A New Clinical Pre-exposure Prophylaxis (PrEP) Program for Individuals at risk for HIV: Improving Access via Telemedicine

Marty S. Player MD, MSCR
Vanessa A. Diaz MD, MSCR
Department of Family Medicine, Medical University of South Carolina
A New Clinical Pre-exposure Prophylaxis (PrEP) Program for Individuals at risk for HIV: Improving Access via Telemedicine

Marty S. Player MD, MSCR
Vanessa A. Diaz MD, MSCR
Department of Family Medicine, Medical University of South Carolina
Support and COI

- Support from SC Telehealth Alliance and Telehealth Pilot Grant
- We have no Conflicts of Interest to report
Learning Objectives

- 1. Identify factors related to HIV transmission risk in South Carolina and challenges to prevention
- 2. Describe development of a telemedicine program for pre-exposure prophylaxis in partnership with community organizations
- 3. Appraise outcomes of a PrEP telemedicine pilot program and apply this knowledge to expansion of future programs
Telemedicine Defined

- ‘Telemedicine’ means the practice of medicine using electronic communications, information technology, or other means between a licensee in one location and a patient in another location with or without an intervening practitioner.
What is Telemedicine?

Telehealth Use Cases, Relevant Modalities, and Investment Required

Use Cases

- Professional Consultation
- Diagnosis & Treatment
- Education & Engagement
- Ongoing Monitoring & Care Coordination

Modalities

- Videoconference or Kiosk
- Asynchronous Store-and-Forward
- Remote Device
- Telephone
- Patient Portal
- Mobile App

- Videoconference or Kiosk:
  - Need software, secure internet access for patients
  - Home and hospital-based technology

- Asynchronous Store-and-Forward:
  - Need additional bandwidth, storage space
  - Can replace non-urgent phone calls and visits

- Remote Device:
  - More expensive hardware investment
  - Used for high-risk patients in non-hospital site

- Telephone:
  - Little tech investment, requires proper staffing
  - Used for pre-visit triage

- Patient Portal:
  - High security needs require significant investment
  - Must integrate EHR

- Mobile App:
  - Minimal hardware investment for providers
  - Complex security and data storage issues
E-visit Program

- SC Telehealth Alliance funded by SC Legislature
  - MUSC Center for Telehealth
- MUSC wanted to start an e-visit program
- 2015 launched Acute e-visit program (virtual urgent care)
  - EPIC/MyChart
  - Started with 5 conditions, expanded to over 20
  - Offered to MUSC employees, expanded to all adult patients
  - ~6000 visits since inception
HIV in the US

- The Southern United States account for 52% of all newly diagnosed HIV cases (2017)
- Almost half (46%) of HIV deaths in the United States were in the South

South Carolina currently ranks 7th in the nation for persons living with HIV

- 14.3 people for every 100,000
- Many rural SC counties at as many as 600-800 per 100,000

Pre-Exposure Prophylaxis (PrEP) medication reduces the probability of HIV transmission for those at high risk

- PrEP availability and access in SC is limited
  - Few facilities and prescribing providers
- Telehealth is a promising approach to help those who would most benefit from PrEP to be connected with PrEP prescribing providers

What is PrEP?

- Once-daily pill for people who do NOT have HIV, meet certain risk factor criteria and want added protection.
- Food and Drug Administration approved an indication for emtricitabine/tenofovir disoproxil (Truvada) for pre-exposure prophylaxis (PrEP) in adults in 2012
  - Addition of adolescents weighing at least 35 kg May 2018
  - Emtricitabine/tenofovir alafenamide (Descovy) approved 2019 (MSM and Transgender women)
The Proof in the Numbers

2010 iPrEx study

- gay and bi men and transgender women
- 92% Prevention
- 99% Protection (with daily use)

2012 Partners PrEP

- 4,500 heterosexual men and women
- Kenya and Uganda
- One positive partner
- 75% New infection reduction
- 90% Overall transmission reduction

---

A 26 year old cis-gender female presents to your office for annual exam. No specific complaints.

On review of her history you note your FNP treated her for primary syphilis 2 months ago and her gyn treated her for chlamydia 4 months ago.

On history she states she has sex with men only, oral and vaginal.

She is single and has no sex partners currently. States only 2 previously in the past year. She has Nexplanon for birth control.

1. Based on which of the following would you offer her PrEP?
   - A. Her age
   - B. Syphilis in the last 6 months
   - C. Chlamydia in the last 6 months
   - D. Inconsistent condom use with her previous partners
   - E. Both B and C

2. Her CrCl is normal. Which formulation is indicated for this patient?
   - A. emtricitabine/tenofovir disoproxil (Truvada)
   - B. Emtricitabine/tenofovir alafenamide (Descovy)
   - C. Either one
   - D. Neither are approved for this patient
PrEP Guidelines USPSTF

- Q1 Answer: B. Syphilis in the last 6 months
- Heterosexually active women and men who have 1 of the following characteristics:
  - A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
  - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (eg, a person who injects drugs or a man who has sex with men and women)
  - An STI with syphilis or gonorrhea within the past 6 months
- Q2 Answer: A. emtricitabine/tenofovir disoproxil (Truvada)
PrEP Guidelines USPSTF

- Men who have sex with men, are sexually active, and have 1 of the following characteristics:
  - A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
  - Inconsistent use of condoms during receptive or insertive anal sex
  - A sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months
- Persons who inject drugs and have 1 of the following characteristics:
  - Shared use of drug injection equipment
  - Risk of sexual acquisition of HIV
PrEP across the US

- CDC estimates ~1.2 million persons were eligible for PrEP in 2015
  - 492,000 men who have sex with men
  - 115,000 persons who inject drugs
  - 624,000 heterosexually active adults*

- A recent study estimates that 100,282 persons were using PrEP in 2017**

---


Rural Population
27.1% SC population in primary care HPSA
- About 1,254,000 people (DHEC, 2017)

15% SC population in rural areas
- About 747,000 people (USDA-ERS, 2016)

Rural is defined as counties without metropolitan areas (based on population and labor market) – USDA-ERS

https://map.aidsvu.org/map?state=SC
Federal Programs

- Trump administration announced in 2019 goal of ending the HIV epidemic in the US within 10 years
- *Ending the HIV Epidemic: A Plan for America*
  - proposed to reduce new HIV infections in the United States
    - by 75 percent in five years
    - by 90 percent by 2030
  - proposes numerous tools to achieve this goal including the use and expansion of PrEP
  - South Carolina identified as one of 7 priority states with high rural burden
    - 10% or more of new diagnoses in 2016 and 2017 were in rural areas
Discussion Question

- What are some barriers to HIV testing and PrEP use among high risk individuals?
- In rural areas and the southern US?
Barriers / Gaps for HIV testing and PrEP uptake

- Stigma
- Fear
- Lack of providers
- Lack of knowledge/awareness

- Lack of access
  - Transportation
  - Hours
  - Locations
  - Funding/insurance/cost

SCDHEC 2016
Barriers to HIV testing

- Three primary care health clinics in Alabama
- 30% of patients had never been tested for HIV
- Highest ranked barrier among patients
  - Perceived costs
  - access to specialty care
  - not feeling at risk
- Implementation of routine “opt-out” HIV testing may mitigate barriers

Barriers to PrEP Uptake

- 2016 study (published 2018) on willingness to use PrEP among Black individuals in the US.
- Nationally representative sample of 855 Black individuals who were HIV negative
  - 14.5% were aware of, and 26.0% would be willing to use PrEP.
- Among high-risk individuals (N = 327)
  - 19.8% knew about and 35.1% would be willing to use PrEP
  - low self-perceived risk (65.1%) most common reason for lack of willingness
- Participants who saw a health care provider less frequently were less willing to use PrEP

Pre-Exposure Prophylaxis in Primary Care

- Interest in LGBTQI health issues
- PrEP:
  - Pre-Exposure Prophylaxis (PrEP) medication reduces the probability of HIV transmission for those at high risk
  - HIV prevention measures for high-risk individuals
  - Daily medication
  - Prescribing in my clinic, referrals from others
- Initiative to “End AIDS” in numerous states and cities
- How might we reach other patients
  - Higher risk
  - Rural
  - Limited access
- Telehealth is a promising approach to help those who would most benefit from PrEP to be connected with PrEP prescribing providers
Tele-PrEP Program

- SCTA Telehealth Pilot Grants
  - support South Carolina clinicians/researchers to develop innovative, scientifically meritorious telehealth projects with an overarching objective of collecting preliminary data
  - $25,000

- Collaboration with community partners
  - Low Country AIDS Services (LAS)/ Palmetto Community Care
  - SHAPE initiative
  - DHEC sites across SC
Study Timeline

- 12 month feasibility study
  - Start up - 2 months
  - Recruitment - 3 months
  - Study period:
    - Evaluation - 2 months
    - 6 months
## Methods

### Palmetto Community Care Collaboration
- Recruitment
- Recurring lab work

### Surveys
- Initial survey: Technology use comfort and PHQ-8
- Final Survey: Satisfaction

### Telehealth: E-visits and Video Visits
- 4 Electronic visit questionnaires between video visits
- Video visits: beginning, 3 months, and 6 months

### Data Analysis
- Chi square: missed doses compared to age, education, impulsivity, and PHQ-8 scores
PrEP Workflow

1. HIV screening through PCC. Participant tests negative & is given info about the study.
2. Participant completes intake form & PCC sends to Study Coordinator.
3. Study Coordinator contacts participant & participant commits to PrEP program.
4. Study Coordinator registers participant in EPIC & gives instructions for MyChart registration.
6. Study Coordinator schedules video visit & reminds participant about surveys.
7. Initial video visit (participant receives gift card if survey is complete).
8. Evisit.
9. Evisit.
10. Video Visit (HIV & BMP Labs).
11. Evisit.
12. Evisit (survey reminder).
14. Participant decides how they will continue care (in-person vs. telehealth services).

PCC = Palmetto Community Care
EPIC = electronic health record database
MyChart = patient portal

Study lasts for 6 months, but participants have the option to continue with medication.
An algorithm for the e-visit was developed, which includes questions that assess adherence as well as barriers to PrEP adherence.
## Preliminary Results

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referrals</td>
<td>40</td>
</tr>
<tr>
<td>Enrolled</td>
<td>20</td>
</tr>
<tr>
<td>Completed Survey</td>
<td>20</td>
</tr>
<tr>
<td>1st Video Visit</td>
<td>20</td>
</tr>
<tr>
<td>Follow-up e-visits 1-3</td>
<td>20</td>
</tr>
<tr>
<td>Completed study</td>
<td>15</td>
</tr>
<tr>
<td>Drop-outs</td>
<td>4</td>
</tr>
</tbody>
</table>
Initial REDCap Survey (n=18)

Assessed demographics, technology engagement, depression (PHQ-8)

- Mean age: 35.4
- 100% Male
- 94.7%- Caucasian, 5.3%- African American
- 57.9% College graduate or post-graduate degree
- 73.7% Reported having a PCP
- 78.6% Reported being seen within the last 6 months

Severity of depression (PHQ-8)

- Minimal: 42.1%
- Mild: 31.6%
- Moderate: 26.3%
Technology comfort

- Comfort with technology and use was high across all participants for:
  - Owning a mobile phone for 3+ years
  - Using the internet multiple times a day on both computer and mobile device
  - Comfort using video on computers or mobile devices

- 95.5% for Mobile Device
- 77.3% for Internet Use
- 95.5% for Mobile Internet Use
- 100.0% for Video Comfort
# E-visit 1 Follow-Up Questionnaire

<table>
<thead>
<tr>
<th>Category</th>
<th>Questions</th>
<th>% (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safe Sex</strong></td>
<td>Since your last visit, have you had unprotected (w/o condom) anal or vaginal sex?</td>
<td>68.4% No</td>
</tr>
<tr>
<td></td>
<td>Since your last visit, have you had unprotected (w/o a condom) oral sex (mouth to penis, mouth to anus, mouth to vagina)?</td>
<td>57.9% Yes</td>
</tr>
<tr>
<td><strong>Medication Adherence</strong></td>
<td>Do you ever forget to take your medication?</td>
<td>73.7% No</td>
</tr>
<tr>
<td></td>
<td>Are you careless at times about taking your medication?</td>
<td>94.7% No</td>
</tr>
<tr>
<td></td>
<td>Sometimes, if you feel worse do you stop taking your medication?</td>
<td>100% No</td>
</tr>
<tr>
<td></td>
<td>Thinking about last week, how often have you not taken your medication?</td>
<td>21.1% Missed 1 or 2 doses</td>
</tr>
<tr>
<td></td>
<td>Did you not take any of your medication over the past weekend?</td>
<td>100% No</td>
</tr>
<tr>
<td><strong>Side Effects</strong></td>
<td>Do you have any of the following side effects?</td>
<td>10.5% Nausea</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.5% Abdominal Upset</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.3% Loose Stools</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21.1% Flatulence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.5% Headache</td>
</tr>
<tr>
<td></td>
<td></td>
<td>68.4% None</td>
</tr>
</tbody>
</table>
PHQ-8 Scores and Medication Adherence

**Severity of Depression (PHQ-8)**

- Minimal: 42.1%
- Mild: 31.6%
- Moderate: 26.3%

**Medication Adherence**

- Overall Missed Doses: 36.8% Yes, 63.2% No
- E-visit 1: N=1
- E-visit 2: N=18
- E-visit 3: N=1

- No missed doses: 9
- 2 Days or less: N=18
- More than 2 days: N=1
100% reported they would recommend telehealth to others for PrEP therapy

Program Satisfaction

**Likely to Use Service Again**
- Yes: 78.6%
- No…

**Satisfaction survey (n=14)**

**Preferred Method for PrEP**
- In-person only: 14.3%
- Telemedicine or Combination: 85.7%
Other TelePrEP Programs

- **PrEPTECH**
  - Pilot program in California; California DOH, UCLA, Gilead
  - PrEP intake appointments by phone, opt-in text messages for medication adherence, PrEP medication by mail

- **Gay City** – LGBTQ community center in Seattle
  - PrEP prescribed via videoconference with a remote PrEP specialist
  - Washington State DOH, Univ of Washington, Gay City community center

- **PrEPIOWA**
  - Clinical pharmacists prescribe medication and counsel patients via telemedicine
  - Iowa DOH, Univ of Iowa

- **For-profit platforms**
  - Plushcare.com
  - Nurx.com
The Future of PrEP

- The Antimicrobial Drugs Advisory Committee recommended approval for emtricitabine and tenofovir alafenamide for PrEP use
  - Fewer bone and renal issues
- National Institutes of Health (NIH) are developing and testing several long-acting forms of HIV prevention that can be inserted, injected, infused, or implanted in a person’s body from once a month to once a year
  - not yet approved by the FDA and are not available for use outside of a clinical trial
Conclusions

- Telemedicine modalities can be successfully used for a PrEP program
- PrEP through telehealth has been well received as a means of treatment
- Participants are engaged and adherent and overall satisfied with treatment
- Care/study coordinators and community partners are key
- Continuing the clinical program and expanding larger in scope remains a challenge