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Preferences for pre-exposure prophylaxis (PrEP) among men who have sex with men and transgender women at risk of HIV infection: a multicentre protocol for a discrete choice experiment in Brazil

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ABSTRACT

Introduction Pre-exposure prophylaxis (PrEP) is an important and well-established prevention strategy for sexual acquisition of HIV. In Brazil, transgender women (TGW) and men who have sex with men (MSM) bear the largest burden among key populations. Little is known about preferences for PrEP characteristics in these vulnerable populations in Latin America. The goal of this study is to investigate preferences of TGW and MSM with respect to PrEP characteristics, whether current user or not, and to assess any attributes and levels that may improve the decision to start using PrEP (uptake) and optimal continuity of use (adherence), which are important dimensions for PrEP success.

Methods and analysis We hereby outline the protocol of a discrete choice experiment (DCE) to be conducted among TGW and MSM in Brazil. The study will be carried out in two phases. The first phase involves literature review and qualitative approaches including in-depth interviews to inform the development of the DCE (attributes and levels). The second phase entails the DCE survey and supporting questions pertaining to sociodemographic and risk behaviour information. The survey is aimed at current PrEP users and non-users, consisting of two modes of administration: face to face in five Brazilian capitals (Rio de Janeiro, Brasília, Manaus, Porto Alegre and Salvador) and online targeting the entire country. A D-efficient zero-prior blocked experimental design will be used to select 60 paired-profile DCE choice tasks, in which participants will be randomly assigned to one of four groups and presented with a set of 15 choice tasks. The planned sample size is 1000 volunteers.

Ethics, timeline and dissemination The study was approved by Comitê de Ética em Pesquisa—Instituto Nacional de Infectologia Evandro Chagas—INI/FIOCRUZ, CEP/INI, CAAE 28416220.2.1001.5262, approval number 3.979.759 in accordance with the Comissão Nacional de Ética em Pesquisa (CONEP—Brazilian National Board of Research Ethics). The study will be conducted between 2020 and 2021. The results will be disseminated to the scientific community and to the public in general through publications in published in peer-reviewed journals and in scientific conferences.

Strengths and limitations of this study

- ► The study uses a discrete choice experiment (DCE) to elicit the preferences of men who have sex with men (MSM) and transgender women (TGW) regarding pre-exposure prophylaxis (PrEP) attributes.
- ► PrEP preferences may be used to further develop health technologies and programmes targeted at key populations.
- ► DCE data will allow researchers to obtain relative preference weights that will improve our understanding about factors that are most important in PrEP uptake and adherence for MSM and TGW.
- ► There may be limitations regarding the generalisability of these DCE results to other populations of users or potential PrEP users.

INTRODUCTION

Brazil has the largest population living with HIV/AIDS in Latin America and men who have sex with men (MSM) are disproportionally affected.[1] Approximately 52% of reported HIV infections among men are attributed to male-to-male sexual contact[2] and new infections are on the rise in this population, especially among young MSM (aged 24 years or younger).[3] Transgender women (TGW) are also overly affected by the HIV epidemic in the country, bearing the largest burden

among any key population.[4 5] Since December 2017, daily oral pre-exposure prophylaxis (PrEP) with emtricitabine and tenofovir disoproxil fumarate (FTC/TDF) has been offered in the Brazilian Public Health System without direct costs, including counselling, testing consultation and other services included in the guidelines, to those at heightened risk of HIV acquisition, including eligible TGW and MSM.[6]

As access to PrEP expands, it is important to consider that its success depends on optimal adherence.[7–10] Data from PrEP programmes generally show declines in the use of PrEP in the initial months stemming from the challenges of daily pill taking.[11] Event-driven PrEP (ED-PrEP) or on demand PrEP, which consists of taking two pills of FTC/TDF 2–24 hours before sex, one pill 24 hours after first pills and one pill 24 hours after the third pill, has been proved to be effective for HIV prevention among MSM, and could be an option for those who are less sexually active and/or do not want/are able to take or adhere to daily PrEP.[12] ED-PrEP has been endorsed by WHO and has been found acceptable among MSM from France, Belgium and Netherlands. Nevertheless, adherence challenges need to be better understood both in terms of the needs and preferences of specific populations. It becomes crucial to investigate the factors that sway the decisions to initiate PrEP and its continuity with adequate adherence and persistence over time. To deal with the resulting challenges, alternative PrEP agents are under development, including long-acting injectables, which have the potential to prevent the acquisition of HIV overcoming the daily oral regimen adherence. Similarly, vaginal rings and films, implants and transdermal compounds are being studied to increase the biomedical possibilities of HIV prevention that attract the greatest possible number of individuals.[7 13]

The aspects surrounding this decision-making process for MSM and TGW are not fully understood. A Brazilian transspecific PrEP demonstration study called PrEParadas showed that TGW had a good uptake and adequate PrEP adherence, despite being a hard-to-engage group. However, more vulnerable TGW had the worst adherence levels, thus deserving more tailored strategies for PrEP delivery.[11] A systematic review showed diminished PrEP awareness and many particularities that could be barriers to adherence for transgender populations, such as concerns regarding interactions with hormone treatment and distrust in health services.[14] Another systematic review grouped the reasons for poor adherence to oral PrEP and for non-acceptance among individuals engaging in high-risk behaviour across different studies, which were: side effects, low-risk perception, logistics of daily life, stigma, medication regimen and socioeconomic factors.[11] Despite challenges worldwide, Brazil's first PrEP demonstration project (PrEP Brasil) showed that interest in PrEP was high, with 60.9% uptake.[15] To sustain interest and compliance, it is crucial to deepen our understanding about PrEP preferences among MSM and TGW in order to tailor and offer the best alternatives for long-term outcomes.

One way to measure PrEP preferences is by asking individuals about their preferences in hypothetical scenarios. These types of strategies are called stated preference techniques and discrete choice experiments (DCEs) are an attribute-based approach to collect this type of data.[16 17] DCE involves presenting respondents with choice sets composed by two or more competing alternatives that vary along several attributes, which are the factors that affect choice. Therefore, in our research question, an attribute is a qualitative characteristic of PrEP, while a level is one of several values one attribute might have. DCE entails a process of identifying the most relevant attributes and their respective levels. An attribute could be the frequency of PrEP use and the attribute levels, could be, daily, event-drive or yearly, for instance.

DCEs have been widely used in health,[18–20] to a great extent in HIV research as well,[21 22] but only a handful of studies have been carried out to solely investigate PrEP preferences.[23–28] A study conducted in South Africa examined youths' preferences for PrEP, focused on relevant characteristics to product delivery and modifiable attributes.[24] One US study focused on PrEP delivery programmes for MSM;[25] another study developed in Uganda assessed the acceptability and potential uptake of PrEP among fishing communities;[26] a study developed in Malawi explored preferences of PrEP delivery among HIV-uninfected female sex workers[27] and a DCE was implemented in Ukraine to study strategies to implement PrEP with MSM.[28] The most important attributes identified in these studies were affordability (or cost), dispensing location, HIV prevention effectiveness, PrEP form and dosing strategy. Although some of these attributes do not apply to health systems with universal healthcare such as Brazil, they stress other important attributes such as PrEP effectiveness towards HIV prevention, PrEP presentation and dosing frequency. It is important to mention that the current DCE literature does not address PrEP preferences for TGW, and to our knowledge, no PrEP DCEs have been performed in Latin America.

METHODS AND ANALYSIS

To measure preferences for PrEP, a DCE was developed based on Random Utility Theory.[29] It is assumed that choices individuals make, maximise their utility. The goal is to estimate preferences according to a particular set of attributes. The first step is to identify and select a set of attributes that will reflect all the characteristics that are relevant for the choice of PrEP. The attributes (presentation of PrEP, whether a pill or an injection, for instance) are broken down by their different levels (eg, pill, injection or implant). The levels of the attributes are varied systematically and shown in a series of different choice sets, each with the same number of alternatives. The preference weights for attributes and their levels make up for the overall utility of each alternative. It is important to note that observed choices inform about relative weights

Table 1 Literature summary on discrete choice experiments applied to PreP

Study	Country	Target population	n	Mode of administration	Attributes and levels
Minnis *et al*[24]	South Africa	sexually active, PrEP-naive youth	807	Face to face	Five attributes: form, dosing frequency, access, pain, and insertion site. Across all groups, duration of effectiveness was the most important attribute, with strong preference for less frequent dosing.
Dubov *et al*[25]	USA	MSM	554	Not explicit	Five attributes related to PrEP administration: dosing frequency, dispensing venue, prescription practices, adherence support and costs.
Kuteesa *et al*[26]	Uganda	HIV-negative members of fshing communities	713	Face to face	Product attributes were: HIV prevention effectiveness, sexually transmitted infection (STI) prevention, contraception, waiting time and secrecy of use.
Lancaster *et al*[27]	Malawi	Female sex workers	150	Face to face	Final attributes included: dispensing location (STI clinic, family planning clinic, ART clinic, NGO-run drop-in centre, NGO-run mobile outreach), clinic wait time (1 hour, 2 hours, 3 hours), provider gender (male or female), frequency of pick-up (1 month, 2 months or 3 months) and provision of additional services (risk counselling, cervical cancer screening, pregnancy testing or contraceptives). Dispensing location was most preferred, followed by the provision of additional services. Women preferred receiving PrEP at family planning clinics or NGO run drop-in centres.
Dubov *et al*[28]	Ukraine	MSM	1184	Online	Five attributes related to PrEP administration: dosing frequency, dispensing venue, prescription practices, adherence support and costs.

ART, antiretroviral therapy; MSM, men who have sex with men; NGO, non-governmental organisation; PrEP, pre-exposure prophylaxis.

of preferences for attributes and levels and about the overall utility of each alternative.

We followed current guidelines from International Society for Pharmacoeconomics and Outcome Research (ISPOR)[30–32] and the mainstream literature on DCE on how to identify and select attributes and levels and followed the steps: review of the literature to better understand the problem, compile and systematise the evidence; consultation of experts on PrEP; in-depth qualitative interviews with current and non-users of PrEP as relevant actors; pilot tests, and, lastly, conduct the DCE both face to face with the aid of tablets and online.

Literature review, evidence synthesis and qualitative phase

We conducted a literature review to identify all important characteristics related to PrEP uptake and adherence, in terms of existing technologies as well as new drugs and technologies in the pipeline. PrEP with oral tenofovir disoproxil fumarate and emtricitabine has been recommended by WHO to reduce HIV incidence. Although highly efficacious, this PrEP presentation may not be optimal for some vulnerable populations. New PrEP agents include novel oral agents, long acting injectables, vaginal rings, topical products (tablets, gels, films, enemas), neutralising monoclonal antibodies and other multipurpose technologies.[7 33–35] In table 1, we provide a list of the PrEP attributes and levels captured in the DCE studies we found during our literature review. The pictorial cards with the five attributes and respective levels, and a sample choice task are provided as online supplemental files.

Consultation of current TGW and MSM PrEP users and non-users and healthcare professionals

At this phase, we had a list of a priori PrEP attributes and levels from the literature review, but discussions with healthcare professionals devoted to HIV care and PrEP delivery to MSM and TGW groups were useful to raise new ones. Emphasising important attributes to patients' realities helped to bring up some new levels and attributes.

Third, we conducted qualitative interviews in the form of in-depth interviews with eight individuals, four current PrEP users (two MSM, two TGW), four non-users of PrEP (two MSM, two TGW) during September 2020. Participants were recruited at Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz (INI-FIOCRUZ), which currently provides HIV prevention services, including HIV testing and provision of PrEP, and hosts clinical trials and demonstration studies such as ImPrEP,[36] from which recruitment to pilot studies and DCE in Rio de Janeiro took place. Individuals participated on a voluntary basis and gave informed consent prior to being included in the study. The interviewer was a researcher from FIOCRUZ. The goal of the interviews

was to hear about general views of PrEP, regarding the chosen attributes and levels; how those currently using PrEP felt about it, and adherence levels and difficulties experienced; and the perceptions that non-users had about PrEP, eventual obstacles, barriers, and any ideas they had. The overall goal was to make sure most important attributes and levels were correctly covered by the DCE, and that none of the chosen attributes was dominant. In total, we conducted 22 interviews with PrEP users/non-users, health professionals (Infectious diseases specialists and PrEP specialised professionals such as a pharmacist, a psychologist and nurses), PrEP study coordinators in all five sites and LGBTQIA + community engagement workers.

Development of the DCE

Literature review and qualitative interviews resulted in a list of five attributes with three or five levels. The first attribute was PrEP presentation (type) in three levels: oral, injectable or implant. The second attribute was frequency of PrEP use with five levels: once daily, on demand, monthly, once every 2 months or once per year. The third attribute was frequency of visits to healthcare services with three levels: once every 2 months, once every 3 months or once per year. The occurrence of side effects was the fourth attribute with three levels: no side effects, mild or moderate. The fifth and last attribute was level of HIV prevention: 9 in 10 users remaining HIV negative, 8 in 10 users remaining HIV negative or 7 in 10 users remaining HIV negative. We designed picture cards for all choice sets to improve understanding (online supplemental material).

DCE recruitment and inclusion criteria

User preferences for different PrEP presentations will be elicited through the administration of DCE in a mixed mode of administration, either face to face or online. Inclusion criteria for face-to-face recruitment include 18 years of age or older; male sex assigned at birth; negative HIV serology. It will take place at five sites devoted to HIV testing and PrEP provision in five Brazilian capitals: Rio de Janeiro, Brasília, Salvador, Porto Alegre, and Manaus. Some of the recruited participants may also be enrolled in other studies within the ImPrEP Project, which is a transnational project in Latin America to generate evidence on the feasibility, acceptability and cost-effectiveness of PrEP among MSM and transgender people.[36 37] DCE may use the infrastructure of other studies for data collection but will have specific training of interviewers and protocols. Furthermore, DCE will not influence other studies in the selection of participants or vice versa.

The online mode of administration will obtain its convenience sample by recruiting eligible MSM and TGW from gay dating apps Hornet and Grindr through paid advertisements leading to the study link. Other studies have been successful in recruiting through these apps.[38–42]

Sample size

We followed the recommendations given by Orme[43] who suggests that if the purpose is to compare groups and detect significant differences, the sample size should be large enough to accommodate a minimum of 200 individuals per group. Given that we are interested in carrying out analyses for four subgroups (MSM current using PrEP, MSM not using PrEP, TGW current using PrEP and TGW not using PrEP), we aim to include 4000 participants; 1000 face to face and 3000 online as we wish to explore different response patterns between the two modes of administration. We foresee it will be possible to recruit at least 3000 MSM and 400 TGW.

Design of DCE

We used the Ngene software (V.1.2.1, 2018, build 18121)[34] to develop the experiment. We took into consideration the number of attributes (5) and levels (3 or 5) to obtain the optimal number of choice sets. Care was taken to ensure the number of choice sets was a reasonable cognitive task. We used a D-efficient zero-prior blocked experimental design[44 45] consisting of 4 blocks of 15 unique choice tasks (D-error=0.03). Implausible combinations of attribute levels were not included. We have also added two dominant questions at the end of the experiment contrasting the least and most desired attribute levels in identified in the qualitative phase of the study.[31] These two questions, in which an alternative has attribute levels that are all better than the attributes of the other alternative in the choice set will allow the tabulation of response errors and indicate how these errors are related to some demographic variables. Our experiment does not anticipate the inclusion of an opt-out option, as its inclusion would limit our ability to estimate the underlying preference structure as this option would result in censoring our data.[31]

Presentation of DCE to participants

We begin by telling respondents they will be introduced to some PrEP options. We then explain they will be introduced to situations in which they will have to choose between two products (product A or product B) considering the characteristics described for each one. We clarify that some of the products may still be under research and development, and that the characteristics presented are hypothetical, that is, they may not reflect the reality of products already available for PrEP. Subsequently, we provide extensive written and pictorial explanations (table 1) of all attributes and levels and of what the experiment consists of. Respondents are told to choose only one of two options, which would be the preferred option, with no right or wrong answer.

Other questions in the survey

The survey contains additional questions that include a checkbox for inclusion criteria, sociodemographic information, hormone/implant use (for TGW), substance use,

sexual behaviour, HIV risk perception and PrEP (use, knowledge and adherence).

Recruitment of interviewers and pilot testing

We recruited healthcare professionals or individuals with previous experience and engagement with MSM and/or TGW communities, to administer the tablet assisted face-to-face DCE part of the study. Specific training was provided to them.

Individual pilot interviews using tablets were conducted with 10 individuals to ensure the wording was appropriate and the questionnaire was comprehensible, feasible and appropriate.

DCE data analysis

To obtain the preferences of TGW and MSM regarding PrEP, in terms of the relative preference weights for chosen attributes and levels, data will be analysed using a conditional logit model, random-parameter logit and latent class models[46] in Stata, Release V.16.1.[47] The preference weights will allow us to describe the relative strength of each attribute and level in comparison, respectively, with all other attributes and levels. For the calculation of ratios describing the trade-offs respondents are willing to make among the attributes, we plan to use risk equivalence (maximum acceptable risk), or time equivalence for changes in attributes or attribute levels.[31]

Ethics, data analyses and dissemination

This DCE has been approved by the local ethics committee (Comitê de Ética em Pesquisa do Instituto Nacional de Infectologia Evandro Chagas da Fundação Oswaldo Cruz, approval number 3.979.759, CAAE: 28416220.2.1001.5262, issued on 18 April 2020). Each local study site collection had separate approvals as follows: Brasília, FIOCRUZ Brasília, approval number 4.218.010, CAAE 28416220.2.2002.8027 (17 August, 2020); Manaus, Fundação de Medicina Tropical Dr Heitor Vieira Dourado, approval number 4.172.506, CAAE 28416220.2.2001.0005 (24 July 2020; Salvador, Secretaria da Saúde do Estado da Bahia—SESAB, approval number 4.291.299, CAAE 28416220.2.2003.0052 (22 September 2020); Porto Alegre, Secretaria Municipal de Saúde de Porto Alegre/SMSPA, approval number 4.188.326, CAAE 28416220.2.2004.5338. Data analysis will be performed according to best practices and recommendations published by the ISPOR.[29–31] The results will be disseminated to the scientific community and to the public in general through publications in published in peer-reviewed journals and in scientific conferences.

Patient and public involvement

Members of the public were involved in the piloting phase of the study. No patients were involved. The results of the DCE will be disseminated to the public in the form of scholarly manuscripts and through other media. A summary sheet will be sent to participants and circulated via the same channels that were used to advertise the experiment.

Study timelines

Survey development ran from December 2019 to December 2020. Survey administration and data collection will be conducted from September to October 2021. Analysis will be conducted from November to December 2021.

ImPrEP DCE study team

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Correction notice This article has been corrected since it was published. The word 'weekly' is changed to 'monthly' in section 'Development of the DCE'.

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Contributors CCdAP and TST conceptualised the study and led the writing of the manuscript, including the development of the statistical approach. PML, BH, AF, JDUB, MVGL, DARdS, MB, MCP, BG and VGV supported the development of project, the research design and contributed to the drafting and editing of the protocol. All authors read and approved the final protocol.

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