

PrEP: Pre-Exposure Prophylaxis in the outpatient private clinic setting

Adopted from office policy and protocols developed by Dr. Quintin R. Robinson and Dr. Zandretta Tims-Cook for AbsoluteCARE Medical Center and Pharmacy



Disclosure

- I, Jewel Sawyer, PA-C, MSHS, AAHIVS am a consultant and/or speaker for **Janssen Therapeutics**.
- I have no relevant financial relationships with manufacturers of any commercial products and/or provider of commercial services discussed in this CME activity
- I do not intend to discuss an unapproved use of a commercial product/device in my presentation

Objectives

- Discuss implementation of PrEP protocol at AbsoluteCARE
- Review counseling, education, screening, prescribing, and follow-up for PrEP
- Discuss stats at particular outpatient clinic
- Identify challenges/barriers of PrEP at clinic

Policy

- Clinical guidelines have been developed for the use of PrEP at AbsoluteCARE which take into consideration the findings and data of studies conducted to date.
- Our protocol includes counseling, screening, prescribing, and follow-up of patients who are offered TDF/FTC 300-200 mg for prophylaxis



PrEP Implementation

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PLAN

1. Background

- AbsoluteCARE Medical Center has delivered high quality, compassionate, culturally-sensitive patient-centered care for 15 years.
- The Medical Center is recognized as a Center of Excellence for HIV care by Georgia Medicaid and is the largest provider of insured HIV Care in Georgia, seeing approximately 3000 HIV positive clients.
- AbsoluteCARE is also recognized as a Level III Patient-Centered Medical Home (PCMH) by the NCQA.

2. Mission Statement

- AbsoluteCARE's goal is to deliver patient-centered care to the HIV affected and chronically ill population.

3. Examine the Current Approach

- Patient interested in PrEP
- Contact healthcare provider for prescription.
- Process varies in different healthcare settings
- No standard to provide services

4. Identify Potential Solutions

- Standardize process
- Include use of Provider/ Risk Reduction Counseling
- Medication Adherence counseling etc.

5. Develop an Improvement Theory

- Streamline PrEP process for practice.
- Start with scheduling appointment to meeting with each member of the team.
- Clearly delineate roles and expectations of team.
- Appropriate risk assessment

DO

6. Test the Theory

- Demonstrate how PrEP implementation at AbsoluteCARE would look
- Schedule patient with provider; review clinical information, risk assessment, complete sexual history
- Categorize risk
- Introduce Risk/Harm Reduction counseling at initial visit
- Complete appropriate HIV and STI testing
- Schedule appointment with Health Educator prior to or immediately after getting prescription

STUDY

7. Check the Results

- Design and implement project
- Compare pre and post collaborative number of patients seen for PrEP
- Number of prescriptions obtained
- Number returned for at least one follow up visit with provider

ACT

8. Standardize the Improvement or Develop New Theory

- Educate medical providers and patients on the appropriate plan and timeline for use of PrEP
- Evaluate process and uptake by providers and clients

9. Establish Future Plan and Process Owner


Counseling

- Counseling is completed by both the provider and Peer Educator at the first visit and each subsequent visit to include:
 - The use of barrier contraceptive methods with each sexual encounter including oral, vaginal, and anal intercourse.
 - The correct storage and use of male condoms, female condoms, dental dams, and finger condoms based on type of intercourse patient participates in
 - The clinical signs and symptoms of common sexually transmitted infections (STI) in themselves and their sexual partner(s) and are advised to seek treatment as soon as possible
 - Patients are also to meet with Peer Educator at each occurrence of an STI in conjunction with routine visits

- All patients who are prescribed PrEP also receive medication adherence counseling utilizing the Health Educator at all visits - initial and follow-up to include:
 - Proper dosing and administration
 - Adherence
 - Possible AEs
 - Duration for efficacy based on modes of sexual intercourse

Screening

- All patients who are prescribed PrEP receive the following baseline lab assessment:
 - 4th generation HIV testing
 - Hepatitis B serology including surface antigen testing
 - Complete metabolic panel
 - Complete blood count
 - RPR (quantitative test if history of syphilis)
 - Gonorrhea/Chlamydia NAAT/Aptima testing (cervical swab for female patients, rectal and urine swabs for MSM patients, and oral swab for all patients)

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- Urinalysis with microscopy (can detect trichomonas)
 - Urine pregnancy test
 - Consider DEXA scan in select patients when medically necessary
 - Hepatitis C antibody testing in IVDU and MSM patients

- Patients who lack evidence of prior hepatitis B virus exposure are advised and offered the HBV vaccination series prior to beginning PrEP
- Patients who test positive for HIV infection at baseline are not offered TDF/FTC as prophylaxis and instead considered for HIV treatment
- Patients who test positive for HBV infection are properly informed that TDF/FTC concomitantly serves as treatment for HBV and prophylaxis against HIV infection
 - Also informed of the risks of increased liver inflammation due to an exacerbation of their HV infection if they discontinue TDF/FTC without replacement therapy

Who do we offer PrEP to?

- MSM (men who have sex with men) at substantial risk of HIV acquisition **based on risk assessment.** ¹
- Adult heterosexually active men and women who are at substantial risk of HIV acquisition.
- Adult injection drug users (IDU) at substantial risk of HIV acquisition
- Heterosexually-active women and men whose partners are known to have HIV infection (i.e., HIV-discordant couples) as one of several options to protect the uninfected partner during conception and pregnancy so that an informed decision can be made in awareness of what is known and unknown about benefits and risks of PrEP for mother and fetus.

Prescribing

- If needed, patients meet with Social Worker prior to prescribing PrEP to evaluate access and reimbursement issues
- Prior to receiving a prescription for PrEP, each patient is encouraged to review and sign an agreement that attest to his or her understanding of the limitations of PrEP. This agreement also delineates office follow up expectations and consequences of poor compliance
- A maximum of 2 refills is given to ensure close follow-up
- No prescription refills over 3 are advised without an accompanying office visit
- Practice improvement consideration: an ongoing roster of ALL PrEP patients, both active and inactive, is to be maintained documenting office visits, prescription fills and STI occurrences.

Follow-Up Care

- Patients who are prescribed PrEP are seen for regular follow-up every 2-3 months
- Baseline lab assessments including STI testing is repeated at every follow up visit with the exception of HBV serologies once immunity is confirmed
- All patients who are prescribed PrEP should be counseled by both Provider and Peer Educator at each visit to continue to use barrier contraceptive methods and risk reduction with all sexual encounters
- All patients who are prescribed PrEP should continue to receive medication adherence counseling by the Provider and Health Educator at each visit

Barriers

- Lack of Insurance/Loss of insurance
- Patients lost to care
- Time requirements for appointments
- Education and engagement of Non-MSM patients particularly our trans* identified patient population
- Monitoring of STI occurrences in PrEP patients



Absolute CARE

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