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ORIGINAL PAPER

Transgender Women's Barriers, Facilitators, and Preferences on Tailored Injection Delivery Strategies to Administer Long-Acting Injectable Cabotegravir (CAB-LA) for HIV Pre-exposure Prophylaxis (PrEP)

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Abstract

Long-acting injectable cabotegravir (CAB-LA) is in advanced stages of clinical trials. Under the standard protocol, CAB-LA is injected into the gluteal muscle by a healthcare provider every eight weeks. To explore transgender women's barriers and facilitators to tailored delivery strategies—including self-injection and injection in "drop-in" centers—we completed in-depth interviews with N = 15 transgender women in New York City. Participants endorsed the alternative delivery methods and the corresponding features we proposed, and expressed likes and dislikes about each. These fell into the following categories: competence (e.g., the person delivering CAB-LA must have skills to do so), convenience (e.g., CAB-LA must be easy to obtain), and privacy or fear of judgement (e.g., participants did not want to feel judged for using CAB-LA by providers or other service consumers). Findings suggest the need to offer CAB-LA to transgender women through multiple delivery protocols.

Keywords Long-acting cabotegravir · Transgender women · Injectable cabotegravir · PrEP

Introduction

Long-acting injectable cabotegravir (CAB-LA) for HIV pre-exposure prophylaxis (PrEP) has received Breakthrough Therapy designation by the United States (US) Food and Drug Administration (FDA) [1]. Current recommendations for this new type of PrEP call for a healthcare provider to administer a single injection (600 mg CAB-LA) every eight weeks in the upper quadrant of the gluteal muscle [2]. Participants in both studies of CAB-LA for PrEP (HPTN-083 (gay and bisexual men and transgender women who have sex with men); HPTN-084 (cisgender women who have sex with men) received a month-long oral lead-in of cabotegravir (daily oral cabotegravir tablet), prior to receiving their first CAB-LA injection. After their last injection of CAB-LA in the study, they were asked to take daily oral PrEP (tenofovir/emtricitabine; TDF/FTC) to cover the "long tail" of CAB-LA [3].

Phase III trials results indicate CAB-LA is highly effective for the prevention of HIV acquisition in cisgender men

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and transgender women [4], providing new prevention options for people who are unable or unwilling to take oral PrEP medications or those who have challenges with oral medication adherence. CAB-LA, therefore, could be particularly meaningful for transgender women among whom oral PrEP uptake has been low [5–7] due to social, structural, and clinical barriers [8, 9]. These barriers include: early messaging about PrEP that excluded transgender women and appeared to prioritize gay and bisexual men (GBM); perceptions that adherence interventions do not address transgender women's PrEP-related challenges (e.g., medical mistrust due to transphobia, managing multiple medications and health appointments, stigma, experiencing destabilizing life events); medication regimens or delivery protocols that feel incompatible with transgender women's preferences; fear of cross-interactions between PrEP and gender-affirming hormone treatments; and misinformation and/or untrue rumors about PrEP [8, 10, 11].

There is a dearth of research on transgender women's perceptions of and preferences on injectable CAB-LA. However, the prior study on this topic shows that transgender women feel that CAB-LA injections could help to overcome challenges with adherence, and feel a lot like contraceptive injections, which was perceived as gender-affirming. On the other hand, results showed that transgender participants were concerned about the CAB-LA injection site (e.g., upper quadrant of the gluteal muscle), since some transgender women use buttock/thigh fillers or implants to feminize their shape, which would complicate CAB-LA injections. Further, some transgender women disliked meeting with a healthcare provider to inject CAB-LA, were concerned about potential cross-interactions with gender-affirming hormone therapy, and disliked the required oral lead-in [9, 10]. Despite these concerns, CAB-LA has been successful in Phase IIb/III trials. Still, it has not received approval and it is unclear how it will be administered for HIV prevention use in "real world" settings.

The present study builds on efforts to better understand transgender women's PrEP-related needs and preferences to address these barriers and improve the accessibility of CAB-LA. As part of earlier focus groups to identify barriers and facilitators to current (e.g., oral PrEP) and potential future PrEP methods (e.g., CAB-LA, subdermal implants for PrEP), transgender women identified two alternatives to the current healthcare provider-based delivery of CAB-LA, including: (1) self-injection (e.g., a healthcare provider would train transgender women to self-inject CAB-LA), and (2) injection in "drop-in" centers (e.g., transgender women could report to specific clinics during designated hours without an appointment and a healthcare provider would administer the injection) [10]. The methods and findings of these focus groups can be found elsewhere [9, 10, 12]. The two alternative injection delivery methods identified in the focus group discussions served as the focus of the interviews for the present research. The current study presents qualitative findings about transgender women's perceived acceptability (e.g., overall like or dislike of the CAB-LA delivery methods), barriers, facilitators, and preferences for engaging these alternative injection strategies.

In subsequent phases of this study, we will test these alternative CAB-LA delivery methods against one another and a control group, using a partially randomized patient preference trials design (PRPPT). PRPPTs can operate in multiple ways [13–15]. In our PRPPT, participants are randomized 2:1 to intervention (self-injection, injection in "drop-in" centers) or control conditions. If randomized to the intervention condition, participants can choose which of the two injection delivery strategies they wish to use during the study; participants in the control condition will employ procedures similar to those used in HPTN-083 [16]. The rationale for this is that participants will have different CAB-LA-related preferences and needs, based on their individual circumstances, that will influence their ability to adhere to the injection protocol. Allowing participants to choose which delivery method they engage will permit them to select the strategy most closely aligned with their preferences, maximizing their odds of correct and consistent CAB-LA use.

Understanding the preferences, acceptability, challenges, and facilitators transgender women have in engaging the tailored injection delivery strategies explored in this study will allow researchers and clinicians to further streamline these product delivery modalities to the needs of these women. Specifically, we posit that by involving end users, such as transgender women, in the development phase of HIV prevention products, we can limit potential future health disparities by addressing barriers to product uptake and adherence in the actual design and delivery of CAB-LA. Subsequently, this manuscript presents NYC transgender women's relative likes, dislikes, and preferences on the following tailored delivery methods of CAB-LA: self-injection, injection at "drop-in" clinics, and lengthier injection appointments at a healthcare provider.

Methods

Participants and Recruitment

Eligible participants self-identified as transgender women. Additionally, they were Spanish or English-speaking, at least 18 years old, lived in the NYC/tri-state area, sexually active (e.g., reported oral, anal, or vaginal sex with another person in the last three months), reported that they did not have silicone injections or implants in their buttock/thigh area (as silicone implants/injections in this area would complicate

CAB-LA delivery), and were willing to take a rapid HIV test (OraQuick Advance®) at the study visit. The sample presented in this work comprises the first 15 transgender women who met our eligibility criteria and agreed to enroll. While estimates vary, some research shows that thematic saturation of 92% occurs with 15 interviews [17], and it was at this point that we observed repetition in thematic content.

Recruitment took place from May to August 2019. Participants were recruited from a convenience sample of transgender women participating in a longitudinal cohort study on transgender identity development and community resilience (*Project AFFIRM*). To ensure a diverse sample of participants, *AFFIRM* uses a purposive, venue-based approach across multiple settings, including offline (e.g., bars, clinics, LGBT-focused events) and online (e.g., LGBT-oriented chatrooms and websites) contexts. Additionally, to supplement recruitment efforts, we posted advertisements about our study on social media sites, and an internal university-based study recruitment system. All participants received an incentive of $50 for their time and travel expenses.

Ethics Approval

The study was approved by the New York State Psychiatric Institute Institutional Review Board (NYSPI IRB). Consent forms were presented in English or Spanish, depending on the language preference of the participant. All participants provided written informed consent prior to participation.

Approach

To determine interest and eligibility, potential participants recruited from *AFFIRM* were screened by answering a brief questionnaire in their preferred way (e.g., via email, telephone, text) and in their preferred language (English or Spanish); all subsequent research activities were delivered in the preferred language. Participants recruited from the online sources described above were asked to click on a link in the posted study advertisement, which took them to a brief web-based screening tool. Eligible transgender women were invited to the research site to complete a two-part in-depth interview (IDI). Because the data presented in this paper were collected exclusively during Part 1 of the IDI, we will limit our description of interview processes to this section. During Part 1, all participants viewed standardized short PowerPoint presentation modules about CAB-LA generally (e.g., participants were given information about the CAB-LA dosing schedule, potential side-effects, efficacy, location/size of the injection), each tailored strategy to deliver the example product (e.g., "self-injection" and injection at "drop-in" clinics), and the existing clinical trials strategy to deliver CAB-LA; participants were informed that during actual use of injections, a clinician would be available to evaluate users for medical eligibility, monitor side-effects, and address questions. Further, they were informed that a month-long oral lead-in would be necessary, as well as additional laboratory screenings (e.g., STI and liver function tests).

Then, participants completed an interviewer-administered, audio-recorded IDI covering factors influencing the acceptability of biomedical HIV prevention products, delivery methods for these products, and strategies to deliver adherence support content (e.g., via telephone, in the clinic, smartphone application (app). We also interviewed participants on the type and structure of education and support resources they believed would be helpful to facilitate adherence; these findings will be reported in a future paper on the development of a smartphone application (app) for CAB-LA adherence. Interviewers in this study included the PI and an RA, both of whom identify as cisgender. To ensure that the information about CAB-LA and tailored injection delivery methods was presented in a standardized way between interviewers (e.g., the PI of this study and a Research Assistant (RA)) and that interviewers were able to correctly answer questions about CAB-LA, the PI provided a training for the RA on this topic.

The overall design of IDIs was guided by the "Mensch Model," which describes the relationship among acceptability, choice, and adherence in behavioral studies of biomedical HIV prevention tools (Fig. 1) [18]. This model operates from a socio-ecological perspective, positing that multiple agents and factors operate at different levels to influence two related but distinct constructs: acceptability and adherence. Examples of items contained in each component of the model are in Table 1. IDIs focused on the relationship between transgender women's needs related to product delivery attributes (delivery method acceptability) and life contexts (influencing factors). Participants were not asked to identify their *anticipated* preferred injection delivery strategy during IDIs. This is because we will determine participants' *actual* preferred injection delivery strategies during a future phase of research that includes a partially randomized participant preference trial where intervention participants will select one of the two tailored CAB-LA delivery strategies to engage over 6 months.

Description of Tailored Injection Delivery Methods

The structure of the two injection delivery strategies was developed based on preferences identified in focus groups described elsewhere [10]. In the self-injection group, participants are trained by a nurse to give themselves the CAB-LA product in their first study visit. Participants give themselves the next two injections at home. Before the injections are due, participants are mailed a pre-loaded

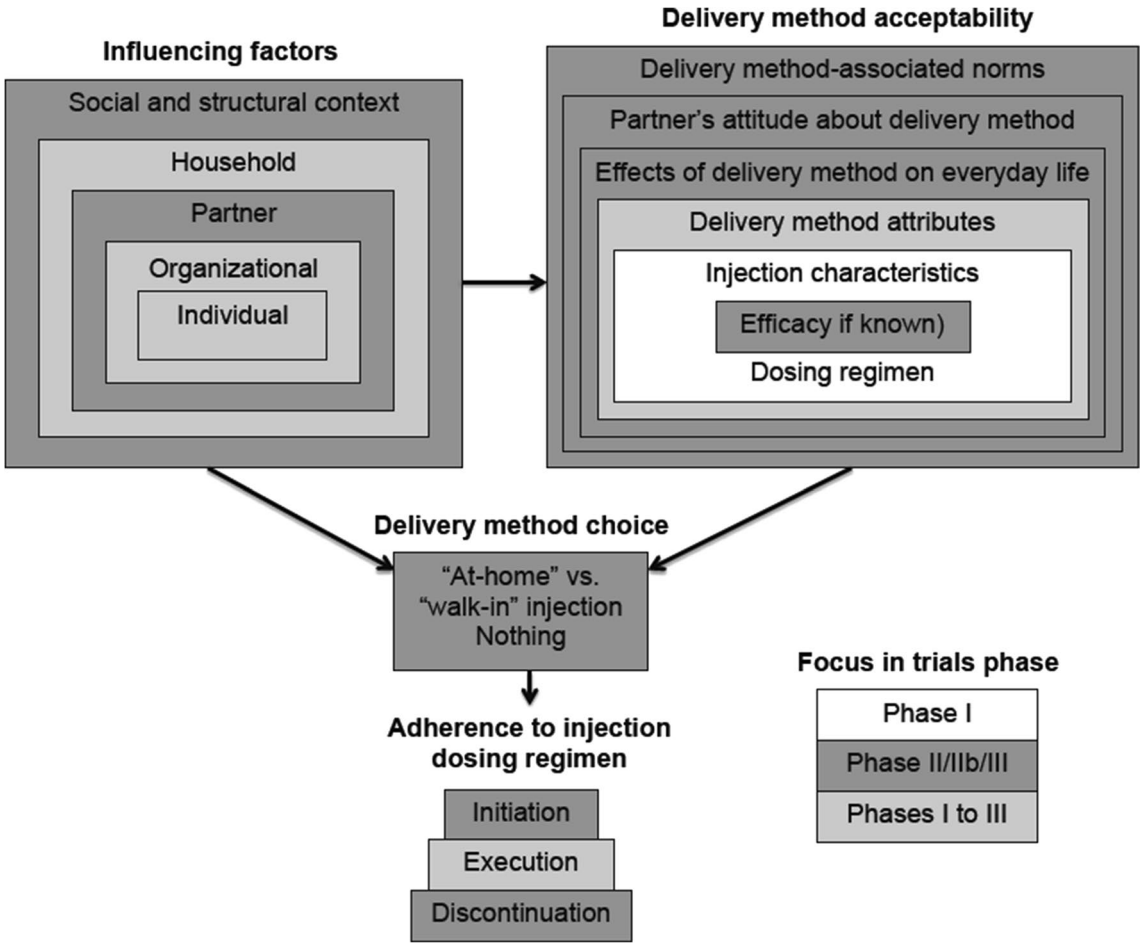

Fig. 1 Conceptual model

Table 1 Examples of influencing factors and acceptability components of biomedical products

Influencing factors	Examples	Acceptability components	Examples
Individual	Age, ethnicity, education, income, employment, risk perception, mental health, drug/alcohol use	Injection characteristic	Injection volume, syringe gage and length, injection type (e.g., IM), injection location on body
Household	Resources, number/type of household members	Efficacy	Efficacy is the same across both delivery methods
Partner	Number, type, communication, decision-making power, violence	Dosing regimen	Frequency of dosing
Organizational	Clinic features (staff quality, wait time, access), workplace (schedule, culture, relationship with co-workers)	Delivery method attributes	Ease and comfort of use, physical sensation in situ, discreteness, side-effects, ancillary benefits
		Effects on everyday life	Convenience, timing of delivery method
Social and structural	Socio-cultural norms, local practices, HIV prevalence, urban/rural location	Partner's attitude	Awareness, support for delivery method use, approval/disapproval

safety syringe, all injection materials (e.g., gloves, alcohol swabs, band-aids), a sharps container to safely store used syringes, and a rapid oral HIV test (OraQuick^{Ò} in-home HIV test) to screen themselves for HIV. This package is shipped to participants' addresses in an unmarked box, and scheduled to arrive approximately 2 weeks before the injection is due. Participants are asked to verify through an

electronic system whether they have received the package; if they have not, they are mailed another.

In the group that receive injections at "drop-in" centers, participants are given an injection by a registered nurse during staggered, daily, two-hour "drop-in" windows Monday–Friday during business hours at the study clinic, a nurse-led, university-affiliated healthcare center. Specifically, the study clinic is open to participants with a designated study nurse available to give participants their CAB-LA injection and rapid blood-based HIV test that delivers results in 60-s (INSTI^{Ò}) immediately upon presenting. Participants do not need an appointment, do not complete additional questionnaires or activities other than the injection/HIV test. Study visits are intended to take less than 10 min (unless participants wish to consult with the nurse for longer).

Analysis

Audio tapes of interviews were professionally transcribed by a third-party service, and validated (e.g., confirmed for accuracy by a member of the research team comparing written transcripts to audio recordings) by the research team. A total of two interviews were completed in Spanish. For these, the same third-party service transcribed the interviews, but did not translate them. Specifically, several members of the research team, including the PI and RA, are fully bilingual (English/Spanish). Retaining the Spanish transcription allows us to validate the Spanish text against the original audio to ensure that the intent and meaning of participants' words are accurately represented. Spanish text was coded in Spanish by members of the research team fluent in this language. If selected for inclusion in this manuscript, Spanish language quotes were then translated by these individuals to English.

Data were organized using Dedoose, and analyzed using recommended practices for qualitative analyses. First, two coders independently identified codes using a multi-layered strategy for each transcript. To begin, the research team developed a list of a priori codes [19] based on topics addressed in the interview guide. Then, coders analyzed text to identify in vivo codes (e.g., language participants used to describe their thoughts/experiences with the topics covered) [20]. Codes were intended to represent the explicit and presumed meanings underlying participants' responses [21].

Working independently, coders then used criteria of "frequency" and "intensity" [22] to identify patterns and develop a list of recurring themes encompassing a priori and in vivo codes. As such, not all themes or sub-themes discussed below are representative of opinions expressed by a majority or even a plurality of participants, and in keeping with qualitative norms, we have not attempted to quantify the results.

To encourage consensus between coders, researchers compared their respective a priori and in vivo codes following the first pass through the data and discussed discrepancies (e.g., placement of specific items of text relative to codes they were intended to represent, discrepancies on how data should be categorized relative to the major themes presented) to reach agreement. To ensure that codes represented the data reasonably and realistically, codes were analyzed alongside text they were intended to represent. A priori codes that were absent from or poorly represented by the text were eliminated. Lastly, coders re-examined the data for an all-inclusive assessment of possible themes. Coders met again to discuss a priori and in vivo codes, verify that examples of text illustrated the themes they were intended to represent, and ensure consensus.

Results

Overall, the participants in this study expressed interest in CAB-LA and the three methods we propose to deliver this medication were seen as appealing alternatives to oral PREP medication. However, their responses to the proposed protocols for administering said CAB-LA differed. We identified three overarching themes that describe issues shaping desirability and feasibility of these protocols: competence/experience, relative convenience, and privacy or fear of judgement.

Competence & Experience

We define competence as the "state of having sufficient knowledge, judgment, skill, or strength" [23]. Experience, on the other hand, may simply indicate past exposure to a skill. Both competence—either their own or others'—and experience were qualities that shaped participants' preferences about administering CAB-LA injections.

Professional Expertise

Participants—even some of those who preferred self-injection—frequently explained that the assumed competency of professional health providers in delivering the CAB-LA injection properly was a major benefit of both drop-in and standard protocols. This competence was perceived as enhancing safety and reducing stress. For some, it was a key factor behind their stated preference for the provider-based protocols.

For example, Participant 101 explained that, although she liked many aspects of the self-administration protocol, having a health care worker administer the injection was appealing: *"I like the self-administration, but I also like the doctor administration more [or] the nurse administration more because I know that the medicine went in correctly."*

In addition, participants saw the clinical competence of a doctor or nurse as important due to the challenging location and size of the CAB-LA injection compared to the typical delivery of gender-affirming hormone treatments. As Participant 91 explained:

> Well, I mean, as a converse to self-injection, what I like about [the drop-in] is that you have a healthcare professional there whose job is to make sure this is done right. And so there's a certain amount of comfort in knowing that it's being done right. And, you know, it relieves you of the responsibility of having to do it yourself. And with more experience comes a better understanding of what's going—like, what spots to hit, and what not to hit, and like—you know, just, overall, it would be a better injection experience when a healthcare professional does it. Right?

The perceived safety benefits extended to knowing that there was someone with clinical competence available to assist with any follow-up needs. Participant 201 said,

> Let's say for example, if the nurse gives you the shot and in a couple of days you see, you experience a discomfort or something, right? You can always go back to that nurse and be like, 'Hey,' or call and leave a message and be like, 'Look, you gave me a shot that day, and I see this red spot. Is that normal?' You know that you can ask questions if you go to the drop-in center. I mean, you can ask questions if you do your self-injection, but it's easier for someone who feels safer getting the injection through a nurse to be like, 'I have this red spot. Is that normal?'

Even among some of those who felt capable of self-injection, having a skilled healthcare provider administer the shot was seen as a positive. Asked what she liked about the Drop-In Protocol, for example, Participant 106 explained that she liked the idea of not having to give herself the shot:

> Honestly, it just seems to make it so much easier, and not have to stress about anything. I mean, obviously you have to stress, but not have to stress about, you know, that part [self injecting].

Self-injection Confidence

Several participants, however, claimed that the skills or confidence they had developed using a similar process to self-inject gender-affirming hormone treatments prepared them practically or emotionally for the Self-Injection Protocol.

After watching the informational video, Participant 191 quizzed the interviewer about needle gauges and explained that she had injected hormones using a similar size. *"I have some understanding of how to do the needles, and I know the higher the gauge, the thinner. And I used to inject hormones like in the fat, so—like in the belly area, so for me, I'm like, oh, ok. And that [video] didn't look that bad,"* she said. She also noted her experience assisting a previous partner. *"I used to have an ex-husband that was trans, so I used to do his shots. So, for me, it's easier."*

Similarly, when asked what she liked about the Self-Injection Protocol, Participant 105 cited the use of her existing skillset. *"What you are comfortable doing already, especially trans women, 'cause I inject hormones in myself. So, I would know how to do that already with any medicine."*

However, possessing the skills to self-inject was not the only factor related to self-injection experience that made the protocol accessible. For some, prior experience self-injecting gender affirming hormones made the whole process feel less daunting. For example, Participant 106 expressed relief when the interviewer described the size and location of the proposed CAB-LA injection. *"Exactly where I get my hormones,"* she said. *"Ok, that's not bad at all… There's a lot of people [that] are not cool with giving themselves shots, but yeah, for me it's different because obviously I have to give myself a hormone shot, so I'm more used to it."*

One woman, Participant 212, even noted that, although she already self-injected, she would have to learn the specific skills needed to administer the CAB-LA shot. Nonetheless, she was confident that her existing competence at self-injecting gender-affirming hormones meant she could learn this as well:

> The thing I like is that I'll learn a new way to give myself an injection, because I've never injected myself in that part of my glutes. I do it in my thighs. So this is something I like.

Empowerment

Several participants saw developing competency in self-injection as something that would provide both a sense of empowerment and potentially a more positive healthcare experience. Participant 105 shared a popular sentiment, explaining what she liked about self-injecting: *"You know what you're doing. You have control over it."*

Participant 201 explained that she thought she would probably take more care with her own body than a healthcare provider would.

> The self-injection, what I like about it is that you do it yourself, so… you're more careful. I feel like sometimes, even though a nurse takes—you know, a nurse practices because they go to school to give shots and stuff like that, I feel like sometimes they're not mindful of people's pain… But I feel like you tend to take care of yourself more when you do a self-injection.

For Participant 701, competence with self-injection was a pathway to caring for oneself more generally. *"I like the fact that it actually forces you to be responsible with your own healthcare,"* she explained.

> That's actually something that I think is just a good thing, especially for people who are used to being marginalized by the medical community. To be able to take your health into your own hands is, I think, very comforting and very empowering for a lot of people.

Discomfort with Self-injection

For others, however, lack of experience or doubts about their ability to learn the skills to administer CAB-LA properly presented a barrier to the self-injection protocol.

One concern that came up repeatedly was about self-inflicting pain, especially because the CAB-LA is a relatively large injection. Participant 91, for example, said:

> I know personally, sometimes I'm not able to do my own shot for my hormones, simply because either like, I hit a nerve in there somewhere and I just have to pull it out, it hurts too bad, and I have to have somebody else to do it.

Participants also expressed concerns about the challenging injection site. As Participant 231 explained:

> "If it's the type of injection that needs to go specifically in the, in a specific area, that can be kind of a deterioration from wanting to actually do it yourself, because you're like, 'What if I poke the wrong spot? What if I poke a spot that's not muscle? What if I poke a spot and I start bleeding?" she said.

Similarly, Participant 701 explained that the location on the body would make it a difficult self-injection. *"I feel that I can psychologically inflict pain on myself more easily when I'm able to observe it. If I'm not looking at what I'm doing, I feel like it's going to squick me out more."*

Participants drew on personal experiences to suggest that individuals who liked the convenience or privacy of the Self-Injection Protocol, but who doubted their desire or ability to self-inject, might be able to train a partner or close friend to administer the shot for them.

While Participant 118 noted that she is afraid of needles, she said she would still consider the Self-Injection Protocol. *"I have a wife who's a CNA who could do it [the injection] for me,"* she said. Asked whether she found the Self-Injection Protocol—with the shot administered by her wife—easier than the Drop-In, she said: *"Yeah, because it would be done at home. I wouldn't have to travel. And she's there every day, Monday through Friday."* Thus, this practice opens up the benefits of self-injection to individuals who have concerns about their ability to self-inject.

Furthermore, as Participant 105 suggested, having a personal connection with the person administering the shot could even make the experience less intimidating. *"Like [name omitted] is scared of needles, but when I, when she's going to take her hormones, I give her her shot,"* she said.

Convenience

The second theme we identified as a factor in participants' perceptions of the proposed protocols was convenience, broken down as access to services, time to complete visits, and flexibility of appointment scheduling.

Accessibility

Participants repeatedly brought up the importance of geographically accessible clinic locations for both Standard and Drop-In Protocols. Participant 118, for example, explained that while she would be able to get most places, this would not be possible for many in the transgender community. *"I mean, you would have to have a space—if some people have their way, in every borough,"* she suggested.

On this same note, participants reported that one of the reasons they would consider self-injection was its relative convenience: it required no travel and no scheduling. Finding time for and traveling to visits with doctors—whether at a drop-in clinic or for a set appointment—was a challenge. Participant 701 explained:

> I like the fact that all of the materials are included and made very easy to get ahold of. You don't even have to go in [to the city] to get them. That's really a good thing. I know for myself, personally, coming into the city is a trek, and it's one that I don't like to make often,

Indeed, the need to travel to medical visits presented a potential barrier to attending and thus a hindrance to adherence to the PrEP medication. For example, as Participant 105 explained when discussing the Drop-In Protocol, *"Adding another appointment is not good. I mean, it's not that it's not good, but it's inconvenient, and people are just going to say, 'Fuck it, I'm not going to go.'"*.

That said, even self-injection can have accessibility barriers related to individuals' housing status. Participant 101, for example, suggested, *"The good solution for the homeless, it should be a main—like only for homeless a place inside of the hospital that everybody's stuff gets shipped to*."

Time to Complete Visits

However, for those willing and able to travel to the visit site—or among those for whom the benefits of clinics staffed with healthcare providers outweighed the inconvenience—the overall convenience of the visit still made a difference. Participants had different opinions about the appropriate amount of time they would be willing to spend in waiting rooms or visiting with the provider.

Some liked the efficiency and flexibility of the drop-in clinic's short visit, so long as steps were taken to ensure that capacity wouldn't get overloaded and lengthen wait times. Participant 106 compared the experience to attending a clinic for gender-affirming hormones:

> When I think about going to Callen-Lorde [Community Health Center], the only thing I dislike is just waiting in the line, or just having the appointment and then still having to wait… I'm just one of those people—I hate waiting, so as long as I don't have to wait, we'll be fine.

Participant 118 said that keeping the visit itself to 10 min (as planned in the Drop-In Protocol) would be appealing to many people. *"You can come in, sign in, get it done, and leave. That's a, b, c in 10 min and you're out. People are going to like that."*

However, a handful of participants worried that the Standard Protocol visits—estimated to take about an hour—may be too lengthy for people's schedules. Participant 701 said, "*An hour's a long time to sit for something pretty simple. And seeing everything that happens, it's obvious why it takes so long. But it's a long time."*

Similarly, Participant 106 didn't know if she would be able to squeeze these time-consuming appointments into her typical day:

> Sometimes it can be overwhelming, if that makes sense, having all of those [surveys] to do, and then you've got to be there for an hour. It's like, you just not—you know, it's just like you don't always have like an hour sometimes. I mean, you do, but sometimes for me, I'm always rushing. So it would kind of just turn into a hassle.

Flexibility

In addition to the time spent at the office, participants weighed the issue of scheduling an appointment. Some saw the flexibility of a drop-in option as something that would allow them to balance their PrEP visits with other, often shifting, obligations.

Participant 311, for example, liked the idea of having multiple days and times to choose from to accommodate her schedule.

> [I like] that you can choose Monday through Friday and the two hours a day. You know, if you can't come Monday, you can come on Tuesday. If you can't come Tuesday, you can come on Wednesday. So, it's not fixed. And you don't have to make appointments, because sometimes your work schedule changed… and then you have to change [your appointment]. So, you have all the five days and you can just drop in and then no appointment. That's very good.

On the other hand, participants noted that the ability to make an appointment—as in the Standard Protocol—came with advantages. "*You can call ahead and make your schedule, you know, schedule your appointment… so you can do it around a time that's convenient to you,"* explained Participant 201.

The ability to schedule a visit, rather than dropping in without an appointment, was seen by some as a way to keep things timely and avoid the risk of sitting in a waiting room for extended periods. *"I like setting up a specific time,"* said Participant 231. *"[It] means as long as I show up at that time, I will be seen at that time."*

Privacy or Fear of Judgement

A third significant factor that emerged as participants assessed the three potential protocols was how they were perceived by themselves and others, including medical professionals, and individuals, both transgender and cisgender. This theme, typically rooted in gender dysphoria and/or a fear of judgment, generally manifested as a desire for privacy, though to varying degrees.

Participant 191 summed up a sense of general gender dysphoria that came up among many of the participants in this study.

> "A lot of transwomen come, you know, a lot of transwomen have issues with being out in public, so I feel like it's going to be a deterrent for them, because they don't want to be out, they don't want to be around, you know, a lot of people," she said.

Thus, several participants expressed relief that the Self-Injection Protocol meant no travel or worry about somebody seeing their body. In fact, privacy and body image issues were cited frequently as reasons participants liked the Self-Injection Protocol. Participant 1007, for example, explained that just leaving the house *"can sometimes be very difficult for people with persistent dysphoria."*

Participant 221 extended this idea, explaining that concerns were also about exposing one's body to another person, even a medical provider.

> "[Self-injection] could be, you know, a good option for folks who may not have had positive experiences with being injected by a provider, or in a medical setting, or they might have, you know, kind of, certain concerns about their body, you know, and they may not feel comfortable exposing that part of their body to someone. So that's when self-injection can be an option," she said.

However, the Self-Injection Protocol wasn't without its challenges. Of note, while Participant 211 liked the option, she expressed concern that being unstably housed could raise privacy issues. *"They may not always be able to adequately store their syringes or, you know. It depends, like if there's any changes in their housing situation, or changes in privacy in their home, and things like that."*

Nonetheless, participants expressed more privacy-related concerns about the protocols that required going to a clinic, worrying about interactions with healthcare providers or other patients. For example, a concern that several participants expressed repeatedly was about the Standard Protocol's lengthy and detailed questionnaire. Participant 201, for example, worried about being judged by the health care staff. *"The only thing I would probably… feel a bit uncomfortable with is telling someone my sexual behaviors…*" she said, laughing. *"…And I'm like, oh my god, are they going to judge me?".*

Similarly, Participant 311 felt that the questions could be embarrassing and potentially a barrier for some.

> This one [protocol], I have come in every, like the same thing, and every time I would have to tell you what happened to my sexual—I think it's kind of revealing. Too much information of my sex life… Too much information. Because nobody wants to tell strangers, even their close friends, they don't want to tell them what they do with sex and with whom.

Another issue that came up for several participants was the fear of the waiting room. Some, like Participant 201, worried about how they might be perceived by cisgender patients visiting the same providers.

> It's difficult sometimes to like—that's why a lot of trans folks don't go to health providers, because, you know, the uncomfortability that they experience when they're sitting—and before, when I started to transition, I know this is a funny way of saying it, but I called it the Ugly Duckling stage. The Ugly Duckling stage is like when you're beginning your process of hormones, so you still look masculine, but you're dressing feminine. You still have that strong structure. I call it the Ugly Duckling stage… because it's the transition stage. Yeah, so but, you know, a lot of girls might not feel comfortable sitting in a clinic where there's a whole group of people.

Others were more worried about being "outed" in the waiting room for receiving PrEP to others in the trans community. For example, when Participant 101 was asked what she didn't like about the Drop-In Protocol, she explained:

> I don't like the fact that we will all be in one room waiting to see a doctor… People may know people from other ways of life and many not want them to know what or how is going about.

Participant 211 also worried that the drop-in waiting room could be too revealing. *"The community is kind of small, so like, I guess, what can we do to ensure, like, people's privacy? Like, you know, 'cause someone comes in, and maybe there's people that recognize them,"* she said.

Discussion

Overall, participants supported the tailored injection delivery methods proposed in this study. Overwhelmingly, transgender women felt that these streamlined strategies could help them to overcome some of the barriers faced in PrEP uptake and sustained use, or that they may experience with CAB-LA in the future. Participants identified three major categories of barriers and facilitators associated with our proposed strategies: competence, convenience, and privacy or fear of judgement. These categories intersected with both "influencing factor" and "acceptability components" domains of the Mensch model.

Participants agreed that it was necessary for the person injecting CAB-LA to be competent in this skill, consistent with the "delivery method attributes" and "individual characteristics" components of the Mensch Model. For example, some participants believed that they were the most competent person to administer the injection, while others found the formal training of a healthcare worker to be necessary and/or reassuring. Transgender women may be especially able to engage self-injection, and have endorsed this approach in other research [10]. Specifically, some transgender women already self-inject gender-affirming hormone medications in their gluteal muscle. More broadly, self-administered intramuscular gluteal injections are not new treatments, and have been used to treat conditions such as multiple sclerosis and female infertility [24, 25]. In this study, transgender women asserted that because of their experience with or interest in self-injection, the idea of gaining or perfecting these skills was appealing. To many participants, acquisition

of self-injection skills translated to greater control over their health, and/or better care more generally. This is consistent with some existing findings; self-management of appropriate domains of HIV can improve symptom frequency and intensity, psychosocial, and mental health-related outcomes [26].

Thus, autonomy may be especially empowering and beneficial for transgender women. Anticipating discrimination in healthcare settings, and feeling mistrustful of the healthcare system is prevalent in this population, and has been shown to delay care-seeking behavior [27–29]. Thus, building self-injection competence in transgender women has the potential to build HIV prevention self-management skills, and could facilitate uptake and consistent use of CAB-LA. However, to understand the specific preferences and support needed by transgender women to successfully engage self-injection (and other tailored injection strategies) it will be necessary to conduct a demonstration trial. This would allow researchers to amend the proposed protocols based on the real-world experiences of end-users from this population, rather than speculating on their anticipated needs.

Alternatively, some participants felt that healthcare providers had greater CAB-LA injection competence, gained through their clinical training. This was mainly due to the size (e.g., 3 mL), and location on the body of the injection (e.g., upper quadrant of the gluteal muscle). Specifically, participants feared that because the injection is relatively large, and that the location could be physically difficult to access unassisted, it would be safer and more comfortable to have a medical provider deliver it. Additionally, injection by a healthcare provider reduced anxiety related to the after-effects of CAB-LA, which can include injection-site pain, or redness or bruising. Knowing that the injection had been given by a healthcare provider increased the perception, by some participants, that it had been given properly, and therefore after-effects were not associated with an injection-related injury. This could be especially important, since in an earlier trial of CAB-LA, 59% of individuals who used this medication experienced injection-site pain [30]. Injection-site pain was also a common short-term side-effect in HPTN-083 [16].

Assurance that the "drop-in" injection protocol will keep total visit times to under 10 min (e.g., total visit time is the time from when a participant arrives at the clinic, to the time they leave) increased willingness to engage this strategy. This was true even though it would require an additional trip, highlighting the importance of the "effects on everyday life" component of the Mensch model. Still, some participants noted that finding any time to access medical appointments more generally is difficult. Among, participants who wanted to see a healthcare provider for their injections, it was important that the sites where injections are delivered should have high geographic accessibility. Specifically, participants reported that even in NYC, a city with a robust and relatively affordable public transportation infrastructure, accessing clinic sites located outside of their local communities or boroughs is difficult for many transgender women. Specifically, participants reported that cars-for-hire (e.g., taxis, app-based ride sharing, local car service) are cost-prohibitive, and that traveling by public transportation (e.g., subway, bus) is time-consuming. Other studies show that using transit for transgender women can expose them to harassment, discrimination, and/or violence [31–33], strengthening the case for convenient PrEP access. Thus, participants felt that for "drop-in" injections to be truly successful, it is necessary to have drop-in clinic locations in each of the five boroughs.

Alternately, some participants reported that any additional clinic visits, even if they were short, are inconvenient, and could pose a barrier to uptake and sustained use of CAB-LA among transgender women. For example, some participants explained that in addition to transportation challenges, economic insecurity may make it difficult for transgender women to attend visits. This is consistent with existing literature, that shows that structural forms of discrimination against transgender people that undermine their financial and housing stability can have negative implications for health seeking behavior [34]. Thus, some participants endorsed the convenience of self-injection as a motivating factor for using this strategy to deliver CAB-LA. However, participants noted that not everyone has a permanent address, and that a convenient pick-up location of self-injection materials could amplify the benefits of this strategy for this subset of transgender women. Additionally, providing a location for safe disposal of sharps containers may also be necessary and important for this group.

For those participants who wanted to have a healthcare provider administer CAB-LA, flexibility in when this is possible was important. Specifically, some participants supported the idea of offering staggered, set windows of time that they could access the drop-in clinic without an appointment. On the other hand, other participants believed that the drop-in system could increase wait times in the case that multiple people arrived at the clinic at the same time. They instead perceived a traditional appointment model (e.g., participants call in advance to book a time to receive the injection) as more time efficient.

Further, some participants disliked that the CAB-LA injection required them to reveal their gluteus, which coincides with the "effects on everyday life" and "social and structural" concerns components of the Mensch model. For example, disrobing in a clinical setting can be distressing for some transgender women [35]. Adding to this discomfort, participants reported that they feared judgement from healthcare providers for revealing details about their sexual behavior. This concern intersects with the "organizational" component of our model. Specifically, these individuals

anticipated that clinical or research staff would disapprove of their risk behaviors or gender identity, and felt reluctant to answer sensitive questionnaires. This fear is not unfounded, since experiencing judgement by healthcare providers is not an uncommon experience for transgender women [36]. Further, other participants reported that just leaving the house or being around people can be difficult if a person is experiencing severe or persistent gender dysphoria. This discomfort may stem from fear of misgendering or other stigmatizing encounters [37], or anxiety associated with using public facilities (e.g., public restrooms) [38], among other things. Furthermore, some participants acknowledged that being in the clinic waiting room could also induce distress, since they could be recognized by someone they know, regardless of that person's gender, which could unintentionally reveal health information about them (e.g., that they may be at risk for HIV). For these individuals, self-injection represented an attractive alternative, since it allowed for privacy and would not require them to interact with anyone else.

Results from other studies [39] show that effective patient education and care strategies can improve participant experiences with CAB-LA. This is likely especially important for indivdiuals who elect to self-inject; we considered this in our current research. Specifically, to optimize the participant experience and adherence in this study, we are developing a smartphone app to provide CAB-LA content, including self-injection support resources. The app is currently in beta testing and results will be presented in a future manuscript.

Though we did not explore this topic in this study, another consideration for future research is how routine lab management might fit into CAB-LA protocols. Specifically, uptake and sustained use of CAB-LA may require liver and kidney function tests, STI monitoring, and bone density testing [40]. It will be important to integrate this routine monitoring into patient schedules; understanding both consumers' and providers' preferences will be important. One potential strategy to incorporate routine lab management into the streamlined delivery of CAB-LA injections is to integrate this into the smartphone application we are building as part of this study. This is in line with other trends, driven by the COVID-19 pandemic, that necessitate "at home" and/or self-management for continued PrEP use, such as self-HIV testing, and telehealth consultations with PrEP providers. Another topic that was not discussed in this study is the possibility of integrating CAB-LA with gender-affirming care visits for transgender women. Future studies should consider exploring this option, since it could be a convenient way to integrate PrEP care into this population's existing health routines.

Though it appears that these tailored CAB-LA delivery strategies are hypothetically acceptable to transgender women, empirical data in the form of a randomized control trial (that also assesses cross-interactions with gender-affirming hormone medications) demonstrating acceptability and feasibility are needed. It will also be necessary in this phase of research to understand how the oral lead-in might affect adherence and willingness to start CAB-LA, since a prior study suggests this is a potential barrier [9]. Additionally, future studies should assess provider buy-in (e.g., prescribers and nurses) of these interventions (and CAB-LA more generally) to determine clinical feasibility. Lastly, it will be necessary to develop effective communication strategies, tailored to the needs of transgender women and their PrEP providers, to optimize discussions around the uptake and sustained use of this product. Without these critical components, it is unlikely that CAB-LA or the tailored CAB-LA delivery strategies proposed here will be implemented in the "real world." We note that qualitative work by our group is currently under way to understand provider perspectives on CAB-LA and how tailored delivery strategies could fit into existing or future clinical practice.

Taken together, our findings show that it is important to present multiple types of injection strategies to transgender women. Specifically, different women in the population will have different skills, comfort levels, and expectations about CAB-LA injections. This necessitates the cultivation of a suite of delivery options to optimize uptake and sustained use of this HIV prevention method.

Limitations

This research was conducted in NYC, and the experiences of transgender women in this setting may differ from those individuals living in other regions of the country, or in less urban contexts. Specifically, in NYC there are multiple healthcare organizations that prioritize the unique needs of this population, and transgender-focused health advocacy groups. Though we can only speculate, transgender women living in other settings may not have the same level of access to transgender-competent care, which could increase the need for, and impact of self-injection. More research on transgender individuals residing in the interior of the United States, suburban, and rural contexts is urgently needed. Furthermore, participants endorsed positive and negative beliefs about each of the proposed tailored injection strategies. We did not ask participants to indicate which strategy they would prefer, since they will be asked to do this in subsequent phases of research (e.g., in a partially randomized patient preference trial). Thus, at this time, we do not have a clear idea of which strategy participants favored. Additionally, all interviews and coding processes were carried out by cisgender-identified individuals. This could introduce bias or unintentionally omit nuances that would be otherwise captured by gender diverse personnel. Additionally, the lengthy nature of control group procedures may not be replicated

in "real world" implementation of CAB-LA delivery. That is, different settings will have different strategies to identify, initiate, and maintain transgender women on CAB-LA. Also, the survey and other research procedures used here are unlikely to be replicated in actual clinic visits. Extended visit procedures will be a universal feature across sites, as we assume in this research. Lastly, we acknowledge that the lack of demographic information about our participants is a significant limitation. Still, we feel that even with these limitations, given the dearth of research on this topic and the likely imminent approval of CAB-LA, we make an important contribution to the literature.

Conclusion

Our findings support the need for and feasibility of offering PrEP through multiple protocols. Transgender women face several social, psychological, and structural barriers to accessing medical care or participating in clinical trials. By providing options that build on existing strengths and make space for personal preferences, there is greater potential to ensure trials (and care provision) is inclusive of this high-risk group.

Authors' contributions Dr. CTR is the PI of the study, drafted this manuscript and performed primary data collection duties. Dr. SAMcK and Mr. JL-R (who also participated in data collection) analyzed data and drafted results. Dr. CD managed data and Drs. AC-D, RS, TJH, JB, and WB provided mentorship support to Dr. CTR, as part of her K01. All authors listed in this citation contributed to critical revision of this work.

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Declarations

Conflict of interest The authors have no conflicts to declare.

Ethical Approval Research was approved by the Institutional Review Board (IRB) at the New York State Psychiatric Institute.

Consent to Participate Prior to participation, all participants provided written informed consent. Participation was voluntary and confidential; any identifying information has been removed from quotes presented in this manuscript to protect confidentiality.

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