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Abstract

Once-daily oral tenofovir/emtricitabine is highly effective as pre-exposure prophylaxis (PrEP) against HIV but is dependent on adherence, which may be challenging for men who have sex with men (MSM) and use substances. Digital pill systems (DPS) permit the direct, real-time measurement of adherence, though user perceptions of data privacy in this context are unknown. Thirty prospective DPS users – HIV-negative MSM with non-alcohol substance use – completed in-depth qualitative interviews exploring preferences around privacy, access, and sharing of DPS adherence data. Participants discussed some concerns about the impact of DPS use on personal privacy, and emphasized the need for robust data protections in the technology. Participants were interested in having on-demand access to their adherence data, and were most willing to share data with primary care providers and long-term relationship partners. Future investigations exploring bioethical frameworks around DPS use are warranted, and user preferences should inform best practices for protecting DPS data.

Key Words: Digital pill system, data privacy, PrEP, HIV prevention, medication adherence

Introduction

Men who have sex with men (MSM) bear a disproportionate burden of human immunodeficiency virus (HIV) acquisition in the United States (US); in 2019, 70% of new HIV infections in the US were among MSM.[1,2] Following the approval of oral tenofovir disoproxil fumarate/emtricitabine (TDF-FTC) as preexposure prophylaxis (PrEP) for HIV prevention by the US Food and Drug Administration (FDA) in 2012, the multinational Pre-exposure Prophylaxis Initiative (iPrEX) trial demonstrated that daily oral PrEP is nearly 99% efficacious for protecting individuals against HIV, but that its effectiveness is closely linked to adherence.[3] In the same study, PrEP efficacy decreased to 76% among individuals with suboptimal adherence (i.e., fewer than four daily PrEP ingestions per week).[3]

Substance use represents a significant risk factor for PrEP nonadherence and subsequent HIV acquisition among MSM as compared to their heterosexual counterparts.[4–6] In one study of MSM on PrEP, the use of club drugs (e.g., methamphetamine, cocaine) increased the odds of missing a PrEP dose by 55% the same day, and by 60% on the day after substance use.[7] The increased probability of PrEP nonadherence due to substance use is compounded by the higher likelihood of condomless sexual intercourse while using substances, which is a primary risk factor for HIV transmission.[8] Given the persistent barriers to PrEP adherence faced by MSM with substance use[9,10], there is a continuing need to develop novel

tools to measure and respond to suboptimal PrEP adherence in this population.

Multiple techniques exist for measuring PrEP adherence, including individual self-report, pill counts, pharmacy prescription refills, pharmacological measurement of drug concentrations, and electronic adherence monitors (EAMs), though each have drawbacks.[11,12] Self-report, although still the most commonly used method for measuring medication adherence, is limited by social desirability and recall biases.[13] Pill counts, while more objective than self-report, may describe adherence behaviors in the aggregate, but miss granular changes in day-to-day adherence.[11] Pharmacy refills are also an indirect measure of adherence, and fail to capture data about ingestion events beyond whether a prescription has been filled.[12–15] Many pharmacological methods (e.g., measurement of drug concentrations in hair, plasma, and urine) succeed in obtaining objective adherence data over time[16], but require specialized equipment and analysis, and are therefore not easily scalable for clinical use.[12] Electronic measures of adherence, like medication event monitoring systems (MEMS), offer objective information about adherence patterns as quantified via the opening and closing of pill bottle caps – and have been demonstrated as acceptable among individuals using PrEP[17] – but fail to directly measure pill ingestions.[18,19]

Digital pill systems (DPS) have the capacity to directly and objectively measure real-time adherence to PrEP.[20] The “digital pill” component of the

DPS is comprised of a standard gelatin capsule with an integrated electronic radiofrequency emitter, which overencapsulates a single dose of PrEP.[21] Once activated by chloride ions in gastric fluid following ingestion, a radiofrequency signal is transmitted to a wearable Reader device, which then stores and relays time-stamped ingestion data to a web-based portal and smartphone application.[21] Clinicians and researchers can view real-time ingestion data via the online interface; patients have access to historical ingestion data through the smartphone application (Figure 1). By providing real-time, direct evidence of PrEP adherence and nonadherence, DPS present a novel opportunity to better understand patterns of adherence and nonadherence, and can be integrated into behavioral interventions aiming to measure, interpret, and improve adherence behavior.

Our preliminary qualitative work found that MSM with non-alcohol substance use largely viewed the DPS as valuable and helpful for improving their accountability around PrEP adherence. However, despite general acceptance of DPS technology in this population, user perceptions surrounding the privacy of their personal adherence data and potential stigma associated with using the DPS with PrEP remain unknown. A recent review concluded that the ethical issues of privacy, autonomy, and data security in the DPS setting is underdeveloped and unexplored, and the studies reviewed did not directly assess perceptions of ethical issues among potential users.[23] Given that reactions to DPS technology may differ across populations, disease states, and in the context of adherence for prevention versus treatment, it is important to consider data privacy-related concerns related to the DPS that are specific to MSM taking PrEP. This manuscript describes formative feedback from prospective DPS users – HIV-negative MSM with non-alcohol substance use – surrounding their preliminary perceptions of privacy, access, and data sharing in the context of PrEP adherence measured by the DPS.

Methods

Participants

HIV-negative MSM who self-reported substance use were purposively sampled to participate in individual, semi-structured qualitative interviews. Recruitment strategies included community and social media outreach, as

well as flyering at health centers and recruitment events throughout the greater Boston area. Participants met the following inclusion criteria: (1) 18 years or older; (2) self-reported HIV-negative; (3) cis-gendered MSM; (4) currently on PrEP or eligible to initiate PrEP; and (5) self-reported non-alcohol substance use within the last 6 months. Participants were excluded from the study if they (1) were living with HIV; or (2) did not speak English. All participants were prospective DPS users who were recruited to provide formative qualitative feedback on the DPS technology prior to its deployment in a clinical trial, which was conducted subsequently by our study team.[24] Institutional Review Board (IRB) approval was obtained from Fenway Health. All study visits were conducted between November 2018 and July 2019.

Procedures

Potential participants were screened via phone or in person to determine eligibility. Individuals meeting inclusion criteria were invited to attend a one-time, in-person study visit at the study site, which consisted of informed consent, a semi-structured qualitative interview, and a brief quantitative assessment covering demographics, sexual risk, sexual history, and substance use. Qualitative interviews were digitally recorded and conducted by the principal investigator (PRC) and/or a trained member of the study team (MJB). A model of the DPS was introduced to participants during interviews in order to aid in their understanding of the technology. Remuneration was provided. We adhered to the Consolidated Criteria for

Reporting Qualitative Research (COREQ) in the design and reporting of this investigation.

Measures

Quantitative assessment. Participants reported sociodemographic information, including age, race, ethnicity, sexual orientation, relationship status, education, and income. The assessment also contained questions around (1) health history, including medical conditions, mental health problems, and sexually transmitted infections; (2) sexual history, including sexual partners in the last three months, preferred sexual activities, use of substances before or during sexual activity, and condom use; and (3) substance use history, including types of substances used, as well as frequency and severity of use. Some of these data are reported elsewhere.

Qualitative interview. Qualitative data were collected using a semi-structured interview guide, which contained open-ended questions and probes to facilitate discussion. Prior to implementation, the interview guide was piloted with two members of the study team to ensure clarity of questions and probes. Development of the interview guide was informed by the Technology Acceptance Model (TAM), which explains the acceptability of a given information system or technology as based primarily on its perceived usefulness and ease of use.[25] Interviews covered a range of topics, including existing strategies for maintaining medication adherence; perceived utility of a DPS for adherence measurement; general perceptions of DPS technology, design, and messaging components; and willingness to

engage with a DPS. This manuscript is principally focused on participants' perceptions of and preferences around data privacy, access, and sharing in the context of DPS; data from these interviews were used to optimize the acceptability of using a DPS to improve PrEP adherence. Sample interview questions and probes are provided in Table 1. Interviews were between 30 and 60 minutes in duration.

Table 1. Sample qualitative interview content areas, questions, and probes

Content area	Sample questions and probes
Perceptions of and concerns around DPS data privacy	• The digital pill allows your provider or study team to view your adherence. What do you think of this? • What concerns do you have regarding the privacy of your data?
Preferences for DPS data sharing and access	• Who do you think should have access to adherence data? Why? • Tell us your thoughts on what it means for others to see your adherence data. Would you be comfortable showing people that you are on PrEP? That you are adherent/nonadherent?

Analyses

Descriptive statistics were calculated for quantitative variables. Digitally recorded interviews were professionally transcribed, and transcripts were analyzed using applied thematic analysis.[26,27] Four study team members (GRG, MJB, LM, YM) independently reviewed transcripts to create an initial framework identification of themes and interpretation of data. Major and minor themes were generated and reviewed, and data were coded into key categories and themes. Reexamination of themes and codes, as well as formal coding and analyses, were performed by three

independent coders (GRG, MJB, YM) and facilitated by NVivo software (version 12).[28] Salient messages were then extracted. Coders iteratively reviewed and compared their findings at each stage in order to resolve discrepancies and ensure the reliability and validity of the process.

Results

Ninety individuals were screened in total, of whom 64 were eligible. Reasons for ineligibility included no reported substance use (n = 24) and a positive or unknown HIV status (n = 4); two individuals were ineligible for both reasons. Thirty-four individuals were eligible but did not enroll, as a result of scheduling challenges or an inability to be contacted by the study team. A total of 30 participants enrolled in the study, and completed quantitative assessments and in-depth qualitative interviews. All participants identified as cisgender MSM (median age: 37 years old, range: 23-63). Participants were primarily White (63%), non-Hispanic or Latino (73%), and at least college educated (77%). Sociodemographic data are presented in Table 2.

Table 2. Sociodemographic characteristics

Variable	Sample (N = 30)	
	n	**%**
Age (in years)		
Median (IQR)	37 (23.8)	–
Range	23-63	–
Race*		
White	19	63
Black/African American	2	67
More than one race or Other	6	20
Other	2	67

Ethnicity		
Not Hispanic or Latino	22	73
Education		
High school graduate/GED	2	7
Some college education	5	17
College graduate	8	27
Some graduate education	6	20
Graduate/professional	9	30
Income (annual)*		
Less than $6,000	3	10
$6,000 to $11,999	4	13
$12,000 to $17,999	2	7
$18,000 to $23,999	3	10
$24,000 to $29,999	2	7
$30,000 to $59,999	6	20
More than $60,000	9	31
Sexual orientation		
Homosexual or gay	24	80
Bisexual	5	17
Other	1	3
Relationship status		
Single	21	70
In a committed relationship	2	7
In a domestic partnership	3	10
Married	3	10
Divorced	1	3

** Data missing from one participant.*
Percentages may not total 100 due to rounding.

Quantitative Results

With respect to current PrEP use and adherence, 56.7% of the sample (n = 17) was taking PrEP, and 16.7% (n = 5) of participants reported missing at least one dose in the prior two weeks. The mean number of sexual partners in the past three months was 13.87 (range 0 – 200), and 60% of participants (n = 18) reported ever having had a sexually transmitted infection. In terms of reported substance use, most participants endorsed use of alcohol (n = 22), stimulants (n = 19), and marijuana (n = 20); additional reported substances included sedatives (n = 6),

hallucinogens (n = 3), opiates (n = 3), and heroin (n = 1), as well as other substances, including poppers and amyl/butyl nitrate (n = 18).

Qualitative Results

Individual qualitative interviews explored reactions to and preferences around data privacy, access, and sharing in the context of real-time adherence monitoring via a DPS; these data informed the optimization of a DPS designed to measure PrEP adherence. Key findings emerged across three domains: (1) perceived impact of real-time adherence monitoring on personal privacy, (2) reactions to having access to one's own digital adherence data, and (3) preferences around sharing personal adherence data with others. With respect to data sharing, participants discussed their reactions to sharing adherence data with primary care providers, nurses, pharmacists, researchers, public health organizations, pharmaceutical companies, insurance companies, friends and family, and sexual and relationship partners.

Perceived impact of real-time adherence monitoring on personal privacy. While some participants stated that data privacy in the context of the DPS was not of major concern for them personally, they acknowledged that it might be a significant issue for others. These participants expressed confidence and trust that their adherence data would be used in an appropriate fashion; some also described a general lack of familiarity with technology and data security, noting that this may explain

their relatively limited concerns around personal privacy. In addition, participants discussed a perception of the inevitability of data breaches in all contexts and, to some degree, an acceptance of that reality.

> *I don't have personal qualms with taking [digitized PrEP] because… I don't think it would compromise me or anything like that. That may not be the case for other people… Maybe I wish I knew a little bit more about how data and just the medical field, how that all interacts. I don't know that much, and so I feel like… in my own practice, I'm pretty lackadaisical about where my data ends up.* (20s; not on PrEP)

> *For me, it wouldn't matter too much, but I guess other people, it may matter to them 'cause… it could possibly get out, or people can, in the future, maybe have some technology that can read the pill… I'm not a privacy type of person. I don't really care what people think or what they know, in particular, 'cause they're gonna find out. If they really wanna find out, they're gonna find out.* (50s; on PrEP)

Many other participants, however, expressed a desire for specific assurances around the types of protections that would be built into a DPS to enhance the security of their adherence data. A strong preference emerged for participants having control over who would have access to their personal information, as well as transparency around the specific ways in which each recipient would use their DPS adherence data. Despite reporting a belief that sufficient privacy-related laws likely exist to protect their medical data, some participants still voiced concerns around the potential for data hacks and leaks in this context.

> *If this technology moves forward with the digital PrEP, it would be really important to have the security and app both be created well and there should be privacy notices not only for the doctors but for the patients as well. If it's not possible to do a sharing feature in [an] ethical way or… without comprising the privacy and security, then I don't think*

[it] should be done… because, of course, patients' concerns are important, and patient privacy and medical history especially is really important. (20s; not on PrEP)

I don't know how much more of a concern it is than just the privacy of medical data in general, and I do feel fairly assured by our medical privacy laws, which are fairly strict… I don't feel that worried about the intentional misuse of [DPS data] by the medical industry and profession itself, or research profession—but more just hacking and leaks because it's just hard to secure medical data, or data in general. (30s; on PrEP)

Reactions to having access to one's own DPS adherence data.

Most participants were interested in the ability to review their own adherence data from the DPS to understand their medication-taking behavior. They identified multiple benefits of having such access, including an increased sense of accountability and the ability to review whether or not they took PrEP on a given day, as well as the opportunity to track their own progress, receive positive reinforcement, and form better long-term adherence habits; some participants noted that the DPS would be particularly useful when starting a new daily medication such as PrEP for the first time.

I think it'd be cool to track it, and see your progress, and see if you've missed a dosage… For me, I like data, and numbers, and statistics… I guess people track their steps on a Fitbit, or on their phone. I'd liken it to that. (30s; on PrEP)

Ideally it could work if it was just me seeing my accountability and how frequently I took it. That would work for me because I'm not resistant to taking PrEP… I'm very much on board with it. I think in that sense, the data really could only just be mine and no one else would use it and I would be okay with that. (20s; on PrEP)

One participant also noted that having access to real-time PrEP adherence data would help him by providing insights about his level of personal risk, which could enable him to make better-informed decisions about his sexual health (e.g., whether and when to seek HIV testing).

> *I have periods of times where I involve in risky sexual behaviors and, not only sexual, but also other kind of risky behaviors. It would be interesting to have this tracking of, this day, I had a risky exposure. Then, for example… I think it would be very useful to [make] it more easy for patients to know: When do I have to get tested? When is a good time to get tested? Should I call someone?* (20s; on PrEP)

Additionally, a few participants were either uninterested in viewing their own adherence data from the DPS or had concerns about storing it on their cellphones, noting that they would consider any information related to their PrEP adherence behavior to be particularly sensitive.

> *It sounds pretty much like how [I'd] take [PrEP] anyway, except of course, there's another step in it. It would be recorded on my phone. I don't know if I would like that. I don't know if I would want that information in my phone… it's sensitive information.* (60s; not on PrEP)

Preferences around sharing personal adherence data with others. Overall, participants expressed a variety of opinions about granting others access to their personal DPS adherence data. Some stated that data sharing could be beneficial and that they perceived the technology to be sufficiently secure; one participant reported that knowing others had access to his DPS data would provide additional motivation for him to remain adherent.

> *I'd feel like someone was watchin' me… Watching you for a good reason… It would give you more discipline, you know? I think it would [make me] more likely to be taking the pill on a regular basis with that, particularly when I started.* (50s; on PrEP)

Others had more mixed reactions, noting that they would be willing to share DPS adherence data only with select individuals and groups of people, and only under certain circumstances. Some participants reiterated concerns about the invasion of their personal privacy, including uncertainty around the implications of feeling "tracked." Participants also expressed doubt that they would ever be inclined to actively share their adherence data with other people, given the confidential nature of their medical information.

> *The concept of being tracked, it just depends… I would want to know as the patient, where is that information going? I would feel different depending on how the information is being used. If it's just between my doctor and I, and I have assurance that it's just like in a sealed record, I would feel fine doing this. If this was for a research study [and] that [information] could potentially be used or sold, that's when I would be like, "Okay, I have more questions."* (30s; not on PrEP)

> *I wouldn't wanna share it. I wouldn't wanna hide it, but I wouldn't wanna like say, "Hey, look." You know? I think it's really something I wouldn't do. If somebody says, "Well, what's that thing you got?" I would tell 'em, but I'm not gonna show 'em my data or somethin' on my phone.* (50s; on PrEP)

In addition, stigma was cited as a reason for some participants' reluctance to share DPS adherence data with others. These participants described their fear of unwanted PrEP disclosure, as well as an awareness

of stigmatizing beliefs that PrEP users are promiscuous or engage in excessive behaviors that may expose them to HIV.

> *I'm not that paranoid, but I think people are very concerned about these things. Especially when it comes to this. I guess it's not like HIV medication. It'd be like, "Oh, my God. Someone knows I have HIV." With this, it's protection. It's also people can be stigmatized. "Oh, you're on PrEP. You must be a slut"… I feel like there is some stigma, or some people interpret it a certain way when people hear that you're on PrEP.* (30s; on PrEP)

Data sharing with primary care providers. Participants were largely comfortable with the idea of sharing their DPS adherence data with their primary care providers. Many expressed a belief that granting providers access to this information could improve the patient-provider relationship by enhancing transparency and trust, increasing accountability, promoting increased contact during the periods between scheduled appointments, and equipping patients with concrete evidence of their adherence behaviors to share with providers during in-person visits.

> *I see my primary care provider as someone that I will never hide anything from… I will tell them everything, with no shame or anything because I know that, first of all, they must have heard so many stories. Second, that the purpose of a primary health provider is to keep you healthy.* (30s; on PrEP)

> *It would be reassuring that they're paying attention… [and] it'd be interesting to prove that to providers that, "Yeah, I am taking this medication on time. I am taking this every day," because they're really just taking your word for it.* (30s; not on PrEP)

However, several participants also highlighted the potential tension between patient autonomy and provider responsibility in this context,

noting that sharing adherence data from the DPS could amplify these dynamics that already exist in the medical sphere. Participants expressed an appreciation for the likely increase in providers' involvement in their day-to-day health that could result from data sharing, but noted that this might conflict with their desire to maintain the independence and freedom to make their own decisions about taking PrEP, including the amount of information they choose to share about their adherence with providers.

> *I'm of two minds because one, I appreciate it, at least in my own life, when doctors seem proactive about my own health care. Sometimes it feels like… you have to be your own advocate to get care. It's cool that maybe in this imagined future, they're able to really check in on you more. Then I guess the other side of that is almost the surveillance of that. Again, I guess I feel like as long as the patient is allowed to still have their own autonomy, which is to say maybe the doctor is aware, maybe the doctor does reach out, but they can't really do more than that, than just say, "We strongly advise that you take this medication" or "It's in your best interest."* (20s; not on PrEP)

> *I guess there is the invasion of privacy in that… it's your choice whether you tell the full truth to your doctor about whether you're taking medication or not… it's like, if taking your medication is not just about you, but it's like being responsible to others, then I see that playing out more relevantly. If it's just you, then… maybe you should be allowed to just stop [taking medication]… and your doctor may not need to know that.* (20s; not on PrEP)

Additionally, a few participants questioned the feasibility of such an approach to data sharing, and wondered whether providers would have time to monitor their patients' real-time adherence data from the DPS. Participants predicted that this responsibility could ultimately become untenable for providers themselves, suggesting that regular monitoring of

adherence data may need to be completed by other members of a patient's care team.

> *No. I'm very comfortable with my physician… I wouldn't have a problem with that, but I would think, though, with the volume of patients that some doctors have, that it would be like—not irritating them, but somethin' that they would start to ignore after a while.* (50s; on PrEP)

Data sharing with nurses and pharmacists. Participants were generally willing to share personal adherence data from the DPS with nurses and pharmacists, though one person, who was a nurse himself, felt that this information might not be especially relevant for nurses – and expressed concern around the potential for pharmacists to overstep by reaching out to patients directly and pestering them about their prescriptions.

> *Definitely the patient, definitely the physician. Potentially the pharmacist. Maybe, if they give you 30 pills, but you've only taken 20, they're not hounding you to come pick up your prescription… That might be a little bit of a breach of privacy, I suppose. That's really it. Part of me wants to say the nurse checking you in or doing whatever, but why would they need that information? It doesn't seem like it's pertinent to them.* (20s; on PrEP)

Data sharing with researchers and public health organizations. Participants were open to sharing DPS adherence data with individual research teams, noting that reviewing such data would be useful for understanding and ultimately improving PrEP-taking behavior and HIV prevention on a broader scale.

I think because PrEP is so new it would be really beneficial to the community if we did open up that data, if we did make it accessible to people who research… In the grand scheme of things that would be very helpful, but I understand [that] not everyone is as open to have their information or their data shared like that. (20s; on PrEP)

I can see the philosophical kind of problem 'cause like, of course, the research is gonna help patients in the long run, but still who should get access to it? From a patient perspective, if I was having difficulty taking PrEP, I would feel comfortable doing it in collaboration with the doctor in a close research study knowing that it was like, you're not gonna be sold or used for any other purpose. (30s; not on PrEP)

Participants were also generally willing to share DPS adherence data with public health organizations and agencies involved in HIV prevention efforts, such as the National Institutes of Health, the Centers for Disease Control and Prevention (CDC), and the World Health Organization (WHO). Participants emphasized that all DPS data should be anonymized and should not in any way be used to reprimand specific individuals for their adherence behaviors.

I think a global organization like the CDC or the WHO could take that information and expand on that… Maybe seeing how often people take it, if there's a pattern, and when people stop taking it, adherence to it. I think simple things like that would go a long way. (20s; on PrEP)

Government agencies only in an anonymized way that's solely to track and respond to public health issues, not, in any way, a punitive manner… I'm just thinking like the NIH and other, maybe, state health agencies are concerned with the HIV epidemic and are trying to find new ways to address it. (30s; on PrEP)

Data sharing with pharmaceutical and insurance companies.

Some participants expressed a willingness to share anonymized adherence data from the DPS with drug manufacturers, such as Gilead, as well as

insurance providers, explaining their openness to this idea as it being part of their broader responsibility to the community and for the "greater good."

> *I would assume the makers of Truvada would [have access to adherence data]. It would probably be helpful data to them to see [whether] people [are] adhering to this. I think the whole premise behind Truvada is if every single person in the world was on it, there would be no more HIV… I know people in the community talk about it as a community responsibility and I would think that the makers of the drug would want that data to show that hopefully people who take it take it seriously.* (30s; on PrEP)

> *I would have no problem with insurance companies getting access to the data… As long as there's an element of anonymity to it, I personally would not have a problem with it… The way I think about it is the greater good. Ultimately, you need data to make advancements and you need that kind of feedback to understand how you wanna go about things differently. I see it as an educational contribution. At that point, it really has nothing to do with me. It's just the greater cause.* (20s; on PrEP)

However, not all participants felt this way; some voiced concern about the potential for commodification of their DPS adherence data, by pharmaceutical companies in particular, and asserted that it should be kept out of the for-profit sphere altogether.

> *I'm sure a lot of external researchers… and pharmaceutical companies would love to get their hands on the data. I just don't think ethically it is appropriate… Something like this where you're tracking your PrEP or tracking your heart medicine or whatever being sold and commoditized to sell drugs, that would be my concern… Keeping [data] within the public or nonprofit sphere, whether it be a research study on a hospital setting, doctor's office. Trying to keep it outside of, I guess, the corporate arm. Like reselling of information for corporate pharmaceutical gain.* (30s; not on PrEP)

Data sharing with family and friends. Participants had mixed reactions to granting family and friends access to their adherence data from the DPS. Some were open to the idea and described a broad definition of "family" that could encompass close friends, as well as anyone else with whom they felt comfortable enough to trust with their personal health information. A few participants also noted that sharing a person's adherence data with their family members could be useful in the context of many medications besides PrEP, and especially in cases where the patient is an elderly person or a child.

> *It doesn't need to be a blood relation. I think that family in terms of medication is whoever that that persons feels closest to help them stay accountable and to help them provide support. In the LGBTQ community especially, I think there are lots of people that consider family not by blood, but consider family by those that they're closest to. Whether it's a partner, a romantic partner, whether it's a friend, whether it's [a] mentor, I think that the patient should have the ability with the doctor to decide who else is going to be that third party.* (20s; not on PrEP)

> *If you had a family where you could include ways to share that information so that patient, the doctor and maybe one or two other parties had that, that'd be such a relief for many people, giving them peace of mind that someone is actually taking that medication like they said they are.* (20s; not on PrEP)

Some participants, however, doubted that their friends or family members would care enough to help them track their adherence behavior, and others reported that their use of PrEP is a personal decision that they would not be comfortable sharing with members of their family.

Some friends I have, they might get [the alert] and… they'll tell me a week later. You know what I mean. I can see how it would work for some people, but it would depend if they have a friend close enough, responsible enough… I think it would be positive for the person in case they forgot or whatever. Some people forget a lot. If there's somebody else who's interested enough to remind them, it would be very positive. (60s; not on PrEP)

Family, definitely not. My dad knows I'm gay, and I have a gay brother, but it's completely unnecessary. It's your own business. It's either your health provider or at most, your partner. No one more than that, I would say. (30s; on PrEP)

Data sharing with sexual and relationship partners.

Participants had a wide range of reactions to the prospect of sharing DPS adherence data with their sexual and relationship partners. Most were willing to share their data with long-term partners, including those with whom they are engaged in open relationships, which were described as very common. Many participants discussed the ways in which data sharing could enable long-term partners to take better care of one other and encourage each other to stay on track with their adherence, both in the context of serodiscordant relationships with one partner taking PrEP, as well as in relationships where both partners are HIV-negative and taking PrEP. They also described how sharing adherence data from the DPS could enhance the overall sense of security, accountability, trust, and transparency between partners.

For partners, it'd be great. They could keep track of each other. They can make sure they're both adhering to it. Yeah, I can see where that would be very beneficial for partners… If they were in an open relationship or something, or one of them were poz, but undetectable,

then they could really watch the other's back, and make sure they're both taking care of each other. (20s; on PrEP)

It's encouraging transparency… Because when you trust the other person, you're trusting them enough to know… about your physical and mental health as well. This app could help [foster] or make the bond stronger because it makes the other person considerate about each other's health. (20s; not on PrEP)

Other participants were more skeptical of the idea of sharing DPS adherence data with long-term partners, describing a general lack of interest and perceived need, and noting that they would therefore be unlikely to involve their partners in this area of their lives. Participants also discussed the ways in which sharing adherence data with their partners might infringe on their privacy if partners were to begin meddling unnecessarily in their personal healthcare decisions.

I probably wouldn't [share data with partner] 'cause we're just busy, middle-aged queens. You know what I mean? … Grown up people don't go, "Look at my new app. It's so cool." But younger people do. (50s; not on PrEP)

Having that as an option, maybe, is a good idea, but not necessarily a requirement. If I know I'm bad at taking pills, and I wanna be held accountable, then I'll have my partner… get these updates, so they can say, "Oh, my god. You didn't take your meds today and you really need them. You should take them," versus not. [But if] I don't want my partner to know, then, all of sudden, now he knows, and he's hounding me about it, and it's not his business… I can see the lines getting a little blurred there. (20s; on PrEP)

Participants also discussed sharing adherence data from the DPS with more casual sexual partners, which elicited a range of responses. Many were open to data sharing in this context, describing a similar

array of potential benefits to those raised in reference to long-term relationship partners; these included an enhanced sense of self-protection, trust, and transparency. Participants also reported that, with informal sexual partners in particular, sharing DPS adherence data could make both people feel more connected to and comfortable with each other, especially when it relates to discussing matters of sexual health in person, as opposed to online or via a dating app.

> *I personally like the idea because… if you're having sex with an individual, you should ask them, "Hey, do you have anything? When's the last time you were tested?" Blah, blah, blah. The number of times that I've been shown a piece of paper to prove it is basically none. You really have to take someone's word for it. [But] this is data, it's incontrovertible. I think it's an added layer of – one, I would trust what you're saying more and two, you're more likely to actually be honest with what you're saying if you have the data to back it up.* (20s; on PrEP)

> *That allows someone to make a judgment even if they're maybe a little bit inebriated that says, "Oh, if this person is on PrEP, I can see they're on PrEP"… that's peace of mind for the person that's making the decision. For the person that's providing that information, it is a sign of trust that you're saying… "Here's a small data point of my medical history. I'm sharing something and I'm opening up to you." Depending on the way someone likes to have sexual activity, that could help them feel more connected to the person or feel like now we're sharing something that's real life. It's not just in a sex dungeon or it's not just like flirting at a club or dancing in a backroom.* (20s; not on PrEP)

Finally, a number of participants had concerns about sharing their DPS adherence data with more casual sexual partners. These participants felt that this could make a sexual encounter feel transactional, awkward, or otherwise diminish their enjoyment of the interaction. Participants expressed that data sharing in this context

would not only be unnecessary, but that having a sexual partner offer or request such a disclosure of information would represent a form of over-sharing that could be indicative of other personal issues. One participant also mentioned the potential for PrEP-related stigma in this scenario, explaining that a casual sexual partner could falsely conclude that a person is excessively promiscuous, or mistake their adherence data for HIV treatment, rather than prevention.

> *"Hey, let me show you my statistics" is not very sexy. That would work, I think, in many situations, but it makes it very transactional… I think it minimizes that drive to want to have sex… If somebody did that to me, if they're that cautious, I'd be like, that's great, but what will you be like when I meet you? Are you gonna be so nervous and uncomfortable and anxious… that it's not gonna be fun and we're not gonna click?* (30s; on PrEP)

> *It is too much… That would be a whole new sort of premature intimacy syndrome… because what someone is then looking for is, "We're going to have physical interaction, and there will be absolutely no negative externalities that will result from this."… I just feel, as a gut thing, anybody that wants that level of detail is bringing so many other issues.* (50s; on PrEP)

Discussion

Adherence to daily oral TDF-FTC for PrEP is essential for HIV prevention, and DPS represent a novel and promising method for tracking and encouraging PrEP adherence. Previous work has demonstrated the feasibility and acceptability of DPS for measuring PrEP adherence among MSM with substance use, a population that is at a higher risk of suboptimal PrEP adherence and HIV acquisition.[29] This investigation found that MSM with non-alcohol substance use recognize potential privacy concerns related

to the use of a DPS, yet would be willing to not only access their own PrEP adherence data via a DPS, but also to share their PrEP adherence information with a diverse group of individuals. The implications of this research may help to inform the specifications and design of privacy protections for DPS use, especially in the context of PrEP, and can shed light on additional avenues through which to share and provide access to DPS-mediated adherence data.

Digital data privacy, as it relates to the collection and transmission of PrEP adherence data via the DPS, was an important consideration for participants in the present study. While some individuals expressed confidence that sufficient measures would be put in place to protect their data, others were more resigned to the inevitability of information breaches in today's data-driven world, suggesting a belief that the risk of privacy loss exists for any data-producing behavior. Recognizing that overt references to PrEP could be removed from the DPS was enough to assuage some participants' concerns. Yet, for others, the ubiquity of mobile phone data, and increasing quantification of daily activity through technologies like smartwatches and fitness trackers, was an indication that the security of their personal data would be impacted regardless of built-in protections. These perceptions are consistent with a 2019 report published by the Pew Research Center, in which 70% of surveyed adults reported believing that their personal data is less secure now than it was five years ago, and 63%

reported understanding very little or nothing at all about current data privacy laws and regulations.[30]

Nevertheless, as is consistent with previous work, most participants in this study expressed a desire for specific assurances that their DPS adherence data would be protected.[31,32] These findings suggest that issues surrounding DPS adherence data sharing and privacy should be discussed with new users and addressed by research teams at the outset during enrollment. Increased efforts to protect personal health information – including data minimization, data anonymization, withholding information around the particular drug in use with the DPS, eliminating in-app references to the applicable disease state, and developing standards around how long data will be stored and users' rights to withdraw their data – may help to assuage individuals' privacy concerns associated with DPS use.

Participants also recognized that their PrEP adherence data from the DPS could be shared with other parties in certain circumstances, and emphasized the importance of user control – or, at minimum, disclosure – of which outside entities would have access to their data. In general, participants were largely willing to share data with their clinical care teams, noting that such information had the potential to increase patient accountability, improve the capacity of providers to monitor and communicate with patients between appointments, and better enable patients to track their own patterns of adherence. Participants were also largely willing to share anonymized data with governmental public health

organizations, like the US Centers for Disease Control (CDC), noting that such data could help inform the development of large-scale HIV prevention efforts. With respect to pharmaceutical and insurance companies, responses were more mixed; only some participants were willing to share data with these entities – and viewed doing so as contributing to the "greater good" – while others worried about the use of their personal data for profit. Additional clarity is needed with respect to data protections under the Health Insurance Portability and Accountability Act (HIPAA), including, in particular, the specific contexts in which DPS adherence data would be considered protected health information (PHI) under HIPAA. Future investigations should explore acceptable mechanisms through which anonymized, population-level PrEP data collected from DPS may be used to inform public health interventions, assess PrEP rollout in areas with limited PrEP access, or leverage incentives to help maintain and boost adherence.

Notably, some participants were also willing to share data with close family members or friends, depending on the specific relationship dynamics, as well as with relationship partners. These participants reported that providing nonadherence notifications to close family members could be an effective tool for keeping them on track with their adherence – and, in some cases, more effective than sharing data with healthcare providers. In the context of long-term relationships, sharing PrEP adherence data from the DPS was viewed by many participants as a means by which to improve accountability, trust, and transparency between partners. These findings

are especially meaningful in the context of PrEP, where, unlike with other medications (e.g., for heart disease treatment), one individual's nonadherence to PrEP can directly impact the decision-making of their partner as it relates to HIV prevention behaviors. DPS data could therefore potentially drive adherence interventions that involve family members and significant others; future studies could recruit couples, in which both partners are taking PrEP, to examine whether DPS data can be used to enhance adherence behavior in a relationship context. Importantly, if found to be acceptable, further investigations might also explore the use of DPS to support PrEP adherence in serodiscordant couples, or those in open relationships where one or both partners may be at a high risk of HIV infection.

Finally, the prospect of sharing DPS data with casual sexual partners elicited a range of responses. Although some participants were unwilling to share adherence data in this context, due to concerns that it could make sexual encounters too transactional, others described sharing PrEP adherence data as a way to equip individuals with concrete information to protect themselves against HIV transmission prior to sexual encounters with new partners. These participants also noted that the process of sharing data could also enhance feelings of comfort and connectedness between new sexual partners – which, as in the context of sharing data with relationship partners, is particularly relevant for PrEP use, given the direct impact of one's PrEP adherence behavior on the HIV prevention decisions of

their sexual partners. Interestingly, the possibility of incorporating DPS-collected PrEP adherence data as a feature in popular dating apps was also discussed by several participants. Individuals' preferences for sharing adherence data on these apps, many of which already allow users to indicate their PrEP status, could inform the manner and granularity with which PrEP ingestion patterns are measured by the DPS; for example, it is possible that MSM may consider not just PrEP status, but real-time PrEP adherence patterns, in the context of selecting sexual partners – and that DPS data can play a role in this process. Future work could explore the effect of viewing others' DPS-collected PrEP adherence data on one's selection of sexual partners, as well as best practices for enabling the sharing of DPS adherence data and patterns on other digital platforms.

With respect to key bioethics principles, it will also be important to consider that, while sharing DPS adherence data with a sexual partner (either within or outside of a dating app) would be a voluntary choice on the part of an individual, new expectations and/or norms around this behavior may be created if many people begin to engage in DPS data sharing. Such norms are likely to be prosocial and advantageous to public health efforts related to HIV prevention; however, relevant potential tradeoffs between personal autonomy and beneficence (in terms of distributing HIV protection) would be more subtle in this context – where data sharing is not a requirement of a law or employer, but instead is a social norm within a community – and therefore warrant additional exploration.

This investigation has several limitations. First, the study was conducted at a single site – a community health center dedicated to the care of LGBTQ+ people and other underserved populations.[33] Perceptions of data privacy considerations surrounding the use of a DPS for PrEP adherence measurement may be different among participants recruited from a site that provides HIV prevention services versus one that does not. Second, the majority of participants in this investigation were White, well-educated, and relatively young (median age: 37 years old, range: 23-63) males. For comparison, in 2019, 93.8% of individuals on PrEP in Massachusetts, where the study was conducted, identified as male, and 62.8% were between the ages of 25-44.[34] Prior experience and comfort with technology, as it relates to participants' ages, may have also influenced their perspectives on DPS technology and digital adherence data. Finally, this qualitative investigation sought preliminary feedback on the DPS from prospective users who did not participate in real-world use of the technology. User experiences, preferences, and considerations related to DPS data privacy among actual DPS users may vary, and warrant additional study.

Conclusions

The security, privacy, and sharing of real-time adherence data are critical components of the deployment of any DPS for PrEP adherence among MSM with substance use. Robust data protections and key assurances around methods for securing and anonymizing PrEP adherence

data are important and should be developed as a core part of DPS deployment frameworks and best practice guidelines. Future research should include the development of novel methods for sharing DPS-collected PrEP adherence data and delivering DPS-based adherence interventions that engage partners, family members, and significant others as adherence supports for PrEP.

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Figure 1. Overview of digital pill system (DPS) components

The DPS comprises an ingestible electronic sensor integrated into a gelatin capsule that over-encapsulates tenofovir disoproxil fumarate/emtricitabine (Truvada™) as a “digital pill” (A). Following ingestion, the sensor is activated by gastric fluid and broadcasts a radiofrequency signal that is then acquired by a wearable Reader device (B). The Reader relays ingestion data to the user’s smartphone via Bluetooth, which can display and transmit real-time adherence metrics. Ingestion data is then sent through the cloud to an online interface where it is accessible to clinicians and researchers.[22]

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"I'd feel like someone was watchin' me… watching for a good reason": Perceptions of data privacy, access, and sharing in the context of real-time PrEP adherence monitoring among HIV-negative MSM with substance use

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