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Title: Improving Identification of Mental Health/Substance Use Disorders in HIV Primary Care: Pilot Clinical Response

Principal Investigator: Anne Monroe, M.D.

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JHM IRB - eForm A – Protocol

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1. Abstract

Although mental health (MH) and substance use (SU) disorders are highly prevalent among HIV-positive individuals, they are under-recognized and frequently undertreated or untreated. The overarching hypothesis for this project is that that patient-reported depressive, anxiety, or posttraumatic stress symptoms and substance use are important predictors of poor retention in care and that a feasible, clinic-based approach for responding to positive screening tests for depressive, anxiety, or posttraumatic stress symptoms and substance use will improve recognition and treatment of these issues, and ultimately retention in HIV care. This phase of the project is a feasibility pilot of an intervention to respond to positive screening tests captured through the Patient Reported Outcomes questionnaires (PROs). The PROs are currently performed in the clinic, however, the results are not reviewed with patients or transmitted to providers. This pilot assesses the feasibility of moving the PROs into the clinical realm by having patients review their PRO results, having patients identify an issue they would like to discuss with their provider, and determining whether this process increases discussion of MH and SU disorders in the subsequent clinical visit and increases referrals to MH and/or SU treatment.

2. Objectives (include all primary and secondary objectives)

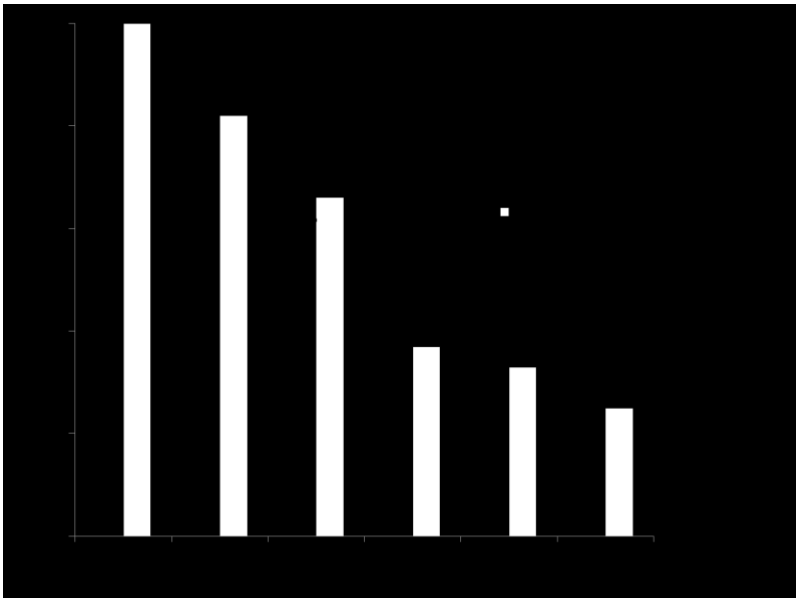
Pilot-test whether PRO results being reviewed with patient and selectively transmitted to the provider influences 1) discussion of MH and SU disorders in the subsequent clinical visit 2) referrals to MH and/or SU treatment 3) depression/anxiety/posttraumatic stress score on subsequent PRO 4)Substance Use score on subsequent PRO.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Significance

The benefits of antiretroviral therapy (ART) for improving clinical outcomes and prolonging life in HIV-positive individuals[1-3] and in reducing HIV transmission to HIV-negative individuals[4] are well-known. In order to maximize ART benefit, patients must both access and remain fully engaged in HIV care. The HIV care continuum, previously referred to as the HIV treatment "cascade," is series of steps necessary to achieve and maintain HIV suppression. These steps include testing and diagnosis, linking to care, being retained in care, being prescribed ART, and adhering to ART to achieve HIV suppression.[6-8] Among patients successfully retained in care in a multisite US cohort, 83% were prescribed ART, and 72% achieved viral suppression.[9] However, as shown in Figure 1 (left), the largest "drop-off" in the continuum involves patients who link to care but are not retained in care, creating a large obstacle to viral suppression.

Figure 1. The HIV Care Continuum in the U.S. (Mugavero et al. 2013)[14]



Retention in care may be defined as remaining in medical care,[10] and various metrics based on missed and kept HIV primary care visits have been proposed to measure retention. Patients who are not retained in care have higher risk of treatment resistance, worse clinical outcomes, and higher mortality.[11-13] In addition, patients who are not retained in care and do not achieve viral suppression are more likely to transmit HIV to others,[14] hindering efforts to reduce incidence rates in key sub-populations. Improving linkage to, and retention in, care is a primary goal of the White House National HIV/AIDS Strategy[15] for the United States and a priority of the Department of Health and Human Services (DHHS) and its various agencies.[16]

Mental health (MH) and substance use (SU) disorders are highly prevalent among HIV-positive individuals and are associated with worse HIV outcomes. The lifetime prevalence of depression among HIV-positive individuals has been reported as high as 45%,[17] with recent depressive symptoms endorsed by 20-50% of patients.[18-20] The prevalence of problematic drug and alcohol use is also high, reported in 10-40% of patients.[21-26] Dual diagnosis is common; a large prevalence study demonstrated that 38% of HIV-positive patients had both a mood and a SU disorder.[27] MH/SU disorders among HIV-positive patients are associated with worse adherence to medication, appointment attendance, and other self-care.[28-32] Previous studies have revealed an association between these disorders and worse retention in care.[33, 34]

There is inadequate treatment of depression and SU among HIV-positive patients, starting with under-recognition of these disorders. Pence and colleagues have described a "depression cascade" in HIV care,[35] demonstrating suboptimal depression outcomes. Prior research has demonstrated that effective depression and SU disorder treatment can improve HIV clinical outcomes.[36-38] However, as in general primary care, depression is under-recognized[39] and goes untreated or undertreated in many HIV-positive patients.[40,41] As a result, of all HIV-positive patients with depression, only 5% of the patients are estimated to achieve symptom remission.[35] Among patients with SU disorders, both discussions with providers regarding SU and receipt of SU disorder treatment are low.[42]

Computer-assisted interviewing may lead to increased patient disclosure and provider recognition of MH/SU disorders. Standardized, practice-based screening using patient-reported outcomes (PROs), rather than typical clinical care or chart review, increases identification of MH disorders.[43] There are many

potential benefits to using computer-assisted screening to increase patient reporting of MH/SU disorders. Routine use of patient reporting may enhance patient-provider communication. Furthermore, it may increase provider recognition of these problems and appropriate treatment and/or referral. Computer-assisted screening has been shown to have high acceptability in HIV clinics.[44, 45] There are potential barriers to clinical use of these screening measures, however, including clinic space considerations, increased staff burden, and competing priorities for both patients and providers.[46] To increase chances of success, PRO data must be integrated into clinic flow in a patient- and provider-friendly manner, with high perceived value of the information to providers.[47]

Increased recognition of MH/SU disorders is the first step in improved care. Standardized screening, by itself, is insufficient to improve patient outcomes.[48] Screening for depressive and anxiety symptoms in primary care is only recommended by the USPSTF when services for accurate diagnosis, treatment and follow up are available.[49] HIV primary care guidelines emphasize the importance of developing a management plan when MH/SU issues are identified.[50] Following a positive screen for depressive symptoms, a comprehensive MH assessment must be performed, followed by the provision of treatment when necessary, either in the primary care setting or through referral to a MH specialist.[51] For SU disorders, a positive screen should lead to additional assessment, and then brief intervention and/or referral to specialty treatment.[52] In a prior study using PRO screening for depressive symptoms in an HIV clinic with referral to psychiatric care only for patients screening positive, only 46% of patients received subsequent MH treatment.[28] Therefore, the proposed intervention will not only aim to increase identification of these disorders but also to implement standardized responses to improve uptake of treatment of these disorders and retention in HIV care.

Summary: Significance

Improving retention in care is a crucial component of addressing the domestic HIV epidemic. Inadequate recognition and treatment of MH/SU disorders hinders retention efforts. A feasible, acceptable clinic-based intervention to increase identification and treatment of individuals with MH/SU disorders may have an impact on retention in care.

4. Study Procedures

a. Study design, including the sequence and timing of study procedures
(Distinguish research procedures from those that are part of routine care).

Patients will be scheduled for their semiannual PRO and asked to come early to complete PRO. Because the PRO cannot be administered by phone, telephone screening is not possible and screening will be performed in person. When potentially eligible subjects arrive, they will complete a screening consent form. Screening will consist of completing their regularly scheduled PRO questionnaire. Following completion of the PRO, the PRO will be scored in real-time to determine if the potential participant has a positive screen for a MH or SU issue. The MH screens are for depressive symptoms, anxiety symptoms, and posttraumatic stress symptoms; the SU screens assess whether the potential patient is currently using alcohol, opiates, cocaine, or amphetamines. All potential subjects will receive $5 for completing screening.

Individuals with positive MH or SU screen will be eligible for enrollment. The potential participant will be offered participation, and if he/she is interested, an informed consent discussion will be conducted.
Participants will be given the opportunity to determine which positive screen, if any, he/she would like to discuss with his/her provider for discussion at the next HIV primary care appointment. He/she will be notified that all positive screens will be shared with the provider prior to their next HIV primary care visit, and that any positive screen the patient has chosen to discuss with their provider will be specified. The patient's provider will receive the PROs result

(score, interpretation, and recommendation) prior to their next HIV primary care visit. This information will be conveyed to the provider by a written note in the patient's Epic chart that will be part of the clinical documentation for that encounter placed by the Principal Investigator for the study (Anne Monroe, MD).

Participants will complete a brief questionnaire evaluating their satisfaction with the intervention.
Outcome assessment: The subsequent HIV primary care visit will be audio-recorded. Transcribed audio recordings will be analyzed to assess whether a discussion of SU/MH issues occurs and whether a referral for SU/MH treatment is made.

For all participants, results of all of the PROs will be saved into the study database. Demographic and clinical characteristics (sex, race, age, years since HIV diagnosis, and years in care at Hopkins HIV clinic, as well as details re: MH/SU treatment) for all participants will be obtained from the medical record or by asking patients directly (see Demographic Questionnaire form for reference).

Patients enrolled in the Johns Hopkins HIV Clinical Cohort (JHHCC):
Patients enrolled in the JHHCC participate in PRO completion every 6 months. Any JHHCC participant who is due for a PRO assessment is eligible for the study.

Providers at the Moore Clinic:
The pilot study will offer participation to all HIV providers at the Moore Clinic. We anticipate about 32 providers will enroll in the study. If a provider does not consent to the pilot study, this provider's patients will be ineligible. The next HIV primary care visit with a patient enrolled in the study will be audio-recorded.

In an effort to be collaborative and efficient in the research process, if both a patient and provider are enrolled in the study Maximizing Respect and Improving Patient Outcomes in HIV and Substance Abuse (MaRIPOHSA) (IRB protocol number: IRB00047417), we will collaborate with the MaRIPOHSA study team and use recordings from the MaRIPOPHSA visit to capture this study's intervention (our team members have all been approved by the IRB to be included on the IRB approval for MaRIPOHSA).

b. Study duration and number of study visits required of research participants.
Participants will complete 1 clinical research visit and 1 HIV primary care visit. The length of time will vary depending on the duration of time between a clinical research visit and the next HIV primary care visit. This will typically occur on the same day or within a week.

Providers will be enrolled in this study from the time they consent until their next clinical visit per patient enrolled. The number of visits audio-recorded for each provider will depend on how many of the provider's patients consent to participating in the pilot study.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.
This pilot study will not include blinding, as participants will consent to participate and will be aware of the intervention in order to consent, thereby making it unfeasible to blind patients or providers.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

Not applicable

e. Justification for inclusion of a placebo or non-treatment group.
Not applicable.
f. Definition of treatment failure or participant removal criteria.
Not applicable

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
Not applicable

5. Inclusion/Exclusion Criteria

Inclusion:

Patients:

Patients who are living with HIV, attend the Moore Clinic, are enrolled in the JHHCC and are due to complete the PROs assessment within the current JHHCC research structure are offered participation. Patients are eligible if they are 18 years or older and English speaking.

Providers:

Clinic personnel, including physicians, nurse practitioners, and physician assistants, who are the primary care provider for a patient who has consented and enrolled in the pilot study.

Exclusion:

Exclusion criteria for patients include: not willing or able to provide informed consent,patients who do not score positive on a MH/SU PRO measure, and primary care provider has not consented to the study.

6. Drugs/ Substances/ Devices

a. This does not apply.

7. Study Statistics

a. Primary outcome variable.
The primary care visit immediately following the completion of the JHHCC research visit will be audio-recorded using a digital recorder. Audio-recordings will be transcribed verbatim; only names of participants or other named individuals will be redacted. Transcription will be performed on a rolling basis as the interviews are completed. The primary care visits will analyze the following primary outcome variables. **First**, the recorded visits will allow us to compare provider discussion of SU and/or MH issue. **Second**, the recorded visits will allow us to use qualitative methods to analyze the structure of the clinical visit (e.g. what health issue became the priority, dominant point of discussion, major outcomes) related to SU/MH in the intervention group compared to the control group. **Third**, we will analyze referrals or treatment plans for SU and/or MH as documented in Epic that resulted from the recorded primary care visit.

b. Secondary outcome variables.
N/A
c. Statistical plan including sample size justification and interim data analysis.

We will fit mixed-effects logistic regression models for dichotomous variables (discussion of MH/SU at visit Y/N, referral for MH/SU care Y/N).

The sample size (n60 patient participants) will allow for adequate determination of the feasibility of the intervention and to estimate effect size to justify a larger multisite RCT of this strategy.

d. Early stopping rules.
N/A

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
The potential risks are low, but include loss of confidentiality, potential discomfort, and boredom or inconvenience for participating.

b. Steps taken to minimize the risks.
We will inform patients and providers that they may withdraw at anytime. Additionally, all participants will receive a study identification number, so their personal information is not linked to the PROs score and audio recording.

c. Plan for reporting unanticipated problems or study deviations.
Unanticipated problems or study deviations will be reported to the IRB, the NIH, and if applicable to all study participants in a letter.

d. Legal risks such as the risks that would be associated with breach of confidentiality.
We will ensure protection of the medical records and personal health information. Only the principal investigator and the research coordinator/assistant will have access to patient's identifying information. All data will be held confidential and stored in locked files, accessible to authorized staff and investigators only. Audio files will be downloaded to secure servers that are password protected. After completion of the study and data analysis, these files will be destroyed. All staff members have completed the IRB certification so they are all aware of the importance of patient confidentiality. All newly hired staff will not be allowed access to any study information until they have completed and passed all IRB human subjects research certification examinations.

e. Financial risks to the participants.
Not applicable

9. Benefits

a. Description of the probable benefits for the participant and for society.

There is no direct benefit for study participants in this aim. We seek to fill an important gap in knowledge regarding successful interventions to increase engagement and retention in HIV care. Retention is crucial to improve clinical outcomes for HIV-positive patients and to decrease HIV transmission. We believe that the risks to subjects are low and reasonable give the anticipated benefits.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.
Patients:
Patients who consent to screening for this study: $5.00 remuneration. Patients will receive an additional $15.00 compensation to have their routine clinical care audio-recorded. The

total potential compensation for patients who both screen positive on their PRO assessment and decide to enroll in the study is $20.00.
Providers:
Total potential compensation for provider who consent to the study is $100.00 (per provider enrolled) for participation in audio-recording routine clinical visits.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.
All study procedures will be free to participants.

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