



PrEP@home: Tele-PrEP in the time of COVID-19

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National LGBT Health Education Center

April 29th, 2020

thefenwayinstitute.org

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Mission: To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy

Integrated primary care model, including HIV and transgender health services

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TODAY'S FACULTY

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Medical Director and Co-Chair of The Fenway Institute

Professor of Medicine at Harvard Medical School

Professor of Global and Population Health at Harvard School of Public Health

Director of HIV Prevention and Research and an Attending Physician at Beth Israel
Lahey Health

Adjunct Professor of Medicine and Community Health at Brown University

Julian Dormitzer, RN, BSN

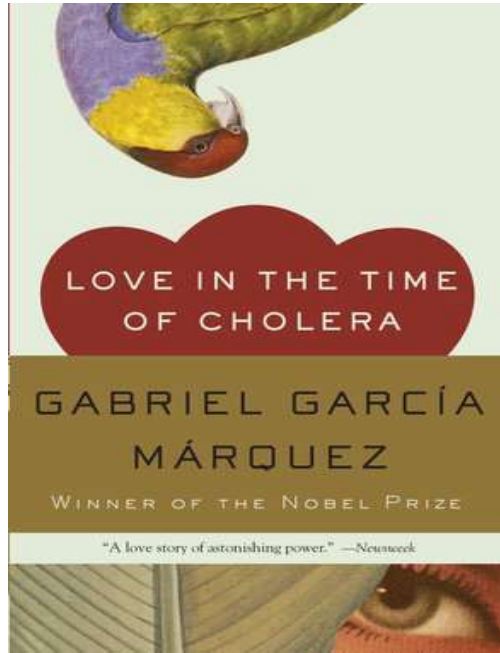
Project Manager, Adolescent Trials Network, Fenway Health

Primary Care Nurse Practitioner, Fenway Health

DISCLOSURE

No presenter has financial conflicts of interest.

PrEP in the time of COVID-19



“The only regret I will have in dying is if it is not for love.”

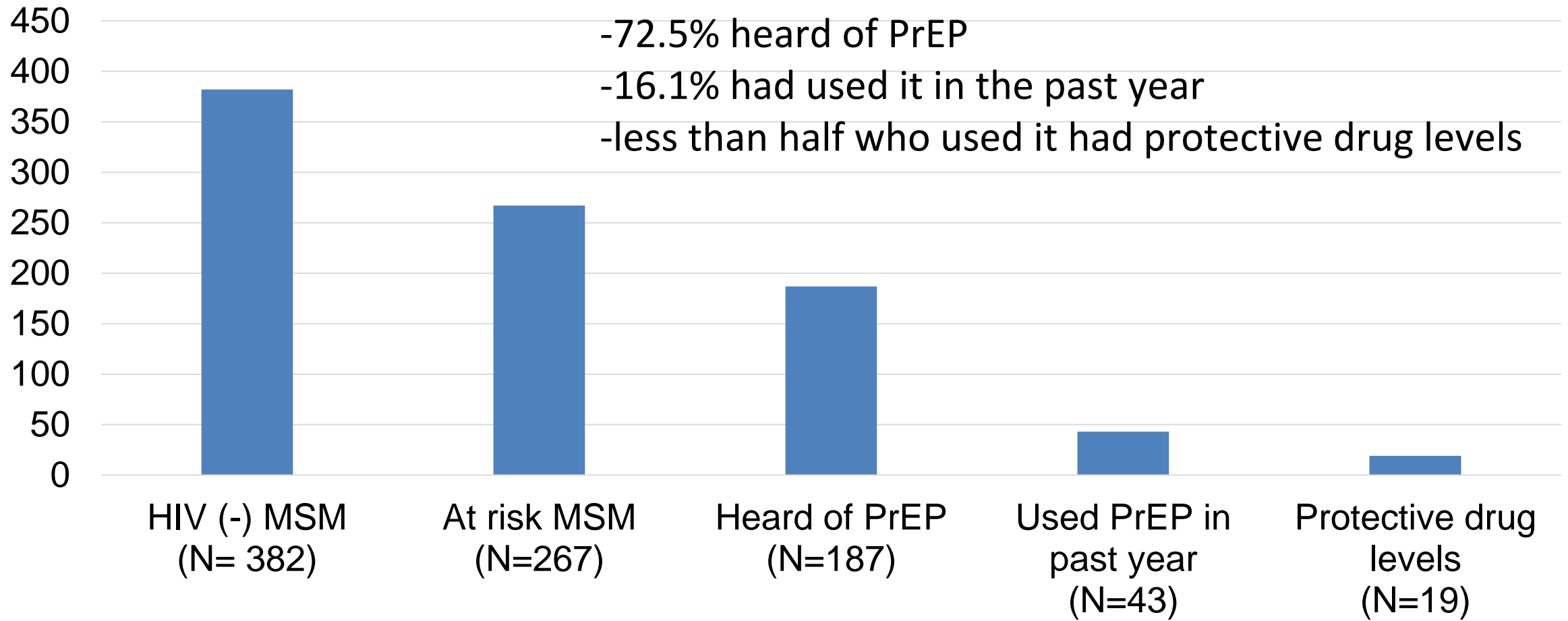
Gabriel García Márquez

[Love in the Time of Cholera](#)

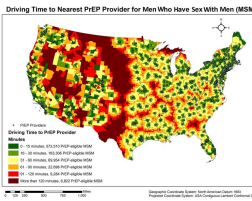
- **Background and rationale**
 - in the era of social distancing, PrEP use may be less, but not zero
 - Telemedicine has become normative
 - PrEP monitoring may not require frequent face-to-face visits
- **PrEP@home and ePrEP**
 - research studies that suggest feasibility
- **Fenway Health experience**
 - front-line experience with virtual PrEP

PrEP Cascade in Urban US MSM (HPTN 078)

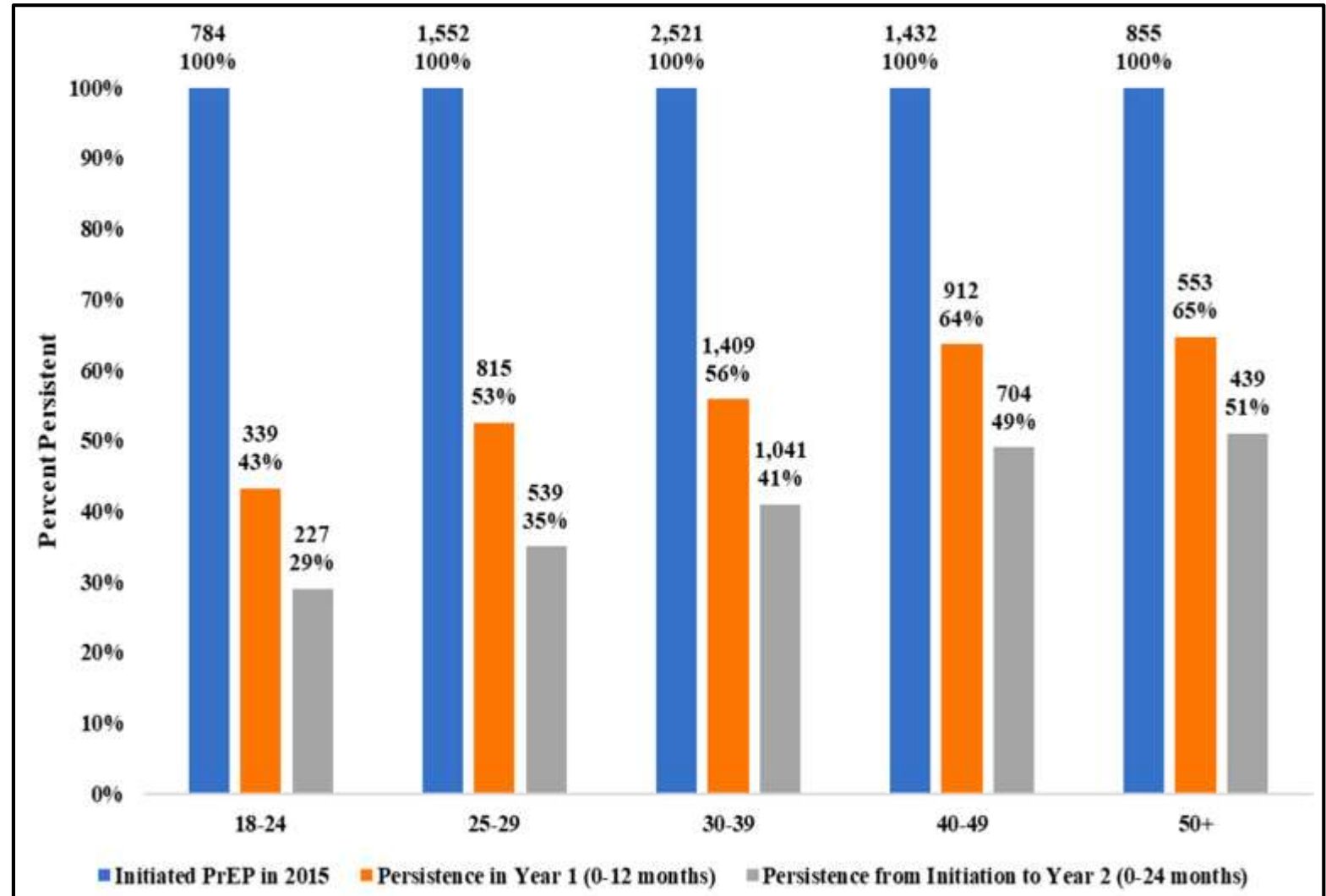
(Boston, Baltimore, Atlanta, Birmingham)



PrEP discontinuation is a substantial issue



- Pharmacy data
- n=7,148
- Individuals with $\frac{3}{4}$ period coverage classified as persistent
- Y1 discontinue: 44%
- Y2 discontinue: 37%
- Y0-Y2 discontinue: 59%



Coy, K
...
Siegler,
A.J.
(2019).
Persistence on
HIV
Preexposure
Prophylaxis
Medication
Over a
2-Year
Period.
JAIDS

Reasons for non-persistence in HIV and PrEP care



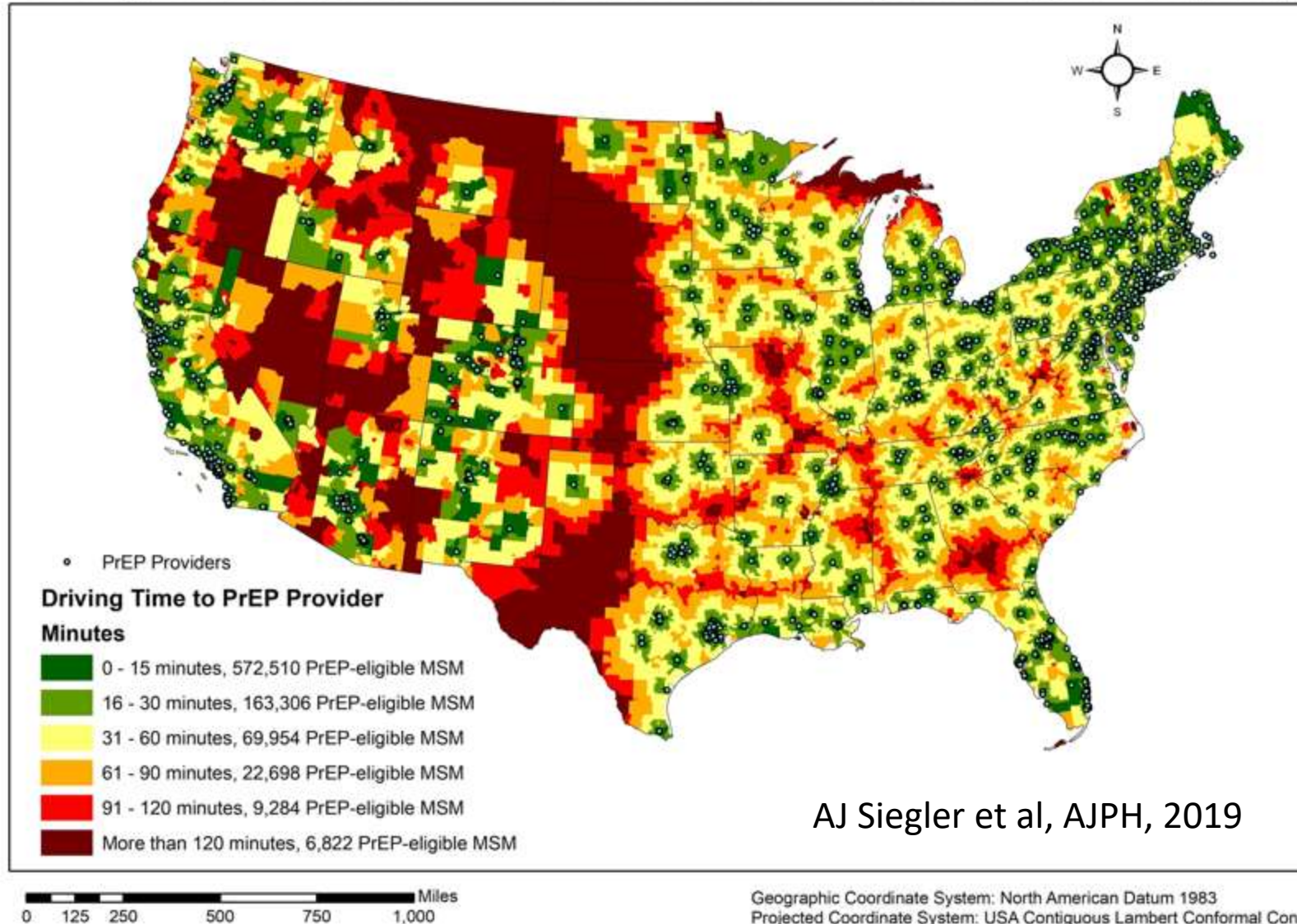
- Insurance/coverage/cost issues
- Medication challenges: Side effects, regimens
- Perceived need/benefit
- Shame

- Other events in life require attention
- Too busy, hard to get time off work
- Transportation barriers
- Navigating care: extra planning, scheduling
- Stigma perceived when seeking care

Potentially mitigated by home care

PrEP Deserts in the US

Driving Time to Nearest PrEP Provider for Men Who Have Sex With Men (MSM)

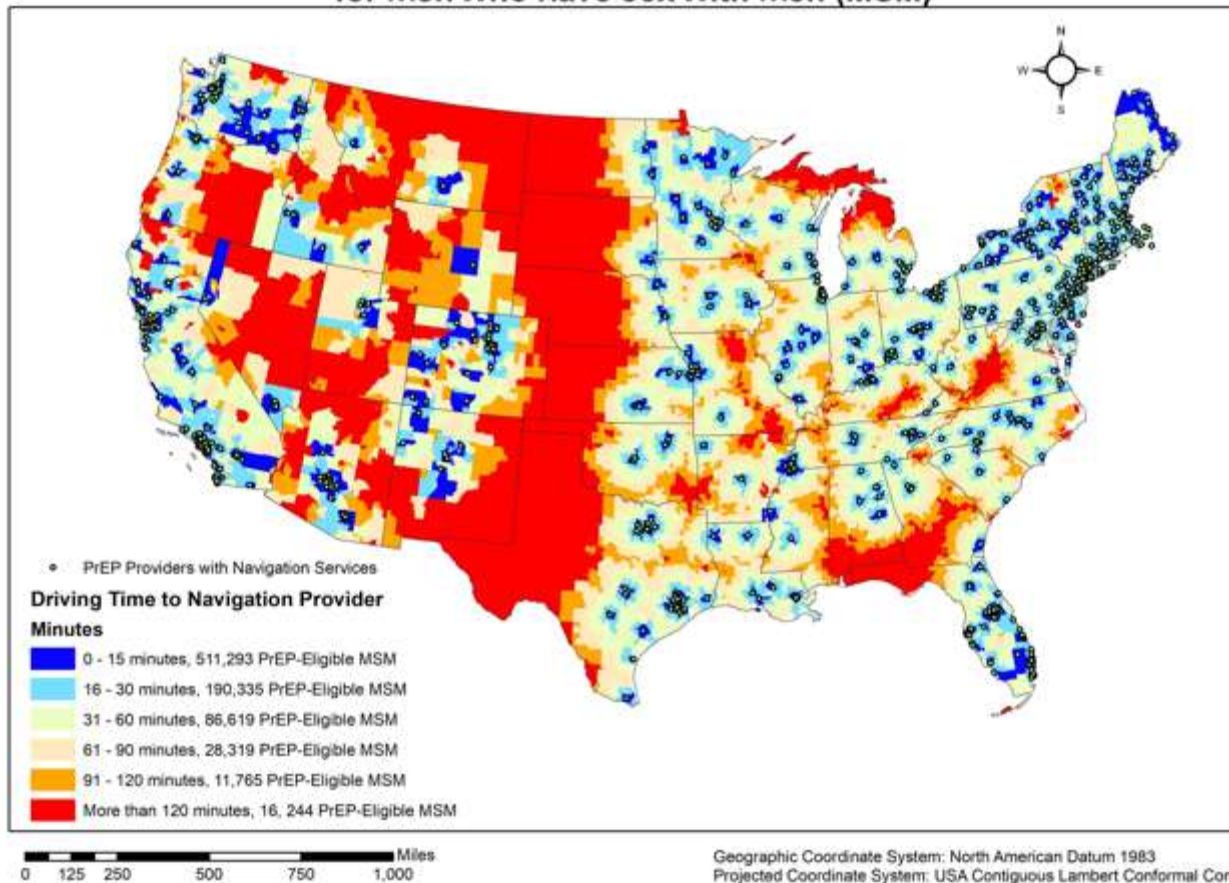


AJ Siegler et al, AJPH, 2019

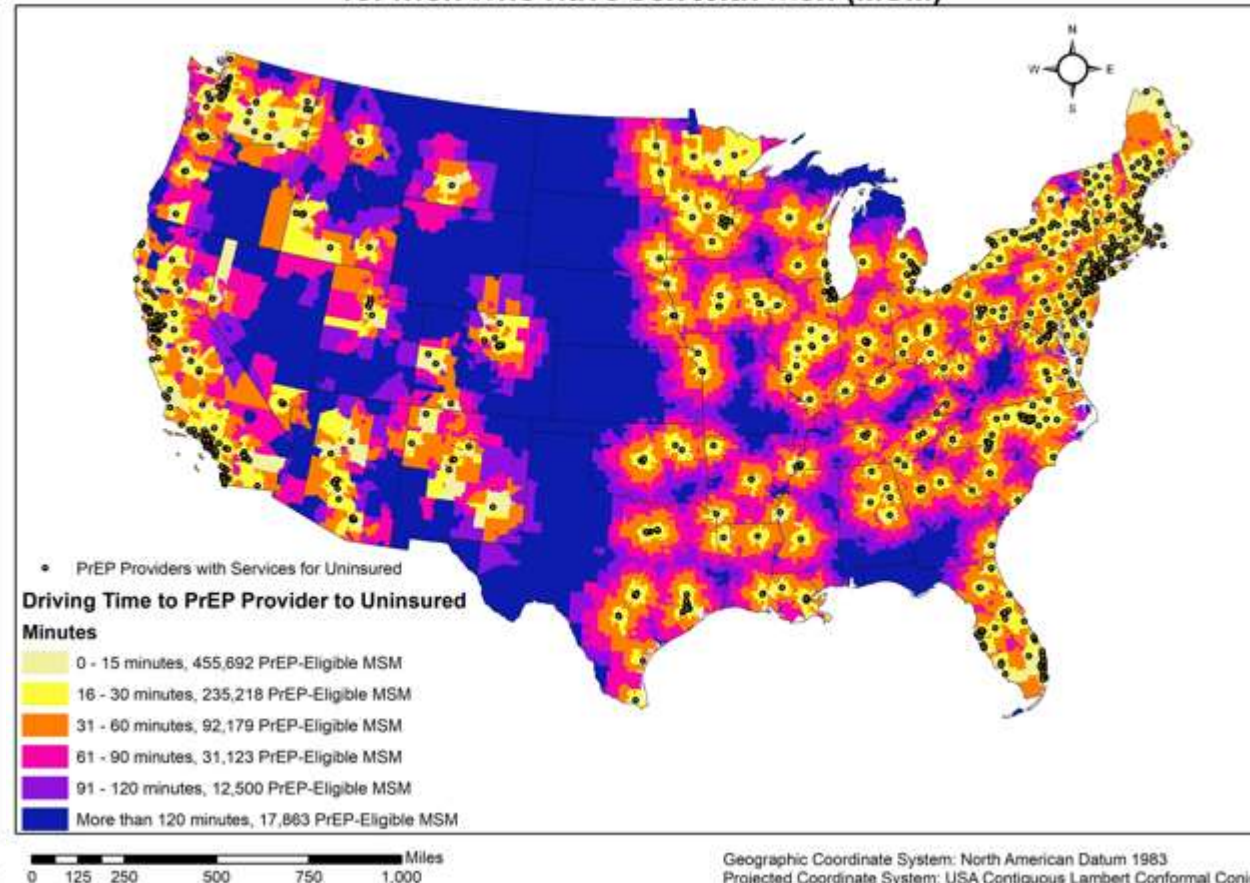
Larger deserts for more specialized services needed by those with less advantage

AJ Siegler et al, AJP, 2019

Driving Time to Nearest PrEP Provider with PrEP Navigation Services for Men Who Have Sex With Men (MSM)



Driving Time to Nearest PrEP Provider with Services for the Uninsured for Men Who Have Sex With Men (MSM)





Possible solution to epidemiological challenges:

PrEP@home: self-monitoring PrEP

Providing tailored, appropriate care

Home care system for PrEP could reduce clinician visits from 4/year to 1/year



1. Kit mailed



2. Urine, throat, rectal specimens



3. Blood specimens



4. Prepaid mailer, survey

Participant Test Summary Form		PrEP@ Home	
Participant Information			
Participant Name	Doe John E	Optimal	Elevated
	Last First MI		
Participant Initials	D J E	Date Specimens Collected	6/13/2016
		Date Specimens Tested	6/17/2016
Section 1: HIV Testing			
HIV	Oraquick	Optimal	Interpretation: Non-Reactive HIV test
Section 2: Symptomatic Screening for Acute HIV			
Fever, Swollen Glands, Sore Throat, Muscle and Joints Aches and Pains,		Optimal	Interpretation: No Acute HIV symptoms

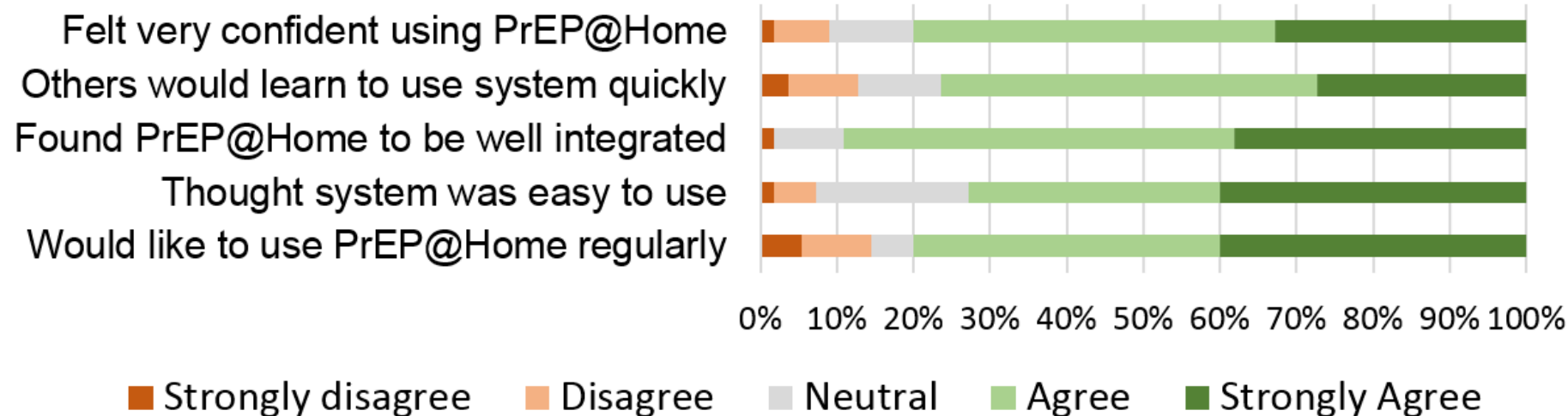
5. Results report to clinician



6. Rx, care as needed

Siegler AJ, Mayer KH, Liu AY, Patel RR, Ahlschlager LM, Kraft CS, et al. Developing and assessing the feasibility of a home-based PrEP monitoring and support program. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2018;Jul 4.

Pilot results: Usability

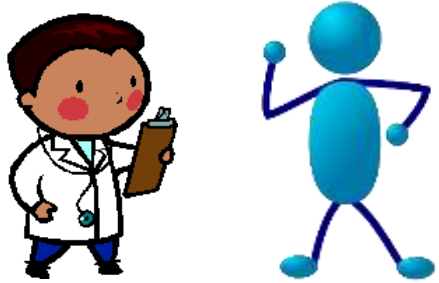


48/55 (87%) indicated they would like to use PrEP@Home in place of their next in-person clinical visit

22/55 (40%) would have a greater likelihood of remaining on PrEP if PrEP@Home was available

Next step: RCT (NIMH: R01MH114692, PI Siegler and Mayer) to determine retention in care and cost-effectiveness. RCT will oversample young and minority MSM (50%) to be able to determine intervention impact in more vulnerable populations

Low-touch PrEP home care: Reduce clinician visits from 4/year to 1/year



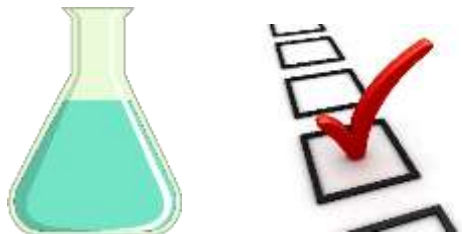
Standard PrEP
Initiation and follow
up at 1 and 3 months



Subsequent follow-up
visit, participant
receives kit from
central lab



Participant uses kit,
returns mailer to lab



Lab receives kit.
Results collated with
behavioral survey.

A screenshot of a 'Participant Test Summary Form' from 'PrEP@ Home'. The form contains various fields for participant information, test results, and dates. It includes sections for 'Participant Information', 'Test Results', and 'Dates'. The form is titled 'Participant Test Summary Form' and 'PrEP@ Home'.

Results sent to
provider



EMORY UNIVERSITY
PrEP
AT HOME 

Siegler AJ, Mayer KH, Liu AY, Patel RR, Ahlschlager LM, Kraft CS, et al.
Developing and assessing the feasibility of a home-based PrEP monitoring and support program. CID.

Update on PrEP@home

Boston, Atlanta, Jackson, St. Louis

155 randomized, diverse sample

Lots of interest, good retention, but early days

Then, COVID-19

Some starting remotely in the control group but very slow

ePrEP: ATN 159

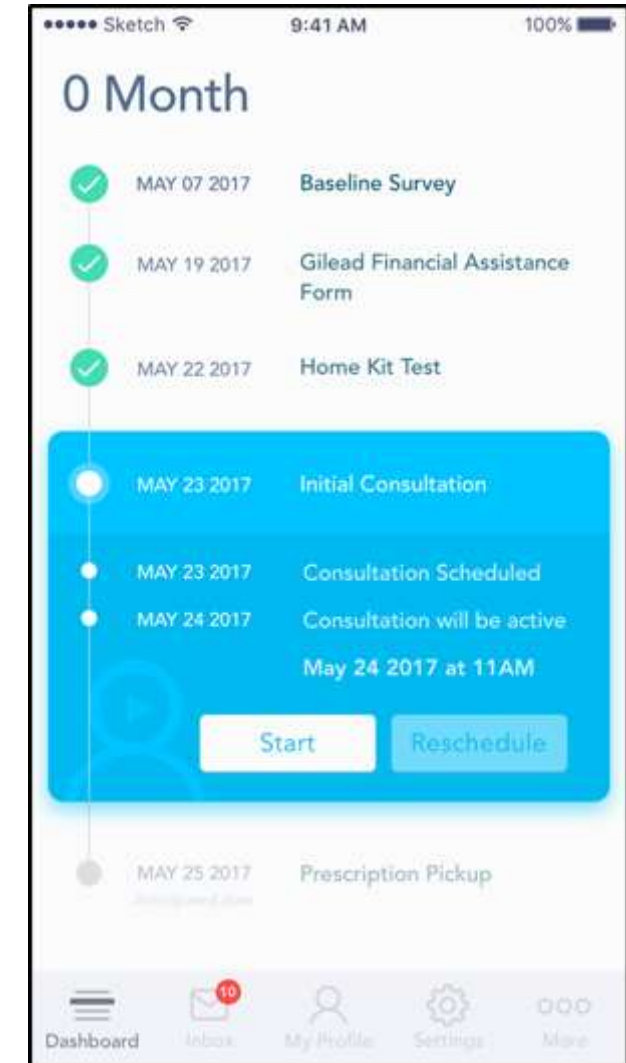
Full telemedicine PrEP

- PrEP care delivered to home
- Patients randomized to telePrEP or standard in-person PrEP care referral

Mobile app for YMSM

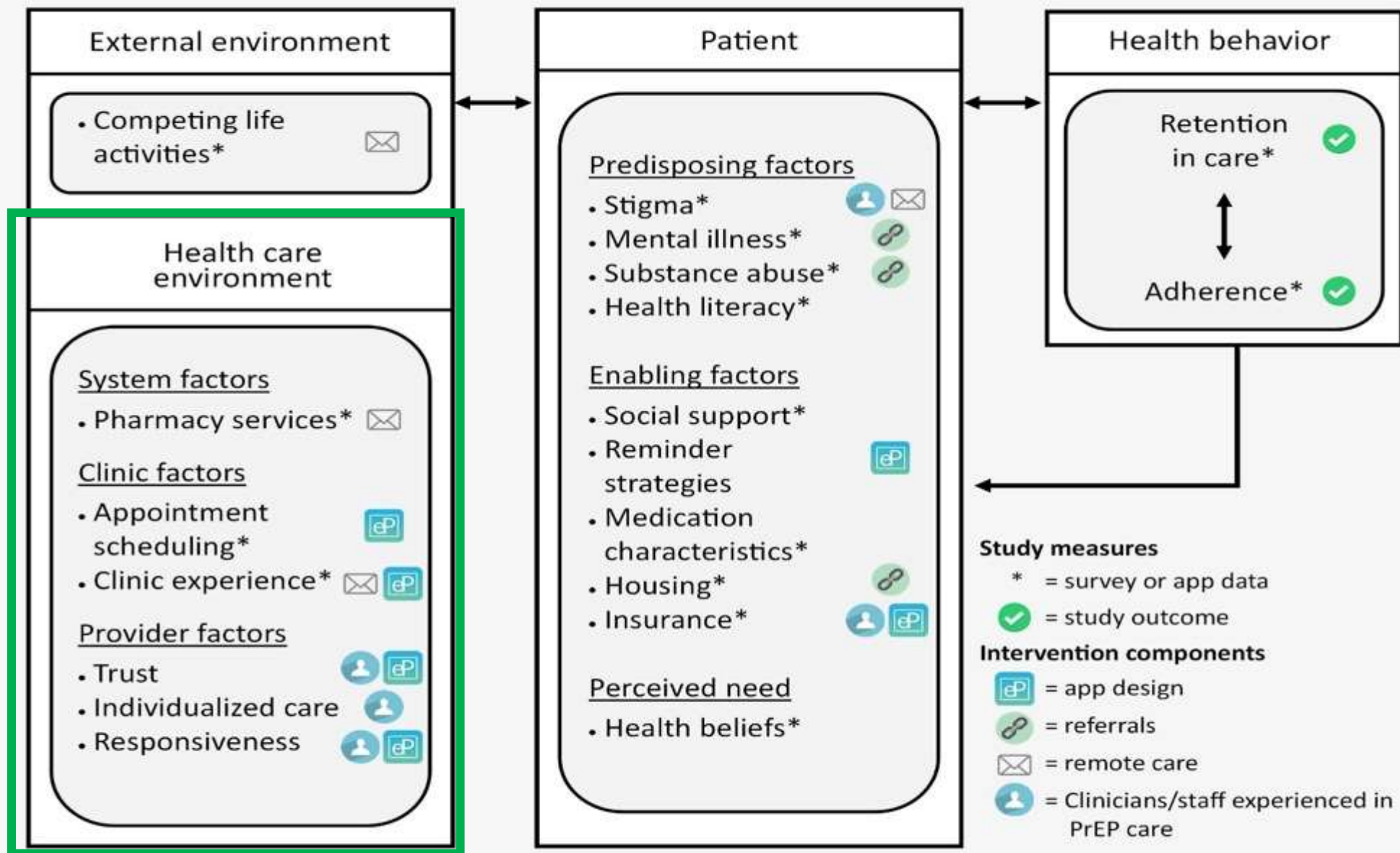
- Telemedicine consultations
- Text message interface
- Surveys built into app
- Automated reminders
- Progress tracking

Home specimen collection /
mailing












PI: Siegler and Mena

Anderson's Behavioral Model



Siegler AJ, et al. An Electronic Pre-Exposure Prophylaxis Initiation and Maintenance Home Care System for Nonurban Young Men Who Have Sex With Men: Protocol *JMIR Res Protoc.* 2019;8(6)

Baseline

-  Baseline Survey
 -  MAY 17 2018 Module 1 Survey is Completed
 -  MAY 30 2018 Module 2 Survey is Completed
 -  MAY 30 2018 Module 3 Survey is Completed
-  Photo Upload
 -  MAY 31 2018 Photo ID is uploaded
-  Complete Gilead Tasks
 -  MAY 31 2018 Gilead Financial Assistance Form
 -  MAY 31 2018 Upload Document

Upload Photo

< Upload

We require you to upload the following documents to verify.

To upload a pdf or image file first select a document type.

Document Type

Select Document Type

Select Document Type

Gilead Document

Personal ID Card

Insurance Card

Prescription Label

Cancel

1 Month

- NOV 14 2018 **Follow-up Survey**
Follow-up Survey is Pending
[Take Survey](#)
- NOV 12 2018 **Consultation**
Schedule Consultation
- NOV 12 2018 **Please schedule your consultation**
[SCHEDULE](#)

3 Month

- JAN 14 2019 **Follow-up Survey**
Survey has not been completed
- **Home Test Kit**
- JAN 12 2019 **Ordering Kit**
- JAN 12 2019 **Consultation**
Schedule Consultation

< Schedule

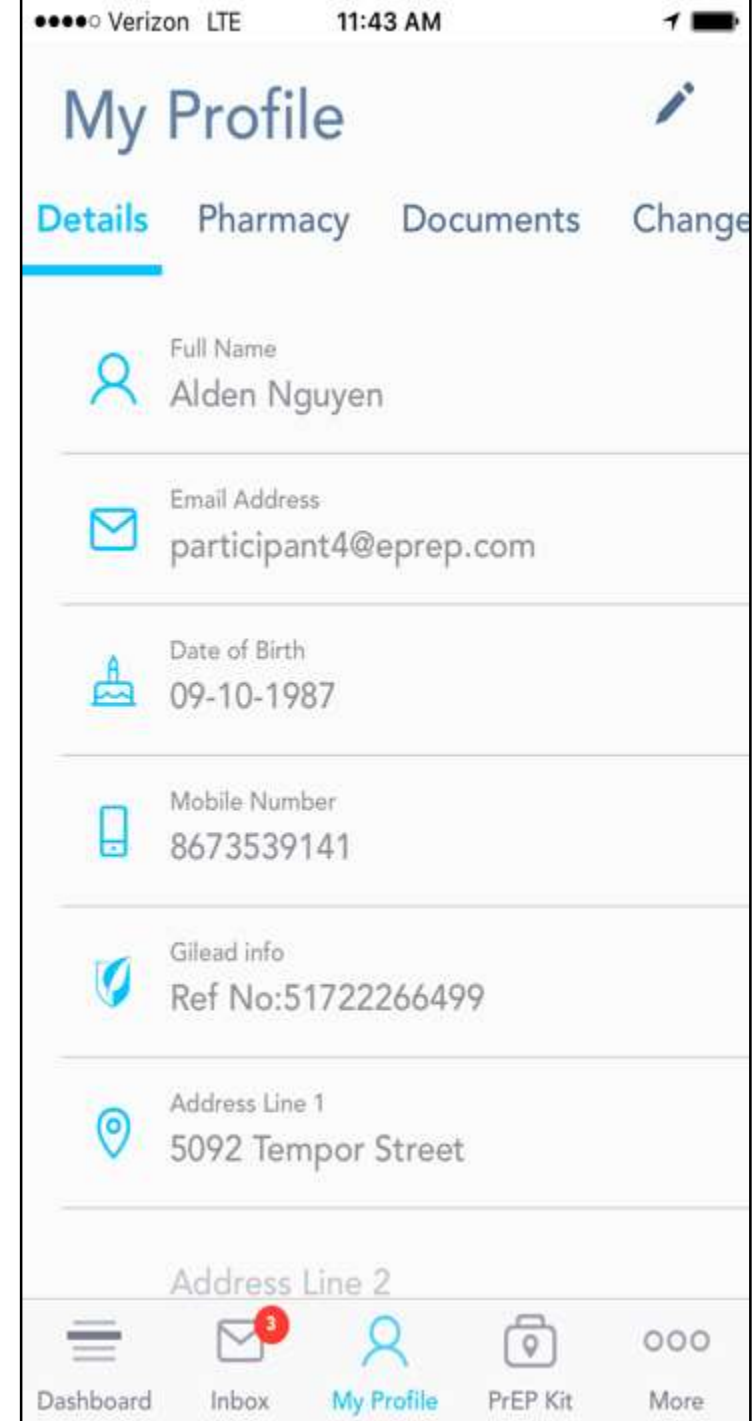
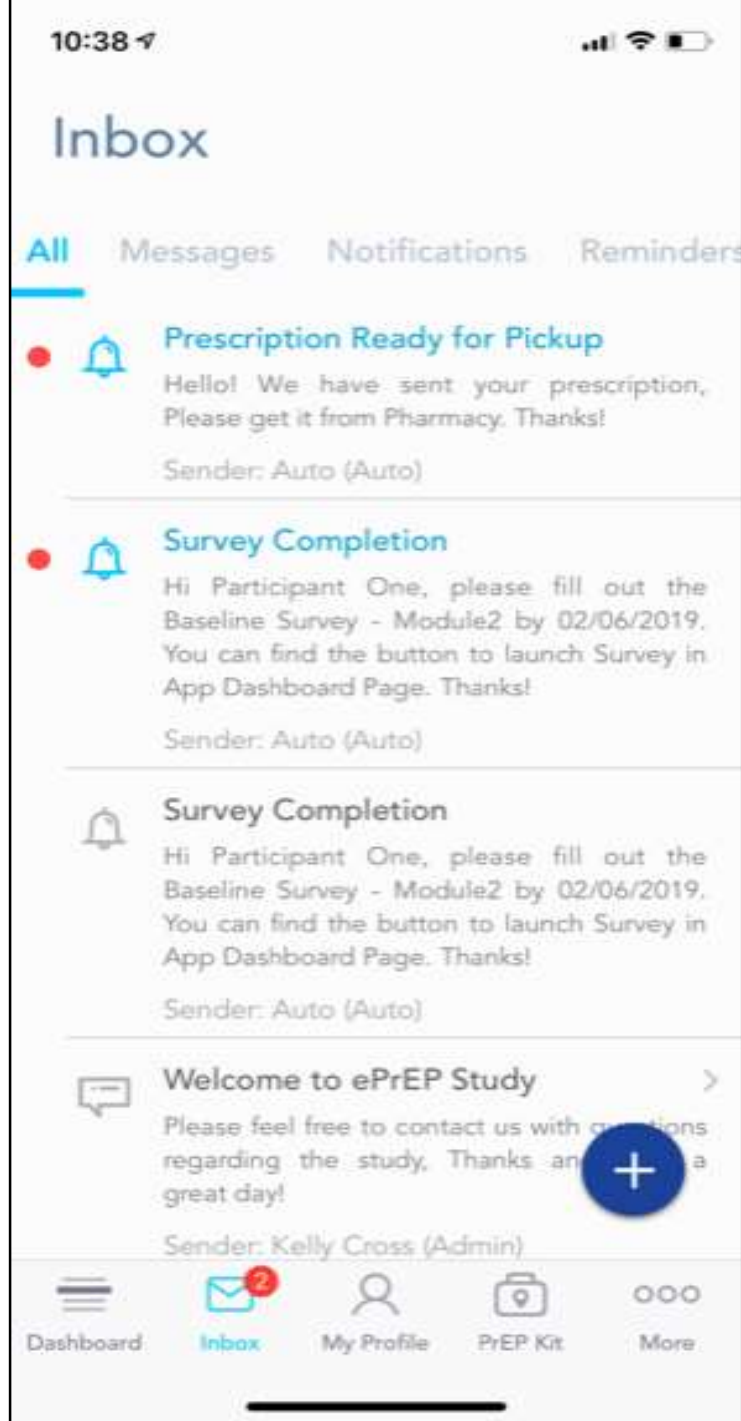
Select your preferred date and time to schedule the consultation with clinician

 [Select Date](#)

 [Select Time](#)

November 2018

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	



Up next for ATN 159

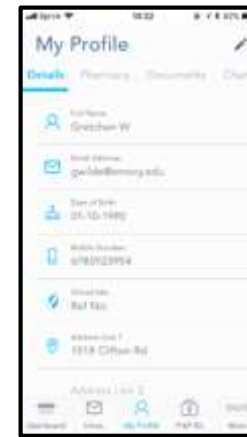
RCT Enrolling now

n=240, 12-month follow-up

Sites: North Carolina, Mississippi, Georgia

MSM sample to be

- Aged 18-24
- Minimum 50% Black or Latino
- Rural (NCHS)



Aim 1. Assess movement along PrEP Care Continuum

Hypothesis. Participants randomized to ePrEP will be further along the PrEP cascade than participants assigned to control condition, including PrEP initiation and maintenance.

Additional Aims: (1) contextualize trial results, **(2)** exploring rural context of care, **(3)** Cost-effectiveness analyses of the ePrEP intervention.

Remote Collection Capabilities

Molecular has performed over 300,000 self-collected sexual health screenings in the last 12 months. Rejection rate on these specimens is less than 1% of the total volume.

They can ship to all US states and territories apart from NY, NJ, and RI.

PrEP Related Assays

- HIV
- Creatinine
- HBV
- HCV
- Syphilis
- TFV-dp
- 3-site Chlamydia
- 3-site Gonorrhea

Collection Methods

- Dried Blood Spot (DBS)
- Blood Microtainer
- Serum Separator Card
- Wet Urine
- Saliva
- Buccal Swab
- 3 Site Collection for STIs

Other Capabilities

- Cholesterol & Lipids
- Thyroid Panel
- Testosterone
- AMH
- Gluten / Celiac
- HbA1C
- Flu Panel / COVID-19
- IDCompare

FOR MORE INFO CONTACT:

Brad Thorson, Public Health Partner

BThorson@MolecularTestingLabs.com



Tele-PrEP in Clinical Care at Fenway Health

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PREP CARE DURING COVID-19 PANDEMIC

On April 8th 2020, the CDC issued interim guidance on public health activities related to HIV, TB, Hepatitis C and STD testing and treatment

HIV Priorities

Linkage to care programs for persons newly diagnosed HIV

HIV testing in clinical care settings (as deemed appropriate)

Return to care for persons with unsuppressed viral load

Linkage to PEP and PrEP for persons at high-risk for HIV

Maintenance of services for persons enrolled in PrEP/PEP

(Centers for Disease Control and prevention, 2020).

PREP INITIATION AT FENWAY

16 new PrEP initiations since 3/23/202

- 10 of which were conducted via telehealth w/ local lab collection utilizing self-swab technique
- More than 200 PrEP follow-up telehealth visits.

PREP INITIATION VIA TELEHEALTH

Access for HIV risk using current CDC guidelines:

- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months
- Anal sex without condoms in the last 6 months
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection

COVID-19 consideration: How has this changed during recent period of social distancing?

PREP INITIATION VIA TELEHEALTH

Assess for subjective symptoms
of acute HIV infection:

- fever - fatigue
- headache - decreased appetite
- nausea - diarrhea
- rash - night sweats

COVID-19 considerations:

- Many of these may also be true of COVID-19 infection
- Assess timeline, and most likely type of exposure
- Pulmonary manifestations?

DRUG SELECTION AND ADHERENCE COUNSELING

- Conduct routine patient education regarding Truvada vs. Descovy. Practice shared decision making whenever possible
- Counsel patient on importance of daily adherence and perform 2-3 minute barrier assessment. Encourage pt to tie pill taking to daily activity given current COVID-19 shutdown and encourage them to re-examine dosing behaviors when things begin to open up again
- Discuss possible s/e and provide number to call if they have questions or experience worrisome s/e

BASELINE LAB WORK

- HIV 1&2 Ag/Ab 4th generation
- RPR Dx RFX FTA
- Creatinine
- Hep B Ag and Ab testing
- Hcg qualitative if applicable
- CT/CG
 - Urine
 - Rectal (encourage self swab)
 - Throat (encourage self swab)

COVID-19 considerations:

- **Phone based COVID-19 sx screen**
- **Encourage pt to call ahead and schedule appt with local lab**
- **Implement self-swabbing processes**

PHARMACY

- Find out if any pharmacies in your area are providing free delivery
- If not, encourage pt to use pharmacy closest to their home

PREP MAINTENANCE VIA TELEHEALTH

For patients who are continuing to engage in high risk sex asymptomatic for bacterial STI

- Continue to refill PrEP without requiring 3 month follow-up labs. Counsel patient that this is temporary. Routine follow up will continue to be required post COVID-19 shutdown
- Encourage patients to return for STI testing once clinical care has resumed in your area
- Counsel patient on importance of daily adherence and perform 2-3 minute barrier assessment given change in daily routine due to COVID-19

PREP MAINTENANCE VIA TELEHEALTH

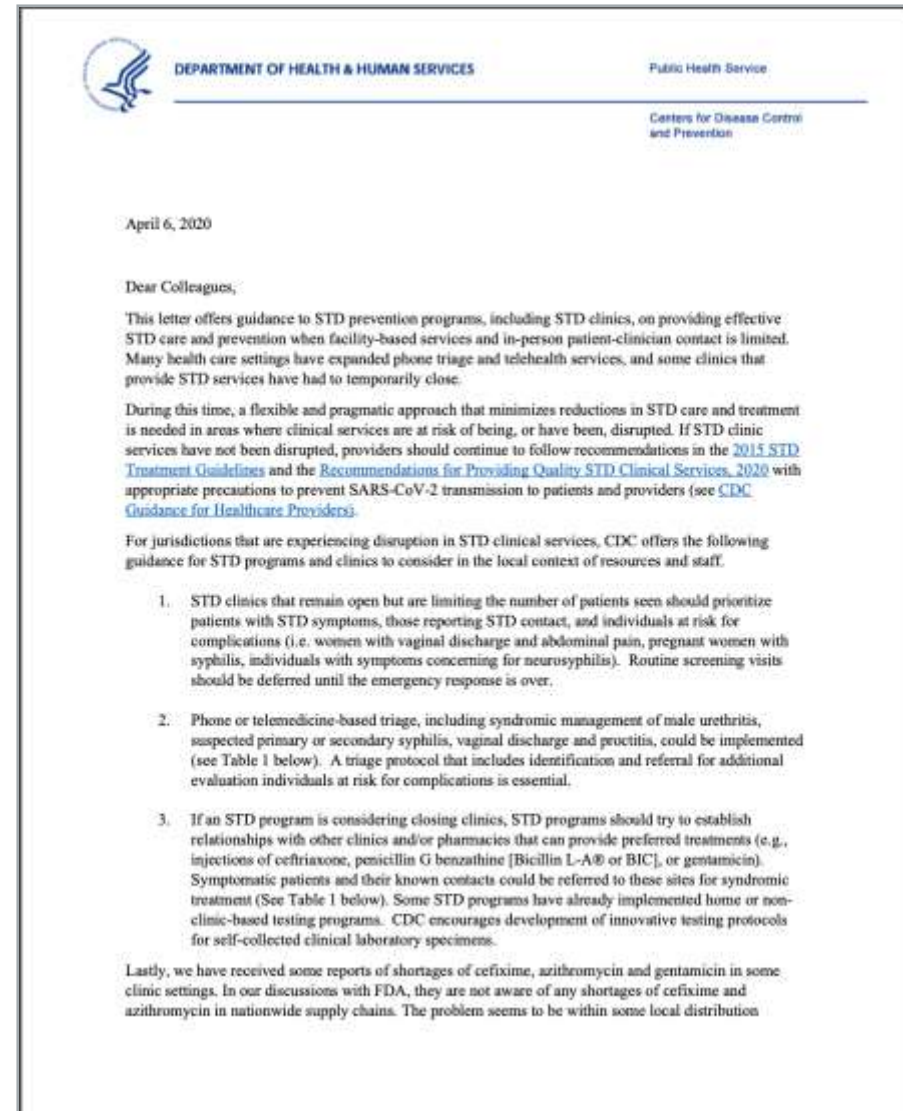
If patient is symptomatic for an STI, follow institutional guidelines to ensure patient receives appropriate treatment and testing

Open STD clinics: prioritize serving symptomatic patients or patients with known exposure. Coordinate in clinic visit after phone based COVID-19 screening is performed

Closed STD clinics: utilize telephone triage to provide syndromic management of symptoms in accordance with CDC guidance issued April 6th 2020

Guidance issued by DHHS and CDC on April 6th 2020 addresses therapeutic options to consider when in-person clinic visits are not feasible:

<https://www.ncsddc.org/wp-content/uploads/2020/04/STD-Treatment-Options-04062020.pdf>



CASE PRESENTATION #1

C.B. is a 46 yo cis-MSM on phone for 20 minute telehealth visit requesting PrEP initiation

- Reports increased anxiety which he attributes to COVID-19
- 10 months of lifetime PrEP experience, most recently 2 years ago
- Reporting increased HIV risk during quarantine, condomless anal sex with 4 new partners of unknown status within last month, most recently 6 days ago
- Feeling well, no fever or malaise
- Denies s/s of bacterial STI
- Unstably housed

PREP PLAN FOR C.B.

- Complete assessment for acute HIV
- Counsel patient that baseline testing is needed and provide information for local lab. Let patient know that he should anticipate being asked to self collect applicable specimens
- 30 day Rx for Truvada sent to pharmacy, refills pending lab results
- Schedule f/u telehealth visit in 10-14 days for assessment of s/e and adherence

CASE PRESENTATION #2

J.C. is a 26 yo cis-MSM on phone for 20 minute telehealth PrEP f/u visit

- Has one long-term primary partner, reports two additional condomless partners since last follow up visit in mid-January
- Only sexual partner during quarantine is primary partner
- Endorses 100% adherence, no missed doses within last 12 months
- Denies s/s of acute HIV or bacterial STI

PREP PLAN FOR J.C.

- Given pts high adherence to PrEP medication, f/u testing not required during COVID-19 shutdown
- 3 month refill of PrEP sent to pharmacy with request to ship to pts home
- Pt encouraged to come to lab for STI testing when clinic operations return to normal
- Pt counseled on importance of daily adherence if he continues to be sexually active during quarantine
- Reminded that PrEP f/u guidelines will return to required testing every 3 months post COVID-19

REFERENCES

Bachmann, L.H., Thorpe, P., Bolan, G., Mermin, J. (April 6 2020). STD treatment options. Retrieved from <https://www.ncsddc.org/wp-content/uploads/2020/04/STD-Treatment-Options-04062020.pdf>

Centers for disease control and prevention. (2020). Interim CDC guidance on handling non-COVID-19 public health activities that require face-to-face interaction with clients in the clinic and field in the current COVID-19 pandemic. Retrieved from <https://www.cdc.gov/coronavirus/2019-ncov/hcp/non-covid-19-client-interaction.html>

Acknowledgement

Aaron Siegler, Emory





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THANK YOU!

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This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U30CS22742, Training and Technical Assistance National Cooperative Agreements (NCAs) for \$449,981.00 with 0% of the total NCA project financed with non-federal sources. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government