2019

Outcomes from an urgent care pre-exposure prophylaxis (PrEP) protocol for the prevention of HIV

Jack J. Mayeux

OUTCOMES FROM AN URGENT CARE PRE-EXPOSURE PROPHYLAXIS (PrEP) PROTOCOL FOR THE PREVENTION OF HIV

by

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A DNP PROJECT

Submitted in partial fulfillment of the requirements for the
Degree of Doctor of Nursing Practice
to
The School of Graduate Studies
of
The University of Alabama in Huntsville

HUNTSVILLE, ALABAMA
2019

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Date

DNP PROJECT APPROVAL FORM

Submitted by _____Jack J. Mayeux____ in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

10/9/19 _____ Committee Chair
(Date)

_____ Clinical Site Mentor

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_____ College of Nursing, Dean

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ABSTRACT
The School of Graduate Studies
The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate: Jack J. Mayeux

Title: Outcomes from an urgent care pre-exposure prophylaxis (PrEP) protocol for the prevention of HIV

Objective: To evaluate the effectiveness of a pre-exposure prophylaxis (PrEP) implementation protocol designed for use within the urgent care, specifically, to improve awareness and knowledge of PrEP, reduce barriers to PrEP use, and improve the rate of PrEP use.

Design: IRB approved quality improvement project to disseminate a PrEP initiation protocol for the urgent care provider.

Setting/Local Problem: Six urgent care clinics located throughout the state of Louisiana.

Participants: Physicians, nurse practitioners, and physician assistants providing patient care at six urgent care locations aged 19 years and older.

Intervention/Measurements: An urgent care specific PrEP protocol was developed and disseminated to 31 providers. A Pre-test was administered and collected at the beginning of the project as a baseline, followed by a post-test at week 20.

Results: Overall results of the survey show a significant change ($t(28) = -3.04$, $p = .005$) between the pre-intervention ($M = 30.82$, $SD = 6.66$) and post-intervention ($M = 35.82$, $SD = 7.59$) surveys. Additionally, the protocol resulted in a significant improvement in the knowledge rating $t(28) = -6.20$, $p = .001$ and the level of comfort with PrEP $t(28) = -4.70$, $p = .001$ among the medical providers.

Conclusion: The overall development and dissemination of PrEP protocol for the urgent care setting produced positive statistically significant increases in overall provider knowledge of PrEP, comfort with PrEP, and a decrease in barriers associated with PrEP use in the urgent care setting.

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Outcomes From An Urgent Care Pre-exposure Prophylaxis (PrEP) Protocol For The Prevention Of HIV

Section I: DNP PROJECT

Identification of the Problem

Background of the Problem

While there are many sexually transmitted infections (STI) that cause a burden on society, few have the scope and magnitude of human immunodeficiency virus (HIV) (Centers for Disease Control and Prevention [CDC], 2014). Currently, there are 1.1 million people in the U.S. with HIV, with approximately 15% unaware they are already infected (U.S. Department of Health and Human Services [HHS], 2017). Despite these current statistics on the rate of HIV, strides have been made in reducing the rate of new infections. The latest statistics show the rate of new HIV infections have fallen from 41,800 for 2010 to 38,500 in 2015 (CDC, 2018). Furthermore, the rate of newly diagnosed individuals with HIV in the U.S. has also declined by 5% from 2011 to 2015 (CDC, 2018). These statistics do show improvement in the spread of HIV; however, more can be done by health care providers to support prevention.

There are many methods of preventing and reducing the spread of HIV, including the use of condoms, limiting the number of sexual partners, and not sharing needles for drug use. An additional method of HIV prevention that has been developed within recent years is pre-exposure prophylaxis (PrEP). PrEP is a once-a-day pill regimen recommended for people not infected with HIV and who participate in high risk behavior for exposure. High-risk behavior can constitute multiple sexual partners, men who have sex with men (MSM) and participated in anal sex without a condom or who have been diagnosed with an STD in the past six months, intravenous drug users, or those individuals with partners who are HIV positive (CDC, 2017b).

When taken as directed, this pharmacological method can reduce the risk of HIV contraction by more than 90% (CDC, 2018). With its high-effectiveness on HIV prevention and ease of use as a once daily pill, PrEP utilization by primary and specialty clinics has drastically increased since its approval in 2012 (Smith, Mendoza, Stryker, & Rosen, 2016; U.S. Food and Drug Administration [FDA], 2012). There are an estimated 136,000 individuals currently taking PrEP for HIV prevention within the U.S., with a steady increase each quarter since approval (Ryan, 2017).

While PrEP has demonstrated the ability to reduce the risk of new HIV infections in high-risk individuals, there remains a lack of clinician knowledge and use of this important preventative tool. Multiple studies have identified barriers including clinician awareness, overall knowledge of purpose and benefit, comfort with use, and intention to prescribe PrEP in various settings of practice, including the urgent care setting (Blumenthal et al., 2015; Finocchario-Kessler et al., 2016; Krakower, Ware, Mitty, Maloney, & Mayer, 2014; Mimiaga, White, Krakower, Biello, & Mayer, 2014; Ng, Caires, & Mayeux, 2018). The lack of comfort and use of PrEP within the urgent care setting is in part due to a lack of guidance. While guidelines for clinicians who initiate PrEP are widely available, there is unfortunately a gap that still remains (Mayeux, Ng, & Caires, 2018). Currently, PrEP guidelines are only intended for primary care or specialty providers, such as infectious disease (CDC, 2017b). Unfortunately, this lack of PrEP guidelines comes at a time when the urgent care setting is seeing significant growth not only in relation to the number of clinics, but also with patient volumes (Urgent Care Association of America [UCAOA], 2017). Urgent care centers number more than 7,400 locations, with an average of 12,000 patient visits for each center in 2016 (Mayeux et al., 2018; UCAOA, 2017). Moreover, with this increase in patient volume and number of urgent care clinics, there is also an

upsurge in requests for STI testing and treatment (Pearson, Tao, Kroeger, & Peterman, 2017). Due to the high number of urgent care centers, large patient volume, and frequent requests for STI testing, the urgent care center is in a prime position to help with PrEP initiation and subsequent reduction in the spread of HIV.

Purpose and PICOT Question

The purpose of the Doctor of Nursing Practice (DNP) project was to evaluate a PrEP implementation protocol designed for use within the urgent care setting. This project will proceed to implement this protocol in six urgent care centers within Louisiana and assess outcomes of the developed protocol. Outcomes of protocol implementation that are being assessed include provider change in awareness and knowledge of PrEP, opinion of protocol ease of use and applicability, reduction of barriers to PrEP use, and the change in the rate of PrEP use.

DNP Project Objectives

The objectives of the DNP project include the following:

1. To assess the awareness and willingness to provide PrEP services among clinicians within urgent care settings measured by a pre-intervention survey.
2. To evaluate the efficacy and feasibility of implementing the proposed PrEP protocol within urgent care settings measured by change from the pre and post-intervention surveys.
3. To evaluate a change in knowledge, willingness, and intent to prescribe PrEP by clinicians in an urgent care setting measured by change from the pre and post-intervention surveys.

PICOT: Does the proposed PrEP protocol affect urgent care providers' awareness, knowledge, perceived barriers, and willingness to initiate PrEP services within the urgent care setting over a 16-week period?

Review of Evidence

Search Strategy

An in-depth review of literature was completed to assess the current state of knowledge and use of PrEP within the urgent care setting. The Preferred Reporting Items for Systemic Reviews and Meta-Analysis (PRISMA) statement was used as a guideline for conducting and reporting this review (Moher, Liberati, Tetzlaff, & Altman, 2009). The electronic databases that were searched and included: The Cumulative Index to Nursing and Allied Health Literature (CINHAL), Scopus, Embase, and PubMed. The databases were searched in this order. Additionally, governmental websites were also searched for specific mention and reference to the use of PrEP in the urgent care setting. These electronic databases were searched for studies published between January 2012 through December 31, 2018 for those allowing specific date exclusion. Those electronic databases not allowing for search exclusion to the day or month were searched for studies published between January 2012 through 2018 with the last search being performed on January 14, 2019.

The following search terms were used within each database search and timeframe: "pre-exposure prophylaxis," "preexposure prophylaxis," "PrEP," "pre-exposure prophylaxis urgent care," "preexposure prophylaxis urgent care," and "PrEP urgent care." Numerous results were returned with the previously stated search terms, except for "preexposure prophylaxis" and "preexposure prophylaxis urgent care." The titles and abstracts of all studies retrieved in the literature search performed were reviewed for inclusion. Studies without mention of PrEP within

the urgent care context for HIV prevention were eliminated. Also, following the PRISMA statement, studies were removed for duplication if they had already been included from a previous search term and/or electronic database (Moher et al., 2009).

Results

The literature search initially revealed 21,503 possible relevant articles for inclusion (see Figure 1 for flow diagram). After excluding the articles pertaining to PrEP but not to HIV and with the exclusion of duplicate articles, 1,515 titles and abstracts were screened for eligibility. Of these articles reviewed, 1,513 articles were excluded, as they were not specific to the urgent care area. In total, two studies were included in our systematic review. It is important to note that while there is extensive literature published on the topic of PrEP, the research on this topic in the context of the urgent care setting is limited. The findings of this literature review and subsequent evaluation of the selected articles show a lack of PrEP use and knowledge within the urgent care setting. Ng et al. (2018) found that while urgent care services and use have increased over the last four years, this article shows a lack utilization of PrEP within the urgent care setting throughout the U. S. Similarly, Underhill et al. (2014) found that even those individuals at highest risk for HIV infection, such as MSM and street-based sex workers, were not offered PrEP in various health care settings, including the urgent care. Furthermore, both studies identified the lack of comfortability, knowledge, and guidelines as reasons that PrEP services were not offered to those whom PrEP is intended (Ng et al., 2018; Underhill et al., 2014). While neither publication conducted research on ways to improve PrEP utilization, their conclusions and theories on why PrEP use is lacking within the urgent care setting indicate a gap in current research and a need for tools to increase provider knowledge.

Emergency Department Use of PrEP

Due to the limited literature and research conducted on PrEP within the urgent care setting, additional studies dealing with PrEP use within the emergency department (ED) were reviewed. Similarities between the urgent care and ED settings would allow PrEP research conducted in the ED to translate to the urgent care setting. Urgent care clinics were created by emergency medicine physicians as the need arose to provide immediate care found in emergency care departments, but without the high acuity or price tag (McNeeley, 2012). Studies dealing with PrEP within the ED setting were identified while conducting the previously mentioned literature review. An additional search was conducted to help identify studies pertaining to PrEP within the ED setting. The search string "pre-exposure prophylaxis" AND "emergency department" were used within the CINHAL, Scopus, Embase, and PubMed electronic databases. Studies were included for analysis if they were found to include PrEP use for the prevention of HIV within the ED setting. This search was limited to full text studies published between January 2012 and December 31, 2018. This search returned 529 results, which were reviewed by title and abstract for inclusion. A total of eight studies were identified as specifically researching some component of PrEP within the ED setting.

ED Patient Views and Attitudes Toward PrEP. Issues surrounding the use of PrEP within the ED setting can often be broken down by either patient or provider barriers to initiation. Two studies sought to understand patient knowledge and attitudes toward PrEP within the ED setting (Calderon et al., 2012; Moore et al., 2018). Calderon et al. (2012) found that only 13.3% of participants reported any knowledge of PrEP and 40% indicated they were unlikely to use PrEP in the future. These results should be interpreted with caution as this study was

conducted soon after initial approval of PrEP in 2012 and many advertising campaigns have since been initiated to increase patient awareness.

A second study conducted by Moore et al. (2018) attempted to study if confidentiality could be a concern and cause for a lack of PrEP use in the adolescent and young adult population. A common theme throughout this study was that those individuals who worried about parental knowledge of PrEP initiation and use were less willing to initiate this prevention method. Another finding of this study demonstrated a need for increased education and guidance from the standpoint of the ED provider. Since both studies show a lack of patient knowledge and willingness to use PrEP, there is evidence of the need for provider education and patient engagement in HIV prevention methods.

ED Provider Aspects on PrEP Use. While patient education and involvement are critical steps in providing PrEP and reducing the spread of HIV, the same resources should also be given to the medical provider. Six of the eight studies identified for inclusion dealt with provider aspect of PrEP use within the ED setting (Okoye, Chang, Weissman, & Dufffus, 2017; Ridgway et al., 2018; Stanley et al., 2017; Tortelli, Char, Powderly, & Patel, 2017; Underhill et al., 2014; Wood et al., 2018). Multiple studies found that while most providers were aware of PrEP, only 23.9% (Tortelli et al., 2017) were knowledgeable of current guidelines and referral information (Wood et al., 2018). Often, due to the lack of knowledge and misconceptions associated with antiretroviral therapy, there is a significant lack of PrEP use by the ED practitioner (Tortelli et al., 2017). Only 46% of providers who knew of PrEP discussed this topic with a patients (Wood et al., 2018). Additionally, due to a lack of ED provider knowledge and comfort, individuals at the highest risk (MSM and intravenous drug use) for HIV infection were not offered PrEP, resulting in missed opportunities to counsel and initiate this method of

prevention (Okoye et al., 2017; Underhill et al., 2014). Often, the ED offers little assistance or information regarding HIV prevention services (Ridgway et al., 2018). As a result of these missed opportunities, of approximately 504 new individuals who were infected with HIV from January 2013 to September 2016, 84% had ED visits prior to HIV diagnosis (Okoye et al., 2017). Overall, just as with urgent care settings, the ED setting is associated with a lack of knowledge, failure to provide PrEP, lack of comfort, and a lack of recognition for patients who can benefit from PrEP counsel and use.

Discussion and Implications of Literature Review

The findings of this literature review and subsequent evaluation of the selected articles present the notion of a lack of PrEP use and knowledge within the urgent care setting. Due to the lack of specific urgent care literature, assessment and feelings towards PrEP use must be borrowed from other areas of practice, such as that of the ED. There are currently thousands of articles researching various topics dealing with PrEP initiation, continuation, and effect, which are conducted from a primary care or specialty clinic viewpoint. Overall, there is a lack of knowledge, comfort, use, and initiation of PrEP within the urgent care and ED settings (Okoye et al., 2017; Tortelli et al., 2017; Underhill et al., 2014).

Limitations

While this review made every attempt to locate and include relevant literature, inadvertent exclusions are always a possibility. Limitations of Ng et al. (2018) include a lack of original research and use of expert opinion. While the use of expert opinion is valuable in certain aspects, when there is limited research, this is considered the least reliable evidence (Ingham-Broomfield, 2016). Limitations of Underhill et al. (2014) include using anonymous interviewing procedures, not knowing the number of participants who enrolled versus

participated in both stages of the study, and method of recruitment causing a lack of a diverse sample size and reduced generalizability. Overall limitations of this review include no current clinical guidelines with mention or information tailored to the urgent care clinic.

Conceptual Framework

The Care, Cure, Core Model developed by Lydia Hall (Gordon, 2015) provides an appropriate framework to guide the development and implementation of an urgent care specific PrEP protocol, as it places the emphasis on the entire patient instead of one aspect. This model defines the care aspect as meeting the patient's needs, the cure aspect as the area which care is given to the patient, and the core as being composed of the patient's feelings and goals (Gordon, 2015). The Care, Cure, Core Model has many applications to different areas of nursing and can be applied in a conceptual framework to the topic of PrEP implementation within an urgent care setting. While not conforming to the problem at hand in a strict sense, a conceptual framework of this model can be applied for solving the issue of a lack of PrEP protocol and guidance for urgent care providers (see Figure 2 for adaptation) (Gordon, 2015).

Care Component

The care aspect focuses on meeting the patient's needs, including teaching and learning activities (Gordon, 2015). The care aspect of this model can be applied from the nursing perspective of educating and helping the provider through a PrEP protocol, who in turn, educates the patient. Through education, support, and tools provided by the development of a PrEP protocol for urgent care providers, those same ideas can then be passed on to the patient. By delivering education of the provider, knowledge of HIV risk and prevention can be passed ultimately to the patient.

Cure Component

Adapted from the original model in which care is given to the patient to cure or improve the patient's affliction, this facet can be applied through providing a PrEP protocol to clinicians to prevent HIV infection and reduce affliction (Gordon, 2015). Through the use of a PrEP protocol, increased care can be given to the urgent care patient at high risk for HIV infection. With the protection against HIV infection afforded by PrEP use, the cure aspect can be adapted to prevention, as there is no current cure for HIV (CDC, 2017b).

Core Component

The core aspect traditionally consists of the patient receiving care, their feelings, and setting of goals (Gordon, 2015). This protocol will allow the urgent care provider the knowledge and confidence to implement PrEP and help implement goals for care. Through effective education, care, and use of resources by the provider, the patient will have the knowledge to evaluate their feelings and set goals for continued prevention of HIV. Ultimately, with the knowledge and education afforded to providers can be passed to the patient to help achieve the goal of remaining HIV negative.

Implementation and Evaluation

The implementation of the DNP scholarly project focused on disseminating a PrEP initiation protocol for the urgent care provider and studying the change in PrEP awareness, knowledge, comfort, and willingness to initiate PrEP. Also, this project intended to evaluate a change in perceived barriers and the rate of PrEP use after protocol implementation. Input and guidance for this project was provided by a DNP scholarly project site mentor based within the urgent care clinic. Additionally, input and guidance were given by the DNP project chairperson at the University of Alabama in Huntsville (UAH).

Initially, approval of the project proposal was sought by all members of the DNP project team. The student investigator then proceeded to develop the informed consent, recruitment script, and survey questions. After completion of the project materials, an institutional review board (IRB) application was completed and submitted to UAH IRB committee with approval being granted (see Appendix A).

Methods

The DNP project was conducted according to the methodology and conceptual framework defined in the project proposal. The DNP project was designed as a non-probability one-group design, with a convenience sample of 31 urgent care providers. From March of 2019, the first contact with prospective participants was made by the student investigator in person or by email at one of six Coastal Urgent Care, LLC (CUC) locations in Louisiana (see Appendix B for facility support letter). These providers were recruited by a discussion with clinic managers at the various CUC locations. The primary investigator lead a brief discussion and/or sent a recruitment email which included a study invitation letter with study description, an informed consent letter, IRB approval, and a pre-test survey link (see Appendix C for recruitment letter) (Appendix D for informed consent). Both paper forms and digital form (Qualtrics) were available for the participants to complete. Additionally, the informed consent was attached at the beginning of the pre-test survey, with each participant having to agree to the terms of the study for continuation and inclusion. Upon completion of the pre-test survey, the PrEP protocol was given to the participants for use as they see fit for the duration of the 16-week project. At the end of the 16-week period, a post-intervention survey was emailed by the primary investigator for participant completion within two weeks. This email was sent to all participants and included a link to the post-intervention survey in Qualtrics.

Assessment and instrument. The instrument for use within this DNP project is an adapted version of a 57-item survey by Blackstock et al. (2017) in which researchers attempted to understand current use, knowledge, and barriers to PrEP adoption by primary care physicians (see Appendix E for permission letter). The original survey was administered online through Qualtrics. Adaptation occurred by removing questions dealing directly with primary care, medical education, and rewording of some questions to fit the context of the urgent care setting. Questions were also reworded to include nurse practitioners and physician assistants as participants. Validity and reliability of the original survey were not reported within the original research study (Blackstock et al., 2017).

The pre-test questionnaire for this DNP project consists of 11 questions (see Appendix F for pre-test questionnaire). These questions attempt to assess baseline provider knowledge and comfort with PrEP initiation and use in the urgent care setting. Additionally, the pre-test questionnaire attempts to determine the significance of PrEP and identify barriers to PrEP use as perceived by urgent care providers. The post-test questionnaire consists of 14 questions and attempts to asses changes in knowledge, comfort, significance, barriers to PrEP initiation and use which occurred with the dissemination of the PrEP clinical practice guideline (see Appendix G for post-test questionnaire). Also, the post-test questionnaire attempts to determine the positives or useful aspects and areas of needed improvement for the PrEP initiation protocol.

Project measures and variables. The primary question for this DNP project to answer is determining if the developed PrEP protocol increase the awareness, knowledge, and willingness to provide PrEP among urgent care clinicians. The project also seeks to evaluate the efficacy and feasibility of implementing the proposed PrEP protocol within urgent care settings. The independent variables for this project include demographic data such as age, gender, sexual

orientation, education level, race, ethnicity, and years of practice. The dependent variables include PrEP awareness and knowledge, willingness to prescribing of PrEP, efficacy of the implemented protocol, and perceived barriers to PrEP use.

Data collection. Data collection utilized both paper and electronic versions of the survey implemented in person or through the online survey tool Qualtrics. Paper surveys were conducted by the primary investigator in a short person discussion and recruitment emails were sent to other potential participants. The in-person discussion and recruitment emails included a study invitation letter with the study description, an informed consent letter, and IRB approval letter. Inclusion criteria are medical providers (nurse practitioners, physician assistants, or physicians), 19 years old and above, working in any of the six CUC Louisiana locations who chooses to voluntarily complete the informed consent and surveys. Exclusion criteria include patients, children, and any medical providers working in urgent care who decline to voluntarily participate in the DNP project.

Data Analysis. Data and survey results were manually entered into the Statistical Package for the Social Sciences (SPSS). Data analysis will be conducted using SPSS version 25 software. Analysis of categorical data will be completed using the Chi-square test. Analysis of the dependent variables and to asses the change between the pre and post intervention results was completed by using a paired *t* test. Evaluation of this protocol was completed by comparing the pre and post intervention survey results to look for a statistically significant change evidenced by a p value < 0.5.

Evaluation. The goal of the DNP project is to assess the proposed PrEP initiation protocol specific to the urgent care setting and survey any change in the awareness, knowledge, and willingness to use PrEP as a result of the implemented protocol. Evaluation of this protocol

will come about by comparing the pre and post intervention survey results to look for a statistically significant change. Due to a lack of provider knowledge, awareness, and use of PrEP in the urgent care setting, any improvement in these variables can afford overall greater use of PrEP throughout the country (Blumenthal et al., 2015; Krakower & Mayer, 2016; Mayeux et al., 2018; Ng et al., 2018). This project and the protocol developed can improve HIV prevention services in the urgent care setting.

Protocol

The DNP student investigator and project chairperson developed a PrEP clinical practice protocol based on the most current CDC guidelines, but adapted to the urgent care setting (CDC, 2017b) (see Figure 3 for clinical practice guideline). This practice guideline consists of a one-page flow chart that guides the urgent care provider through the steps for consideration to the follow up required. Initially, the practice guideline begins with contemplation and inclusion of those individuals at highest risk, including MSM without condom use and those who have a partner who is HIV positive. Next, the practice guideline directs the provider through symptoms of acute infection and the laboratory requirements needed to initiate PrEP (CDC2017b). Additionally, this practice guideline discusses what should be performed if a positive lab result is received and those which would require referral to a specialist for treatment and PrEP initiation, such as Hepatitis B. Finally, the practice guideline then discusses the medication to be initiated and the follow up laboratory and appointment requirements. With the clinical practice guideline being provided electronically, participants have the opportunity to save this document within their smartphone for quick and easy reference.

Timeline

This DNP project was executed in the March 2019 and 16-weeks to complete the study period. After the 16-week study period, data analysis and synthesis of findings occurred.

Data Storage

No participant information was collected in the process of this DNP project, and no provider identification or confidential personal data was required. The completed surveys will not be shared or disseminated to participants' peers, professional colleagues, management, or stakeholders. Hardcopies of the paper-based surveys and signed consent forms completed by participants were collected by the DNP project investigator and stored in a separate folder. Qualtrics surveys were utilized for participants who choose to complete the online consent forms and pre-test surveys. In such situations, only the primary investigator had access to the password. Paper surveys and consent forms collected are maintained in a separate secure folder to ensure the security of the data and protect the participants from possible identification. The data is stored in the primary investigator's office in secure locked binders. The data was transcribed into a password-protected desktop computer and password-protected codebook in the SPSS software program. Only the primary investigator has access to the password.

Implications and Application to Practice

Although the role of the urgent care clinician with the introduction and continuation of PrEP is currently under-utilized, the developed clinical practice guideline can dramatically change this concept. With the guidance provided by the developed practice guideline, provider knowledge, comfort and use of PrEP within the urgent care setting can be improved. This practice change would benefit all patients seeking this valuable HIV prevention tool. Additionally, current barriers to PrEP initiation can be reduced to help increase PrEP use.

Overall, due to a large number of urgent care centers located across the U. S. and the massive volume of patients seen for various conditions, increasing PrEP utilization based on established guidelines has the potential to provide a significant impact on HIV prevention.

Section II: DNP Project Product

Professional Journal Selection

The dissemination of the DNP project and findings is an important process to help improve health promotion and disease prevention (Kerner, Rimer, & Emmons, 2005). Research completed and not disseminated or shared with others has limited purpose and benefit to the population. The journal selected for dissemination of this DNP project is the Journal of the Association of Nurses in AIDS Care (JANAC).

Scope of Journal

The scope of JANAC is limited to publishing articles and content that are applicable to HIV and AIDS issues. Topics cover the full spectrum of global HIV issues including prevention, advocacy, and epidemiology.

Aims of Journal

The aims of JANAC are to publish high quality, peer reviewed articles related to the global HIV epidemic. This is in an effort to increase awareness, prevention, research, and the quality of life for those individuals living with HIV around the world.

Outcomes from an Urgent Care Pre-Exposure Prophylaxis (PrEP) Protocol for the Prevention of HIV

Title Page

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Disclosures

Jack J. Mayeux is an employed staff Nurse Practitioner of the company where the quality improvement project was performed. Jack J. Mayeux has no financial interests to disclose. Yeow Chye Ng reports no financial or potential conflict of interest. Matthew M. Bice is an owner and collaborating physician of the company where the quality improvement project was performed. Matthew M. Bice has no financial interest to disclose.

Acknowledgments

No funding was received.

Abstract

Pre-exposure prophylaxis (PrEP) and urgent care medical providers can be powerful allies when combined in the fight against HIV infection. Unfortunately, PrEP use in the urgent care setting is underutilized due to a lack of resources, medical staff knowledge, and comfort on the part of providers. An urgent care specific PrEP protocol was developed and 29 providers from six different urgent care facilities in Louisiana participated over a 20-week period quality improvement project. The developed urgent care specific PrEP protocol resulted in an increase in knowledge, comfort, and a reduction in barriers associated with PrEP use. Overall, the urgent care PrEP protocol showed the ability to assist the urgent care clinician in many areas noted as reasons for reduced PrEP use. The urgent care PrEP protocol serves as an additional tool for the urgent care providers in HIV biomedical preventative care.

Key Words:

HIV, pre-exposure prophylaxis, PrEP, protocol, quality improvement project, urgent care

Manuscript

Outcomes from an urgent care pre-exposure prophylaxis (PrEP) protocol for the prevention of HIV

While there are many sexually transmitted infections (STI) that cause a burden on society, few have the scope and magnitude of human immunodeficiency virus (HIV) (Centers for Disease Control and Prevention [CDC], 2017a). Currently, there are 1.1 million people in the U.S. living with HIV, with approximately 15% unaware they are already infected(U.S. Department of Health and Human Services [HHS], 2017). Despite these current statistics on the rate of HIV infection, great strides have been made in reducing the rate of new infections. The latest statistics show the rate of new HIV infections have fallen from 41,800 for 2010 to 38,500 in 2015 (CDC, 2018). Furthermore, the rate of newly diagnosed individuals with HIV in the U.S. has declined by 5% from 2011 to 2015 (CDC, 2018). These statistics do show improvement in slowing the spread of HIV; however, progress on reducing yearly HIV infections have stalled to approximately 39,000 new infections each year (HHS, 2017).

There are many methods of preventing and reducing the spread of HIV, including the use of condoms, limiting the number of sexual partners, and not sharing needles for drug use. An additional method of HIV prevention that has been developed within recent years is pre-exposure prophylaxis (PrEP). PrEP is a once-a-day pill regimen recommended for people not infected with HIV and who participate in high risk behavior for exposure(U.S. Food and Drug Administration [FDA], 2012). High-risk behavior can constitute multiple sexual partners, men who have sex with men (MSM) and participating in anal sex without a condom or those who have been diagnosed with an STD in the past six months, intravenous drug users and individuals with partners who are HIV positive (CDC, 2017b). When taken as directed, this pharmacological

method can reduce the risk of HIV contraction by more than 90% (CDC, 2018). With its high-effectiveness on HIV prevention and ease of use as a once daily pill, PrEP utilization by primary and specialty clinics has drastically increased since its approval in 2012(Smith et al., 2016; FDA, 2012). There are an estimated 135,000 individuals currently participating in PrEP for HIV prevention within the U.S.(AVAC, 2019). While these numbers are encouraging, more can be done to initiate PrEP in those individuals at high risk for HIV and reduce the currently stalled HIV infection rate (HHS, 2017).

Problem

While PrEP has demonstrated the ability to reduce the risk of new HIV infections in high-risk individuals, there remains a lack of clinician knowledge and use of this important preventative tool. Multiple studies have identified barriers including clinician awareness, overall knowledge of purpose and benefit, comfort with use, and intention to prescribe PrEP in various settings of practice, including the urgent care setting (Blumenthal et al., 2015; Finocchario-Kessler et al., 2016; Krakower et al., 2014; Mimiaga et al., 2014; Ng et al., 2018). Specifically, Underhill et al. (2014)found that even those individuals at highest risk for HIV infection, such as MSM and street-based sex workers, were not offered PrEP in various health care settings, including the urgent care. The lack of comfort and use of PrEP within the urgent care setting is in part due to a lack of guidance and protocol(Ng et al., 2018).

While guidelines for clinicians who initiate PrEP are widely available, there is unfortunately a gap that still remains (Mayeux et al., 2018). Currently, PrEP guidelines are only intended for primary care or specialty providers (CDC, 2017b). Unfortunately, this lack of PrEP guidelines comes at a time when the urgent care setting is seeing significant growth not only in relation to the number of clinics, but also with patient volume(Urgent Care Association of

America [UCAOA], 2017). Urgent care centers number more than 7,400 locations, with an average of 12,000 patient visits for each center in 2016 (Mayeux et al., 2018; UCAOA, 2017). Moreover, with this increase in patient volume and number of urgent care clinics, there is also an upsurge in requests for STI testing and treatment (Pearson et al., 2017). Due to the high number of urgent care centers, large patient volume, and frequent requests for STI testing, the urgent care center is in a prime position to help with PrEP initiation and subsequent reduction in the spread of HIV.

Purpose

The purpose of this project was to evaluate a PrEP implementation protocol designed for use within the urgent care setting. Outcomes of the developed protocol implementation that were assessed included provider change in awareness and knowledge of PrEP, opinion of protocol ease of use and applicability, reduction of barriers to PrEP use, and the change in the rate of PrEP use. Additionally, this project sought to assess the efficacy and feasibility of implementing the proposed PrEP protocol within urgent care settings.

Clinical Question

Does the proposed PrEP protocol affect urgent care providers' awareness, knowledge, perceived barriers, and willingness to initiate PrEP services within the urgent care setting over a 20-week period?

Methods

Approval for this project was granted by the University of Alabama in Huntsville Institutional Review Board. This project was implemented over a 20-week period to give providers adequate time to utilize the developed protocol within practice for initial and follow up care as the longest recommended follow up time is 90 days for PrEP (CDC, 2017b).

The urgent care PrEP clinical practice protocol was developed based on the most current CDC guidelines, but adapted to the urgent care setting(CDC, 2017b) (see Figure 1 for clinical practice guideline).This practice guideline consists of a one-page flow chart that guides the urgent care provider through the steps for PrEP initiation beginning with patients indicated for use through prescription and the required follow up.

Design

This project consisted of a non-probability one-group design, with a convenience sample of 31 urgent care providers. Inclusion criteria for participating within this project consisted of medical providers (nurse practitioners, physician assistants, or physicians), 19 years old and above, working in an urgent care clinic. Beginning March 7, 2019, the first contact with prospective participants was made by the primary investigator in person or by email at one of six urgent care locations in Louisiana. A brief discussion and/or recruitment email which included a study invitation letter with study description, an informed consent letter, IRB approval, and a pre-test survey link was given to every participant. Additionally, the informed consent was attached at the beginning of the pre-test survey, with each participant having to agree to the terms of the study for continuation and inclusion. Upon completion of the pre-test survey, the PrEP protocol was given to the participants for use as they saw fit for the duration of the 20-week project. At the end of the time period, a post-intervention survey was emailed for participant completion.

Data Collection

The electronic pre and post-intervention surveys were administered using the online survey tool Qualtrics. The instrument for use within this project is an adapted version of a 57-item survey by Blackstock et al. (2017) in which researchers attempted to understand current use,

knowledge, and barriers to PrEP adoption by primary care physicians. Consent was obtained to use an adapted version of the original survey. Adaptation occurred by removing questions dealing directly with primary care, medical education, and rewording of some questions to fit the context of the urgent care setting. Questions were also reworded to include nurse practitioners and physician assistants as participants. Validity and reliability of the original survey were not reported within the original research study(Blackstock et al., 2017).

The pre and post-intervention surveys for this project consisted of 12 questions ($\alpha = .77$). These questions attempt to assess baseline provider knowledge, comfort, and previous experience with PrEP initiation and use in the urgent care setting. Additionally, the pre-test questionnaire attempts to determine provider opinion on the significance of PrEP and identify barriers to PrEP use as perceived by urgent care providers. The post-test questionnaire consists of 12 questions ($\alpha = .78$) and attempts to assess changes in knowledge, comfort, significance, barriers to PrEP initiation and use which occurred with the dissemination of the PrEP clinical practice guideline. Also, the post-test questionnaire attempts to determine the positives or useful aspects and areas of needed improvement for the PrEP initiation protocol.

Data Analysis

Demographic data and results of the pre-intervention and post-intervention were manually entered into the Statistical Package for the Social Sciences (SPSS). Data analysis was conducted using SPSS version 26 software. Demographic data was assessed on the pre and post intervention assessments with post intervention data being included for analysis. Analysis of the pre and post intervention results was completed by using a paired *t*-test for a statistically significant change evidenced by a *p* value of less than .05.

Results

Demographics

A total of 31 urgent care providers met inclusion criteria. Of these, one provider did not consent to participate and another never initiated the project leaving 29 providers who agreed to take part in the project. The participants were composed of 20 (69%) male and 9 (31%) female. All 29 participants were Caucasian. By age, 1 (3.4%) was 21-29 years, 12 (41.4%) were 30-39 years, 9 (31%) were 40-49 years, 4 (13.8%) were 50-59 years, and 3 (10.3%) were 60 years and older. The participants' consisted of 5 (17.2%) physicians, 19 (65.5%) nurse practitioners, and 5 (17.2%) physician assistants. The level of education was 24 (82.8%) holding a master's and 5 (17.2%) a doctorate degree. Work or employment status consisted of 21 (72.4%) full time and 8 (27.6%) part time working less than 32 hours per week. Years of practice for participants comprised 3 (10.3%) 0-2 years, 9 (31%) 3-5 years, 6 (20.7%) 6-10 years, 4 (13.8%) 11-15 years, 1 (3.4%) 16-20 years, and 6 (20.7%) greater than 20 years.

Clinical Outcomes

The overall results of the survey show a significant change ($t(28) = -3.04$, $p = .005$) between the pre-intervention ($M = 30.82$, $SD = 6.66$) and post-intervention ($M = 35.82$, $SD = 7.59$) surveys. There was a significant improvement between the pre-intervention knowledge rating (M=1.76, SD=.912) and the post intervention knowledge rating (M=2.97, SD = .981), $t(28) = -6.20$, $p = .001$. The level of comfort with PrEP saw a significant increase from the pre-intervention survey ($M = 3.58$, $SD = 1.70$) to the post-intervention survey ($M = 5.24$, $SD = 2.11$), $t(28) = -4.70$, $p = .001$. A reduction in overall barriers was achieved when comparing the pre-intervention ($M = 12.31$, SD= 4.78) versus the post-intervention groups (M= 14.72, $SD = 4.98$); however, this parameter was not statistically significant ($t(28) = -1.85$, $p = .074$). Participants

reported a significant decrease in barriers for PrEP use associated with a lack of guidelines or protocol specific to the urgent care setting between the pre-intervention ($M = 2.21$, $SD = 1.08$) and post-intervention ($M = 3.07$, $SD = 1.22$) groups, $t(28) = 2.68$, $p = .012$. Also, there was a significant increase in the rating given to PrEP guidelines or protocol helping to facilitate PrEP use when comparing the pre-intervention ($M = 2.83$, $SD = 1.31$) and post-intervention ($M = 3.66$, $SD = 1.23$) groups, $t(28) = -2.26$, $p = .031$.

When examining the number of participants who prescribed PrEP pre-intervention ($M = 1.90$, $SD = .310$) versus post-intervention ($M = 1.93$, $SD = .258$), there was not a significant change ($t(28) = -1.000$, $p = .326$), as there were two participants who reported prescribing PrEP before and after protocol dissemination. The overall feasibility of PrEP use in the urgent care setting did not improve when comparing the pre-intervention ($M = 13.17$, $SD = 2.49$) to the post-intervention ($M = 12.89$, $SD = 1.97$) surveys, however, this change was not statistically significant ($t(28) = -.429$, $p = .671$). Table 1 presents the supplemental data not included in the results section.

Discussion

The purpose of this project was to improve provider comfort and knowledge associated with PrEP, feasibility of initiating or continuing PrEP in the urgent care setting, reduce barriers and increase PrEP use by providing a tool for the initiation of PrEP in the urgent care setting. The overall development and dissemination of the PrEP protocol for the urgent care setting produced both statistically and non-statistically significant results. While the urgent care PrEP protocol dissemination did not trigger any new PrEP prescribing activities from the providers during the 20-weeks intervention, there are currently two participants who have initiated PrEP services with their patients.

There was a positive statistically significant increase in overall provider knowledge of PrEP, comfort with PrEP, and a decrease in barriers associated with PrEP use in the urgent care. Additionally, participants reported a significant decrease in the barriers for PrEP use associated with a lack of guidelines or protocol specific to the urgent care setting. These results suggest that the developed PrEP protocol has the potential to increase urgent care provider willingness to initiate and/or continue PrEP for the patient at risk of HIV infection. Of the two participants who reported prior prescribing PrEP experiences, they agreed or strongly agreed that initiating or continuing PrEP in the urgent care setting is feasible and promising. Given these results, the developed protocol could help the urgent care provider to initiate PrEP, reduce the spread of HIV in the U.S., and reduce the overall cost burden to the health care system. The prevention of one HIV infection in the U.S. has the potential to save between $300,000 and $500,000 over the lifetime of a patient who became infected at age 35 years(Gardner, 2016).

On the pre-intervention survey, a majority of participants (48.3%) rated their knowledge of PrEP as poor. While this expectedly increased on the post-intervention survey, the results of post-intervention questions attempting to assess the correct medication, labs, and typical side effects of PrEP are encouraging. A large percentage of the participants correctly answered these parameters of PrEP care with 86.2% correctly identifying the correct medication, 72.4% selecting the correct labs, and 82.8% identifying the most common side effects. These factors are necessary for the initiation of PrEP and are important to discuss with patients.

Future Research

Further research is needed to help identify new and improved current tools that can assist practitioners with PrEP initiation and continuation. A larger project with greater protocol dissemination to clinics in underserved areas is needed to provide more feedback and

improvement of this preventative tool. Additionally, research on the applicability of the developed PrEP protocol to other settings, such as primary care, is needed to determine if improvement seen in the urgent care setting will translate across care.

Limitations

This project was limited by the small sample size of only 29 urgent care providers. Additionally, the composition of the participants was limited, as all were Caucasian and the majority (65.5%) consisted of nurse practitioners. A larger sample size with a more diverse group of participants could have varying results on the effect of the developed protocol. An additional limitation is the study length of 20-weeks. Greater use of the PrEP protocol and uptake in prescribing of PrEP could occur with a longer study timeframe.

Conclusion

Increased utilization of PrEP is needed to reduce the spread of HIV and the developed protocol has a place in helping increase PrEP use. The urgent care setting is a dynamic growing resource that can help with the identification of high-risk individuals and utilization of PrEP. The results of this project suggest that with support and a specific protocol that is easy to access and tailored to the urgent care setting, improvement in multiple aspects of PrEP use can occur.

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TABLE

Table 1. *Statistical Analysis of Pre and Post-intervention Questions*

Measure and Question	Pre-intervention *M*	*SD*	Post-intervention *M*	*SD*	Paired *t*-test *p*-Value
PrEP Knowledge					
What level would you rate your knowledge of PrEP?	1.76	0.91	2.97	0.98	.001
PrEP Comfort	3.58	1.70	5.24	2.11	.001
What level would you rate your comfort with PrEP use?	1.79	0.81	2.59	1.05	.001
What is your level of comfort with prescribing PrEP?	1.79	0.97	2.65	1.11	.001
Barriers to PrEP	12.31	4.78	14.72	4.98	.074
What degree is time constraints of discussion, screening, and counseling a barrier?	3.03	1.21	2.59	1.21	.130
What degree is a lack of knowledge and experience with laboratory requirements a barrier?	2.38	1.04	3.28	1.25	.010
What degree is a lack of guidelines and protocol for PrEP use a barrier?	2.21	1.08	3.07	1.22	.012
What degree is a lack of training and education on PrEP a barrier?	2.07	0.99	2.86	1.32	.018
What degree are the clinical and lab requirements to PrEP use a barrier?	2.62	1.29	2.93	1.38	.320
Feasibility of PrEP	13.17	2.49	12.89	1.97	.671
Rate your feeling of agreement or disagreement with: It is more feasible to provide PrEP in a specialty or primary care clinic.	3.76	0.87	3.67	1.10	.818
Rate your feeling of agreement or disagreement with: It is feasible to initiate PrEP in the urgent care setting.	3.00	1.13	3.24	1.12	.345
Rate your feeling of agreement or disagreement with: It is feasible to continue PrEP in the urgent care setting.	2.93	1.03	3.07	1.06	.588
Rate your feeling of agreement or disagreement with: I am concerned about the potential side effects of PrEP.	3.48	0.94	2.90	0.97	.006

Note. Cronbach's alpha 0.78. p value significant if $p<0.05$

FIGURES

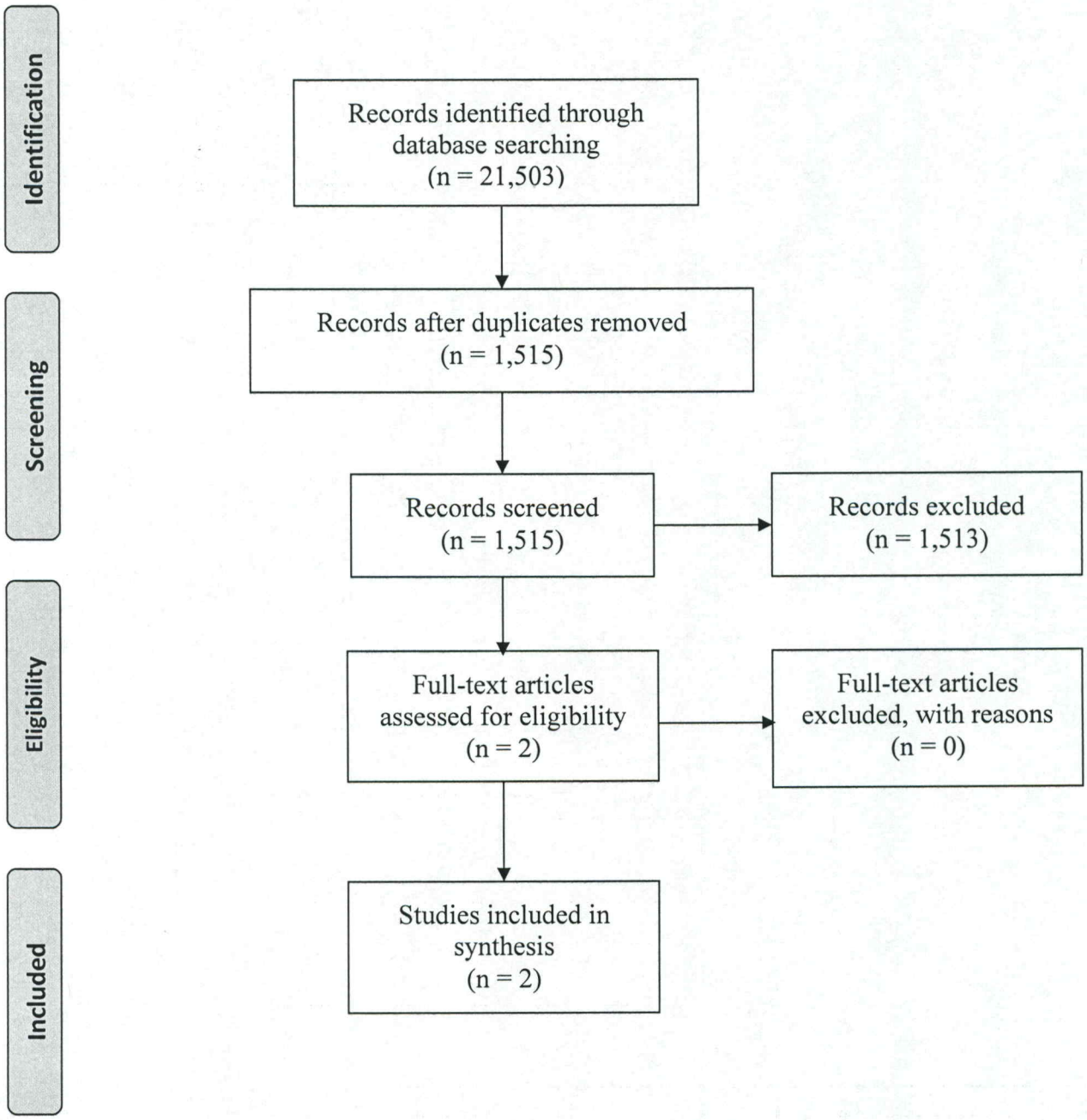


Figure 1: PRISMA flow diagram.

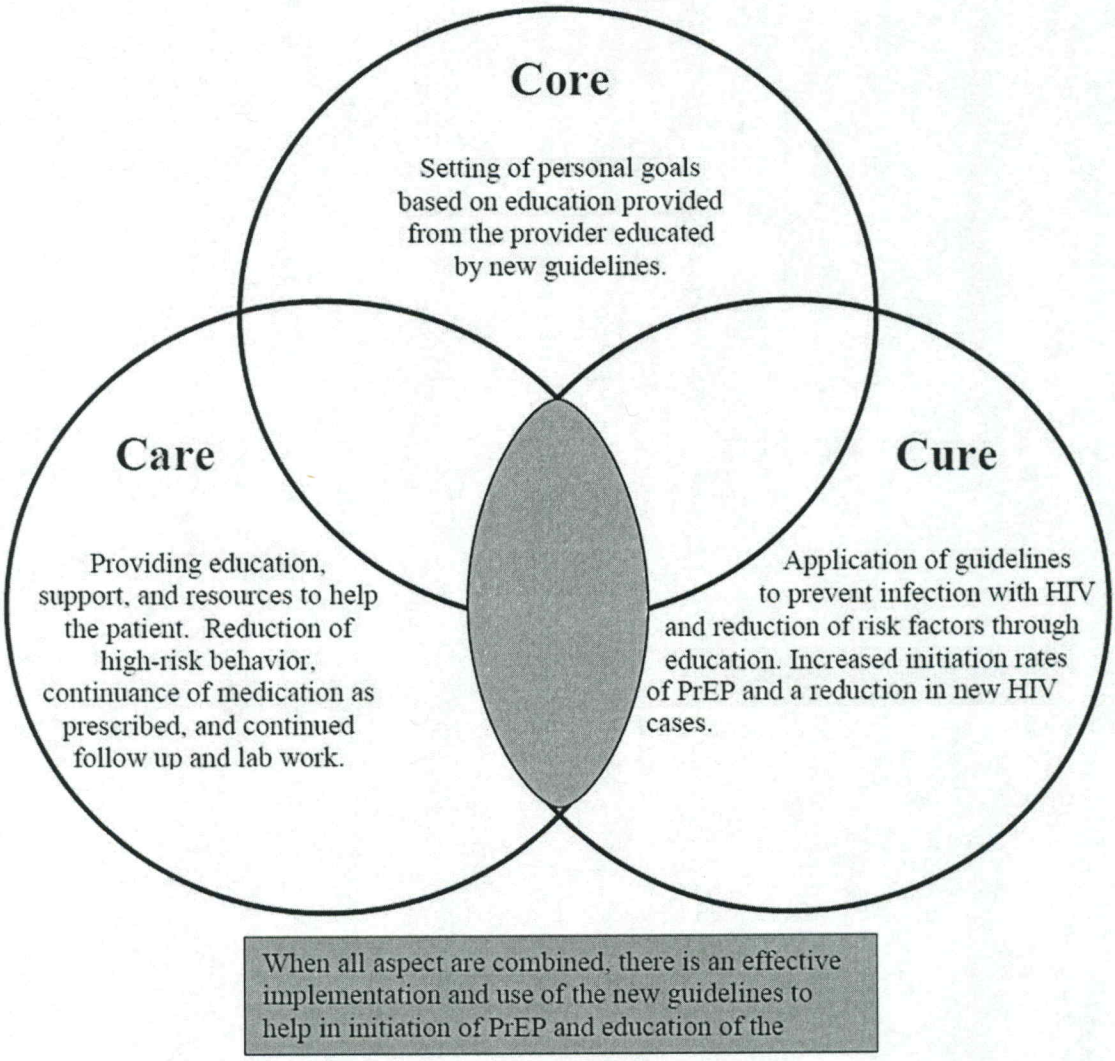
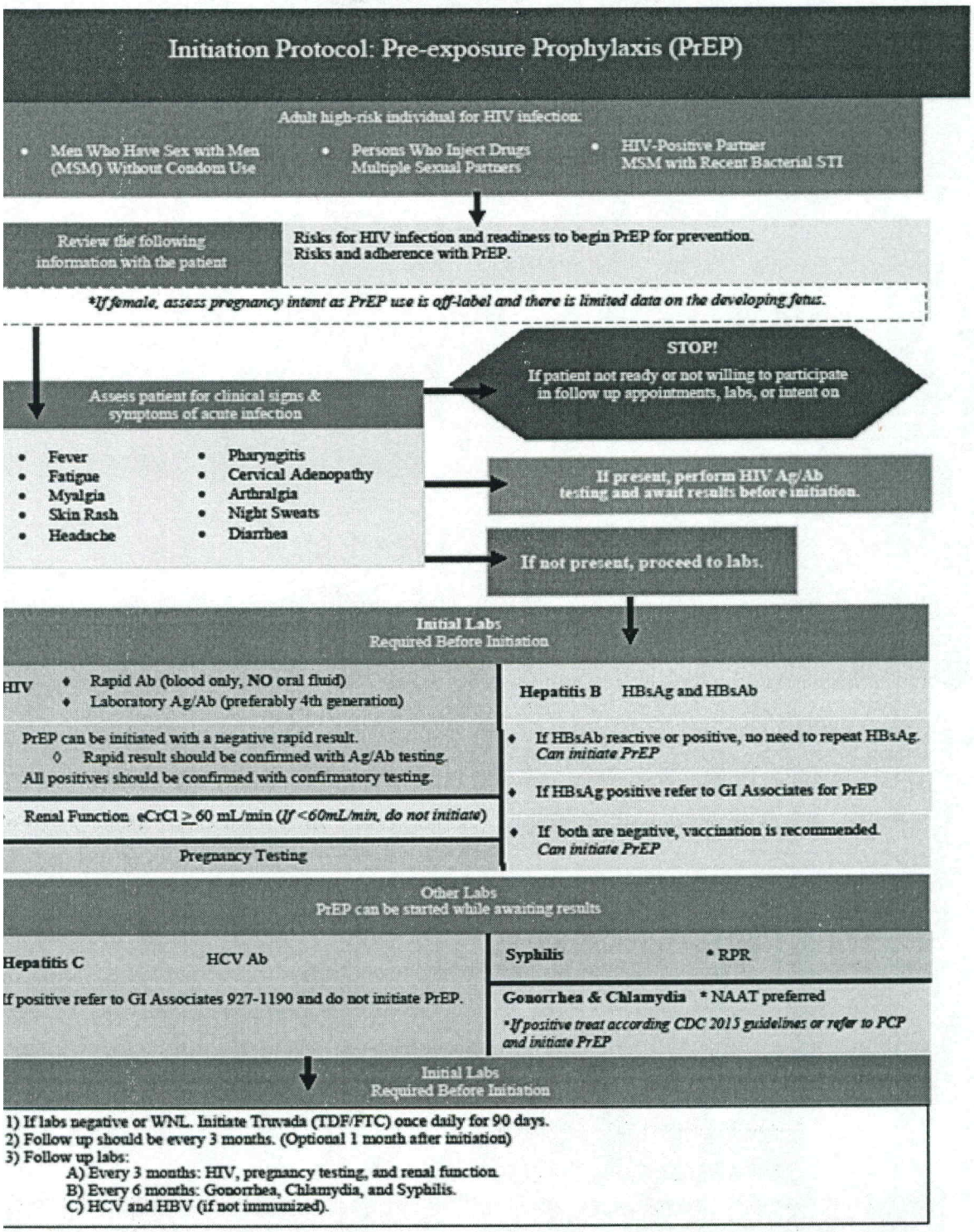


Figure 2: Conceptual Framework and Application of the Care, Cure, Core Scheme by L. Hall, 1965.



e 3: Urgent Care PrEP Initiation Protocol

osed protocol has been verified by content expert

APPENDIX A

UAH IRB Approval Letter

THE UNIVERSITY OF
ALABAMA IN HUNTSVILLE

☒ Expedited (see pg 2)
☐ Exempted (see pg 3)
☐ Full Review
☐ Extension of Approval

March 7th 2019

Jack Mayeux
Department of Nursing
University of Alabama in Huntsville

Dear Mr. Mayeux,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Pre-exposure Prophylaxis (PreEP) Protocol for the Urgent Care Setting*, and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Bruce Stallsmith

Bruce Stallsmith
IRB Chair
Professor, Biological Sciences

APPENDIX B

Facility Support Letter

ATTN: Matthew M. Bice, MD; Owner Coastal Urgent Care, LLC

I, Jack J. Mayeux, would like to do a DNP project implementing a QI project on a pre-exposure prophylaxis (PrEP) protocol for the urgent care, and would like to use the Coastal Urgent Care facilities.

To give permission for me to do this project within your clinics, please sign below.

I, Matthew M. Bice give Jack J. Mayeux permission to do his DNP QI project at our facilities,

1124 South Burnside Ave Suite A100, Gonzales, LA 70737; (225) 647-5503

9808 Bluebonnet Blvd, Baton Rouge, LA 70810; (225) 224-8121

1411 St Charles St, Houma, LA 70360; (985) 709-0136

2031 Audubon Ave, Thibodaux, LA 70301; (985) 803-8383

5314 Airline Dr, Bossier City, LA 71111; (318) 678-5272

1009 South Service Rd West, Ruston, LA 71270; (318) 242-1440

Signature

Jan 4, 2019

Date

APPENDIX C

Recruitment Letter

Coastal Urgent Care Provider,

Re: Pre-exposure Prophylaxis Protocol for the Urgent Care Setting, Jack Mayeux and Dr. Yeow Chye Ng

You are invited to participate in a quality improvement project to evaluate the effectiveness of pre-exposure prophylaxis (PrEP) protocol use within the urgent care setting. This study is designed to assist us in better understanding how to streamline PrEP implementation within an urgent care setting. This study is being conducted by Jack Mayeux, MSN and Dr. Yeow Chye Ng, PhD with the University of Alabama in Huntsville. This is a 4-month project. Participation in this study is voluntary. You must be 19 years old or older and currently practicing as either an advanced nurse practitioner, physician assistant, or a physician in an urgent care facility. Once written consent has been given, you will be asked to complete a pre-intervention survey, followed by evaluating our proposed PrEP protocol for the next 16 weeks. It is up to your professional judgement to decide if our proposed PrEP protocol would best fit your professional and patient's needs within the urgent care setting. There will be a follow up post-intervention survey at the end of the 16-week period. This protocol and the information contained have been adapted from the Centers for Disease Control and Prevention (CDC) current guidelines.

Participant codes will be used to record your data, and these codes will be made available only to those researchers directly involved with this study, thereby ensuring strict confidentiality. Participation is completely voluntary, and you may opt out of participation at any point during the research process. At no point will a decision to participate or not to participate

result in any impact on the individual or institution/company. There are no financial incentives for participation within this study. This research project has been evaluated and approved by the University of Alabama in Huntsville's Institutional Review Board. If you have any questions, please ask them now.

If you have questions at a later date, you may contact the Principal Investigator Jack Mayeux, at 225-938-8056 or at jjm0029@uah.edu or the faculty supervisor Dr. Yeow Chye Ng, PhD, 1610 Ben Graves Drive Huntsville, AL 35899, at 256-824-2451 or at YeowChye.Ng@uah.edu.

Sincerely,

Jack Mayeux, MSN, APRN, NP-C

Yeow Chye Ng, PhD, CRNP, AAHIVE

APPENDIX D

Informed Consent

You are invited to participate in a quality improvement project to evaluate the effectiveness of pre-exposure prophylaxis (PrEP) protocol use within the urgent care setting. This study is designed to assist us in better understanding how to streamline PrEP implementation within an urgent care setting.

The primary investigator is Jack Mayeux, from the University of Alabama in Huntsville.

PROCEDURE TO BE FOLLOWED IN THE STUDY: This is a 4-month project. Participation in this study is voluntary. You must be 19 years old or older and currently practicing as either an advanced nurse practitioner, physician assistant, or a physician in an urgent care facility. Once written consent has been given, you will be asked to complete a pre-intervention survey, followed by evaluating our proposed PrEP protocol for the next 16 weeks. It is up to your professional judgement to decide if our proposed PrEP protocol would best fit your professional and patient's needs within the urgent care setting. There will be a follow up post-intervention survey at the end of the 16-week period.

DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: There are no expected risks associated with your participation.

EXPECTED BENEFITS: Results from his study can benefit society by giving urgent care providers the information and tools needed to professionally initiate PrEP services.

INCENTIVES AND COMPENSATION FOR PARTICIPATION: The incentives for participation in the research are developing and gaining updated protocol procedures while providing PrEP services specifically for urgent care providers. No compensation in any form (monetary, occupational, or professional) is provided for participation in this study.

CONFIDENTIALITY OF RESULTS: Participant codes will be used to record your data, and these codes will be made available only to those researchers directly involved with this study, thereby ensuring strict confidentiality. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research and only using your participant number. Due to the potential limited confidentiality of email communication, only the initial invitation to participate in this study containing the

recruitment letter and informed consent will be transmitted through this method. Acknowledgement and agreement of the informed consent will take place within the pre-intervention survey taken within Qualtrics.

FREEDOM TO WITHDRAW: You are free to withdraw from the study at any time. You will not be penalized if you decide to withdraw. At no point will a decision to participate or not to participate result in any impact on the individual or company. Investigators reserve the right to remove any participant from the session without regard to the participant's consent.

CONTACT INFORMATION: If you have any questions, please ask them now. If you have questions at a later date, you may contact the Principal Investigator Jack Mayeux, at 225-938-8056 or at jjm0029@uah.edu. or the faculty supervisor Dr. Yeow Chye Ng, PhD, 1610 Ben Graves Drive Huntsville, AL 35899, at 256-824-2451 or at YeowChye.Ng@uah.edu. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (IRB) at 256.824.6992 or email the IRB chair Dr. Bruce Stallsmith at irb.@uah.edu.

If you agree to participate in our research, please sign and date below.

This study was approved by the Institutional Review Board at UAH and will expire in one year from March 7, 2019.

_____ _____

Name (Please Print) Signature Date

APPENDIX E

Permission for Adaptation of Survey

From: Jack Mayeux <jjm0029@uah.edu>
Sent: Monday, February 11, 2019 12:34 PM
To: Oni Blackstock
Subject: [UNTRUSTED]Request for Permission to Use Adapted Survey

Dr. Blackstock,

I am a student at the University of Alabama in Huntsville working on my doctorate degree in nursing. My project is focusing on PrEP in the urgent care setting. I found your study titled "A Cross-Sectional Online Survey of HIV Pre-Exposure Prophylaxis Adoption Among Primary Care Physicians" during my literature review. I wanted to email and ask permission to use elements of your survey for an adapted survey within my project. If this is acceptable you simply need to email me back stating your permission. I appreciate any help you can provide and I thank you for your time.

Jack Mayeux, MSN, APRN, FNP-C

From: **Oni Blackstock** <oblackstock@health.nyc.gov>
Date: Mon, Feb 11, 2019 at 12:10 PM
Subject: Re: [UNTRUSTED]Request for Permission to Use Adapted Survey
To: Jack Mayeux <jjm0029@uah.edu>
CC: Edelman, E. Jennifer <eva.edelman@yale.edu>

Thanks for your interest in our survey and for reaching out! Yes, you have permission to use elements of the survey for an adapted survey. Please make sure to cite our study in any publications that results from use of the survey.

Thanks, Oni

Oni J. Blackstock, MD, MHS
Assistant Commissioner | Bureau of HIV/AIDS Prevention and Control
New York City Health Department | oblackstock@health.nyc.gov
(P) 347.396.7786 | (F) 347.396.7791
she, her, hers
#PlaySure #BeHIVSure

APPENDIX F

Pre-Exposure Prophylaxis Protocol for the Urgent Care Setting: Pre-Test Questionnaire

Q1 **Consent Form: Pre-exposure Prophylaxis Protocol for the Urgent Care Setting** You are invited to participate in a quality improvement project to evaluate the effectiveness of pre-exposure prophylaxis (PrEP) protocol use within the urgent care setting. This study is designed to assist us in better understanding how to streamline PrEP implementation within an urgent care setting. The primary investigator is Jack Mayeux, from the University of Alabama in Huntsville. PROCEDURE TO BE FOLLOWED IN THE STUDY: This is a 4-month project. Participation in this study is voluntary. You must be 19 years old or older and currently practicing as either an advanced nurse practitioner, physician assistant, or a physician in an urgent care facility. Once written consent has been given, you will be asked to complete a pre-intervention survey, followed by evaluating our proposed PrEP protocol for the next 16 weeks. It is up to your professional judgement to decide if our proposed PrEP protocol would best fit your professional and patient's needs within the urgent care setting. There will be a follow up post-intervention survey at the end of the 16-week period. DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: There are no expected risks associated with your participation. EXPECTED BENEFITS: Results from his study can benefit society by giving urgent care providers the information and tools needed to professionally initiate PrEP services.

INCENTIVES AND COMPENSATION FOR PARTICIPATION: The incentives for participation in the research are developing and gaining updated protocol procedures while providing PrEP services specifically for urgent care providers. No compensation in any form (monetary, occupational, or professional) is provided for participation in this study.

CONFIDENTIALITY OF RESULTS: Participant codes will be used to record your data, and

these codes will be made available only to those researchers directly involved with this study, thereby ensuring strict confidentiality. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research and only using your participant number. Due to the potential limited confidentiality of email communication, only the initial invitation to participate in this study containing the recruitment letter and informed consent will be transmitted through this method. Acknowledgement and agreement of the informed consent will take place within the pre-intervention survey taken within Qualtrics. FREEDOM TO WITHDRAW: You are free to withdraw from the study at any time. You will not be penalized if you decide to withdraw. At no point will a decision to participate or not to participate result in any impact on the individual or company. Investigators reserve the right to remove any participant from the session without regard to the participant's consent. CONTACT INFORMATION: If you have any questions, please ask them now. If you have questions at a later date, you may contact the Principal Investigator Jack Mayeux, at 225-938-8056 or at jjm0029@uah.edu. or the faculty supervisor Dr. Yeow Chye Ng, PhD, 1610 Ben Graves Drive Huntsville, AL 35899, at 256-824-2451 or at YeowChye.Ng@uah.edu. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (IRB) at 256.824.6992 or email the IRB chair Dr. Bruce Stallsmith at irb.@uah.edu. If you agree to participate in our research, please sign and date below. This study was approved by the Institutional Review Board at UAH and will expire in one year from <date of IRB approval>.

○ I consent, begin the study (1)

○ I do not consent, I do not wish to participate (2)

Q23 Please type participant number:

_____

Q2 Do you have any knowledge of pre-exposure prophylaxis (PrEP)?

- ○ Yes (1)
- ○ No (2)

Q3 If yes, what level would you rate your knowledge of PrEP?

- ○ Poor (1)
- ○ Fair (2)
- ○ Good (3)
- ○ Very Good (4)
- ○ Excellent (5)

Q4 Have you been approached for PrEP by a patient?

- ○ Yes (1)
- ○ No (2)

Q5 Have you ever personally prescribed PrEP to a patient?

- ○ Yes (1)
- ○ No (2)

Q6 Have you ever referred a patient for PrEP (e.g., to a PrEP provider or HIV clinic)?

- ○ Yes (1)
- ○ No (2)

Q7 Please rate your level of comfort with the following questions:

	Poor (1)	Fair (2)	Good (3)	Very Good (4)	Excellent (5)
What level would you rate your comfort with PrEP use? (1)	○	○	○	○	○
If you identified a patient at high risk for HIV acquisition, what is your level of comfort with prescribing PrEP? (2)	○	○	○	○	○
How would you rate your knowledge of PrEP's potential side effects. (3)	○	○	○	○	○

Q8 How willing are you to prescribe PrEP in the next 3 months?

- ○ Not at all (1)
- ○ Slightly (2)
- ○ Moderately (3)
- ○ Extremely (4)

Q9 Do you feel PrEP is an important tool in HIV prevention?

- ○ Yes (1)
- ○ Unsure (2)
- ○ No (3)

Q10 Rate your feelings with agreement or disagreement with the following statements:

	Strongly Disagree (1)	Disagree (2)	Neither Agree Nor Disagree (3)	Agree (4)	Strongly Agree (5)
It is more feasible to provide PrEP in a specialty or primary care clinic. (1)	○	○	○	○	○
It is feasible to initiate PrEP in the urgent care setting. (2)	○	○	○	○	○
It is feasible to continue PrEP in the urgent care setting. (3)	○	○	○	○	○
I am concerned about the potential side effects of PrEP. (4)	○	○	○	○	○

Q11 Please rate the degree to which each of the following is a potential impact or barrier to your PrEP use within the urgent care setting:

	Not at all likely to be a barrier				Extremely likely to be a barrier
	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)
Time constrains of discussion, screening, and counseling. (1)	○	○	○	○	○
Lack of knowledge and experience with laboratory requirements. (2)	○	○	○	○	○
Lack of guidelines and protocol for PrEP use. (3)	○	○	○	○	○
Lack of provider training or education on PrEP. (4)	○	○	○	○	○
Clinical and lab monitoring requirements. (5)	○	○	○	○	○

Q12 Rate the degree to which each of the following would facilitate your prescribing PrEP:

	Not at all likely to be a barrier				Extremely likely to be a barrier
	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)
Access to resources such as PrEP prescription guidelines and protocols. (1)	○	○	○	○	○
Practice or institutional willingness to implement new clinical protocols. (2)	○	○	○	○	○
Peers who are knowledgeable about or supportive of PrEP use. (3)	○	○	○	○	○

Q13 With respect to gender, how do you self-identify?

- ○ Male (1)
- ○ Female (2)
- ○ Transgender (3)
- ○ Gender non-conforming (4)
- ○ Choose not to answer (5)

Q14 With respect to sexual orientation, how do you self-identify?

- ○ Heterosexual (1)
- ○ Gay (2)
- ○ Bisexual (3)
- ○ Lesbian (4)
- ○ Other (5)

Q15 Which category below includes your age in years?

- ○ 21-29 (1)
- ○ 30-39 (2)
- ○ 40-49 (3)
- ○ 50-59 (4)
- ○ 60 or older (5)

Q16 What is the highest level of education completed or degree received?

- ○ Master (1)
- ○ Doctorate (2)

Q17 What is your current role?

- ○ Physician (1)
- ○ Nurse Practitioner (2)
- ○ Physician Assistant (3)

Q18 What race do you identify?

- ○ White (1)
- ○ Black or African American (2)
- ○ American Indian or Alaska Native (3)
- ○ Asian (4)
- ○ Native Hawaiian or Pacific Islander (5)
- ○ Other (6)

Q19 Do you identify as Hispanic or Latino?

- ○ Yes (1)
- ○ No (2)

Q20 Number of years in practice.

- ○ 0 to 2 (1)
- ○ 3 to 5 (2)
- ○ 5 to 10 (3)
- ○ 10 to 15 (4)
- ○ 15 to 20 (5)
- ○ greater than 20 (6)

Q22 Thank you for completing this survey. Please download and/or print the provided PrEP Protocol and use at your discretion.

APPENDIX G

Pre-Exposure Prophylaxis Protocol for the Urgent Care Setting: Post-Test Questionnaire

Q23 Please type participant number:

_____

Q2 Since the last pre-exposure prophylaxis (PrEP) survey and PrEP protocol dissemination, what level would you rate your knowlPedge of PrEP?

- ○ Poor (1)
- ○ Fair (2)
- ○ Good (3)
- ○ Very Good (4)
- ○ Excellent (5)

Q3 What medication comprises current CDC approved PrEP? (select one)

- ○ Emtricitabine/Rilpivirine (1)
- ○ Dolutegravir/Tenofovir (2)
- ○ Emtricitabine/Tenofovir (3)

Q5 Have you ever personally prescribed PrEP to a patient since obtaining the PrEP protocol?

- ○ Yes (1)
- ○ No (2)

Q6 What level would you rate your comfort with PrEP use?

- ○ Poor (1)
- ○ Fair (2)
- ○ Good (3)
- ○ Very Good (4)
- ○ Excellent (5)

Q8 How willing are you to prescribe PrEP in the next 3 months?

- ○ Not at all (1)
- ○ Slightly (2)
- ○ Moderately (3)
- ○ Extremely (4)

Q9 Identify which laboratory testing is required to initiate PrEP: (choose all that apply)

- ☐ Renal Function (1)
- ☐ Pregnancy Testing (2)
- ☐ Herpes Simplex Testing (3)
- ☐ Hepatitis B (4)

Q7 Please rate your level of comfort with the following questions:

	Poor (1)	Fair (2)	Good (3)	Very Good (4)	Excellent (5)
What level would you rate your comfort with PrEP use? (1)	○	○	○	○	○
If you identified a patient at high risk for HIV acquisition, what is your level of comfort with prescribing PrEP? (2)	○	○	○	○	○
How would you rate your knowledge of PrEP's potential side effects. (3)	○	○	○	○	○

Q26 Please select the most common side effects of PrEP: (choose all that apply)

- ☐ Headache (1)
- ☐ Abdominal Pain (2)
- ☐ Weight Loss (3)
- ☐ Painful Urination (4)
- ☐ Vision Changes (5)

Q27 Do you feel PrEP is an important tool in HIV prevention?

- ○ Yes (1)
- ○ Unsure (2)
- ○ No (3)

Q28 Please list your reason for the previous question's answer:

_____

_____

_____

_____

_____

Q10 Rate your feelings with agreement or disagreement with the following statements:

	Strongly Disagree (1)	Disagree (2)	Neither Agree Nor Disagree (3)	Agree (4)	Strongly Agree (5)
It is more feasible to provide PrEP in a specialty or primary care clinic. (1)	○	○	○	○	○
It is feasible to initiate PrEP in the urgent care setting. (2)	○	○	○	○	○
It is feasible to continue PrEP in the urgent care setting. (3)	○	○	○	○	○
I am concerned about the potential side effects of PrEP. (4)	○	○	○	○	○

Q11 Please rate the degree to which each of the following is a potential impact or barrier to your PrEP use within the urgent care setting:

	Not at all likely to be a barrier				Extremely likely to be a barrier
	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)
Time constrains of discussion, screening, and counseling. (1)	○	○	○	○	○
Lack of knowledge and experience with laboratory requirements. (2)	○	○	○	○	○
Lack of guidelines and protocol for PrEP use. (3)	○	○	○	○	○
Lack of provider training or education on PrEP. (4)	○	○	○	○	○
Clinical and lab monitoring requirements. (5)	○	○	○	○	○

Q12 Rate the degree to which each of the following would facilitate your prescribing PrEP:

	Not at all likely to be a barrier				Extremely likely to be a barrier
	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)
Access to resources such as PrEP prescription guidelines and protocols. (1)	○	○	○	○	○
Practice or institutional willingness to implement new clinical protocols. (2)	○	○	○	○	○
Peers who are knowledgeable about or supportive of PrEP use. (3)	○	○	○	○	○

Q29 What do you like about the one-page PrEP protocol you were given?

_____

_____

_____

_____

_____

Q30 Is there any additional information you would like the protocol to provide?

_____

_____

_____

Q13 With respect to gender, how do you self-identify?

- ○ Male (1)
- ○ Female (2)
- ○ Transgender (3)
- ○ Gender non-conforming (4)
- ○ Choose not to answer (5)

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- ○ Master (1)
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- ○ Physician (1)
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- ○ Physician Assistant (3)

Q18 What race do you identify?

- ○ White (1)
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- ○ American Indian or Alaska Native (3)
- ○ Asian (4)
- ○ Native Hawaiian or Pacific Islander (5)
- ○ Other (6)

Q19 Do you identify as Hispanic or Latino?

- ○ Yes (1)
- ○ No (2)

Q20 Number of years in practice.

- ○ 0 to 2 (1)
- ○ 3 to 5 (2)
- ○ 5 to 10 (3)
- ○ 10 to 15 (4)
- ○ 15 to 20 (5)
- ○ greater than 20 (6)

Appendix H

Cover Letter

Outcomes from an Urgent Care Pre-Exposure Prophylaxis (PrEP) Protocol for the Prevention of HIV

Jack Mayeux and Yeow Chye Ng wrote the first draft and completed both the initial and final revisions of the manuscript. Matthew M. Bice reviewed and edited the final version.

We attest this manuscript is submitted in accordance with the current JANAC author guidelines. All authors have contributed to this manuscript. This manuscript has been read and approved by all listed authors, and the work is original and not under consideration by any other journal. The authors would like to disclose that Jack J. Mayeux is a current employee of the company where the quality improvement project was performed. Jack J. Mayeux has no financial interests to disclose. Yeow Chye Ng reports no financial or potential conflict of interest. Matthew M. Bice is an owner and collaborating physician of the company where the quality improvement project was performed. Matthew M. Bice has no financial interest to disclose.