

Case Report

The Use of HIV Pre-Exposure Prophylaxis for those with Mental Disorders: An Ethics Case Study

Julie M. Aultman*

Department of Family and Community Medicine, Northeast Ohio Medical University, USA

*Corresponding author

Julie M. Aultman, Department of Family and Community Medicine, Northeast Ohio Medical University, Rootstown, Ohio, USA, Tel: 1-330-325-6113; E-mail: jmaultma@neomed.edu

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Abstract

A hypothetical case study about a patient with schizoaffective disorder and a history of drug abuse is presented to expose interdisciplinary, healthcare experts to some of the pragmatic and ethical issues surrounding the study and use of HIV pre-exposure prophylaxis (PrEP), particularly for at risk populations who have been diagnosed with complex mental disorders, including drug addictions. Controversial PrEP clinical trials have been conducted in recent years, but when the target population includes persons with severe mental illness (SMI), the controversial issues surrounding these trials is heightened.

ABBREVIATIONS

PrEP: Pre-Exposure Prophylaxis; **HIV:** Human Immunodeficiency Virus; **FDA:** Food and Drug Administration; **NNRTI:** Non-Nucleoside Reverse Transcriptase Inhibitor; **SMI:** Severe Mental Illness; **SSI:** Social Security Income

INTRODUCTION

The following hypothetical case study is designed to expose interdisciplinary, healthcare experts to some of the pragmatic and ethical issues surrounding the study and use of HIV pre-exposure prophylaxis (PrEP) for at risk populations who have been diagnosed with complex mental disorders, including drug addictions. Controversial PrEP clinical trials have been conducted in recent years, but when the target population includes persons with severe mental illness (SMI), the controversial issues surrounding these trials is heightened.

CASE PRESENTATION

A.P. is a 27-year-old, unemployed mechanic, who was recently diagnosed with schizoaffective disorder. Despite his adherence to prescribed psychotropic medications and therapy, he experiences delusions and hallucinations, and severe, depressive symptoms (hopelessness, depressed mood, feelings of guilt). A.P. has a history of intermittent intravenous heroin use, which began when he was 14-years-old and continued through trade school. Following a 6-month jail sentence for the possession of drugs and subsequent loss of employment two years ago, A.P. has stopped using heroine. A.P. adheres to a prescribed treatment regimen

of anti-psychotics and cognitive behavioral therapy, and has a good, therapeutic relationship with his psychiatrist. Despite all efforts, his depressive symptoms are not completely managed, and, on occasion, he experiences auditory hallucinations (voices that tell him that he is worthless). Because of these uncontrolled symptoms, he has thought about using heroin again, which "make the voices stop."

Currently, A.P. adheres to the treatment regimen for his schizoaffective disorder, and has gained stable employment at a local garage. He has no family support, but is financially stable and lives alone in an apartment in a safe and supportive community. However, his psychiatrist is concerned that A.P. may return to his previous drug habits, placing him at risk for HIV. The psychiatrist suggests that A.P. enroll in an upcoming, placebo-controlled, clinical trial that will examine the use of Truvada®, a once-a-day, anti-HIV drug, used as a pre-exposure prophylaxis (PrEP). Given A.P.'s history of drug use and mental health disorder, he would qualify as an "at risk" mental health subject who may benefit from the study, and could help future similar at risk populations. Investigators of this study are only recruiting patients who are identified with severe mental illness (SMI) and who are or may become engaged in risky behaviors (substance abuse and/or unprotected sex).

DISCUSSION

The case of A.P. raises several ethical concerns regarding PrEP clinical trials and the target population, i.e., subjects with severe mental illness (SMI) who are in need of special protections

based on their particular vulnerabilities. While the prevalence of HIV is high among persons with SMI, arguably there is a lack of justice when targeting this particular population for a clinical trial of this nature.

It is also important to note that SMI is a classification for determining a person's level of disability, and often used to indicate eligibility for benefits (e.g., social security income (SSI)) despite the general lack of adequate treatment and entitlements a person classified as SMI receives [1]. Persons with SMI may be diagnosed with a number of different mental disorders (e.g., schizoaffective disorder) that could be classified as SMI based on factors such as degree, type and duration of impairment. However, SMI is not a classification void of subjectivity, which challenges the idea of a purposive sample and whether data acquired from this sample can be generalizable to larger populations, e.g., all persons taking psychotropic medications.

While it is important to study the risks and benefits of PrEP, including particular drug interactions with psychotropic medications, there needs to be justification for why persons with mental disorders would benefit from PrEP compared with other interventions and resources, e.g., behavior therapy, needle-exchange programs, education.

Furthermore, it is important to understand the overall purpose and benefits of PrEP, and the possible physical and psychosocial harms associated with this preventive measure if PrEP would be marketed to this population. Additional ethical issues specific to this study include the informed consent process with individuals who may or may not have the capacity to consent, privacy and confidentiality of the subject, and the fair distribution of care and resources following adverse events, including HIV transmission among the placebo group. Finally, with respect to the case of A.P. it is important to examine the therapeutic relationship and whether the psychiatrist should recruit patients like A.P. for this particular study.

Background: PrEP and Clinical Trials

Truvada®, a pre-exposure prophylaxis (PrEP), is a first-line anti-HIV drug for persons who may become HIV positive and capable of infecting others. Truvada® is the brand name for tenofovir and emtricitabine, a combination product (non-nucleoside reverse transcriptase inhibitor (NNRTI), and the first PrEP drug approved by the Food and Drug Administration (FDA) this past summer. Truvada® is taken daily to prevent HIV with a predicted 99% effectiveness.

There are several ongoing or completed randomized controlled PrEP trials using tenofovir and/or a tenofovir and emtricitabine combination (Truvada®).

Early PrEP trials are attributed to decreasing mother-to-child HIV transmission and empowering women to prevent HIV, however these trials are not devoid of scandal [2,3]. Patton and Kim (2012) write, [2].

The history of trials of different combinations of anti-HIV medications and at different points is a whole book in itself, including scandals related to drug side effects in infants, development of resistance to mothers, and the implications of product dumping. These issues alone should have given pause

to any leap from the probable success of drugs in MTC to the likelihood that either seek-and-treat interventions, or PrEP were a scientific slam-dunk" (p. 300).

Another target population for these studies has been homosexual males based on the assumption that PrEP would be a first line defense in preventing the spread of HIV among this susceptible group. The Centers for Disease Control initiated guidelines for the use of PrEP in gay men prior to the full FDA approval. However, there is no absence of criticism regarding the poor quality of the clinical trial conducted at several sites, which were primarily international. Several features of PrEP clinical trials that point to poor quality, such as a lack of assessment of adherence by drug-level testing among all trial participants, a lack of information about the long term health effects in uninfected persons, particularly uninfected men who became infected while on PrEP medication, a lack of guidance surrounding the feasibility of implementing PrEP, and the presence of common concerns among investigators of clinical trials, including the inability to replicate actual environments and behaviors due to the controlled nature of the trial setting.

Furthermore, the Truvada® trials (international iPrEX study) focusing on HIV seronegative men who have sex with men and transwomen were initially conducted in Ecuador and Peru, expanding to Brazil, Thailand, South Africa, and the United States. However, there was a low number of U.S. subjects (227 total) even though "the United States remains the largest likely market for PrEP" [2]. Despite the potential less-than-optimal quality of the clinical trial, research data revealed the benefits of PrEP leading to full approval by the FDA. Subsequent studies have improved upon the overall design and methods of testing PrEP, as well as extensive risk-reduction counseling and education for participants, and assessments of biomedical and behavioral safety, adherence, and acceptability [4]. However, since its approval last summer, few patients have been able to access the preventive care, and more, particularly outside of the LGBT community, are unaware of its existence.

In a recent article, "There is a wonder drug that prevents HIV infection. Why Haven't You Heard of It?" author [5], presents some of the reasons why PrEP may not be widely publicized or accessible and available for patient use. For one, healthcare providers are concerned about the lack of patient adherence, resulting in the "emergence of drug resistant strains." PrEP distribution is also limited due to healthcare provider's moralistic objections; PrEP is viewed as an excuse to not use condoms and other measures to prevent the transmission of sexually transmitted diseases, i.e., behavioral disinhibition. That is, there is the assumption that individuals would either abandon previous risk management behavior or not choose to engage in such preventive behaviors despite their proven public health benefits and cost-effectiveness. This is similar to the post-exposure prophylaxis (PEP) arguments where healthcare providers objected to its use for homosexuals "claiming it would become a "morning after" approach that would undermine the practice of safe sex, a caveat emptor approach to homosexual sex" [2]. There is also a lack of knowledge about PrEP among providers and the public, which inhibits appropriate distribution of PrEP.

Controversial Study Design and Methods

The study in question is not focusing on the efficacy of Truvada®, but on the benefits and burdens of Truvada® in a specific subject population: persons with severe mental illness and who may acquire HIV through risky behaviors. Individuals with “SMI” or SMI are an at-risk population for contracting or transmitting HIV [6-11]. Most HIV/AIDS patients suffer from co-occurring mental health disorders, including, but not limited to, substance abuse disorders, psychotic disorders, and anxiety disorders. [7]. explain, “While people with psychotic disorders who are adherent to medications are quite often knowledgeable about how to use condoms and clean needles, they are often disorganized and unable to negotiate protection during sex” (p. 203). While the case presentation focuses on an individual with a history of drug use, and who may take precautions to prevent HIV (e.g., use clean needles), an additional concern is the potential transmission of HIV through unprotected sex.

This study is controversial for a number of reasons even though persons with SMI are an at-risk population and may be able to benefit from PrEP. First, risks associated with mutation, medication resistance, and interactions with psychotropic drugs may outweigh the benefits of prevention. Second, just because this population may be at-risk, this does not mean that persons with SMI would benefit from this study. Investigators should identify potential benefits of PrEP for preventing HIV in this purposive sample of persons, and not just persons in the general population that happen to be diagnosed with a mental disorder even though data may be generalizable to larger populations. A lack of direct benefits specific to this study should be justified, and, if approved under IRB scrutiny, ultimately conveyed during the recruitment and informed consent process. Third, there may be issues regarding the informed consent process and whether this targeted population would be able to give their full, informed consent. If this is unachievable, what protections are in place to ensure appropriate protections of human subjects, e.g., assent and guardian consent? A fourth issue that may arise involves the protection of subject privacy and the maintenance of confidential data, especially given the multiple levels of vulnerability (such as mental illness, illegal and legal substance abuse, unprotected sex, susceptibility to HIV, sexuality, racial and ethnic disparities, and economic disparities). Fifth, there is a lack of clinical equipoise, comparing existing resources, standards, and preventive measures with or in conjunction with PrEP. Each of these considerations and limitations will be discussed in subsequent sections, in addition to critical ethical issues surrounding the availability and accessibility of PrEP.

Do the Benefits Outweigh the Risks?

One of the combination drugs of Truvada®, tenofovir, has several side effects such as kidney failure, liver damage leading to lactic acidosis, hypophosphatemia, decrease in immune responses, among other uncomfortable side effects that could lead to serious illness in patients. Despite such reported side effects, Truvada® is viewed as a mildly toxic drug that has benefits preventing HIV, particularly among gay men, who are experiencing condom fatigue and/or men who are resistant to safe sex practices. Underlying assumptions are that the standard of care, i.e., education, behavioral interventions, mental health

and community support, etc., is inadequate, or potential at-risk populations are resistant to such public health initiatives. Thus, in response to these assumptions explain [2].

This is important because researchers must show why a new intervention need not be compared with the current standard but can be tested against a placebo or “treatment-as-usual” scenario. Assessment of the ethics of using a placebo is more complicated in cases where a behavioral intervention is compared to a drug, and while trials of this kind are not unknown, they usually involve adding an enhancement onto an existing treatment or intervention for people who already have a condition or disease, not replacing a successful health promotion strategy with drugs for people who are well (p. 303).

When we consider potential subjects like A.P., who are currently under the care of a psychiatrist, receiving and adhering to a regimen of psychotropic medications and behavioral therapy, the question arises as to why these exiting interventions are not enhanced, rather than initiating PrEP. That is, it is important to initiate traditional HIV prevention strategies for a patient who may be “at-risk” prior to simply enrolling him into a randomized placebo-controlled study where he may not receive any intervention at all, or receive Truvada® without additional therapy and resources. A more ethically appropriate trial would examine the effects of behavioral interventions and support with PrEP compared to those interventions with a placebo; subjects would still receive a level of care and investigators would determine the effectiveness and related side-effects with PrEP. Such changes to the methods of the study would achieve clinical equipoise, whereby the investigators are uncertain as to whether there are benefits to PrEP and existing interventions (which would reduce risks of non-adherence), compared to existing interventions, as well as whether risk compensation is present [4].

If investigators initiate a study that tests PrEP with no intervention or placebo intervention, there is an imbalance of known benefits, i.e., it is more beneficial to have some treatment against HIV transmission compared to nothing at all, as well as placing subjects at risk for HIV, especially if they are in a placebo group (no intervention or use of sugar pill) and thinking that they are being protected. Furthermore, with respect to risk compensation and persons with SMI, it is important to determine whether additional harms may be present among those who change their behaviors in response to the *perceived* HIV risk, which may be exacerbated by their mental illness (es).

A.P. has not received interventions specific to HIV prevention, but additional or enhanced therapies targeting prevention could be introduced, and should be an integral part of the Truvada® trial. From a behavioral perspective, it would be beneficial to understand whether Truvada® affects the behavior of subjects.

Additional risks, including drug reactions, should also be considered. Given that A.P. is currently adhering to psychotropic medications, it is important to consider the possible drug interactions with Truvada®, which could yield serious health risks. With respect to the use of some antidepressants and typical and atypical anti-psychotic medications (e.g., Thorazine, Haldol, Clozaril), there is no published data about the drug interactions

specific to the combination product [12]. Thus, it is important to understand these drug interactions and the possible side effects prior to enrolling subjects like A.P. Without such knowledge, this limits the informed consent process in detailing the possible risks involved in the study.

Also, consistent with what healthcare providers are concerned about with PrEP, in “acute psychotic episodes, adherence to antiretroviral medications may be a problem leading to mutation and resistance to medication” (p. 203). Further research is needed to identify whether mutation and resistance to medications, including psychotropic medications, may occur. This is another reason why behavioral interventions in combination with PrEP should be introduced in studies similar to those presented in our case study.

Informed Consent Process

As previously stated, additional research is needed prior to enrolling subjects like A.P. into a Truvada® trial for purposes of identifying and informing subject of the potential risks. Without such information, A.P. and others would not be able to make informed decisions about their participation. From an ethical standpoint, this diminishes the dignity of the human subject by impeding his right to self-determination.

In addition to the need for further information and disclosure about the risks and benefits of Truvada® when combined with other behavioral therapies and psychotropic medications, investigators and healthcare providers who are recruiting subjects should also consider the possible limitations in working with persons with severe mental illness. It is essential to introduce professional mental health screenings to ensure subjects are able to provide informed consent, since this population is susceptible to acute and chronic psychotic episodes, which may affect their ability to understand the information that is being provided, and their participation in the study. When determining a subject's capacity to consent to research, competency standards provide essential guidance, despite the lack of consistent and universally accepted standards among healthcare, research, and legal communities. Four competency standards are commonly used in research settings: evidencing a choice in regard to research participation, factual understanding of the issues, rational manipulation of information, and appreciation of the nature of the situation [13,14].

For those who are unable to consent, or whose consent is not voluntary or diminished (i.e., not all of the competency standards are met), it is essential to impose safeguards in protecting this vulnerable population. This is not to say that persons with SMI should not participate in studies that may improve their overall health, or yield important information that can help future populations. Safeguards simply recognize the vulnerability of this population, and promote voluntariness and the ethical principles of respect for persons and beneficence in medical research. Furthermore, safeguards throughout the study, such as mental health screenings, competency assessment tools (e.g., MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR), education, and support can prevent adverse events or reactions that may further compromise the subject [15,16].

For subjects who may not be able to provide informed consent

due to a lack of one or more capacities, e.g., inability to express a choice, implementing an assent process along with guidance to guardians who are asked to provide informed consent on behalf of the subject, is essential. The study should provide justification for enrolling a vulnerable population without the capacity to consent. Also, ensuring that guardians act on behalf of the subject and not based on their personal interests is an important component to the informed consent process, which may include a reliable screening tool. Although A.P. has the capacity to consent due to his adherence to a regimen of behavioral therapy and psychotropic medications, a supportive therapeutic relationship, and community support, he may be compelled to volunteer for this study so as to not disappoint his psychiatrist.

While there is no overt coercion or manipulation, investigators should be cautious in making sure that there is no undue influence or conflict of interest that may compromise the voluntariness of the subject. Clinical subjects are often influenced by those who they trust, believing their providers know what is best, and perceive recruitment in a study to be an actual clinical recommendation. By not fulfilling the perceived recommendation, subjects may feel as though they have disappointed their providers or would be viewed as failures.

This is particularly relevant among persons with severe, mental illness who may be experiencing symptoms similar to A.P. such as feelings of helplessness and guilt. To circumvent this potential issue, a third party individual or an investigator with no conflict of interest should recruit, enroll, and consent the subject. The psychiatrist would play an important role by identifying potential subjects for study personnel to recruit (based on such factors as subject inclusion and exclusion), and providing subject-initiated guidance without influencing subjects' voluntary decision to participate.

The Therapeutic Relationship

Besides being mindful of potential conflicts of interest and undue influence, healthcare providers, such as A.P.'s psychiatrist, should be well informed of their patients' participation in such research studies if they are not engaged in the research.

First, healthcare providers can be essential as a second-line defense against unethical clinical research. Although Institutional Review Boards (IRBs) and other regulatory oversight committees provide a first-line defense by reviewing and approving research studies, potentially harmful or unethical practices that have or have not been approved should be questioned by healthcare experts. Just because a study protocol has been approved does not always mean that appropriate safeguards are in place or investigators will act responsibly.

Thus, providers who may assist investigators in the recruitment process, or who simply know their patients are enrolled in a clinical trial, should offer their patients guidance, determine if appropriate safeguards are in place, and take necessary precautions in the event that study interventions negatively affect or affected by existing clinical interventions. Education and evidence-based support through networks such as the MacArthur Network on Mental Health and Law (<http://www.macarthur.virginia.edu/treatment.html>) can further assist

healthcare providers in identifying and implementing the best clinical research safeguards and guidance.

For example, if the psychiatrist did not know A.P. was enrolled in a Truvada® trial in which mental health care interventions along with the anti-HIV drug were initiated, this could compromise existing interventions, e.g., alter patient behaviors and overall mental and physical health.

Second, assuming the study's methods are sound, the mental health care that is being provided should be carefully monitored in conjunction with the interventions of the study. This can be a challenge for not just the provider, but for the investigators as well; there may be a lack of communication between providers and investigators due to legal requirements of patient privacy (i.e., HIPAA) and the over-reliance of subjects to convey personal information about existing treatments and their effects.

One way to enhance communication, as well as subject safety, is to involve the provider with the permission of the subject. By involving the providers, investigators will be able to gauge consistency of care among different providers, whether subjects convey accurate information regarding adherence, risks, etc., and report subtle effects from the experimental intervention (PrEP) that may only be recognized by the provider.

Also, if the investigator(s), guardian, or other (e.g., family or friend) fail to recognize harmful side effects experienced by the patient-subject, which may be identifiable adverse events and drug reactions, the healthcare provider should initiate withdrawal of the subject from the study, especially if the subject lacks the capacity to withdraw from the study. Advocacy is an important role that healthcare providers should assume when their patients enroll as study subjects.

With respect to the specific case of A.P., the psychiatrist should not recruit A.P. for this study, or future studies studying PrEP, without initiating education and enhancing therapy for not just HIV prevention, but to address his concerns about future drug-use. Clearly A.P. is still experiencing uncomfortable symptoms related to his multiple mental health disorders, and while he may be susceptible to HIV, it is essential for the psychiatrist to work with A.P. in managing his symptoms so that harmful "self-medication" is not a future option.

Privacy, Confidentiality, and Considerations of Justice

Additional ethical considerations include the privacy and confidentiality of subjects like A.P. Since health information is being collected by an investigator(s), including information that has implications of criminality (illegal drug use), adhering to laws (e.g., HIPAA for U.S. subjects) and upholding the duty of non-disclosure (confidentiality) is important for the overall wellbeing of subjects. The stigmas of HIV and mental illness can negatively impact the health and wellbeing of persons, and when confidential information is either breached in the healthcare setting and/or in the research setting, this can exacerbate existing illnesses. While communication is essential to understand existing and/or experimental interventions, the communication among investigators, subjects and their healthcare providers and guardians must be protected through various safeguards (data security such as encrypted and password protected computer

systems, de-identified or limited health information, HIPAA and data use agreement contracts, etc.). Informed consent and subject enrollment should be done in a safe, private environment with investigators and those who are essential to the study (e.g., guardians).

In addition to privacy and confidentiality, there are potential concerns of justice. First, with respect to subjects such as A.P., the investigators need to justify their inclusion and exclusion factors. Because populations with SMI are at-risk for contracting HIV through unprotected sex and intravenous drug use, this seems to be a reasonable justification for recruiting individuals such as A.P. In fact, it is important to consider this population for inclusion in randomized clinical trials, as this population, particularly those syndemic patients who suffer from co-occurring affective disorders (e.g., depression, schizoaffective disorder, and HIV) are often excluded from trials [6].

However, if the methods were to be changed to include behavioral therapies and support for both the control and test groups, it is important to determine, from a justice perspective, whether this population will be afforded treatment (during and following the trial) that is fairly distributed based on the individual needs of the participants. In other words, there is not a "one size fits all" approach to providing behavioral therapy and other therapeutic treatments alone or in conjunction with the PrEP that will educate, prompt adherence, and further reduce the risks associated with HIV transmission and possibly the use of Truvada®.

Furthermore, it is important that while a particular population is targeted, that there is diversity in the subject pool (gender, race, ethnicity, age, levels of function, severity of illness, economic status, and so on). In fact, initial questions that an IRB reviewer of this study should ask include: "Why are only patients with severe, mental disorders at risk? What is meant by "severe" (given that the type of mental disorder is not necessarily severe, but how it manifests in the individual)? A.P. has been diagnosed with schizoaffective disorder, which is not fully managed, but may not be considered a SMI other than for billing purposes or acquiring benefits (e.g., SSI). The severity of an illness has elements of subjectivity that need to be examined before labeling and recruiting subjects. Furthermore, mental illness is a moving target – patients may experience mild symptoms for a period of time, but then experience more severe ones for another period of time; illness management can be difficult at times. One of the issues in the Truvada® clinical trial was that both the national and international subject populations were limited. With a mere 227 U.S. participants localized in San Francisco and Boston, there is a lack of diversity within the U.S. population, since the focus is on two, urban, high-income settings with specific socio-cultural aspects surrounding sexual practices. More recent studies have also reported similar limitations [4].

Additional justice issues that investigators should consider include the overall feasibility of the study and its outcomes. Will Truvada® be made available to only certain "at-risk" populations and not others? Will subjects and future patients be afforded the mental health treatment and support to prompt adherence, along with metabolic monitoring, particularly given that multiple medications, e.g., psychotropic medications, will be needed?

Mental health cares in the United States and globally is not widely available to all, or may be inconsistent due to limited resources.

With respect to our global community, Patton and Kim (2012) write, "It is even harder to understand whether those who are given PrEP in resource-strapped countries will be offered the same level of metabolic monitoring available to PrEP takers in high-resource settings, or whether their long-term health will be sacrificed to the actuarial objective of reducing HIV transmission" (p. 303). So while Truvada® and other PrEP treatment may have greater benefits over burdens, and reduce the transmission of HIV, are pre-exposure prophylaxis treatments cost effective in the long run, especially when there are so many psychosocial components to consider when using PrEP?

CONCLUSIONS

The case of A.P raises several issues regarding the HIV pre-exposure prophylaxis and clinical trials focusing on at-risk populations with severe, mental illness. The brief description of the study design and methods, including the recruitment and enrollment of this population, is problematic, especially given the already controversial history of these types of targeted clinical trials. This case study has been designed to demonstrate the need for psychiatric care and support, and infectious disease education, to prevent the transmission of HIV infection. Just because an FDA-approved drug may prevent the transmission of HIV does not mean that this resource is available, accessible, and useful for patients. In fact, Truvada® and similar drugs can be harmful without fully understanding the possible drug interactions, and adherence issues, thus exacerbating existing health impairments. The discussion following the case, although not fully comprehensive, points to some important ethical considerations when evaluating this type of drug trial. Ultimately, PrEP may be valuable to many at-risk populations, but further research is needed in order to protect future human subjects.

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