entered: 153
- ☐ Enrollment temporarily suspended by sponsor
- ☒ Closed to accrual, but procedures continue as defined in the protocol (therapy, intervention, follow-up visits, etc.)
  - Date closed: 05/15/2016
  - Number of participants receiving interventions: 76
  - Number of participants in long-term follow-up only: 77
- ☐ Closed to accrual, and only data analysis continues
  - Date closed:
  - Total number of participants entered:

4. Types of Change

Check all types of change that apply, and describe the changes in Item 5.c. or 5.d. as applicable. To help avoid delay in IRB review, please ensure that you provide the required materials and/or information for each type of change checked.

- ☐ **Protocol revision (change in the IRB-approved protocol)**
  In Item 5.c., if applicable, provide sponsor's protocol version number, amendment number, update number, etc.
- ☒ **Protocol amendment (addition to the IRB-approved protocol)**
  In Item 5.c., if applicable, provide funding application document from sponsor, as well as sponsor's protocol version number, amendment number, update number, etc.
- ☒ **Add or remove personnel**
  In Item 5.c., include name, title/degree, department/division, institutional affiliation, and role(s) in research, and address whether new personnel have any conflict of interest. See "Change in Principal Investigator" in the IRB Guidebook if the principal investigator is being changed.
  - ☐ **Add graduate student(s) or postdoctoral fellow(s) working toward thesis, dissertation, or publication**
    In Item 5.c., (a) identify these individuals by name; (b) provide the working title of the thesis, dissertation, or publication; and (c) indicate whether or not the student's analysis differs in any way from the purpose of the research described in the IRB-approved HSP (e.g., a secondary analysis of data obtained under this HSP).
- ☐ **Change in source of funding; change or add funding**
  In Item 5.c., describe the change or addition in detail, include the applicable OSP proposal number(s), and provide a copy of the application as funded (or as submitted to the sponsor if pending). Note that some changes in funding may require a new IRB application.

☐ **Add or remove performance sites**
In Item 5.c., identify the site and location, and describe the research-related procedures performed there. If adding site(s), attach notification of permission or IRB approval to perform research there. Also include copy of subcontract, if applicable. If this protocol includes acting as the Coordinating Center for a study, attach IRB approval from any non-UAB site added.

☐ **Add or change a genetic component or storage of samples and/or data component—this could include data submissions for Genome-Wide Association Studies (GWAS)**
To assist you in revising or preparing your submission, please see the IRB Guidebook for Investigators or call the IRB office at 934-3789.

☐ **Suspend, re-open, or permanently close protocol to accrual of individuals, data, or samples (IRB approval to remain active)**
In Item 5.c., indicate the action, provide applicable dates and reasons for action; attach supporting documentation.

☐ **Report being forwarded to IRB (e.g., DSMB, sponsor or other monitor)**
In Item 5.c., include date and source of report, summarize findings, and indicate any recommendations.

☐ **Revise or amend consent, assent form(s)**
Complete Item 5.d.

☒ **Addendum (new) consent form**
Complete Item 5.d.

☐ **Add or revise recruitment materials**
Complete Item 5.d.

☐ **Other (e.g., investigator brochure)**
Indicate the type of change in the space below, and provide details in Item 5.c. or 5.d. as applicable.
Include a copy of all affected documents, with revisions highlighted as applicable.

5. Description and Rationale

In Item 5.a. and 5.b, check Yes or No and see instructions for Yes responses.
In Item 5.c. and 5.d, describe—and explain the reason for—the change(s) noted in Item 4.

☐Yes ☐No **5.a. Are any of the participants enrolled as normal, healthy controls?**
If yes, describe in detail in Item 5.c. how this change will affect those participants.

☐Yes ☐No **5.b. Does the change affect subject participation, such as procedures, risks, costs, location of services, etc.?**
If yes, FAP-designated units complete a FAP submission and send to fap@uab.edu. Identify the FAP-designated unit in Item 5.c.
For more details on the UAB FAP, see www.uab.edu/cto.

5.c. Protocol Changes: In the space below, briefly describe—and explain the reason for—all change(s) to the protocol.

1. Please *add* the following personnel on this study protocol
   a. Gerald McGwin Jr, PhD, School of Public Health (SOPH), Department of Epidemiology. Dr. McGwin will advise on data analysis and publishing manuscripts for iENGAGE. He will also be a mentor to the PhD student who is planning to conduct her dissertation thesis using iENGAGE data (details added below). No conflicts of interest reported.
2. We would like to request approval for conducting interventionist interviews to gain their perspective on implementing iENGAGE intervention. A trained interviewer will conduct interventionist interviews over phone or using WebEx/skype/go to meeting or similar software. Interviews will be recorded using a digital recorder or using the recording options available on WebEx or Skype. These interviews will be transcribed later using a third party (Same day Transcription Company). All interviews will be uploaded to UABHS secure FTP server (powered by GLobalscape) to allow secure storage and data analysis later on. Interventionist information sheet and interview guide attached for review.
3. Using iENGAGE data for dissertation:
   a. Student Name: Riddhi Modi. She is a UAB site coordinator on this study protocol and is a PhD student in School of Public Health (SOPH) at UAB in the Department of Epidemiology.
   b. As a part of dissertation thesis, she will be using the iENGAGE data to conduct her research on HIV status disclosure and HIV related outcomes (Viral load suppression and retention in HIV care) among iENGAGE participants. She will use data collected as part of iENGAGE study protocol to conduct this research.

c. Her mentor in SOPH is Dr. Gerald McGwin and her advisor for iENGAGE project is Dr. Michael Mugavero who is the PI for this study.

5.d. Consent and Recruitment Changes: In the space below,
(a) describe all changes to IRB-approved forms or recruitment materials and the reasons for them;
(b) describe the reasons for the addition of any materials (e.g., addendum consent, recruitment); and
(c) indicate either how and when you will reconsent enrolled participants or why reconsenting is not necessary (not applicable for recruitment materials).

Also, indicate the number of forms changed or added. For new forms, provide 1 copy. For revised documents, provide 3 copies:
- **a copy of the currently approved document (showing the IRB approval stamp, if applicable)**
- **a revised copy highlighting all proposed changes with "tracked" changes**
- **a revised copy for the IRB approval stamp.**

▶ There will be no changes made on the consent. New CE submitted for interviews. (03)

Signature of Principal Investigator _____ Date 5/5/2017

FOR IRB USE ONLY

☐ Received & Noted ☑ Approved Expedited* ☐ To Convened IRB

Marquerite L Kinney
Signature (Chair, Vice-Chair, Designee)

6/13/17
Date

DOLA 5/2/17

Change to Expedited Category Y / N / NA

*No change to IRB's previous determination of approval criteria at 45 CFR 46.111 or 21 CFR 56.111