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
<table>
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<th></th>
<th>Any cellphone</th>
<th>Smartphone</th>
<th>Cellphone, but not smartphone</th>
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<tbody>
<tr>
<td>Total</td>
<td>95%</td>
<td>77%</td>
<td>17%</td>
</tr>
<tr>
<td>Men</td>
<td>95%</td>
<td>80%</td>
<td>16%</td>
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<tr>
<td>Women</td>
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<td>75%</td>
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<td>94%</td>
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<td>30-49</td>
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<td>85%</td>
<td>46%</td>
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<tr>
<td>White</td>
<td>94%</td>
<td>77%</td>
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<tr>
<td>Black</td>
<td>98%</td>
<td>75%</td>
<td>23%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>97%</td>
<td>77%</td>
<td>20%</td>
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Pew Research Center, Mobile phone fact sheet, February 2018
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.

Chapin-Bardales et al, Annals Epidemiol 2018
How are these tools helpful for delivering HIV prevention interventions?
iTech (ATN) Continuum of Care Interventions

- Get Connected
- MyChoices
- LYNX
- COMPARE
- We Prevent
- TechStep
- ePrEP
- p³
- Life Steps for Youth
- YouTHrive
Mystery Shopping to inform app completed in Philadelphia and launching in Atlanta; RCT underway in Philadelphia, Atlanta, Houston

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

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.

ATN 139; PIs: Bauermeister and Stephenson
Tailoring and Reminders: HealthMindr/MyChoices

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

Initial Quiz

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
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

PI: Brian Mustanski
<table>
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<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>B1 (3 m)</th>
<th>B2 (6 m)</th>
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<tbody>
<tr>
<td>1</td>
<td>Healthy person (city specific)</td>
<td>Hooking Up Online</td>
<td>Soap Opera</td>
<td>Bar/Club</td>
<td>Dating</td>
<td>Healthy Comm</td>
<td>Goal Setting</td>
<td>Regular testing. Biomed prevention. Goal review</td>
<td>Prevention in relationships</td>
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### 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.
Implementation of eHealth Programs?

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

66 counties randomized

2 : 1

44 counties randomized to CBO strategy

22 counties randomized to DTC strategy

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.
N=1200 + messages
RCT
End: 10/2019

N=672 + PrEP Content
RCT
Ends: Spring 2021

N=3600 Comparative Effectiveness Study

N=115 Adolescents Pilot Study

+STI

M^3: 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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