Introduction and Background

PrEP is a World Health Organization (WHO) recommended new HIV biomedical intervention, as it seeks to reach people at high risk for HIV infection [1]. Several study trials targeted at men who have sex with men (MSM), injecting drug users (IDUs), women and serodiscordant couples have shown that when PrEP is taken daily (i.e. oral anti-retroviral drugs containing tenofovir disoproxil fumarate, or TDF), it effectively reduced new HIV infections up to 92% [2, 3]. However, despite the facts that PrEP is efficacious, cost-effective and recommended by the U.S. Centers for Disease Control and Prevention (CDC), PrEP uptake among healthcare providers has reminded low [4, 5].

Each step of the PrEP care continuum is critical for PrEP to have a sufficient impact. Thus this low PrEP prescription in providers demands immediate attention, particularly in regions that have a large burden of HIV and have been slow to implement PrEP, such as Atlanta metropolitan area, Georgia. There is an urgent need to develop an effective intervention to promote PrEP prescription among healthcare providers.

The PRECEDE-PROCEED model can serve as a useful tool to help researchers to develop a promotion intervention on the prescribing behavior [6]. Prior to planning a promotion intervention, researchers need to conduct assessments of the behavioral and environmental factors of the behavior. Bartholomew and colleagues (2011) suggested the assessments should consider applying the ecological model in reviewing the determinants of behaviors at multiple levels: personal, interpersonal, organizational, community, and societal level [7].

Studies to date have listed a number of factors that influence providers' PrEP prescribing behaviors at different levels; for example, concerns about PrEP effectiveness, negative colleague attitude, system limitations, lack of awareness in the community, etc. In this phase, based on the PRECEDE-PROCEED model, researchers should start selecting and categorizing predisposing factors (e.g., personal knowledge, attitudes, and beliefs), reinforcing factors (e.g., behavior, peers), and enabling factors (e.g., availability of resources, accessibility, and skills), as these factors collectively determine behavior change.

However, very limited research has been done on examining the enabling factors of PrEP prescription. Though Krakower et al. (2014) identified normative clinical guidelines (individual-level) and patient motivation (interpersonal-level) as two main facilitating factors for providers to prescribe PrEP [8], knowledge about facilitators at organizational-level (e.g. accessibility), community-level (e.g. resources), or other personal-level factors (e.g. motivation, incentives) are scarce. Krakower and Mayer (2012) pointed out that monetary incentives could improve primary care physician management of disease risk factors for patients [9, 10]. Yet few research studies have investigated the ways to incentivize providers in the context of PrEP care.

In order to fill this gap, this study proposes to examine the enabling factors for active providers to prescribe PrEP at different levels (individual, interpersonal, organizational, community, and societal). In addition, the proposed study plans to explore clinicians' strategies for overcoming barriers and becoming successful PrEP prescribers.

After a full assessment of the influencing factors, the PrEP prescription promotion should begin with establishing a promotion implementation group and including the stakeholders who have a thorough understanding of existing PrEP care practice from multiple perspectives. Such implementation group can facilitate an intervention to be effective and culturally appropriate [7]. However, before developing any promotion implementation plan, researchers need to know: what is the current PrEP care delivery system, and what is the best PrEP care delivery system? Latest studies reported that providers who are practicing PrEP care in the U.S. are taking a "patient/client-centered" model, or a "client-driven" model [17, 18]. However, there is a lack of description and characterization of the existing PrEP care models. It is unclear whether these PrEP care models are functioning as business models, whether they are successful in management and other aspects, or what might be the performances and critical success factors within these models.

Business Process Management Model is an established business model, which has been widely applied in various fields including healthcare [11]. According to CDC, the Business Process Management Model serves as a successful driver in the development of Sexually Transmitted Disease (STD) Prevention across the US. Components of this model include prioritizing patients' needs, assessing resources and productivity, financial management, etc. However, no study has compared the similarities and distinctions between current "client-centered" PrEP care model and the STD business management model. Understanding the possible overlapping success factors in both models is essential to identify opportunities for current PrEP care model to adapt and scale.

Specific Aims

To fill aforementioned gaps, we propose to conduct a qualitative study of interviews with active PrEP prescribers who have been using PrEP in the past 12 months in both primary care and infectious disease settings in the state of Georgia, to gather an in-depth understanding of the following aims:

For multilevel enabling factors of PrEP prescription:

1) To examine and describe the enabling factors for prescribing PrEP at different levels (individual, interpersonal, organizational, community, and societal) among current active PrEP prescribers in Georgia;
2) To examine and describe clinicians' strategies for overcoming barriers and becoming successful PrEP prescribers.

For PrEP care business model:

3) To examine and describe the existing PrEP care models in Georgia, and to examine providers' perception of the performances and critical success factors within these models;
4) To examine and describe providers' perception of the opportunities for current PrEP care model to adapt and scale, by comparing and contrasting the "client-centered" PrEP care model with the STD Business Process Management Model.

Methods

The methodology of proposed qualitative study will be semi-structured Interviews, which are an important way to obtain comprehensive and in-depth qualitative data. This is particularly important when concepts are new or novel.

Procedures and Participant Selection. Semi-structured interviews will be conducted among up to 20 clinicians (10 primary care providers and 10 infectious disease practitioners) who have prescribed PrEP for the past 12 months in Georgia. We will use PrEP Locator (a national online directory of providers of PrEP in the U.S. led by Dr. Aaron Siegler, Research Assistant Professor of Epidemiology at Emory University's Rollins School of Public Health) as a registry for eligible participants in Georgia, and will identify up to 10 eligible primary care PrEP prescribers and up to 10 eligible infectious disease specialists in Georgia. Selected participants will be contacted via phone and asked about their PrEP care service experience in the past 12 months. If patients self-reported having prescribed PrEP in the past 12 months, they will be invited to participate face-to-face interviews in proposed study. Researchers will introduce the interview process, purpose, and incentive to participate in the interviews ($50 gift card per participant). If we are unsuccessful at reaching the selected participants, we will revisit PrEP Locator to identify additional eligible participants. We estimate a conservative period of two months to establish our interview sample.

Semi-structured Interviews. Research staff will schedule participants for the venue-based semi-structured interview at times convenient to participants. Participants will be sent email reminders the day before and day of the interview. Each semi-structured interview will be conducted in person (in order to describe the organizations where the clinicians are at), roughly 60 minutes long, audio-taped, and guided by standard principles of qualitative methods. Two researchers from the proposed research team will be trained to conduct the interviews. Dr. Siegler has rich experiences in conducting semi-structured interviews and will oversee the entire interview procedures.

Measures. The interview guide will focus on current PrEP prescribers and to examine their 1) multilevel enabling factors for prescribing PrEP; 2) strategies for overcoming barriers and becoming successful PrEP prescribers; 3) perceptions of PrEP service business model; and 4) perceptions of the opportunities for current PrEP care model to adapt and scale.

Data Analysis. Semi-structured interviews will be transcribed by a professional transcription service. Qualitative data will be analyzed using standard principles of qualitative methods and NVivo (QSR International, Cambridge, MA), a qualitative data analysis tool. Three coders (the investigators on the team) will independently review transcripts, generate preliminary codes, meet to refine primary and secondary code definitions, then independently code transcripts, applying the agreed upon codes. Independently coded transcripts will be compared for discrepancies; a consensus will be reached. Transcripts will be recoded using the final consensus outline. We will compare and contrast 1) primary care prescribers versus infectious diseases prescribers; 2) urban versus rural PrEP prescribers.

Timeline. In the first two months, we will identify and recruit interview participants. In the following five months, we will conduct up to 20 interviews with PrEP prescribers in Georgia; in the last five months, we will contract for interview transcription, complete interview data analyses and write manuscripts.

Anticipated Results and Healthcare Delivery

We anticipate two scientific manuscripts to be extracted from the results of proposed study: one focuses on the enabling factors of prescribing PrEP in Georgia; another focuses on examining and describing existing PrEP care model in Georgia in comparison to the established STD Business Process Management Model.

The proposed research is particularly timely, as it provides insights from successful prescribers that then might inform strategies to further improve uptake of the recommended HIV prevention strategy. The study also describes current models of PrEP care and explores business and management opportunities for PrEP care delivery to scale in diverse clinical settings.

In summary, the proposed study facilitates PrEP healthcare delivery for HIV specialists, primary care providers, and STD clinicians that deliver care to persons who may benefit from PrEP, including MSM, IDUs, transgender women, and at-risk youth in the State of Georgia.

Project Significance

Georgia is one of the states with highest rates of new HIV diagnoses, and metro Atlanta has the second highest city-specific number of new HIV diagnoses among MSM in the United States [12]. Pre-exposure Prophylaxis (PrEP) holds great promise to prolong life and decrease HIV susceptibility (for those who are HIV-negative). However, actual PrEP usage in clinical settings has remained low. This gap in the PrEP care continuum demands immediate attention, particularly in geographic areas that have a large burden of HIV and have been slow to implement PrEP, such as Georgia [13]. The likelihood of appropriately receiving a PrEP prescription would increase as a result of an effective promotion on providers' prescribing behaviors.

The proposed study, as well as those prior studies, serve as a critical formative research for developing strategies to enhance clinicians' willingness and intention to prescribe PrEP and thus may increase providers' independent momentum to offer PrEP care. This study also assesses the success factors of current PrEP care models, which could help develop effective mechanisms for disseminating PrEP services in Georgia.

The distribution of practical clinical experience about novel healthcare strategies is slow in the field of HIV prevention as well as other topics in health. The findings of this study on PrEP care may have implications for other similar health innovations and help to foster greater clinical community exchange of information and shared practice.

We aim to disseminate study findings via journal publications and conferences presentations to contribute to the evidence base for subsequent action related to PrEP care promotion.