Considerations for TelePrEP Programs

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Authors: Marty S. Player MD MSCR, Vanessa A. Diaz, MD MSCR, Nicole A. Cooper MPH, Travita Lee, MBA

Background

More than 1.1 million Americans are currently living with HIV, and nearly 40,000 Americans are newly diagnosed each year.[1] The Southern United States accounts for more than half of incident HIV infections in the US annually, despite being home to less than 40% of the US population.[2] The federal Ending the HIV Epidemic initiative is focused in priority counties and states across the nation, six of the seven priority states are located in the South.[2] Pre-exposure prophylaxis (PrEP) is a daily regimen of two oral antiretroviral drugs in a single pill, which has proven to be highly effective in preventing HIV infection for individuals at high risk, reducing the risk of acquiring HIV by up to 97%.[3] It is recommended by the Centers for Disease Control and Prevention (CDC™) for the prevention of HIV infection in high-risk adults. High medication adherence is critical to PrEP efficacy but is not uniformly achieved.[4] The CDC™ notes that PrEP uptake has increased in recent years. There were 1.2 million people eligible for PrEP in 2020 and 25% of were taking PrEP, up from only 3% in 2015.[5] PrEP delivery through a telehealth model can quickly link interested individuals to PrEP, and overcome barriers related to stigma and physician trust. The framework utilized in developing and evaluating the telePrEP intervention in this study is the PrEP Care Continuum model proposed by Nunn et al, which describes the steps involved in initiating and continuing PrEP.[6]

TelePrEP Program Components

The purpose of this technical assistance report is to provide a brief review of components that may be considered when developing a telePrEP program. We focus this report on key aspects to consider during program design and implementation: 1) key partnerships 2) visit development and schedule, 3) evaluation tools, and 4) barriers and limitations.

Key Partnerships

Strong partnerships between organizations can set a strong foundation for the creation and maintenance of a telePrEP program. Strong partnerships with groups who work with populations at increased risk of HIV acquisition are needed to facilitate recruitment and retention in a telePrEP program. These types of partners are already content experts and need minimal training on screening and referring to PrEP services. Initiation and maintenance of PrEP therapy requires quarterly lab testing which can be a barrier to some patients. Having key partners throughout your geographic catchment area can alleviate barriers patients may face. This program specifically partnered with one region of the state public health authority. Referrals primarily came from local health departments with sites across an 11-county region of the state. This partnership provided a wide referral base, including nursing and partner services staff, and increased access to care, as health departments served as sites where participant's labs could be drawn. A lab visit is a necessary component of the program, recurring every three months. Study staff developed and conducted staff training for health department partners on eligibility criteria and health department policies were created to guide lab visit procedures. A Memorandum of Agreement (MOA) was established between entities to allow for secure transfer or medical records (lab results) between agencies.

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Visit Development and Schedule

The CDC's™ Clinical Practice Guidelines for PrEP[7] outline indications for PrEP, laboratory testing recommendations, and clinical follow up and monitoring guidelines which can be utilized to develop a telePrEP visit schedule. There are a variety of visit types and technical requirements that can be utilized in a telePrEP program. Specific technical needs include secure storage, electronic medical record, video and e-visit platforms. Possible visit types to incorporate into a program are listed in Table 1.

Table 1. TelePrEP Visit Types

Visit Type	Visit Description	Visit Setting	Example Platforms	Visit Frequency
Lab Visits	Lab draws at a partner site clinic in patients county of residence or neighboring county	In person, home testing		Every 3 months
Video Visits	Synchronous visit with provider. Labs are reviewed and prescription given during this visit	Virtual	Doxy.me©™, Andor©	At initiation, 3 and 6, months
E-Visits	Asynchronous e-visit with provider. Patient completes a questionnaire asking about side effects, symptoms of HIV, possible exposures, etc. Visit can be scheduled, or patient initiated.	Virtual	Zipnosis™, Epic™	At 1, 2, 4, 5, 9 months

In this program, A 12-month visit schedule was developed with lab visits every three months and video and e-visits throughout the program as illustrated in Figure 1. An e-visit algorithm (Appendix A) was developed for participant follow up and an Epic™ SmartPhrase (Appendix B) was developed for use during telePrEP video visits.

Figure 1. 12-Month TelePrEP Visit Schedule

In terms of lessons learned regarding visit scheduling, we discovered several key insights. While having a coordinated and secure portal for labs proved valuable, and we initially devised an intensive visit and follow-up schedule to help maintain medication adherence, our experience revealed different realities over time. We found that patients generally did not follow the intensive visit schedule as planned. Moreover, we learned that such an intensive schedule wasn't actually necessary for maintaining adherence among motivated patients.

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Evaluation Tools

Evaluation is a critical component of a telePrEP program. In this program, electronic surveys were sent to participants at initiation of the program and again at month 3 and 6 of the program. Surveys were created in REDCap©™[8], a web-based application designed to support data capture for research studies, and then sent to participant via email or text message. The Twilio™ platform is a secure, third-party app that can be integrated with REDCap©™ to send survey invitations and messages to participants via text message. The use of the Twilio™ platform incurs a small fee for each text message sent.
Information collected during evaluation may include demographic information, comfort with technology, HIV risk perception[9], medical trust[10], acceptability of the video and e-visits[11]. Additional clinical information can be collected during video and e-visits and captured in the electronic medical record.

In this project have also made efforts to streamline PrEP and TelePrEP visits through integration with the electronic health record system center on the development of an Epic Smart Set, which represents a potentially significant advancement in care delivery. This comprehensive ordering module for PrEP and DoxyPEP encompasses several key components, including standing orders for both initial and follow-up labs, prescriptions for oral PrEP medications, clinical guidance for providers, patient information materials, and specific guidelines for PrEP and DoxyPEP. The system offers valuable customization options, allowing for tailored approaches for new patients, follow-ups, and DoxyPEP, while remaining adaptable to individual patient needs. The anticipated benefits of this integration could be substantial, potentially leading to easier and more appropriate prescribing, standardized care protocols, and enhanced efficiency in PrEP management. Most notably, the system's impact on care may provide reduced prescribing errors, ensure comprehensive patient management, and facilitate consistent adherence to best practices.

Barriers and Limitations

While these components can form strong foundation for a telePrEP program, there are areas for improvement. In our program, approximately half of individuals referred to the program enrolled in the program. Many of the participants could not be contacted after the referral was made, highlighting the need for a workflow that reaches out to potential participants as quickly and efficiently as possible. Our program only received telephone numbers for participants and did not text participants. Identifying more contact options, and including texting, might help increase the enrollment rate. Participants who were reached and decided not to enroll expressed a lack of interest in the program, or said they changed their mind. Of those who consent to participate, some are not able to keep a lab and video visit and receive a PrEP prescription. Getting to a clinic for a lab visit is a barrier for some and home testing is being explored to aid in alleviating this barrier. Home testing may be a good option to increase engagement in the program, ensure more lab tests are completed, and result in more PrEP prescriptions for participants. Loss to follow up is another concern with individuals simply not being able to be contacted. Cost must also be considered as a potential barrier. This program covered costs associated with testing and visits, however participants used insurance or medication assistance programs to access PrEP medication at low cost. Organizations creating and implementing a telePrEP program must consider cost barriers their patients may face and may consider a patient navigator to aid patients in exploring assistance programs and/or insurance barriers. A dedicated program coordinator to track participants and address issues as they arise is helpful

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in keeping individuals engaged in the program. Reasons cited for withdrawal from the program included: competing health concerns, side effects from medication, low risk HIV perception (low number of partners, etc.), moving out of state.

Conclusion

PrEP for HIV prophylaxis delivered via a telehealth program has the potential to reach those most vulnerable and with the least access to PrEP services. In rural areas with disproportionate HIV burden, telePrEP may be a valuable tool to assist in increasing PrEP uptake. We were able to reach high priority patient populations than is seen in general PrEP prescribing within our state and compared to other states with this method of telemedicine and partnership with state health departments. The methods outlined in this document were developed and revised based on experience and should be adapted to fit populations of interest and to meet the needs of patients and providers involved in the program.

For more information on development of a telePrEP program or a consultation with our Center of Excellence, please contact telehealthcoe@musc.edu

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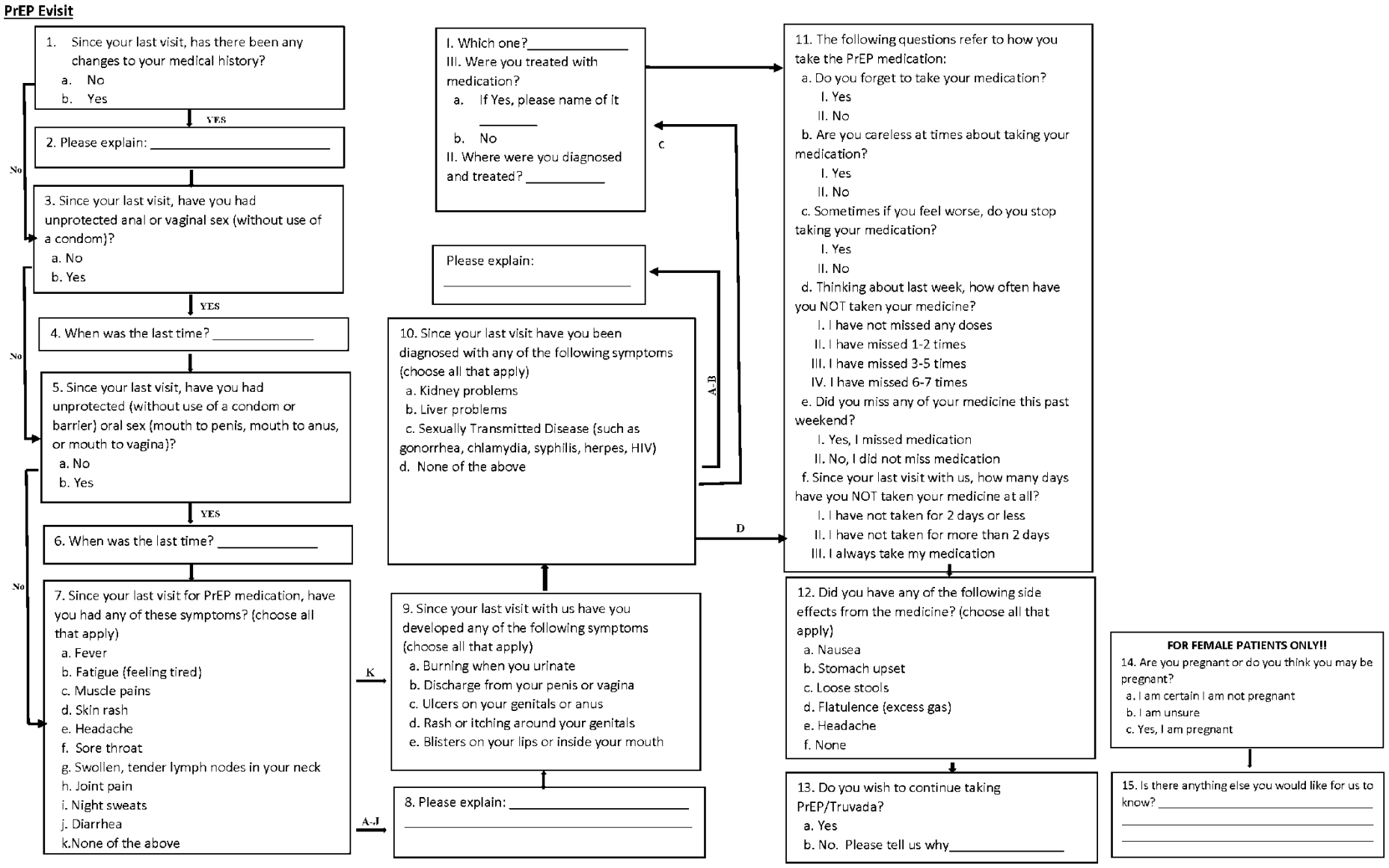
Appendix A: PrEP E-Visit Algorithm



Appendix B: PrEP Epic™ SmartPhrase

This encounter was completed using real-time HIPAA compliant videoconferencing directly with the patient at [Home, Clinic, Hospital]. This service is medically necessary to maintain continuity of care.

[Document telepresenter if used. This guidance disappears when note signed]
Time Based Service (Optional): [XX minutes]
Telemedicine Telepresenter (Optional): [YES/NO]

[XX] y.o. [FIRST NAME] [LAST NAME] identifies as [GENDER] presents for initial evaluation for HIV Pre-exposure prophylaxis therapy.

Patient's pronoun preference: [SHE/HE/THEY/OTHER]

The following portions of the patient's history were reviewed and updated as appropriate:
Sexual History:
Orientation: [XXXXX]
Number of sexual partners: [XXXXX]
Types of sex: [XXXXX]

Risk factors for HIV transmission and a candidate for PrEP therapy:

1. Sex partner(s) known to have or potentially have HIV: [YES, NO, MAYBE, N/A]
2. Multiple sex partners: [YES, NO, MAYBE, N/A]
3. Bacterial sexually transmitted infection (STI/STD) in the past year: [YES/NO]
4. Sometimes forgets to use condoms or chooses not to: [YES, NO, MAYBE, N/A]
5. Commercial sex work: [YES/NO]
6. Injection drug use and share equipment with others: [YES/NO]
7. Do you think you may be at risk for HIV: [YES, NO, MAYBE, N/A]

History of PrEP use:
Do you currently or have you ever taken PrEP/Truvada™/Descovy™ medication: [YES/NO]
If yes, which medication: [XXXXXX]

Labs reviewed:
HIV testing: [POSITIVE/NEGATIVE]
Cr Clearance over 60mL/min (for Truvada™) or >30mL/min (for Descovy™): [YES/NO]
Hepatitis B Surface Antigen (sAg): [POSITIVE/NEGATIVE]
Hepatitis B Surface Antibody (sAb): [POSITIVE/NEGATIVE]
Gonorrhea (urine, rectal, throat): [POSITIVE/NEGATIVE]
Chlamydia (urine, rectal, throat): [POSITIVE/NEGATIVE]
Syphilis/RPR: [POSITIVE/NEGATIVE]
Hepatitis C: [POSITIVE/NEGATIVE]
Hepatitis B immune (positive surface antibody, negative antigen): [YES/NO]
If not immune, recommend Hepatitis B vaccine series.

Assessment and Plan:

1. **At risk for HIV infection:**
   When taken consistently, PrEP has been shown to reduce the risk of HIV infection in people who are at high risk by up to 92%
   Discussed consistent taking of [TRUVADA™/DESCOVY™] daily
   Potential side effects discussed
   Continue to use condoms as prevention for HIV and other STIs
   PrEP does not prevent syphilis, gonorrhea, chlamydia or other STIs
   Regular HIV testing is required for therapy every 3 months

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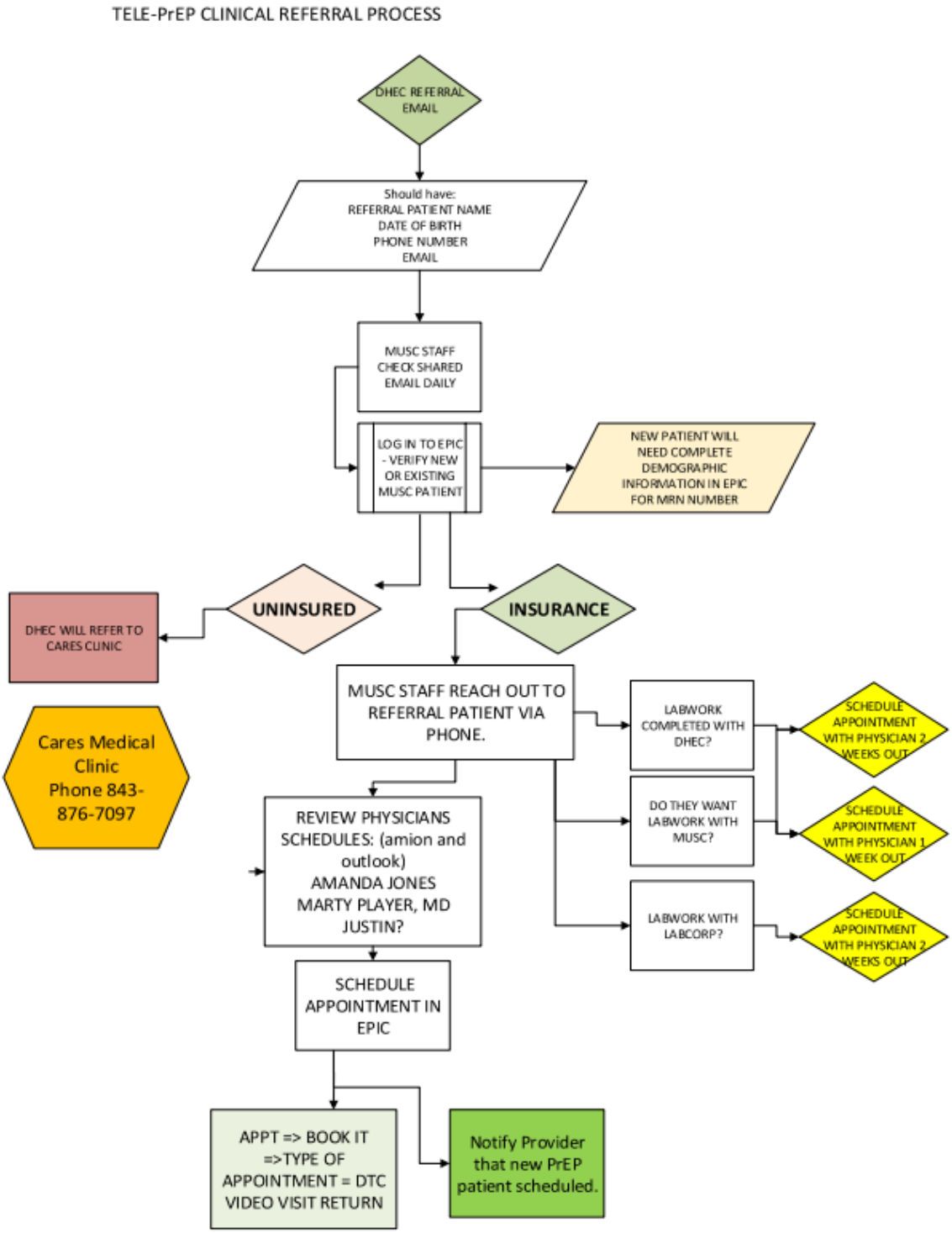
Appendix C: Tele-PrEP Clinical Referral Process



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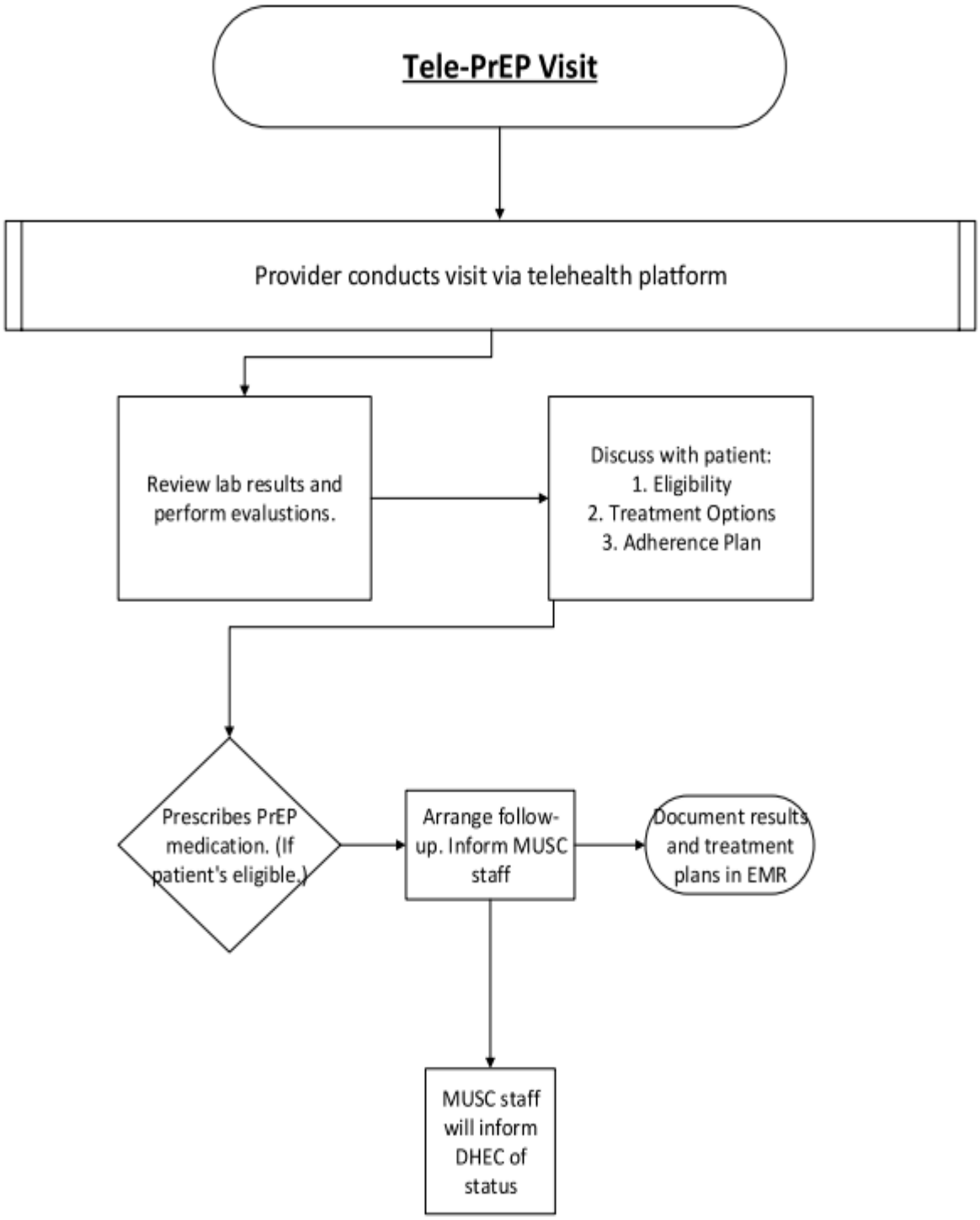
Appendix D: Tele-PrEP Clinical Referral Process



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Appendix E: Tele-PrEP Sustainability Program

MUSC Family Medicine TelePrEP Sustainability Program

1. Referral Process

UNINSURED PATIENTS:

a. Partner site referring nurse or social worker will refer the patient to:
MUSC CARES Medical Clinic
Phone: 843-876-7097
Hours to schedule an appointment: Monday, Tuesday, or Thursday 11 am- 2 pm

INSURED PATIENTS

a. South Carolina partner site's Nurse and Social Worker sends referral via encrypted email to telePrEP@musc.edu with patient's name, date of birth and best contact phone number and/or email.
b. MUSC staff will review the referral emails daily and will reach out to patient to complete My-Chart©™ information and schedule an appointment.

2. Scheduling Appointment
   a. MUSC staff contacts the referred patient to schedule a TelePrEP appointment with a program provider.
   b. MUSC staff will need to inform the patient that lab orders will be submitted by provider, and mention that they will choose a lab from the following lab locations:
      (a) MUSC Lab
      (b) Or local partnering lab site(s) (**Note:** We do not fax lab orders.)
   c. MUSC staff to schedule a telehealth appointment in EPIC™ as a video visit. **Note:** Allow enough time for pre-visit labs to be completed, e.g. 1 week out.
3. Pre-Visit Lab Orders
   a. MUSC staff notifies the program provider of the scheduled appointment.
   b. Provider reviews the referral information and orders appropriate pre-visit labs for the patient.
   c. Lab orders are sent to the patient's preferred lab location.
4. TelePrEP Visit
   a. Provider conducts the TelePrEP visit via telehealth platform.
   b. Discuss PrEP eligibility, treatment options, and adherence plan with the patient.
   c. Reviews lab results and performs any necessary evaluations.
   d. If patient's eligible provider will prescribe PrEP medication and arrange follow-ups.
5. Follow-Up
   a. Scheduled follow-up visits (e.g., every 3 months) for monitoring and prescription refills.
   b. Ongoing adherence counseling and support provided as needed.
6. Documentation
   a. All patient encounters, lab results, and treatment plans are documented in the electronic medical record.
   b. Communication with partner site regarding patient status and outcomes as appropriate.

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