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# 1 TITLE PAGE

- 3 **Title:** The Case for Prescribing PrEP in Community Mental Health Settings
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35 Summary

Pre-exposure prophylaxis (PrEP) is a biomedical HIV prevention modality that is up to 99% effective in preventing HIV acquisition through sex when taken as directed. People with serious mental illness (SMI, e.g., schizophrenia, bipolar disorder) are at high risk for acquiring HIV due to higher-risk sexual behaviors, injection drug use, social factors, and structural discrimination which limit access to all types of preventative health services. This article seeks to demonstrate the importance of prioritizing access to PrEP for people living with SMI treated in community mental health settings. We also describe barriers to prescribing PrEP, including provider attitudes, provider knowledge gaps, patient attitudes and knowledge, and systems issues, all of which address concerns that community mental health clinic administrators might have about taking on this responsibility. In summary, despite these barriers, we believe there is a unique opportunity for community mental health settings to help address the HIV epidemic by facilitating prescribing PrEP to the at-risk populations they currently serve.

Key Words: pre-exposure prophylaxis (PrEP), serious mental illness (SMI), human immunodeficiency virus (HIV), community mental health settings

#### Introduction

In 2018, the Centers for Disease Control and Prevention (CDC) reported more than 1 million people living with HIV in the US and 37,881 new HIV diagnoses that year. HIV continues to disproportionately affect marginalized populations, 1,2 including individuals with serious mental illness (SMI, e.g. schizophrenia and bipolar disorder). In 2017, the prevalence of adults living with SMI in the US was 11.2 million, and recent estimates suggest that 6% of people with SMI are also living with HIV, 4 – a prevalence over ten times higher than the general US population (0.4%). Easy access to biomedical HIV prevention strategies such as pre-exposure prophylaxis (PrEP) are needed to achieve the goals associated with the US federal government's Ending the HIV Epidemic (EHE) initiative, and improving access for people with SMI may be particularly important for addressing HIV health inequities.

PrEP was approved by the Food and Drug Administration in 2012 as a biomedical tool to prevent HIV infection.<sup>8,9</sup> PrEP is recommended for use by populations at high risk for contracting HIV, including men who have sex with men (MSM), transgender and heterosexual individuals at higher risk, those who use injection drugs, and those in serodifferent relationships.<sup>10</sup>

Despite the effectiveness of PrEP, only 20% of people in the US who have an indication for PrEP have a prescription. In response to this shortfall, public health authorities and advocates have called for improved integration of PrEP into national- and local-level efforts to mitigate the spread of HIV. Health, the federal government has encouraged partnerships among government agencies (e.g., Health Resources and Services Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention) to increase knowledge of PrEP among providers, link key populations to PrEP, and address PrEP stigma. Eleven states and at least 23 jurisdictions have initiated local campaigns to increase access to PrEP. At least two of these campaigns, "Getting to Zero San Francisco" and New York's "Ending the Epidemic" initiative, have advocated for integrating substance use and mental health needs into their approach. 15,16

Though integration of mental health and HIV prevention services are important, a recent study showed that only about 20% of mental health clinics serving people with serious mental illness in New York State prescribe PrEP.<sup>17</sup> This is concerning given that many people with SMI engage in high-risk behaviors.<sup>18</sup> In this viewpoint, we provide our perspective on why PrEP should be prescribed in community mental health settings, examine the barriers to doing so, and offer suggestions for overcoming these barriers.

#### **Current PrEP Prescribing Practices**

Several studies have examined which providers and settings are best positioned to offer PrEP. <sup>19-24</sup> The "purview paradox," a term describing a provider's beliefs about who should be responsible for offering patients a particular intervention, captures a phenomenon where both HIV providers and primary care physicians (PCPs) believe that prescribing PrEP is outside of their purview. <sup>21-23</sup>

While HIV providers have more familiarity with the antiretroviral drugs used in PrEP, understand its use as a prevention modality, and have experience with side effects and contraindications, <sup>19-21</sup> they typically work in HIV specialty care settings which limit their interactions with people who do not have HIV. <sup>22</sup> Conversely, PCPs are more likely to encounter HIV negative people who might benefit from PrEP, but they report discomfort in prescribing PrEP. <sup>20,22</sup> For example, concerns include a lack of awareness about PrEP, outdated understanding of antiretroviral medications, a lack of comfort taking a sexual history and assessing HIV risk factors, and structural factors such as lack of time to adequately assess and counsel patients in order to prescribe PrEP according to CDC guidelines. <sup>20,22</sup>

Regardless of specialty, most clinicians agree that PrEP should be offered in environments that serve HIV negative patients (as opposed to HIV care settings).<sup>22</sup> Researchers argue that for PrEP to be most effective, it must be included in the preventative care offered by PCPs who readily engage with eligible populations.<sup>25</sup> Additionally, for patients that may not receive care from a PCP or who are not able to see their providers often, pharmacies and virtual telehealth interfaces can be used as other mediums to provide PrEP.<sup>26,27</sup>

However, the perspectives of mental health professionals working in community mental health settings e.g., psychiatrists, psychiatric nurse practitioners, and physician assistants are notably absent from this discussion in the literature.

#### **Need for HIV Prevention Efforts Targeting People with Serious Mental Illness**

HIV prevention is important to the field of psychiatry given the high burden of HIV among populations with SMI often served in community mental health settings. HIV is likely more prevalent among people with SMI because of high-risk behaviors. Pooled analyses from a systematic review demonstrate that in sexually active individuals with SMI, almost half (45%) of participants never used condoms, 43% engaged in sex with multiple partners, and of those who had used injection drugs, almost two-thirds (65%) had shared injection equipment with another person. People with SMI are also more likely than those without SMI to engage in injection drug use, and the participation of people with SMI in commercial sex work is also a significant risk factor. Additionally, approximately one-third of sexually active individuals with SMI (32%) had a prior sexually transmitted disease diagnosis. Voerall, many of these risk factors are also exacerbated when individuals have significant histories of trauma or when interpersonal power dynamics interfere with a person's ability to negotiate safer sex with a partner. The high percentages of these risk behaviors and their propensity to co-occur in people with SMI indicate a significant population that theoretically has an indication for and would benefit from PrEP.

Among other factors, successful initiation of PrEP requires that providers counsel patients about HIV risk behaviors. A recent study of outpatient mental health clinics in New York found that assessment of HIV risk behaviors during intake doubled from 30% to 60% between 2007 and 2017. Furthermore, research has illustrated that over time, mental health providers have become more engaged in behavioral interventions to mitigate HIV risk. For example, one study of individuals with SMI provided participants with strategies for identifying their own HIV risk as well as methods for reducing their risk, including condom use and techniques for speaking about safer sex with partners. Although significant results were diminished a year after the intervention ended, women who received the intervention viewed condoms more favorably and were more likely to subsequently use condoms; men in the intervention arm accrued more knowledge about HIV risk. Another behavioral intervention implemented by mental health clinicians for people with psychiatric illnesses focused on mitigating both HIV risk and substance use behaviors. Compared to controls, participants receiving the HIV intervention had better knowledge about HIV, fewer partners, and fewer instances of unprotected vaginal intercourse. Participants who received the substance use intervention also had fewer sexual partners and viewed condoms more favorably.

PrEP's effectiveness also depends on an individual's ability to take the medication as prescribed. Although data does not currently exist about PrEP adherence among people with SMI, research has demonstrated that individuals living with HIV and engaged in psychiatric care had better adherence to antiretroviral therapy (ART) compared to those with HIV who were not in psychiatric care. The same study also showed that if patients had more than six visits to their mental health clinic in a year, they were less likely to discontinue taking their HIV medications when compared to individuals who did not have a

visit.<sup>34</sup> Evidence that consistent psychiatric care can help people living with HIV remain on medication supports the idea that it may facilitate PrEP adherence among patients with SMI.

In addition to helping patients with SMI lower their risk for HIV, having psychiatric providers prescribe PrEP may specifically address disparities in care for people who inject drugs. A recent study found that PCPs were less likely to prescribe PrEP to people who used injection drugs than they were to other highrisk populations.<sup>35</sup> This is a missed opportunity, as 47% of these individuals are interested in taking PrEP.<sup>36</sup> Given that community psychiatrists interface with populations with substance use disorders at high rates,<sup>37</sup> having psychiatrists prescribe PrEP may be one way to reduce the gap in access for this vulnerable population.

Lastly, an important, yet underacknowledged mental health benefit of PrEP is related to the increase in pleasure through sex derived from a decrease in concern about HIV acquisition. Some studies suggest that taking PrEP enables HIV negative partners to have more emotionally and physically fulfilling sex lives by reducing concern about HIV. Here is also a decreased propensity to engage in sero-sorting, thus expanding the types of relationships that people may have. He advent of PrEP, which can be taken in private, also offers protection to HIV negative individuals who may worry about negotiating condom use with a partner. Finally, PrEP use may confer mental health benefits to people living with HIV by decreasing their fears about transmitting HIV to their HIV-negative partners.

#### **Prescribing PrEP for a Psychiatric Patient**

There are five key steps to delivering PrEP – 1) Identify PrEP candidates; 2) Provide education about PrEP and facilitate patient initiation; 3) Conduct appropriate initial lab testing (HIV, creatinine, STIs, HBV) and follow-up testing/monitoring; 4) Prescribe PrEP to those who are HIV negative (and link those who are HIV positive to care); and 5) Provide adherence support. The following case (**Box 1**) illustrates how a psychiatrist might identify a patient as an appropriate candidate for PrEP and subsequently initiate treatment.

#### **Box 1: Case Example\***

174 Patient Description:175 EM is a 34-year-old

EM is a 34-year-old African American\* man with a history of schizophrenia. He was diagnosed with schizophrenia at age 21, which has been well treated with risperidone 8 mg once a day. He generally has good adherence to his antipsychotic medication, except when he experiences stress or instability in his relationship with his partner. EM identifies as a gay man and is in a monogamous relationship with his partner of 2 years who is HIV positive.

#### Psychosocial and Sexual Health History:

EM does not have a primary care physician, but he sees his psychiatrist monthly at a community mental health center. In addition to monitoring his psychiatric symptoms, his psychiatrist has conducted a thorough social history and understands that EM's relationship with his partner has impacted his mental health in the past. When asked how stress in his relationship impacts his antipsychotic medication adherence, EM confides to his psychiatrist that he experiences the most stress after condomless anal intercourse because he is concerned about contracting HIV as the receptive partner. The psychiatrist learns that EM's partner is not always adherent to his HIV medication regimen, and EM fears asking his partner to use a condom because he worries that it will erode trust in their relationship. When ruminating about his HIV risk, he often forgets to take his antipsychotic medication for several days. EM estimates that he and his partner have condomless intercourse about 3 or 4 times per month, and he notices that he is more likely to do so when he is not taking his antipsychotic medication.

# 193 |194 | Harm Reduction Philosophy:

After hearing his history, the psychiatrist believes that EM may be a good candidate for PrEP given that he engages in higher risk sexual behaviors with a partner who is HIV positive with an unknown viral load. The psychiatrist recognizes that sex is an important part of EM's relationship and understands why he does not feel comfortable asking his partner to use condoms during every encounter. But since his adherence to his psychiatric medication is heavily influenced by his concern about contracting HIV, his psychiatrist explains the positive physical and mental health benefits he may receive by taking PrEP. Initial testing reveals that EM is HIV negative, and his kidney function is within normal limits. After discussion with his psychiatrist, EM agrees to initiate PrEP.

# Continuation of Care:

During the next visit to his psychiatrist the following month, EM reveals that taking PrEP has decreased his anxiety about condomless intercourse with his partner and helps him to enjoy sex more. He also appreciates having independent control over his HIV risk and has been adherent to his antipsychotic medication every day throughout the last month. He wants to continue taking PrEP, and his psychiatrist refers him to a community-based primary care clinic to receive follow-up HIV and STI testing in two months. EM's psychiatrist will continue to support his adherence to PrEP while the primary care clinic will monitor for any physical side effects and address his medical needs as appropriate.

\* This is a fictional case. Of note, the patient's race is included solely to counteract the lack of representation of patients of color who are offered PrEP. The inclusion of race should not be interpreted as being related to HIV, SMI, or sexual activity.

# The Case for Integrating HIV Prevention into Community Mental Health Settings

Ultimately, integrating PrEP into community mental health settings is a patient care issue. People with SMI experience significant health disparities, <sup>42</sup> and the data reviewed in this article illustrate why prescribing PrEP in community mental health settings could promote health equity. Notably, though there have been a few examples of interventions to improve HIV prevention among people with SMI, <sup>43-45</sup> none of them focused on increasing PrEP utilization.

As illustrated by the patient vignette, community mental health providers already deliver holistic care that takes into account patients' sexual behaviors and drug use practices;<sup>37</sup> this makes these settings ideal to identify PrEP candidates. Providers in these settings take detailed psychosocial histories and are quite well-versed in providing care for substance use disorders, including leveraging harm reduction strategies. In addition, there are multiple opportunities for intervention, given that people with serious mental illness often access community mental health settings more often than primary care settings, and when they access these sites, they attend more frequently.<sup>46-47</sup>

The vignette provides one example of how PrEP might be successfully prescribed by a psychiatrist in a community mental health setting, but we recognize that many other arrangements are possible. A range of providers in mental health settings can ask standardized questions about HIV-related risk behaviors, both at admission and periodically thereafter, and then provide education and identify candidates eligible for PrEP. Psychiatric providers with prescribing privileges could then fulfill the unique role of prescribing PrEP since they readily prescribe medications to their patients. Once patients with SMI are taking PrEP, adherence support could be provided by non-clinicians, similar to the role of PrEP navigators used in primary care.<sup>48</sup>

Additionally, psychiatrists' roles in advancing PrEP could also vary with the clinical environment in which they practice. For example, several community mental health clinics have co-located federally qualified health center (FQHC) satellite PCP providers. <sup>49</sup> As suggested by the vignette, psychiatrists may focus more on identifying appropriate patients for PrEP and may provide the initial prescription but then refer them to a PCP who has more experience monitoring these medications. The psychiatrist and the PCP may then work together to monitor and support the patient's adherence to PrEP. Alternatively, if psychiatrists feel more comfortable monitoring the side effects themselves and if their clinic practices allow for it, they could order HIV/STI testing and basic laboratory studies. This would enable them to reserve referrals to PCPs for patients that need more intensive medical follow-up. And lastly, in settings with fewer providers or where care coordination between specialties may be less robust, a psychiatrist could be supported via telehealth by providers who have more experience prescribing PrEP and can provide appropriate consultations. <sup>50</sup>

Aside from psychiatrists, advance practice nurses, physician assistants, and pharmacists working in community mental health settings could also prescribe PrEP in accordance with applicable state regulations. <sup>25,26,51</sup>

# **Barriers to Prescribing PrEP in Community Mental Health Settings**

Despite the benefits of prescribing PrEP in community mental health settings, there are also significant barriers for clinicians working in these settings, including provider attitudes about PrEP, knowledge gaps among providers and patients about PrEP's utility, and gaps in the mental health care system that make prescribing PrEP difficult. We outline each of these barriers and potential solutions below.

<u>Provider Attitudes about PrEP</u>: To our knowledge, research has not yet been conducted about mental health providers' attitudes towards PrEP, and we believe that this is an important area of research to determine the feasibility of prescribing PrEP in community mental health settings. Although psychiatrists are not likely to doubt the utility of PrEP, they may share concerns that have been expressed by other providers regarding adherence and risk compensation.<sup>20</sup>

While there is a concern that people with SMI might have difficulty taking PrEP as prescribed given that adherence to psychotropic medications is generally around 50%,<sup>52</sup> studies have documented good adherence to non-psychotropic medications among people with SMI.<sup>53</sup> Admittedly, the non-psychotropic medications in these studies were necessary for treating comorbid disease and may not be indicative of how people with SMI will adapt to preventive medications. However, interventions have been developed to address adherence, including placing physical cues in a patient's environment.<sup>52</sup> Finally, a promising and easy to administer urine assay for measuring PrEP adherence has recently been developed,<sup>54</sup> including a point-of-care assay.<sup>55</sup> Although this method has not been specifically tested in populations with SMI and is not yet widely available or used, its acceptance by other PrEP users as well as its ease of administration<sup>54</sup> makes it a potential candidate for evaluating adherence in patients who may have difficulty taking their medications consistently. Furthermore, although not yet available, adherence concerns may be further mitigated by the advent of a long-acting injectable for PrEP, which has recently demonstrated superior efficacy to daily oral PrEP in a large clinical trial.<sup>56</sup> Research has also shown that many patients with SMI appreciate the convenience of injectable medications, with some preferring it over oral regimens.<sup>57</sup>

Psychiatrists may also be concerned about the possibility of risk compensation whereby individuals using PrEP may engage in new forms of high-risk sexual activity because their concerns about HIV are mitigated.<sup>20,38,58</sup> However, evidence of PrEP-related risk compensation is mixed, and the physical and psychological benefits of PrEP arguably outweigh the perceived harms of compensatory behaviors.<sup>59,60</sup>

Several studies have failed to find that participants engage in riskier sexual behaviors after starting PrEP. 61,62 However, a mixed-methods study did find that individuals who start PrEP feel that they themselves have a higher chance of engaging in riskier activities, including condomless sex. 63 Although the overall data is mixed on the degree to which risk compensation is a by-product of PrEP use, the CDC guidelines for PrEP management suggest that providers test for sexually transmitted infections (STIs) in 3 to 6 month intervals, 10 which is designed for early diagnosis and treatment of other STIs should they occur. In addition, prescribers can and should counsel their patients that PrEP does not reduce the risk of other STIs or pregnancy.

<u>Provider Knowledge Gaps</u>: Although PrEP knowledge among mental health providers has not been formally evaluated, psychiatrists in community mental health settings have previously expressed concerns about prescribing "physical health" medications to treat cardiometabolic side effects caused by atypical antipsychotic medications. <sup>47,64,65</sup> Most felt that doing so was outside their expertise, and they needed more training to prescribe non-psychotropic agents. <sup>47</sup> Similar scope of practice concerns should be expected regarding PrEP since other physicians have voiced this concern as well. <sup>20</sup>

In response, "public health detailing" – a process by which academic researchers and public health professionals educate providers about PrEP and provide helpful, evidence-based tools to encourage prescribing – has become an important method of improving knowledge of PrEP's utility among providers. <sup>66,67</sup> It is reasonable that this strategy could be adapted for the needs of psychiatric clinicians to address their specific concerns or questions about prescribing PrEP. <sup>67</sup> The American Psychiatric Association also created a webinar in 2017 for psychiatrists that describes PrEP's efficacy, although it did not focus specifically on populations with SMI. <sup>68</sup> Even if psychiatrists are willing to prescribe PrEP, they may be concerned about interactions with psychotropic medications. While this is a common concern, it is notable that there are no known significant drug-drug interactions between commonly prescribed psychiatric medications and the two medications currently approved for PrEP: TDF/FTC (Truvada) or TAF/FTC (Descovy). <sup>69</sup>

Patient Attitudes and Knowledge Gaps: Similar to the need for studies evaluating PrEP attitudes and knowledge among mental health providers, research assessing similar constructs among people with SMI is needed. As the key stakeholder in this discussion, understanding the awareness of and interest in use of PrEP among people with SMI must be taken into consideration, along with their preferences for PrEP delivery models. As previously stated, research has shown that there is demand for PrEP among people who inject drugs. Given that people with SMI are partly at high risk for contracting HIV because of injection drug use, we are hopeful that if knowledge and access to PrEP is adequate among this population, demand for PrEP will be present as well.

However, from a patient's point of view, we recognize that there may be a decreased willingness to take PrEP because of how the medication has been stigmatized.<sup>38</sup> PrEP is often unfairly interpreted as a sign that a patient engages in promiscuous behavior or is living with HIV.<sup>38</sup> Patients may also have privacy concerns about having their mental health team become aware of their risk behaviors. Given that people with SMI already experience stigma, they may or may not be particularly concerned about this perception. Greater public education to normalize PrEP use may help combat this stigma.

System Gaps: A major structural barrier is whether HIV counseling and preventative services can be reimbursed in specialty mental health settings. If not, these fees may be shifted onto patients with SMI. For those without insurance coverage and unaware of industry and federal assistance, the cost of PrEP can be prohibitive – the cash price for Truvada or Descovy, the only drugs approved for PrEP at this time, is over \$1,811 for a 30 day supply.<sup>70,71</sup>

One factor potentially mitigating costs is that the Affordable Care Act requires most private insurance plans and Medicaid expansion plans to cover preventative services receiving an "A" or "B" grade from the US Preventive Services Task Force (USPSTF) without cost-sharing.<sup>72</sup> In 2019, PrEP was awarded an "A" grade, with the Task Force citing the significant impact this prevention modality could have on curbing new infections and addressing the HIV epidemic at large.<sup>73</sup> However, since PrEP is included

under Medicare Part D, there may still be some degree of cost-sharing that will affect Medicare patients.

An additional cost barrier is that patients, including those who receive their medication at no or low cost, may still face significant out-of-pocket costs for related clinic visits and lab tests. This gap in coverage is predicted to decrease the number of people who may start PrEP.<sup>74</sup> To make matters more complicated, while most major insurers (e.g. Medicaid, Medicare, and private insurers) should be covering PrEP, and the recent decision by the USPSTF could eliminate cost-sharing for certain populations by 2021, it is unclear if psychiatric providers can bill for visits that primarily focus on HIV preventative services. We believe policymakers should amend Medicaid reimbursement policies to allow for HIV/STI testing and delivery of PrEP in community mental health settings.

Lastly, in addition to these financial barriers, there may also be concerns about the success of delivering PrEP in the public mental health system. Even if psychiatric providers want to prescribe and even if patients accept and can afford PrEP, conducting appropriate HIV/STI monitoring <sup>10</sup> may be a challenge in mental health clinics. Clinics will need to develop an infrastructure that allows them to comply with state regulations about reporting HIV/STI results, and their protocols will have to address concerns about patient privacy. While we believe that psychiatric providers and mental health clinics can be trained to engage in appropriate physical health monitoring, people with SMI taking PrEP may have to receive follow-up testing and treatment at primary care or sexual health clinics. While this is not ideal, there are mental health settings with co-located satellite FQHCs where PrEP monitoring can be easily done by primary care providers.<sup>49</sup>

#### Conclusion

In summary, we believe there is a unique opportunity for community mental health settings to help address the HIV epidemic by facilitating prescribing PrEP to the at-risk populations they currently serve: people with SMI. While the need to integrate PrEP into these clinics is clear, incorporating PrEP delivery into our public mental health care system will require leadership buy-in and support for behavioral health providers to make this a reality. Throughout this article, we have described potential barriers to offering PrEP in these settings but also outlined plausible solutions that we hope could make PrEP delivery more achievable. As different models are created to encourage PrEP use in community mental health clinics, high-quality implementation research studies must be done to assess efficacy and effectiveness and help to clarify the best ways forward. It is important to remember that HIV care and treatment advocacy has led the way in promoting health care as a form of social justice, one in which no one is left behind.

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# **Declaration of Interests**

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