

Use of Mobile Technology in Clinical Trials

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Outline

- What useful resources do mHealth applications offer?
- How are these tools helpful to delivering HIV prevention interventions?
- How are these tools helpful to conducting clinical trials?
- How will we scale mHealth prevention interventions in the United States and beyond?

What useful resources do mHealth applications offer?

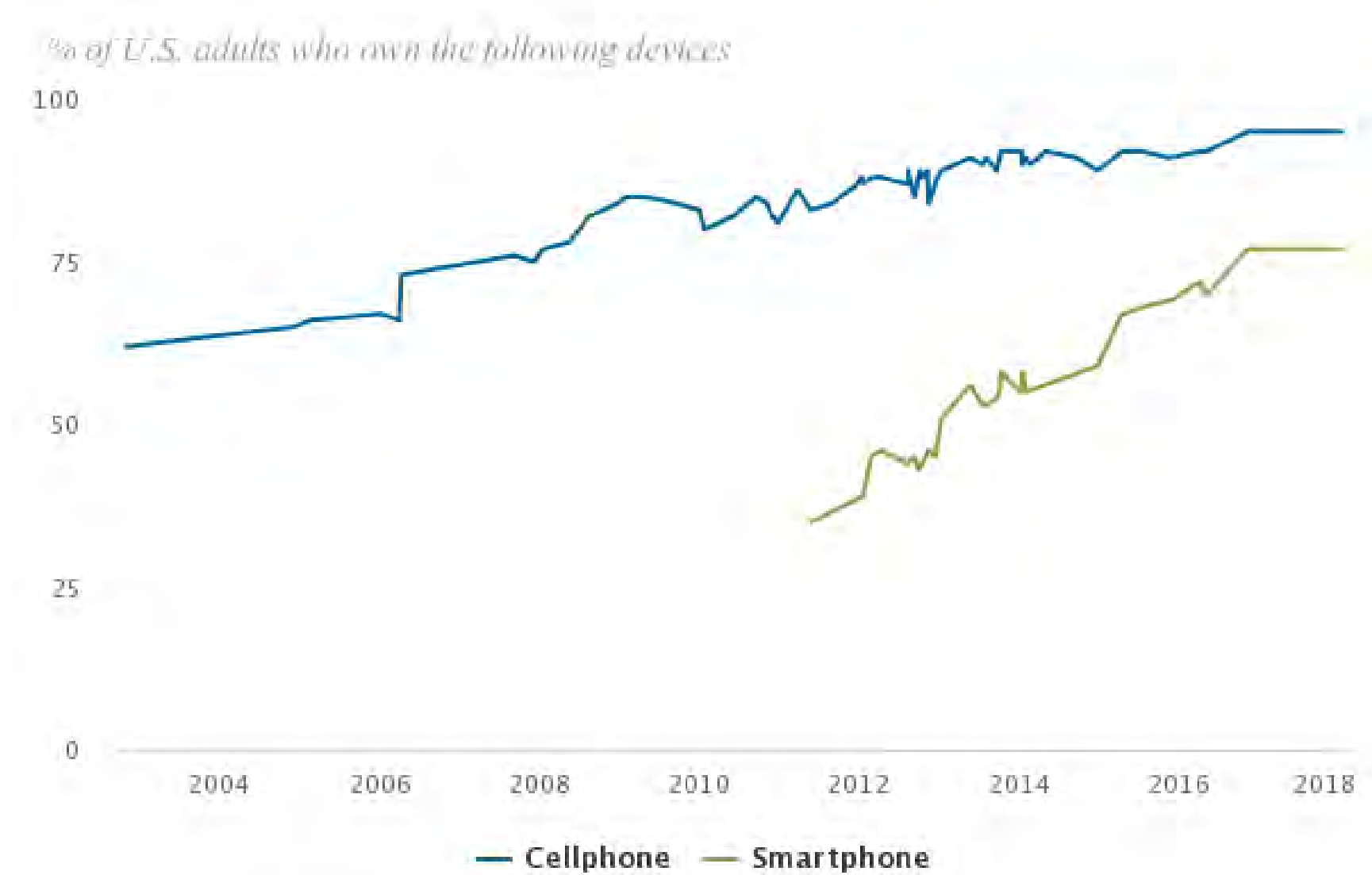
mHealth Tools

mHealth Tools **leverage**:

- Computers
- Mobile phones
- Mobile-optimized websites
- Social media
- Internet

mHealth Tools **offer opportunities to**:

- Reach broad scale
- Reach remote clients
- Provide rich media
- Tailor interventions
- Provide reminders
- Schedule appointments
- Return study lab results
- Link interventions together



Source: Surveys conducted 2002-2018
PEW RESEARCH CENTER

% of U.S. adults who own the following devices

	Any cellphone	Smartphone	Cellphone, but not smartphone
Total	95%	77%	17%
Men	95%	80%	16%
Women	94%	75%	19%
Ages 18-29	100%	94%	6%
30-49	98%	89%	9%
50-64	94%	73%	21%
65+	85%	46%	40%
White	94%	77%	17%
Black	98%	75%	23%
Hispanic	97%	77%	20%

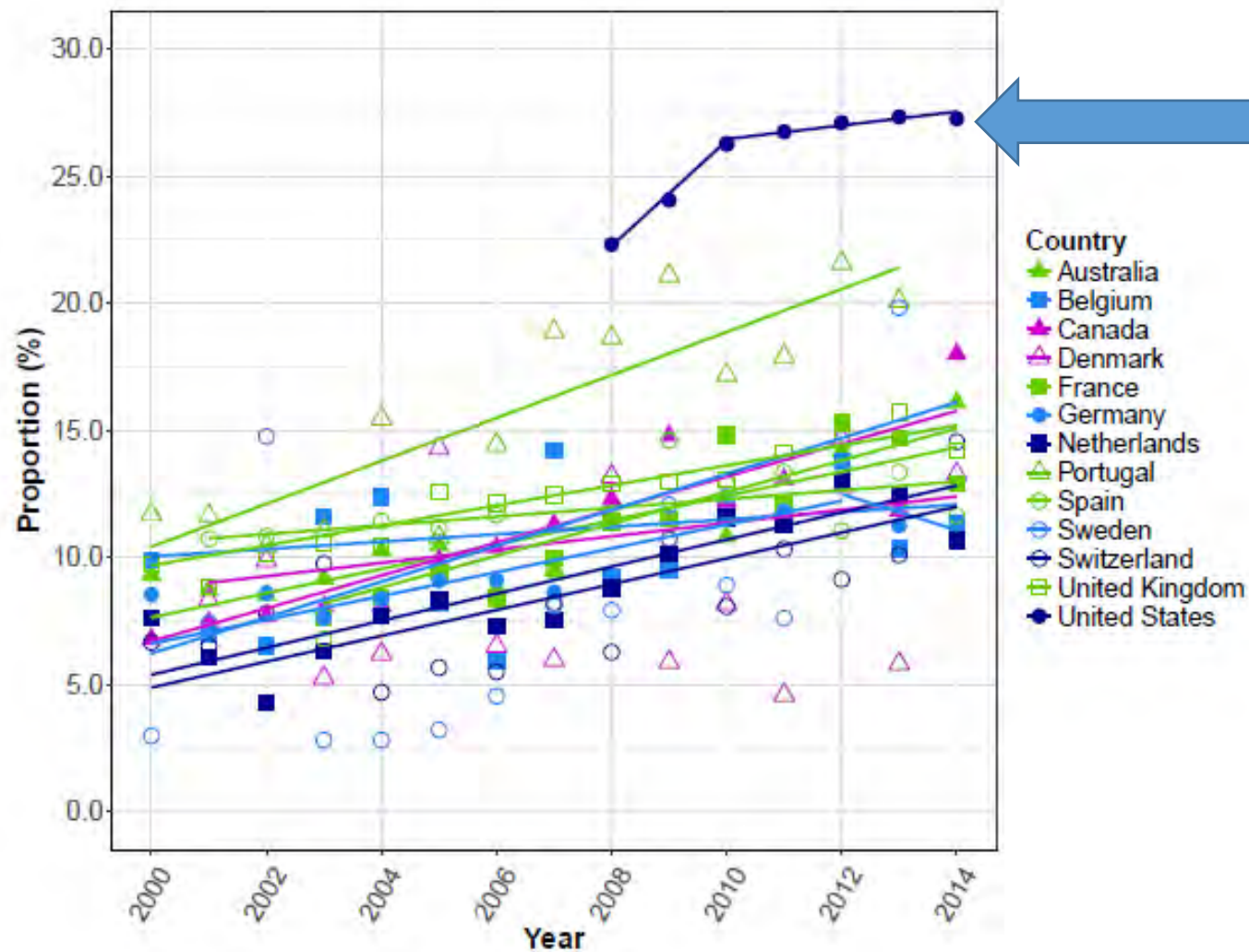
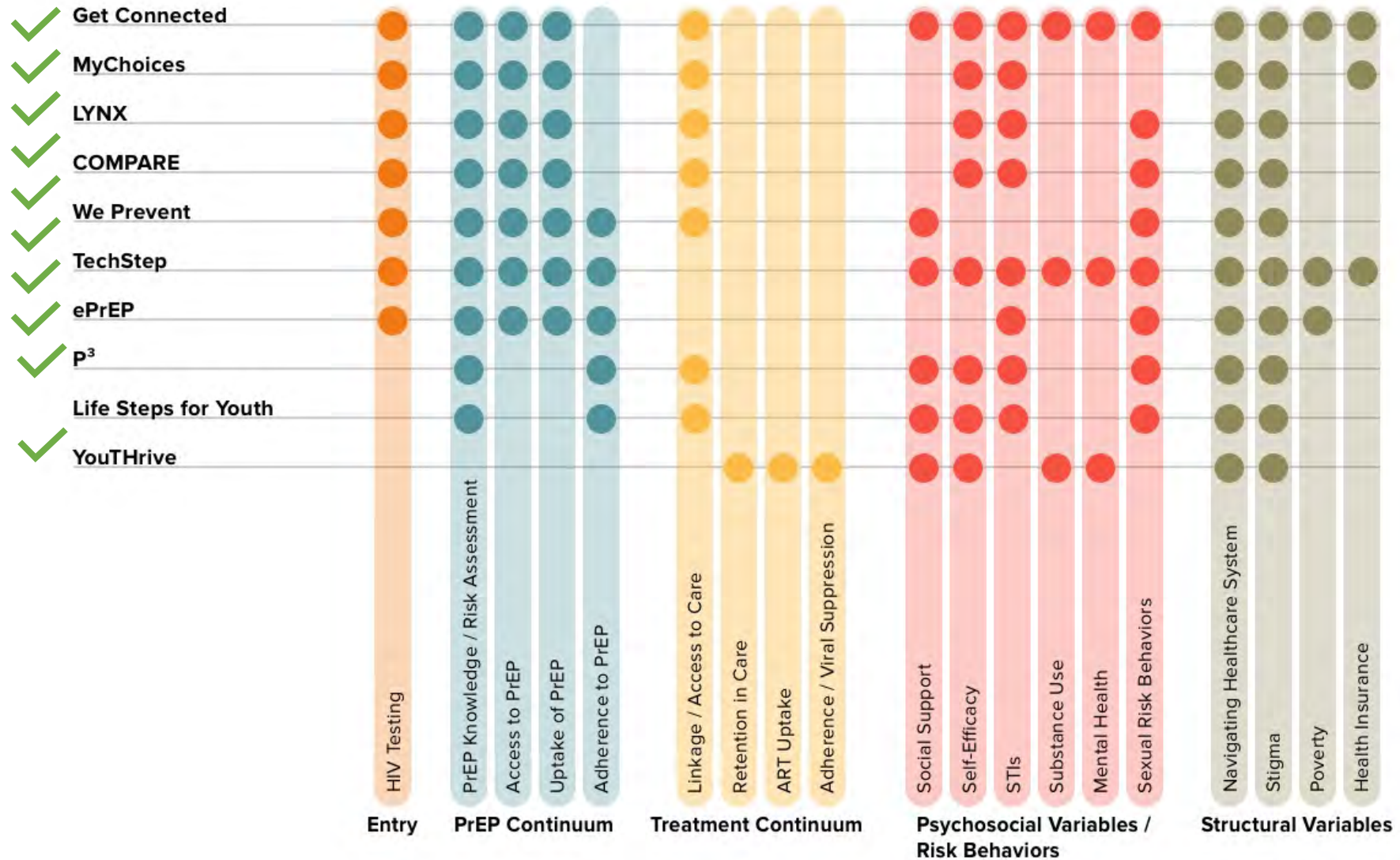


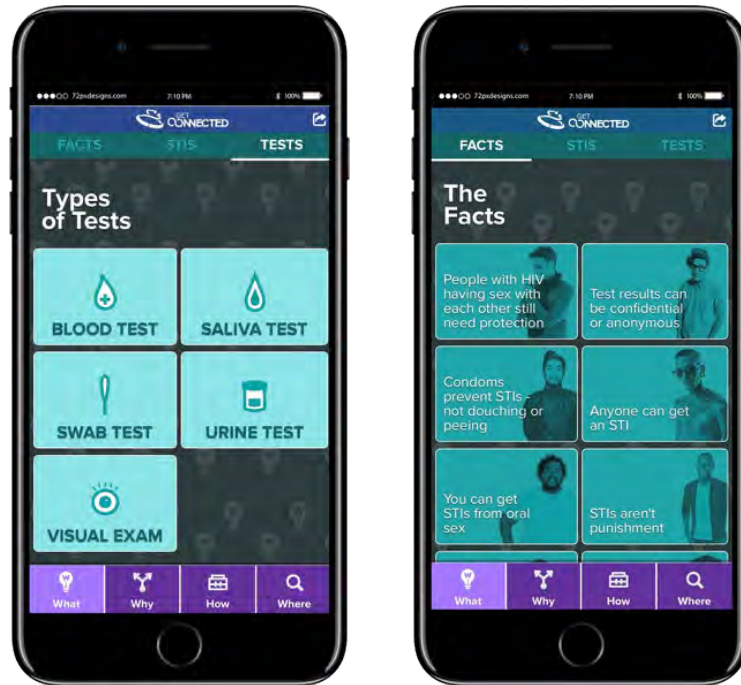
Fig. 2. Country-specific trends in the proportion of HIV diagnoses in young men who have sex with men aged 15 to 24 y, 2000–2014.

How are these tools helpful for delivering HIV prevention interventions?

iTech (ATN) Continuum of Care Interventions



Tailoring: Get Connected



Mystery Shopping to inform app completed in Philadelphia and launching in Atlanta;
RCT underway in Philadelphia, Atlanta, Houston

A motivationally-based, brief online intervention that employs individual and systems-level tailoring technology to reduce barriers to linkage into competent HIV/STI prevention for YMSM.

Site Tailored On:

- Age
- Race/Ethnicity
- Sexual Identity
- HIV Testing
- STI Testing
- Structural Struggles
- Sources of Support
- Values

Tailoring and Reminders: HealthMindr/MyChoices

Verizon LTE 9:54 AM

PrEP Quiz

Have you tested positive for any of the following STIs in the past 6 months: chlamydia, gonorrhea, syphilis.

☐ Yes

☐ No

☐ I don't know

Next

Verizon 9:25 PM

InitialQuiz

If you need more condoms - or just want to try something new! - you can order many types of condoms by clicking below button.

Order condoms

PrEP is a medication that can help prevent someone getting HIV. Because you are currently not taking PrEP, you can learn more about PrEP by clicking below.

PrEP info

It's always important to know your STI status. You can find a testing location by clicking below button. You can also order a free kit to test for STIs at home by clicking below button.

Testing Locator

MyChoices

My Choices

Test Plan

PrEP Info

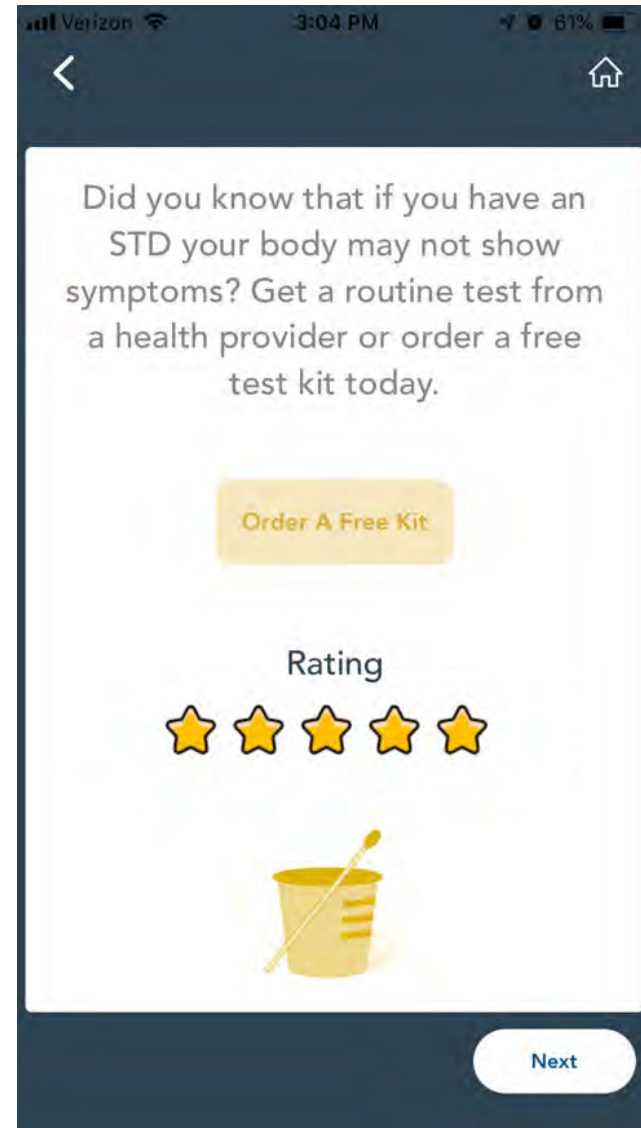
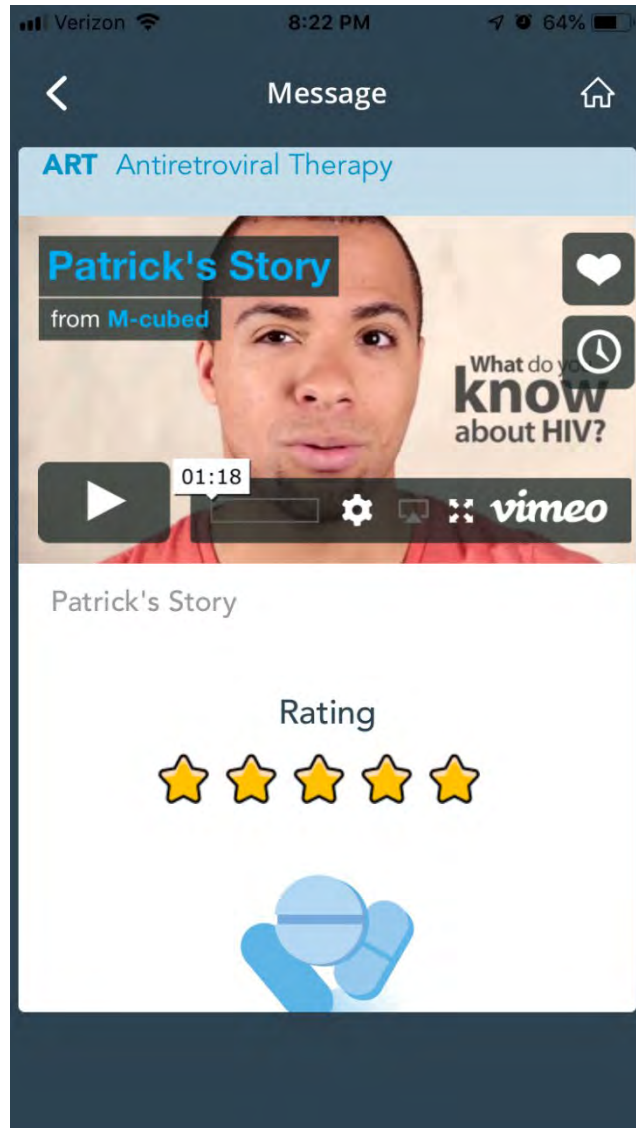
Locations

Ordering

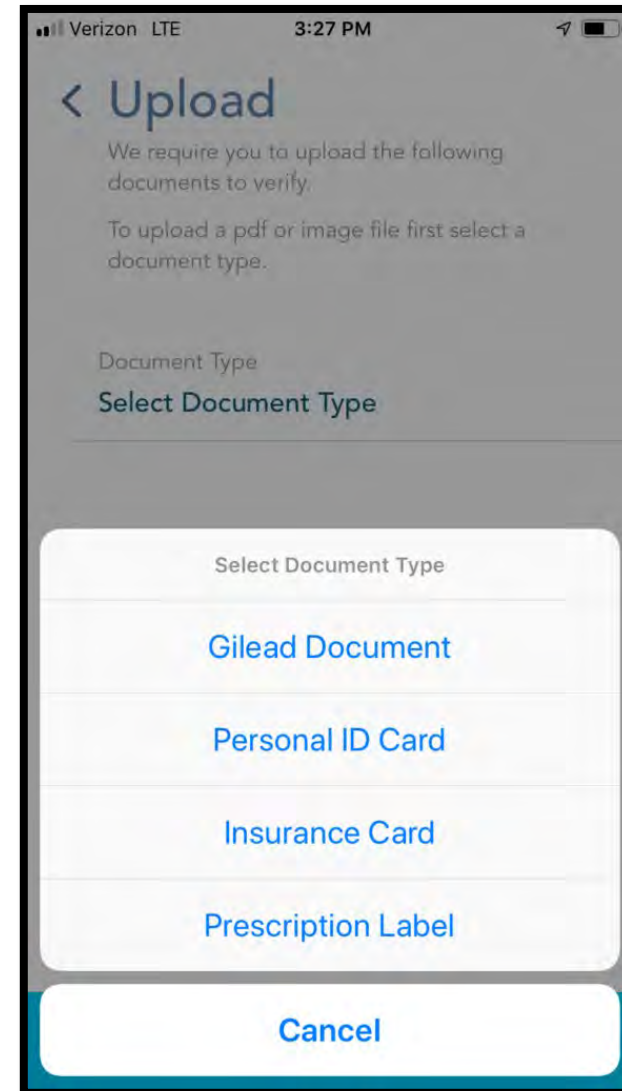
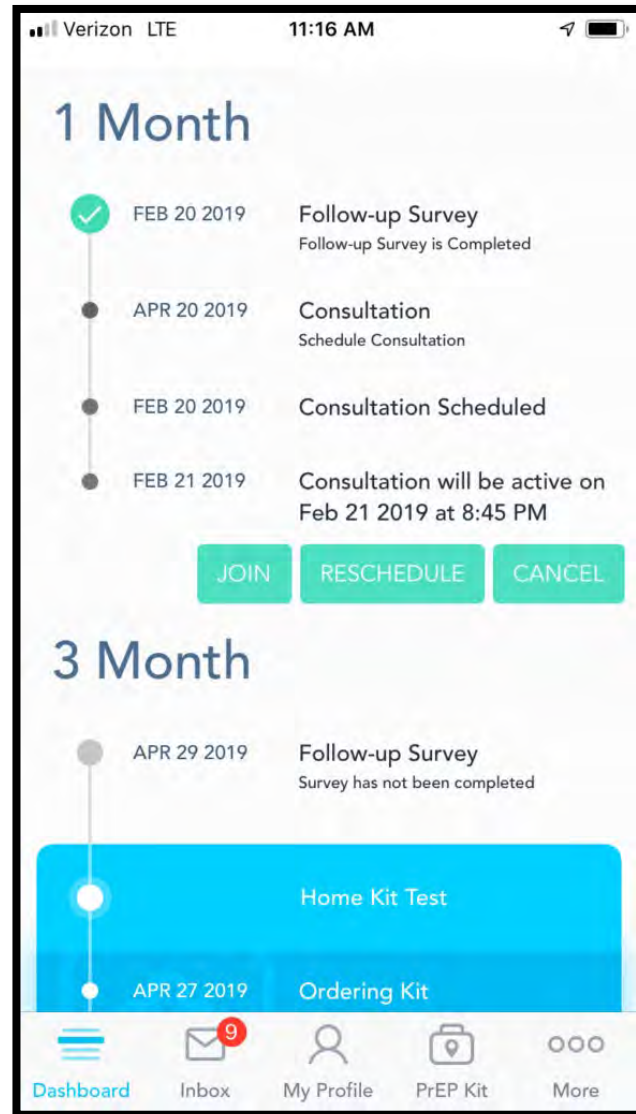
Resources

Need PEP?!

Delivering Rich Media: M³



Broad Reach: ePrEP



How are these tools helpful to conducting clinical trials?

SMART: Study Management and Retention Tool

- SMART provides an online study management portal for:
 - Identifying study visit schedules and progression through milestones
 - Organizing staff efforts for retention
 - Communicating with study participants
 - Returning study results
 - Managing mailout specimen collection fulfillment
- Participant app: scheduling, retention, surveys, ordering commodities
- Current utilization
 - 15 current trials
 - 8 upcoming trials
 - 5000+ participants under study
- Available through Emory CFAR

SMART dashboard

The SMART dashboard interface is divided into several sections:

- Header:** Includes the SMART logo, a search bar for participants, and a user profile for Nicole Luisi (Study Admin).
- Participant Overview:** Shows a total of 11251 participants. A progress bar indicates the status of participants: Prospect, Screened, Eligible, Enrolled, Active, and Completed. Buttons for "Add Task" and "Study Stop" are also present.
- Participant Details:** A sidebar on the left lists individual participants (e.g., 11244, 11245, 11246, etc.). The main area displays details for a selected participant, including:
 - Screening Status:** Screened (8/22/2018), Eligible (8/22/2018), Enrolled (3/14/2019), and Completed (Mark as Completed).
 - Study Arm:** Intervention
 - Pronoun:** He/Him/His
 - Site:** Atlanta
 - Contact Information:** Email (earllooriser@mailinator.com) and Phone ((555)-555-5555).
 - Contact Preference:** No preferences set.
- Timeline:** A section showing key events for the participant, categorized by time points:
 - Baseline:** 05 Sep 2018 - Baseline Visit (In-person baseline visit).
 - 3 Month:** 12 Jun 2019 - 3M Survey (Survey to be completed remotely) and 14 Jun 2019 - Pay 3M Incentive (\$25 incentive).
 - 6 Month:** 10 Sep 2019 - 6M Survey.
- Recent Messages:** A section for viewing and sending messages to the participant, including a "Send" button.

Assessment/data opportunities

- Delivery of ecological momentary assessments
- Location-based triggering of short surveys
- Paradata – indications of use of intervention components, quantitative assessment of engagement with intervention materials
- Collection of images (e.g., OraSure device picture, eligibility documents)

How will we scale mHealth
prevention interventions in
the United States and
beyond?

Keep It Up – Dissemination Plan

- Interactive, online intervention for YMSM
- 7 modules completed over ~ 3 days
- 60% reduction in risk of STI incidence
- How to implement?
 - Centralized
 - Disseminated

HAVE FUN. STAY SAFE.

KEEP IT UP

1	2	3	4	5	6	7	B1 (3 m)	B2 (6 m)
Healthy person (city specific)	Hooking Up Online	Soap Opera	Bar/Club	Dating	Healthy Comm	Goal Setting	Regular testing. Biomed prevention. Goal review	Prevention in relationships



How To Play

Interact: Click objects and people to interact with them.

Look Around: Use the left and right arrows to turn.

Move: Click the green circles on the map to change rooms. You're the blue circle.



Back
Start



Implementation of eHealth Programs?

- Fulfilling promise of “low cost interventions with universal reach”
- How to implement eHealth programs?
 - National delivery
 - Local implementation
 - Hybrid



HAVE FUN. STAY SAFE.

KEEP IT UP



R01MH118213

(NIMH, NIDA, OBSSR, ODP)

PI: Brian Mustanski, PhD



Institute for Sexual
and Gender Minority
Health and Wellbeing

Northwestern



Center for Prevention
Implementation Methodology

FOR DRUG ABUSE AND HIV

CHERISH

Center for Health Economics
of Treatment Interventions for
Substance Use Disorder, HCV, and HIV

HIGHLIGHTS

PROGRAM

An online, CDC rated “Best Evidence” intervention for young MSM ages 18–29

STUDY AIMS

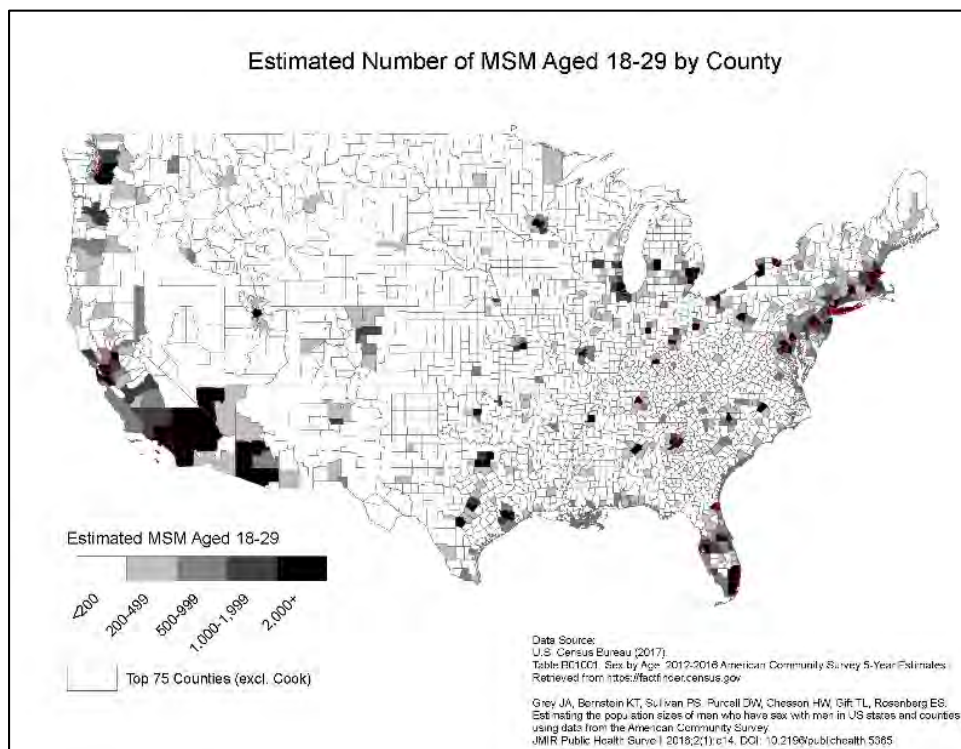
To compare two national implementation strategies

DESIGN

Hybrid effectiveness-implementation (type 3), Cluster RCT $N = 44$ counties

I.S. OUTCOMES

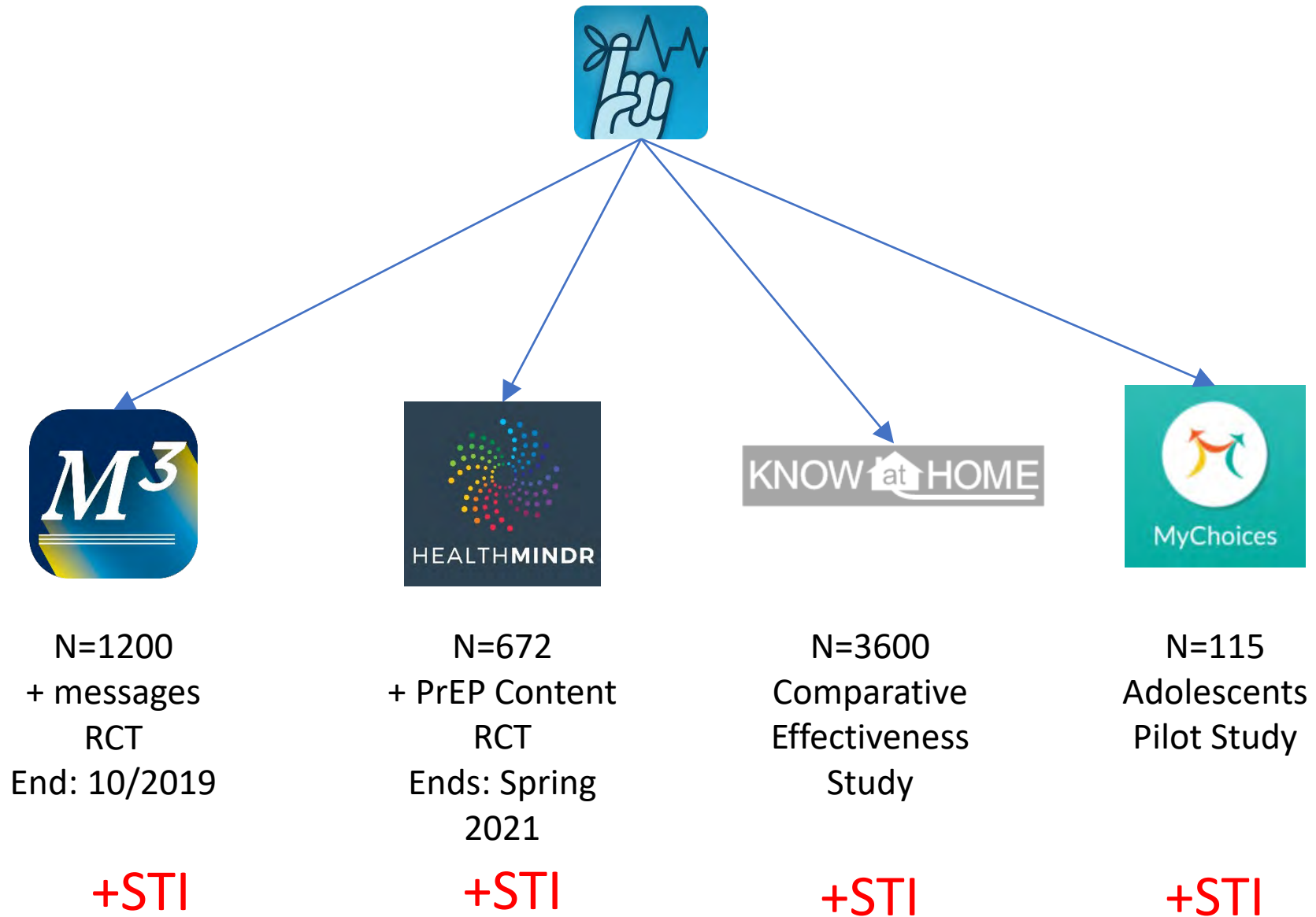
Public health impact (reach x effectiveness [behavior, STIs]), cost effectiveness, RE-AIM



66 counties randomized	
2 : 1	
44 counties randomized to CBO strategy	22 counties randomized to DTC strategy

Request for proposals from CBOs in 44 counties	
Applications reviewed and scored	
22 top scoring applications (1 per county) funded.	
Customization of KIU	
CBO staff deliver KIU to YMSM who test HIV negative through their routine HIV testing programs. STI testing through CBO or remotely.	
CBOs receive quarterly coaching from Northwestern.	
CBO staff engage YMSM in KIU!	Research staff assure survey completion
12 month STI testing performed at CBO or through remote testing.	

Advertising campaign designed and launched for 22 counties.	
At least 100 YMSM are recruited in each county.	
Eligible YMSM receive kit through the mail for HIV/STI self-testing.	
KIU! engagement by NWU DTC staff.	Research staff assure survey completion
12 month STI testing performed through remote testing.	



M³: PI: Sullivan, PO: Mansergh; HealthMindr: PI Sullivan, PD J. Jones; MyChoices PIs Biello/Mayer; iSTAMP PIs: Sullivan, Hightow-Weidman, Stephenson, PO: Macgowan

Stakeholder preferences for deployment of mHealth interventions

- Emory CFAR-supported evaluation of preferences for scaling mHealth HIV prevention interventions among CBO, health department, and CDC colleagues
- Key informant interviews and theater testing of options for management dashboards
- 2-3 state/local health departments
- Completion by fall 2019

Conclusions

- mHealth impacts all phases of clinical trials – intervention content, participant management, delivery, assessment, and scale
- mHealth offers opportunities for optimized delivery and intervention that other tools do not. mHealth can be used in conjunction with biomedical interventions
- There is a rich pipeline of HIV prevention interventions already in place, including through the ATN
- There will be challenges with translating clinical trials of mHealth interventions to scale, and it's best to anticipate and plan for them now
- Tools and expertise are available through HPTN and ATN colleagues, and through the Emory CFAR

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