



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

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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

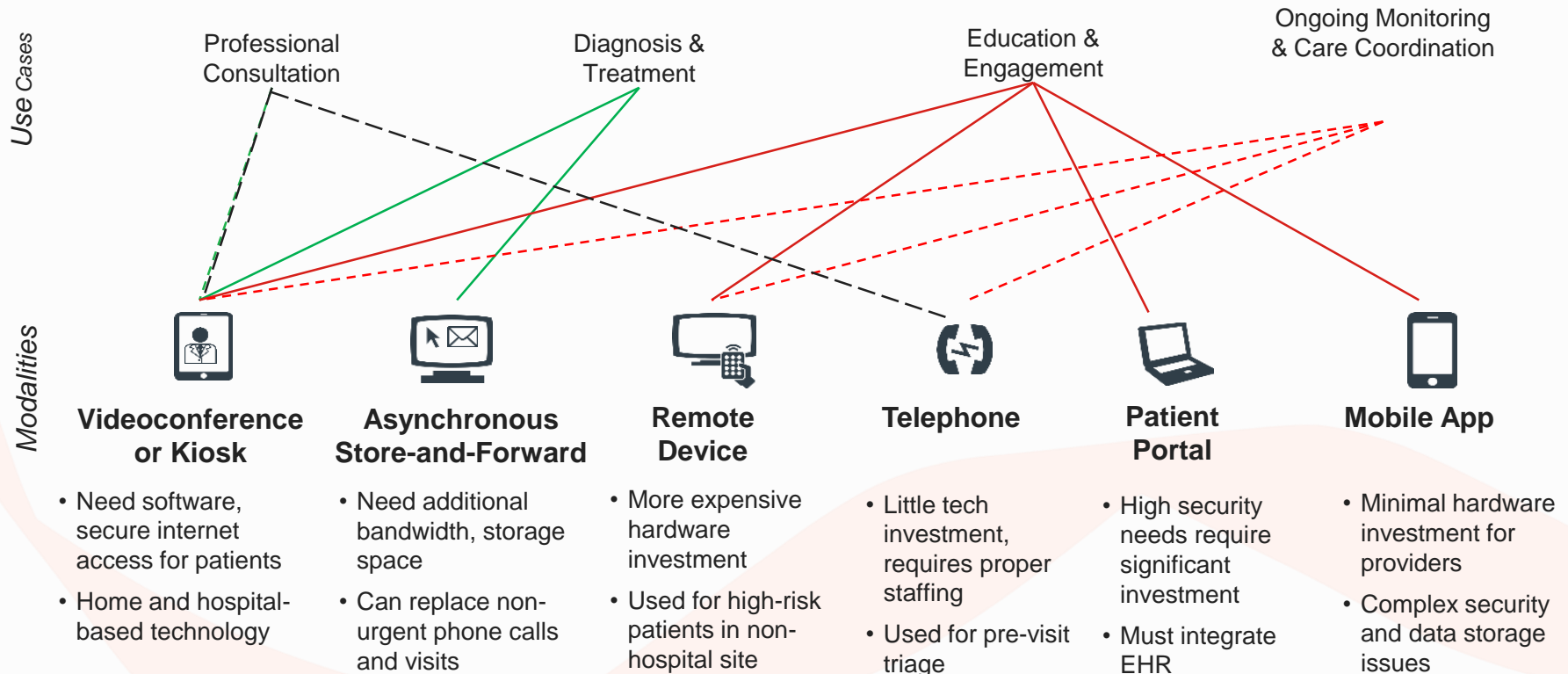
Telemedicine Defined

- '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

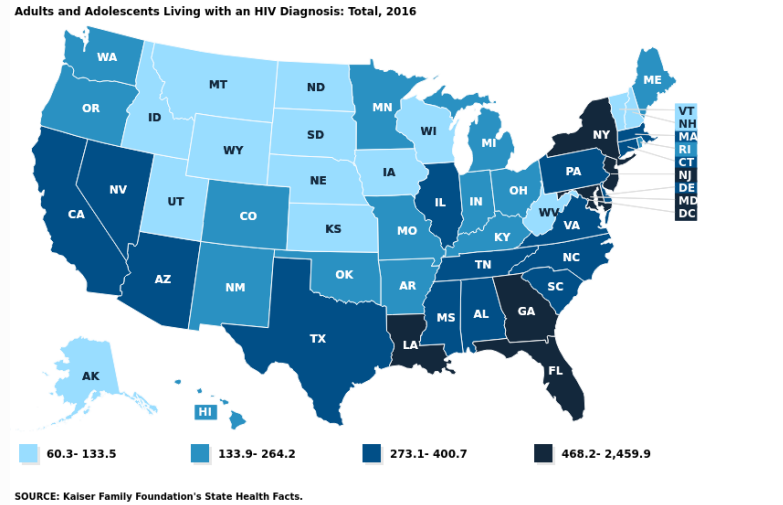


E-visit Program

- 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



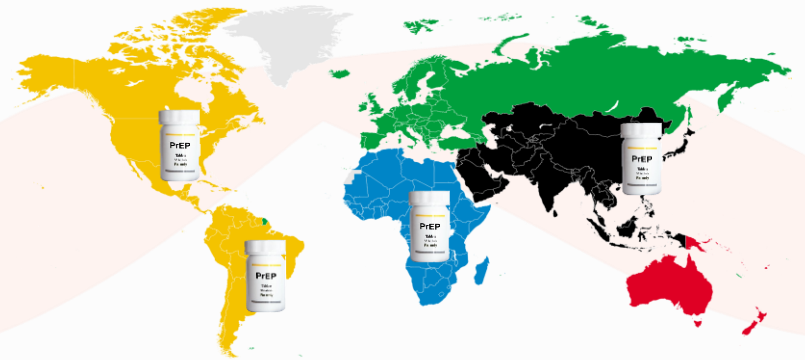
1. HIV in the United States by Region. Centers for Disease Control and Prevention. <https://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html>. Published September 9, 2019. Accessed September 19, 2019.

HIV in South Carolina

- ▶ 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?

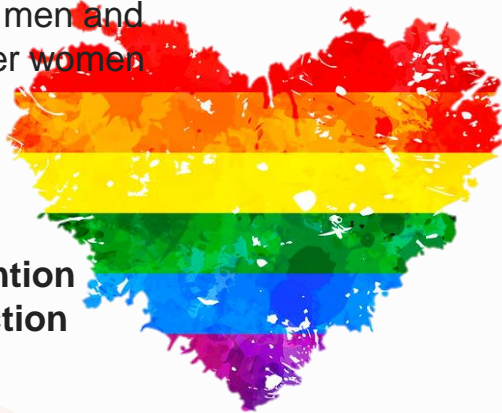
- Once-daily pill for people who do NOT have HIV, meet certain risk factor criteria and want added protection.
- Food and Drug Administration approved an indication for emtricitabine/tenofovir disoproxil (Truvada) for pre-exposure prophylaxis (PrEP) in adults in 2012
 - Addition of adolescents weighing 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

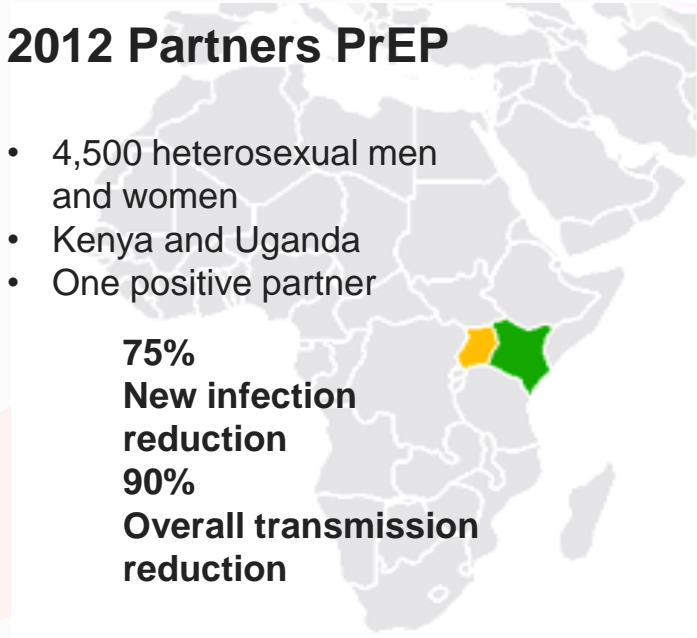


92% Prevention
99% Protection
(with daily use)

2012 Partners PrEP

- 4,500 heterosexual men and women
- Kenya and Uganda
- One positive partner

75%
New infection reduction
90%
Overall transmission reduction



1. Grant RM, Lama JR, Anderson PL, et al. Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *New England Journal of Medicine*. 2010;363(27):2587-2599. doi:10.1056/nejmoa1011205.
2. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *New England Journal of Medicine*. 2012;367(5):399-410. doi:10.1056/nejmoa1108524.

Assessment Question

- 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 patients

- 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

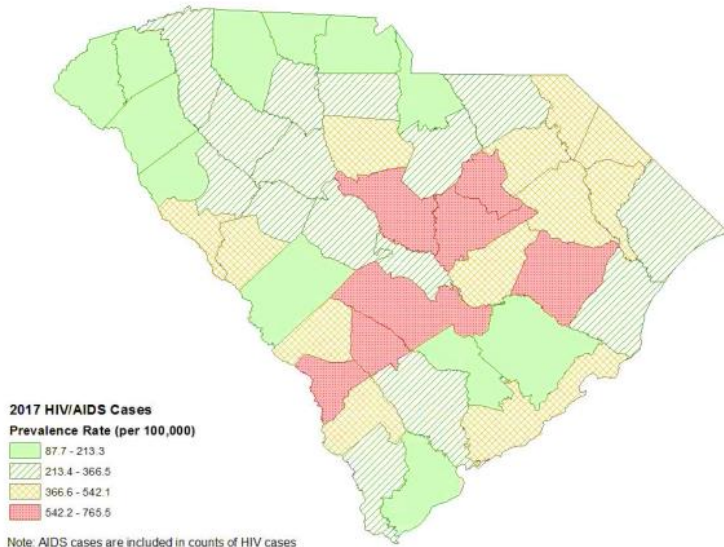
- CDC estimates ~1.2 million persons were eligible for PrEP in 2015
 - 492,000 men who have sex with men
 - 115,000 persons who inject drugs
 - 624,000 heterosexually active adults*
- A recent study estimates that 100,282 persons were using PrEP in 2017**

*Smith DK, Van Handel M, Wolitski RJ, et al. Vital signs: estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition—United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(46):1291-1295.

**Sullivan PS, Giler RM, Mouhanna F, et al. Trends in the use of oral emtricitabine/tenofovir disoproxil fumarate for pre-exposure prophylaxis against HIV infection, United States, 2012-2017. *Ann Epidemiol.* 2018;28(12):833-840.

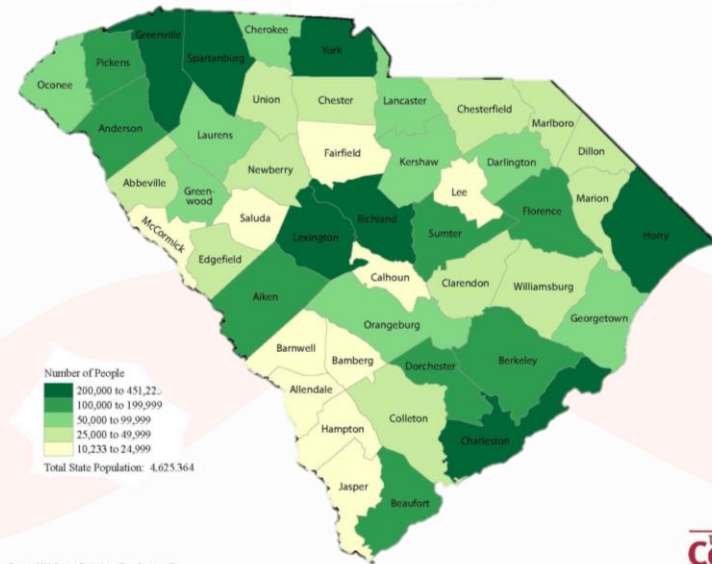
Rural Population

2017 South Carolina HIV/AIDS Prevalence Rate



SOUTH CAROLINA - 2010 Census Results

Total Population by County



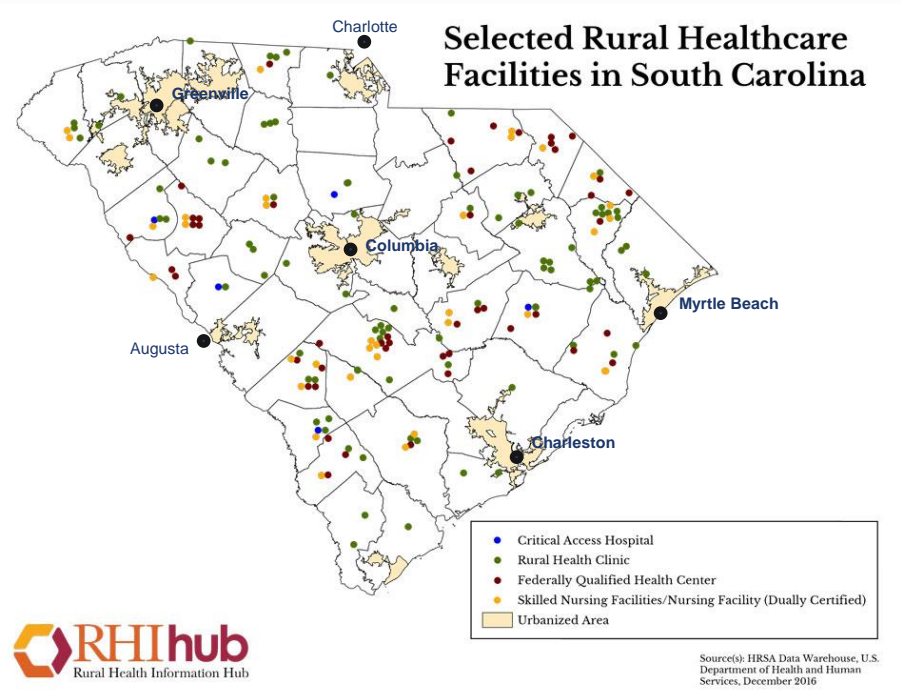
Source: U.S. Census Bureau, 2010 Census Redistricting Data Summary File
For more information visit www.census.gov



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

- 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)

<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

Wise JM, Ott C, Azuero A, Lanzi RG, Davies S, Gardner A, Vance DE, Kempf MC.
Barriers to HIV Testing: Patient and Provider Perspectives in the Deep South. *AIDS Behav.* 2019 Apr;23(4):1062-1072.

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

Ojikutu BO, Bogart LM, Higgins-Biddle M, Dale SK, Allen W, Dominique T, Mayer KH. Facilitators and Barriers to Pre-Exposure Prophylaxis (PrEP) Use Among Black Individuals in the United States: Results from the National Survey on HIV in the Black Community (NSHBC). *AIDS Behav.* 2018 Nov;22(11):3576-3587.

Pre-Exposure Prophylaxis in Primary Care

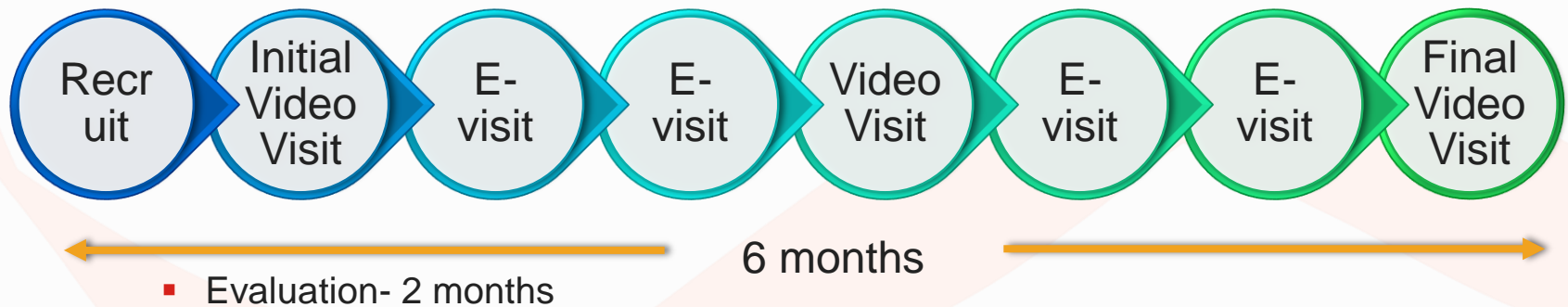
- Interest in LGBTQI health issues
- PrEP:
 - Pre-Exposure Prophylaxis (PrEP) medication reduces the probability of HIV transmission for those at high risk
 - HIV prevention measures for high risk individuals
 - Daily medication
- Prescribing in my clinic, referrals from others
- Initiative to “End AIDS” 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:



Methods

Palmetto Community Care Collaboration

- Recruitment
- Recurring lab work

Surveys

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

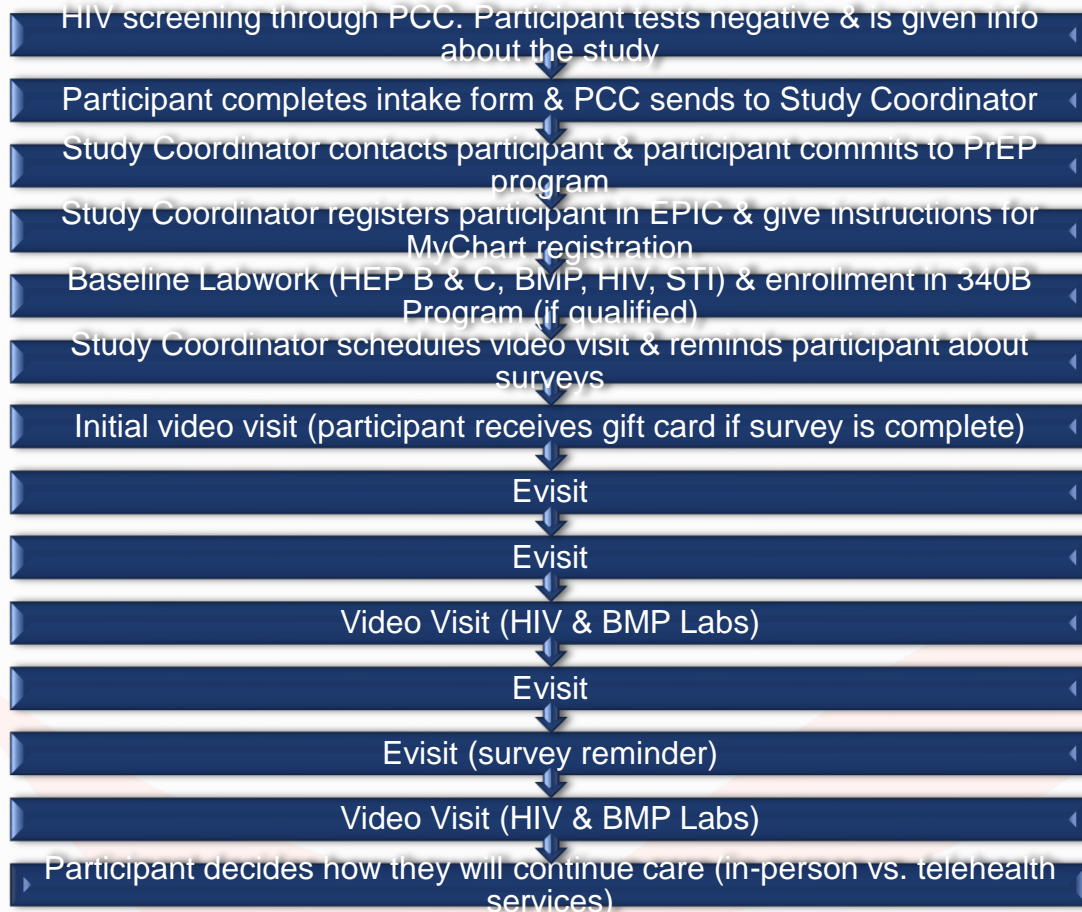
Telehealth: E-visits and Video Visits

- 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

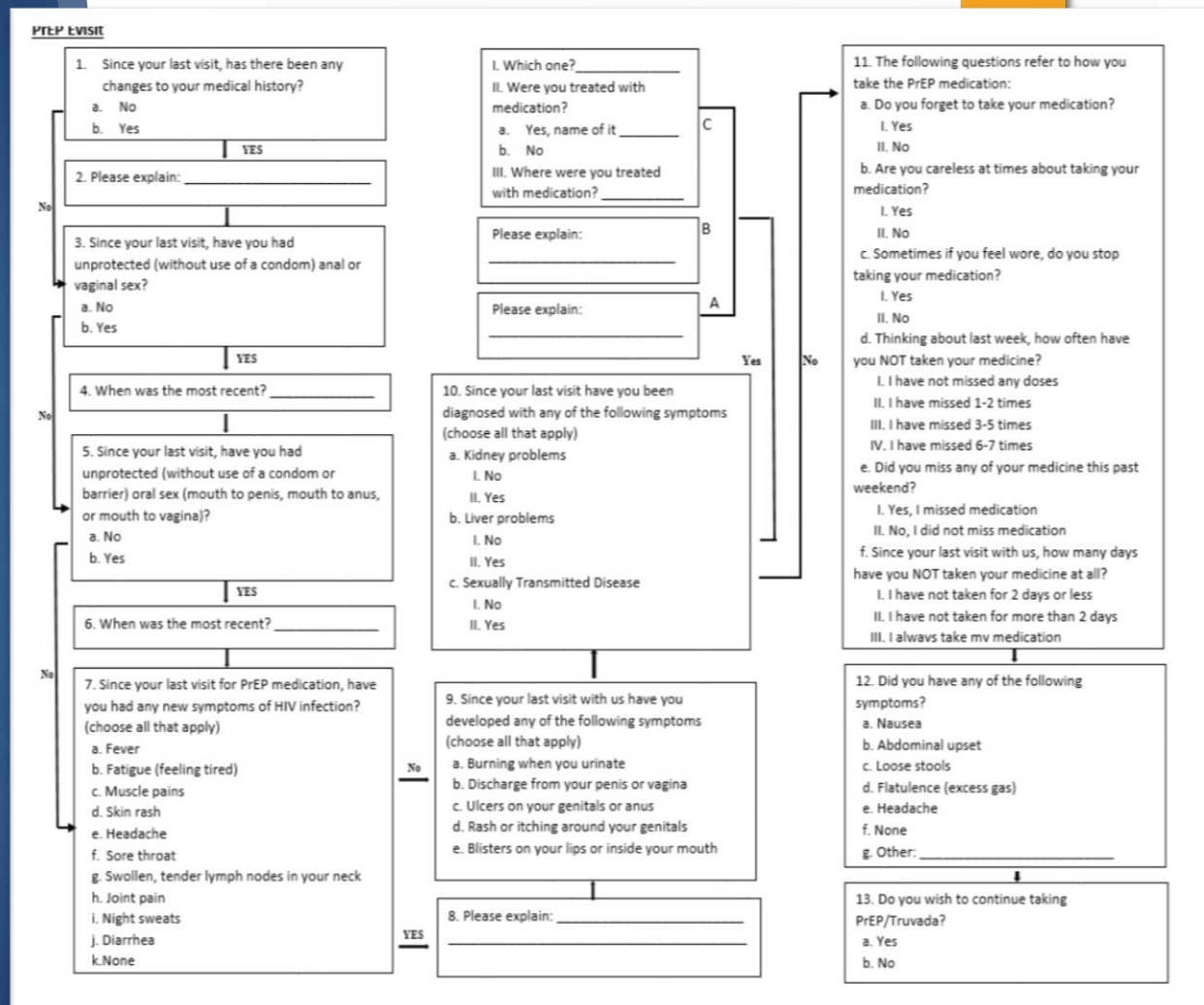


PCC = Palmetto Community Care

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



Referrals: 40



Enrolled: 20 | 25



Completed Survey: 20



1st Video Visit: 20



Follow-up e-visits 1-3: 20



Completed study: 15



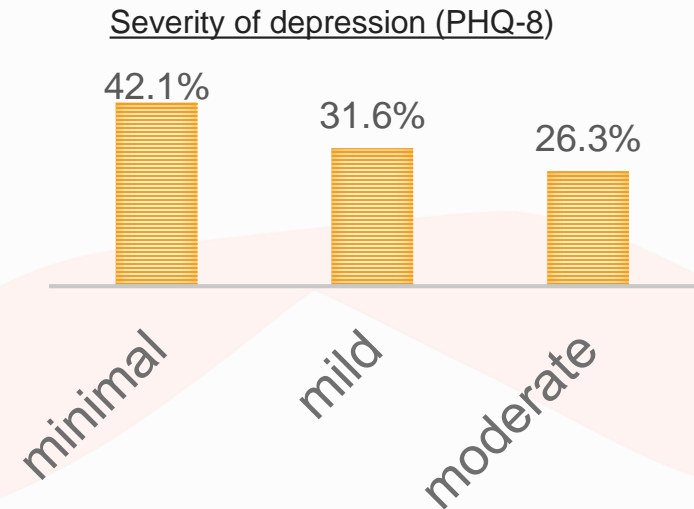
Drop-outs: 4

Initial REDCap Survey (n=18)



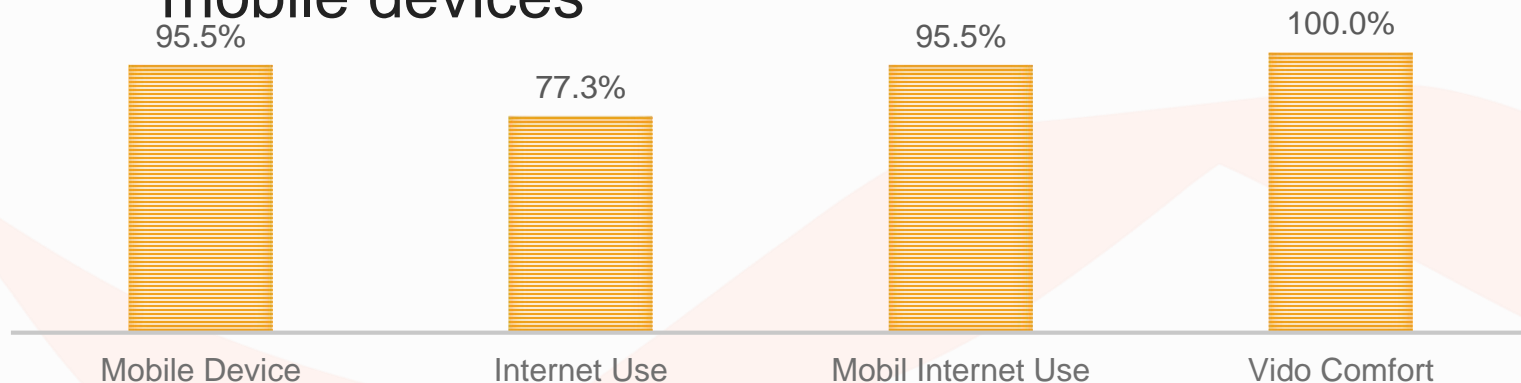
Assessed demographics, technology engagement, depression (PHQ-8)

- 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



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

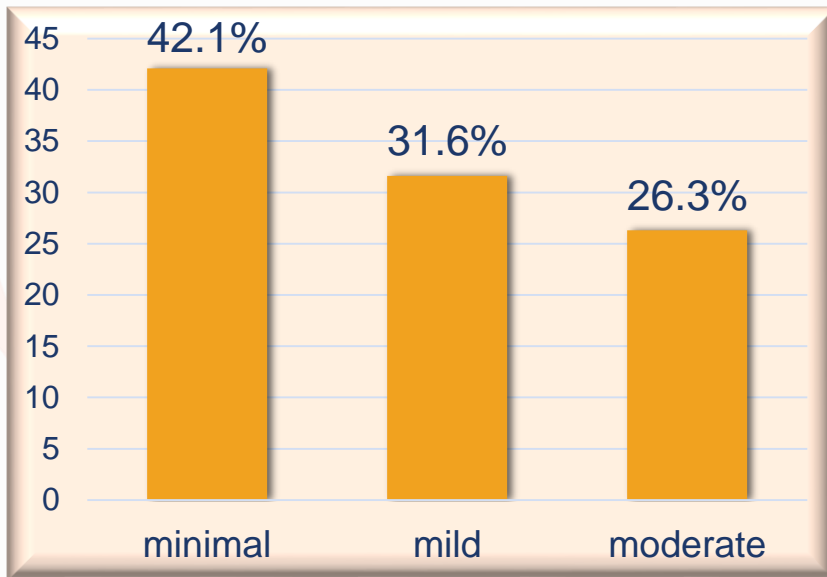


E-visit 1 Follow-Up Questionnaire

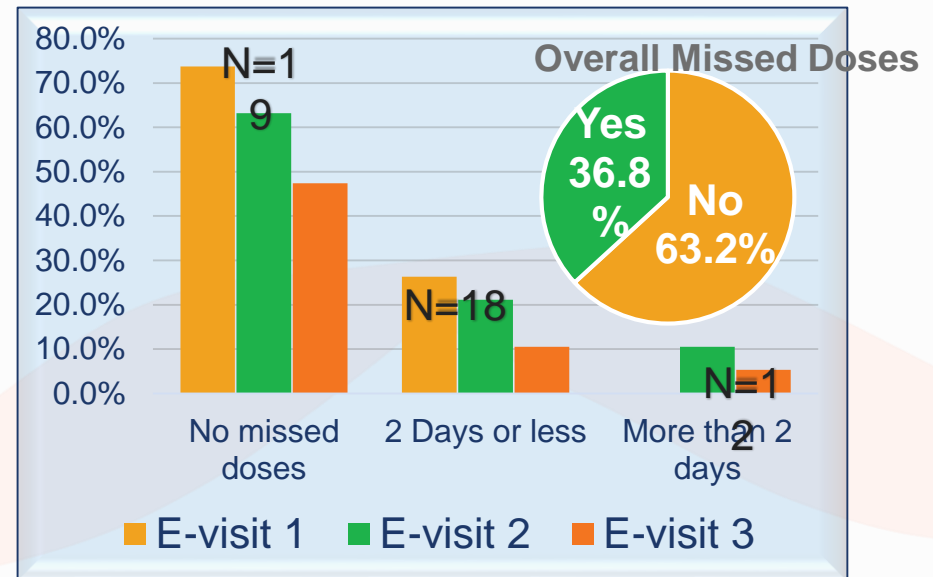
Category	Questions	% (n=18)
Safe Sex	Since your last visit, have you had unprotected (w/o condom) anal or vaginal sex?	68.4% No
	Since your last visit, have you had unprotected (w/o a condom) oral sex (mouth to penis, mouth to anus, mouth to vagina)?	57.9% Yes
Medication Adherence	Do you ever forget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

PHQ-8 Scores and Medication Adherence

Severity of Depression (PHQ-8)

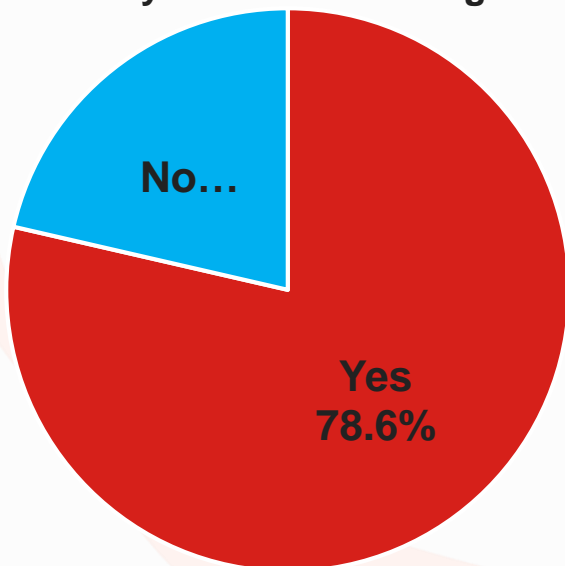


Medication Adherence



Program Satisfaction

Likely to Use Service Again

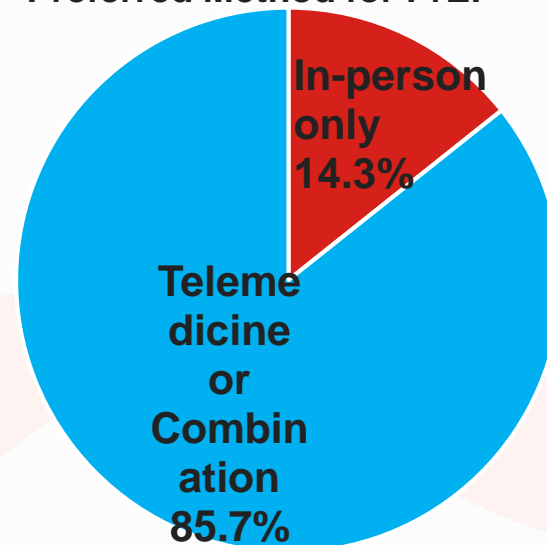


Satisfaction survey

(n=14)

100% reported they would recommend telehealth to others for PrEP therapy

Preferred Method for PrEP



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