



E-VOLUTION

A two-way text messaging intervention to connect with, support, and improve health outcomes for youth living with HIV

**Replication Manual
October 2019**



Acknowledgements

WASHINGTON UNIVERSITY SCHOOL OF MEDICINE

E-VOLUTION Team (Authors)

Katie Plax, MD, Principal Investigator, Medical Director
Division Chief, Adolescent Medicine
Ferring Family Professor of Pediatrics

Kimberly Donica, LCSW, Program Director
Executive Director Project ARK/The SPOT

Jeffrey Glotfelty, MPH, Project Coordinator
Senior Clinical Research Coordinator

Stacey Slovacek, LCSW, Project Assistant
Case Worker

Julia Schlueter, MPH, Evaluator
Clinical Research Specialist

Maria Freshman, MA, Data Control Coordinator
Data Coordinator

Sarah Bekendorf, LMSW
Research Assistant

Donny Gerke, PhD, LCSW, Quantitative Evaluator
Assistant Professor University of Denver

Melissa Jonson-Reid, PhD, LCSW,
Director, PHD Program in Social Work

Ellen Frank-Miller, PhD, MSW, Qualitative Evaluator
Senior Scientist and Adjunct Professor

Sophia Fox-Dichter, MSW
Data Analyst II

Washington University Medical Case Managers, Nurses, and Mental Health Providers

Dana Bowens, MSW
Laurie Gilden, MSW
Kelly Nolan, LCSW
Lisa Jackson-McLean, BSW, MS
Jamie Reed, BA
Liz Neuf, MSW, LCSW
Fallon Johnson, MSW

Tara Triplett, MSW
Braden Tobin, BA
Lisa Stief, BS
Nora Leahy, BA
Stacey Higgins, MA, LPC
Mel Cadenza, BFA
Phyllis Ballard, RN

Youth Advisors in Our SPOT Sessions

Washington University Clinical Sites

St. Louis Children's Hospital Pediatric Infectious Disease Clinic
Washington University Infectious Disease Clinic
SPOT (Supporting Positive Opportunities with Youth) Infectious Disease Clinic

Ernie-Paul Barrette, MD
Associate Professor of Medicine

Tawnya Brown, MSW
Program Director, Infectious Diseases Clinic

Tina Markovich, MBA, BS
Program Director, Infectious Diseases Clinic

Don Hardin
Data Coordinator

Washington University Privacy Officers

Christina Schorb, BS, MBA
HIPAA Privacy Officer

Sondra Hornsey, MSED
HIPAA Privacy Officer

Washington University Information Systems

E. Scott Rich, MBA
Director of Information Technology

Rachel Komeshak
Project Management Office Manager

Health Resources and Services Administration/ HIV AIDS Bureau

HRSA's Ryan White HIV/AIDS Program, Part F: Special Projects of National Significance

John Hannay, Project Officer
Public Health Analyst HRSA

**The University of California, Los Angeles (UCLA),
Department of Family Medicine Project**, Evaluation
and Technical Assistance Center (ETAC)

We want to give a special acknowledgement to our consultants and sub-contractors on this project:

Epharmix, Inc.
Impact Marketing + Communications
Health Literacy Missouri
Jun Bae
Kindea Labs
Yellowbrick Creative Studios

"This resource is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number H97HA28897, Special Projects of National Significance (SPNS) Use of Social Media to Improve Engagement, Retention and Health Outcomes along the HIV Care Continuum for \$1,200,000. 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. For more information, please visit hab.hrsa.gov.

Tables of Contents

Executive Summary	1
Introduction	3
E-VOLUTION Intervention Overview	5
Model At-A-Glance	6
Resource Assessment Checklist	7
The Basics	8
Theoretical Framework.	12
Methods	13
Pre-Implementation	13
Implementation.	23
Adaptable Characteristics	30
Outcomes	31
Alerts.	32
Outcomes/Impact Indicators.	33
Outcomes	34
Conclusions and Recommendations	35
Successes	35
Barriers.	37
Lessons from the Field	38
Considerations for Replication	39
Appendices	41
Works Cited	60

Executive Summary

Intervention Summary

E-VOLUTION utilized automated two-way text messaging coupled with live text messaging between medical case managers and their HIV-infected youth/young adult clients within a Ryan White HIV/AIDS Program in St. Louis Missouri, Project ARK AIDS/HIV Resources and Knowledge.

The E-VOLUTION program focused on and succeeded in improving HIV health outcomes for youth, especially young African American men who had sex with men (MSM). Specifically, the initiative improved—viral load suppression rates, HIV medical visit show rates, and communication with medical case managers, all the while removing barriers and responding to needs through the use of mobile health (mHealth) programming.



Increased virologic suppression



More HIV medical visits kept



Improved CM communication



Rationale and Need

While national HIV infection rates have begun to decline, certain populations, including people of color, young adults, and men who have sex with men, still experience disproportionate rates of infection.ⁱ In addition, youth have the poorest HIV care continuum outcomes including lower rates of linkage to care, retention and viral load suppression (VLS).ⁱⁱ These disparities highlight a need to implement a novel approach, specific to the young adult population that supplements existing services available to those living with HIV/AIDS.

In an alarming trend, during the period of 2010-2013, youth represented both a growing number and proportion of new HIV/AIDS cases within the St. Louis region. In 2013, there were 332 new diagnosed HIV/AIDS cases in the St. Louis MSA. In 2013, youth ages 13-24 represented 33.7% (n=112) of the total 332 new HIV/AIDS cases in the region. In addition, this population was found to have the poorest HIV care continuum outcomes.

Studies have found that, of HIV-infected individuals, patients who received text-messaging support had significantly improved antiretroviral adherence and rates of VLS.ⁱⁱⁱ Text messages communicate appointment reminders to decrease non-attendance rates at HIV clinics^{iv} and personalized affirming or intervention messages for HIV medical care.^v Studies have also shown that automated systems that go beyond the single message or “push” message and utilize a two-way communication have improved results in affecting the desired behavior.^{vi,vii} Mobile technology and text messaging are particularly appropriate for use in a study with adolescents since texting has become their preferred method of communication.^{viii} Cell phones have become indispensable tools in teen communication, with 1 in 3 adolescents sending more than 100 text messages a day.^{ix} Moreover, text messaging holds unique promise for future interventions with underserved and at-risk adolescents who may be more willing to use text messaging.^{xiii}

Intervention Description

The E-VOLUTION texting intervention included two components: an automated two-way text messaging system coupled with live text messaging between medical case managers (MCMs) and their clients, youth/young adults living with HIV. Utilization of the automated two-way text messaging system offered the ability to alert members of the care team, in real-time, allowing for expedited intervention. Then, person to person text messaging between the participant and their MCM provided follow-up of participant needs identified by the automated system.

Key Components of E-VOLUTION included:

E-VOLUTION Digital Communication Strategies		HHS Common HIV Indicator		
		Linkage to Care	Retention in Care	Viral Load Suppression
Automated Text Messaging	Daily Medication Reminders		✓	✓
	Bi-Weekly Mood Check-Ins		✓	
	Appointment Reminders	✓	✓	✓
	Housing/Social Services Check-In		✓	
Person-to-Person Text Messaging Youth/Case Manager		✓	✓	✓

Intervention Summary

For successful start-up of a mHealth program like E-VOLUTION, The Washington University team identified the following activities as crucial during pre-implementation:

- ▶ Assess Organizational Commitment and Capacity
- ▶ Develop Organizational Policies, especially around privacy and text messaging standard practices
- ▶ Assess openness and skill level of staff in regards to using mHealth technology
- ▶ Collect youth feedback
- ▶ Thoroughly train staff
- ▶ Develop a plan for client recruitment and engagement

Elements essential to the replication of E-VOLUTION include:

- ▶ A text messaging delivery system that is mobile-based and agnostic of mobile provider.
- ▶ An automated texting service that pushes out messages AND collects responses to questions.
- ▶ A system that immediately provides real-time alerts to the care team allows a prompt response to client reported issues.
- ▶ A two-way system fortifies a feeling of human connection between care provider and client.

Once enrolled in the automated system, participants began receiving the automated text messages, which asked medically-relevant questions and prompted recipients for a response. EVOLUTION worked with the system vendor to build

an HIV-specific suite to prompt participants with texts about medication adherence, upcoming appointments, general mood, and social service needs.

To supplement the automated two-way text message system, case managers communicated with clients on their work cell phones via text message. Medical case managers were tasked to text, at minimum, monthly with enrollees and to follow-up on any alerts that we triggered by the system.

Key staff needed for delivery of E-VOLUTION include:

- ▶ Project Manager/Financial Administrator,
- ▶ Project Coordinator/Champion, and
- ▶ Field Staff/Manager of client responses to automated system

Evaluation of the E-VOLUTION project revealed the following outcomes:

- ▶ Participation in E-VOLUTION was associated with improved viral load suppression rates
- ▶ Texting with medical case managers improved attendance at medical visits
- ▶ Text messaging improved case managers and clients communication

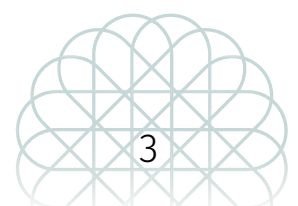
More in-depth discussion of the findings and considerations for replication are included in the full replication manual.



Introduction

In 2015, with funding under the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Special Projects of National Significance (SPNS), Washington University School of Medicine developed the E-VOLUTION program. The program utilized automated two-way text messaging coupled with live text messaging between Ryan White HIV/AIDS Program medical case managers and their clients to improve health outcomes along the HIV care continuum. Mobile text messaging technology was implemented since texting has become the preferred channel of communication for adolescents.^{vii} Project ARK, the Ryan White Part D Program, determined that the majority of youth clients had a private mobile phone to receive health-related information. Cell phones have become indispensable tools in teen communication and 1 in 3 adolescents sends more than 100 text messages a day.^{ix}

The E-VOLUTION program focused on and succeeded in improving HIV health outcomes for youth, especially African American young men who had sex with men. Specifically, the initiative improved viral load suppression rates, HIV medical visit show rates, and communication with medical case managers, all the while removing barriers and responding to needs through the use of mobile health (mHealth) programming.



“ Cell phones have become indispensable tools in teen communication and 1 in 3 adolescents sends more than 100 text messages a day. ”

This manual provides guidance on how to replicate the E-VOLUTION program and a framework for incorporating mHealth services, such as text messaging and a two-way text messaging automated system, into clinical settings.

About SPNS

The SPNS Program is funded through Part F of the Ryan White HIV/AIDS Program, which is operated under HRSA/HAB. HRSA is an agency of the U.S. Department of Health and Human Services (HHS). SPNS supports the development of innovative models of HIV care and treatment in order to quickly respond to emerging needs of clients served by Ryan White HIV/AIDS Program. SPNS advances knowledge and skills in the delivery of health care and support services to underserved populations living with HIV. Through its demonstration projects, SPNS evaluates the design, implementation, utilization, cost, and health related outcomes of treatment models while promoting the dissemination and replication of successful interventions.

About the Use of Social Media Initiative

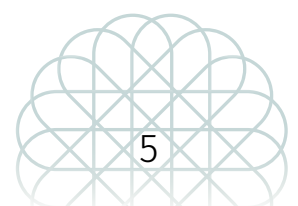
This initiative is a multi-site demonstration and evaluation of innovative social media methods designed to identify, link, and retain HIV positive underserved, underinsured, hard-to-reach youth and young adults (ages 13–34) in HIV primary care and supportive services. These methods include system approaches utilizing a variety of social media, internet, and mobile-based technologies to improve engagement and retention in care and viral suppression. These social media interventions will focus on youth and young adults living with HIV who are aware of their HIV infection status but have never been engaged in care; are aware but have refused referral to care; have dropped out of care; are infected with HIV but are unaware of their HIV status; or have not achieved viral suppression.











E-VOLUTION Intervention Overview

Model at-a-Glance

The table on the following page describes the E-VOLUTION program as modeled by Project ARK at Washington University School of Medicine. Readers can review the step-by-step overview for replication.



Model at-a-Glance

Step 1 	Identify Clients Eligible for Program Youth between the ages of 18–29 that are newly diagnosed, lost to care, or not virally suppressed are referred to the E-VOLUTION program.
Step 2 	Engage Clients and Assess Interest Staff works with client to determine client interest in the program. Staff determine if client has a working cell phone, client completes a safety screening and a consent form for participation.
Step 3 	Prescribe Intervention Staff register client in the two-way text message system and client completes a phone consent via text message to finish registration.
Step 4 	Provide Daily Reminders System provides daily medication reminders, weekly mood check-ins, appointment reminders, and monthly social service needs assessment.
Step 5 	Case Manager Responds to Alerts System alerts case managers of missed medication doses, worsening mood, missed medical appointments and concerns about housing/ bills. Case manager follows-up with client to provide support and closes alert.
Step 6 	Case Manager Pursues Monthly Text Engagement Case Manager sends a minimum of one text message per month to check on the client.
Step 7 	Texting Program in Field for 18 Month Period Two-way text messaging service between case manager and client is utilized for a maximum of 18-months.
Step 8 	Acquire Data from Medical Records to Review Health Outcomes Staff obtain medical records to review client's viral load and history of missed/kept appointments. Staff and client work together to continue to achieve medical adherence and achieve viral load suppression.

 **Resource Assessment Checklist**

The E-VOLUTION program was specifically tailored for implementation in Ryan White HIV/AIDS-funded clinical care centers where medical case management services are available. The structure of services at Ryan White HIV/AIDS Program health programs/centers allows for both the clinical and social support services of the program to be optimized. However, E-VOLUTION can be implemented at any HIV care center or primary care medical site with the right components in place or the ability to develop these necessary components. Questions to consider include:

- Do the clients your organization serves have access to personal, private mobile phones with the ability to text?
- Are the financial resources available for acquiring the required technology? This may include mobile phones for staff and a contract with a technological platform
- Does the organization have the capacity to have or hire a lead staff person to champion the program?
- Additionally, does your organization have the capacity to hire or is there existing staff to enroll clients and field alerts?
- Does your organization provide HIV primary care services or have a formal relationship with an organization that does?
- If an alert is triggered or a client identifies a need, are there available community resources to meet that need?
- Does your two-way text messaging provider allow for tailoring of messages to the target audiences to ensure the delivery of culturally competent care?
- Has your organization established policies around protecting the privacy of patient information when using mobile technology?
- Are staff able to be adequately trained on the technology and policies?
- Does your organization have a crisis intervention plan that can be applied during the use of mobile technology?

“ E-VOLUTION utilized automated 2-way text messaging coupled with live text messaging between medical case managers and their HIV-infected youth/young adult clients. ”

The Basics

WHAT IS E-VOLUTION:

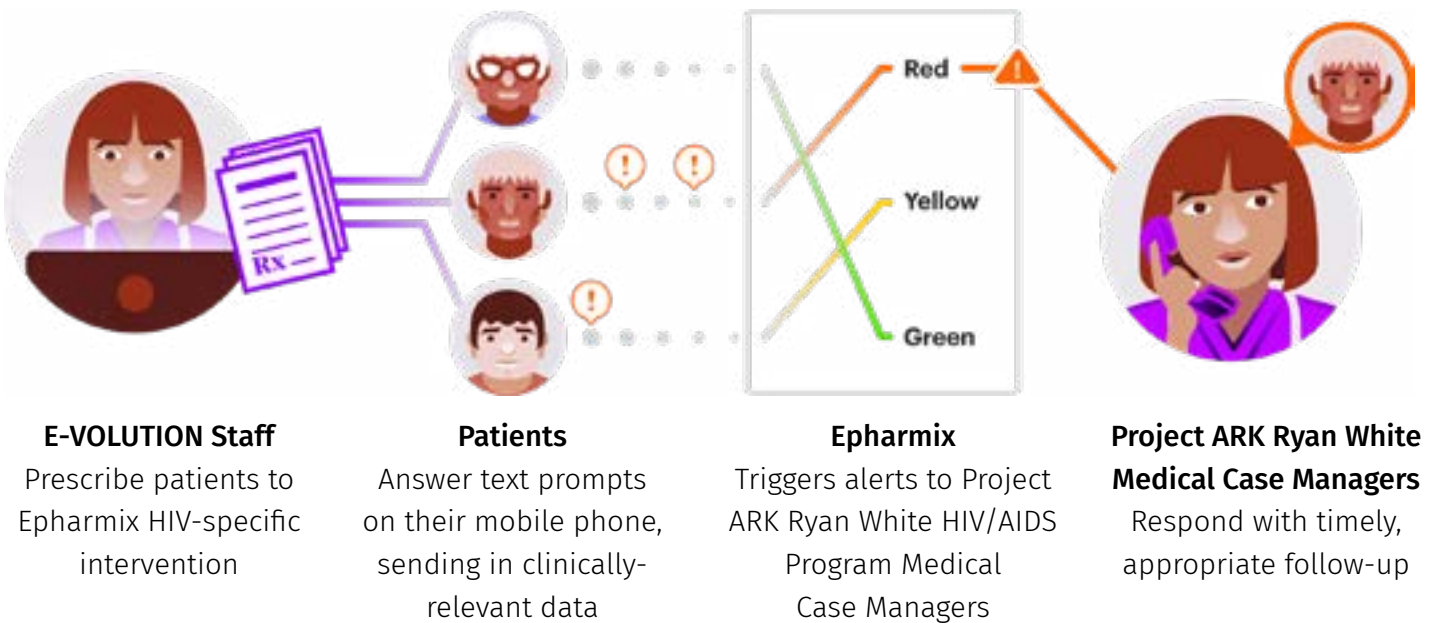
E-VOLUTION utilized automated 2-way text messaging coupled with live text messaging between medical case managers and their HIV-infected youth/young adult clients.

Washington University School of Medicine purchased a two-way text messaging system from Epharmix, Inc. for the E-VOLUTION program to collect condition-specific data. The E-VOLUTION team chose this system because it offered the ability to alert members of the care team, in real-time, allowing for expedited intervention.

Key Components of E-VOLUTION included:

E-VOLUTION Digital Communication Strategies		HHS Common HIV Indicator		
		Linkage to Care	Retention in Care	Viral Load Suppression
Automated Text Messaging	Daily Medication Reminders		✓	✓
	Bi-Weekly Mood Check-Ins		✓	
	Appointment Reminders	✓	✓	✓
	Housing/Social Services Check-In		✓	
Person-to-Person Text Messaging Youth/Case Manager		✓	✓	✓

E-VOLUTION AUTOMATED TEXT MESSAGING WORKFLOW



Source: Epharmix, Inc.

WHO RECEIVED E-VOLUTION:

E-VOLUTION was designed for youth and young adults who are

- ▶ Between the ages of 18–29
- ▶ Are living with HIV
- ▶ Utilize text messaging
- ▶ Are enrolled in clinical care
- ▶ Require support in remaining adherent to HIV care.

Project ARK developed this digital media-based intervention to address gaps in the regional HIV Care Continuum for underserved, underinsured and hard-to-reach youth, who utilized mHealth.

WHERE DID E-VOLUTION TAKE PLACE:

The E-VOLUTION program was implemented at infectious disease clinics that are part of Project ARK in St. Louis, Missouri. Project ARK (AIDS/HIV Resources and Knowledge), a program of the Washington University School of Medicine, has served as the St. Louis region's only Ryan White HIV/AIDS Part D recipient

“ These disparities highlighted a need to implement a novel approach, specific to the young adult population, that supplements existing services available to those living with HIV/AIDS. ”

since 1995. Project ARK provides a comprehensive continuum of HIV care and prevention services including HIV testing, linkage to care, medical and behavioral health services and medical case management and serves the vast majority of youth in care within the region.

In 2014, Project ARK served 332 youth, of which 86% were African American. HIV-infected youth had lower rates of linkage to care, retention in HIV medical care and viral load suppression compared to other age groups served in the program. These disparities highlighted a need to implement a novel approach, specific to the young adult population, that supplements existing services available to those living with HIV/AIDS.



WHY E-VOLUTION:

Using text messaging to provide support for people living with HIV can be an effective tool to improve patient outcomes along the HIV care continuum.^x In a randomized clinical trial of HIV-infected adult patients, those who received text-messaging support had significantly improved antiretroviral adherence and rates of viral suppression compared with the control group.ⁱⁱⁱ Text messages have also been used as appointment reminders to increase attendance rates at HIV clinics^{iv} and are a feasible way to deliver personalized affirming or reminder messages for HIV medical care.^v Studies have also shown that automated systems that go beyond the single message or “push” message and utilize a two-way communication method improved results in affecting the desired behavior.^{vi,vii}

E-VOLUTION, The Washington University (St. Louis, MO)

Program Summary	Social Media Intervention Overview	Evaluation Summary
<p>Target Population</p> <p>Age: 18–29</p> <p>Gender: Male & Female</p> <p>Race/Ethnicity: All (primarily AA)</p> <p>Sexual Orientation: MSM & Heterosexual (primarily MSM)</p> <p>Sample Size: 100 HIV+</p> <p>Language: English</p> <p>Setting: Clinic, University Setting</p> <p>Inclusion Criteria</p> <p>Unaware of HIV status: No</p> <p>Newly Diagnosed: Yes</p> <p>Not linked/engaged in care: No</p> <p>Not retained in care/Out of care: Yes</p> <p>Not adherent to HIV medication: Yes</p> <p>Not virally suppressed: Yes</p>	<p>Intervention type</p> <p>Adapted from prior intervention Adjunct to existing services</p> <p>Technology Platforms Used</p> <p>Mobile App: Yes, adapted</p> <p>Social Media: No</p> <p>Text Messaging: Yes, automated and live</p> <p>Functions</p> <p>Communication: Yes</p> <p>Education: Yes</p> <p>Information: Yes</p> <p>Reminders</p> <p>General: Yes, automated</p> <p>Medical appointments: Yes, automated</p> <p>Skills building: Yes</p> <p>Social support/networking: Yes, virtual/online support group</p>	<p>Evaluation Comparison Group— Yes, historical comparison group</p> <p>HIV Health Outcome Measures</p> <p>Increase HIV testing/Positivity rate/ HIV awareness: No</p> <p>Improve linkage/engagement in care: Yes</p> <p>Improve retention in care: Yes</p> <p>Improve medication adherence: Yes</p> <p>Improve viral suppression: Yes</p> <p>Improve utilization of support services: Yes</p> <p>Improve health literacy: Yes</p> <p>Other Ryan White Part Funding Parts A, B, C, D, F</p>

Theoretical Framework

The structure of the intervention was informed by two specific theories: Supportive Accountability and Environmental Momentary Analysis.

SUPPORTIVE ACCOUNTABILITY

Supportive Accountability^{xi} postulates that motivation towards medical treatment adherence can be affected by:

Presence – having another human being digitally present. This is represented by the medical case managers regularly texting to check in on their clients and responding to red alerts triggered by a participant in need of care.

Clarity – Knowing what the expected adherence for medication and appointments means. These expectations are defined by the reminder texts, for medication and appointments.

Performance monitoring – Having responses be collected for review. A staff member reviews the results collected through the automated system and addresses them with the client, whether that be affirming their success or strategizing solutions for challenges identified.

ECOLOGICAL MOMENTARY ASSESSMENT

This model asserts that collecting information from participants through periodic checks-ins while they are in their natural environment results in more accurate reporting than relying on recall.^{xii} For example, assessment of mood and referral needs through semi-weekly text prompts may elicit more accurate responses than relying upon recalling past emotional well-being and needs at six-month check-ins with case managers. If a participant is currently in crisis or in need of services, the increased frequency of check-ins reduces effort by the participant to seek help and provides an open channel of communication to seek help in the moment.



Methods

Pre-Implementation

The Washington University team identified the following activities as crucial to the successful start-up of a mHealth program like E-VOLUTION. An organization should allow ample time to consider these steps, as some may require unexpectedly long time-frames to receive approval and accomplish staff buy-in.

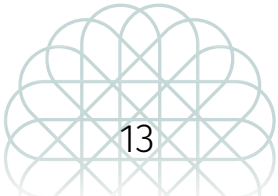
ASSESS ORGANIZATIONAL COMMITMENT AND CAPACITY

Administrative support and buy-in is critical to the successful integration of text-based interventions within a program. Moving towards mHealth is a large programmatic commitment and requires at least one key staff member (a champion) to market, integrate, implement, and monitor services.

HOW MUCH?

Estimated key costs related to implementing text-based interventions are summarized in the table and chart below. A summary of the primary costs include:

1. Purchasing technology platforms/applications that assist in the delivery of the program

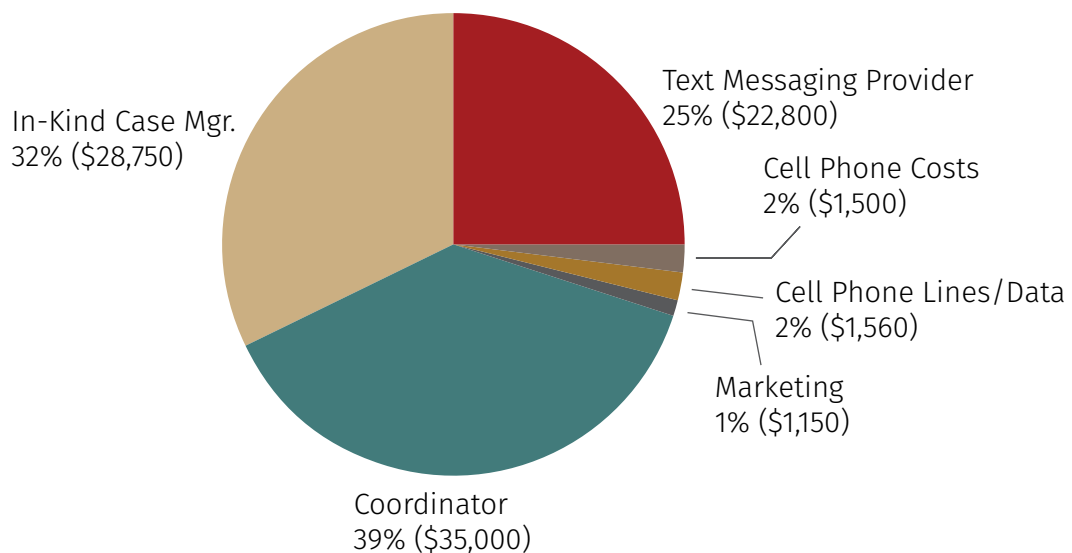


2. Purchasing smartphones for staff and/or clients to interact with the technology
3. Monthly costs for staff cellular phone service
4. Allocation of resources to provide assistance for phones, however E-VOLUTION relied on participants use of their own cell phones and service as an inclusion criteria
5. A staff member to champion the intervention

SPNS COSTING ESTIMATE

Item (based on 10 provider users)	Estimated Cost Annual Cost	In-Kind
Automated 2-way text messaging provider (annual contract)	\$22,800	
Cell phone costs (\$149.99 ea. with 2 year contract)	\$1,500	
Cell phone line/data cost	\$1,560	
Marketing materials	\$1,150	
Coordinator/Champion (.25 FTE-.50 FTE)	\$35,000	
Case Manager/In-kind staff		\$28,750
Total	\$62,010	\$28,750

SPNS Annual Costing Estimate





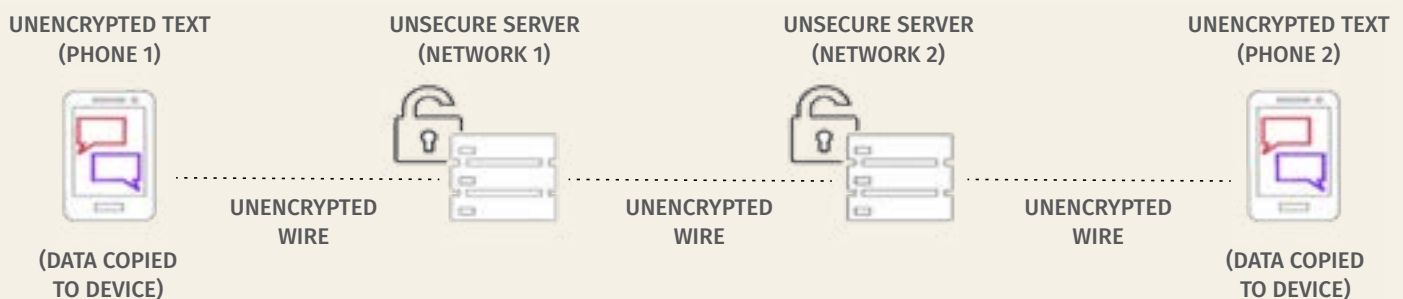
TIP: Text-based interventions require a smartphone to comply with privacy regulations and reduce barriers to monitoring and communicating with patients. For programs that do not have the option of providing new smartphones to staff, there are computer-based solutions that provide the capacity to text-message without a mobile phone. The chosen technology application or service vendor utilized will determine the hardware needs for the program.

Privacy and mHealth



Develop Organization Policies

Text messaging outside of an encrypted application is not a fully secure method to communicate personal health information. Information sent and received by text message is stored on the devices used for communicating (in this case the mobile phones of the staff member and the participant) and can be stored in various points within the network used to pass the message, including cellular provider servers and transmitting stations. Below are some examples of steps programs and individuals can take to reduce the risk of breach of information while texting.



- Mobile Device Management (MDM)
- First Text in Person – Confirm
- White Labelling
- Policy to delete messages from sender phones
- Proper disposal of the device
- Staff Trainings on policy
- Business Associate Agreement (BAA) with Automated Service
- Encryption
- Minimize PHI
- Change to a phone call
- Privacy Settings (Tip Sheet)
 - Single User Phone
 - Password
 - Push Notifications
- Updating if Number Changes
- Delete messages from recipient phones



Privacy

The implementation is dependent on clinical team text messaging communication modifications to meet HIPAA and HI-TECH regulations. Program staff were very intentional in working with the privacy office to detail the specifics of how to deal with client informed consent and texting, especially the sharing of protected health information (PHI). Washington University has an Authorization for Electronic Communications Form (appendix 1) developed to cover email and text messaging. Further conversations with the organizational privacy officer to determine what is allowable and not allowable through text messaging and working with the University's internal privacy office and information security team ensures compliance with HIPAA regulations.



Protection of Privacy

As a result of these privacy conversations, the team developed a Medical Case Manager (MCM) text messaging policy (appendix 2), which is adapted from available materials from University of Wisconsin's Health HIV/AIDS Comprehensive Care Program. This program-specific policy outlined the required actions that MCMs follow to ensure that they are text messaging in ways that reduces the risk of unintentional disclosure of participant information.



Informed Consent/Client Safety

As a result of discussions with the privacy office, the E-VOLUTION team identified a need to educate participants on the real-life risks of text messaging. To assess a participant's understanding of the risks of receiving and sending text messages with their care providers, the E-VOLUTION team adopted a Safety Appraisal which was adapted with permission from materials out of the

Potential Questions on Safety Appraisal

- ▶ What do you think about the possibility of someone else (friend, partner, parent, etc.) seeing messages about your healthcare?
- ▶ What would happen if someone (friend, partner, parent, etc.) saw these kinds of messages (how are you feeling today, reminders for appointments, medication reminders, discussions with your case manager)?
- ▶ Is your phone password protected?
- ▶ Who has access to your phone?
- ▶ Do you have the ability to read your text messages in a private space?
- ▶ Do you know how to change settings on your phone (push notifications, passwords) to make your phone more private?

Center for Innovative Public Health Research (appendix 3). This screener asked participants to imagine people in their lives accessing the text messages sent from the E-VOLUTION program and how they felt they would respond. While completing the screener, the study team also provided strategies for securing phones and protecting participants' private information on their mobile devices. If staff determined that the answers to the screener indicated a potentially unsafe situation, they discussed these concerns with participants and explored whether the participant should proceed with enrollment in the project.

As E-VOLUTION transitioned to sustainability as a direct practice intervention, outside of the overview of the Human Protections Office and Internal Review Board (IRB), a second Authorization, which is to give permission for the automated text messages, was developed with the assistance of university council and the privacy office (appendix 4).

ASSESS OPENNESS/SKILL LEVEL OF STAFF IN USING TECHNOLOGY

The automated text-based intervention was implemented by existing Ryan White-funded medical case managers (MCMs) to provide them additional tools to assess and address the needs of their clients. The MCM staff was instrumental in integrating the texting intervention into the existing Washington University clinical sites. Case managers serving youth and young adults ages 18–29 implemented the project and included—MCM that specialized in work with newly diagnosed youth (Linkage to Care), youth who were never in care/lost to care, transitional age young adults (25–29), and general youth MCM (working with youth up to age 25).

There can be a range in the level of skills and comfort in utilizing the texting intervention among the staff members. Therefore, individual and group training/coaching may be needed to help all staff feel comfortable and proficient with the texting intervention.

YOUTH FEEDBACK

Feedback solicited from youth advisory member committees was extremely important in the development of the intervention. During sessions and one-on-one, key-informant interviews, youth were presented with technology demonstrations and provided critical feedback on digital interventions, the two-way text messaging system, and marketing materials.



TIP: Before enrolling privacy was not a concern but, after participation, privacy was important—continue to assess privacy concerns with participants throughout the intervention).

Key Feedback from formative sessions included:

- ▶ **Text messages (over phone calls) are the preferred method** of communication
- ▶ **Before participation, privacy around text messaging of medical information was not a major concern** since many respondents used passcodes and kept their phones in their possession.
- ▶ **Text messages are useful** to communicate with patients — just be mindful of the subject for the messages and the frequency, as most participants like reminders for medicine and appointments.
- ▶ **Marketing Materials should be relevant** to youth but not disclose their diagnosis. Pictures should look real and age appropriate, messages should be easy to read, and logos and materials should look general and inconspicuous.
- ▶ **4 common themes in both the focus group and interviews:**
 - » **Confidentiality** was a consistent point of importance. Participants want to feel certain that their information is not being released to or seen by unauthorized people.
 - » **Security of the systems:** Security of systems was a concern, including how these systems may be hacked to gather confidential information.
 - » **Utility and accessibility of the tools:** Utility refers to how the participants can use the interactive communication tools, either on a mobile device or a computer. It also includes being able to access this information using a Wi-Fi connection, versus data, in a way that still maintains the security of their information.
 - » **Connection to their health care team and the HIV-positive community:** Connection matters in terms of feeling connected to their own health information, their health care team, and also the broader HIV community as a resource as well as contributing to research.

TRAINING

Comprehensive and on-going staff training were critical for proper integration of the intervention into existing case management activities. Staff were familiarized with the automated texting system and gained mastery with the processes for implementing a text-based intervention. The table below describes the training subjects and time commitment.

E-VOLUTION Staff Training Modules		
Modules	Duration	Curriculum
Text Messaging with Clients	2 Hours	<ul style="list-style-type: none"> ▶ Organizational texting Policies ▶ Texting Guidelines and Expectations ▶ Setting Boundaries & Self-Care ▶ Navigating Challenges ▶ Crisis Intervention ▶ Managing Alerts through Text/Phone Messages
Client Recruitment	2 Hours	<ul style="list-style-type: none"> ▶ Program Marketing ▶ Eligibility for Program ▶ Recruitment Strategies ▶ Client Forms and Documentation ▶ Client Enrollment
Privacy/HIPAA	2 Hours	<ul style="list-style-type: none"> ▶ Safety Screening ▶ White Labeling ▶ Client Consent Forms ▶ Documentation ▶ Push Notifications ▶ Phone Security Settings ▶ Voice Mail Set-Up/Crisis Intervention
Automated Texting Tool	2 Hours	<ul style="list-style-type: none"> ▶ Introduction to the automated texting tool ▶ Introduction to the system dashboard ▶ Administrator Settings ▶ Client Enrollment ▶ Client Consent ▶ HIV-Specific Modules ▶ Assigning Message Modules ▶ Managing Dashboard, Alerts, and Follow-ups
Office Hours: Continuing Education	Weekly – 2 Hours	<ul style="list-style-type: none"> ▶ Weekly Staff Walk-In Office Hours for Programmatic Support

Develop a Plan for Client Recruitment/Engagement

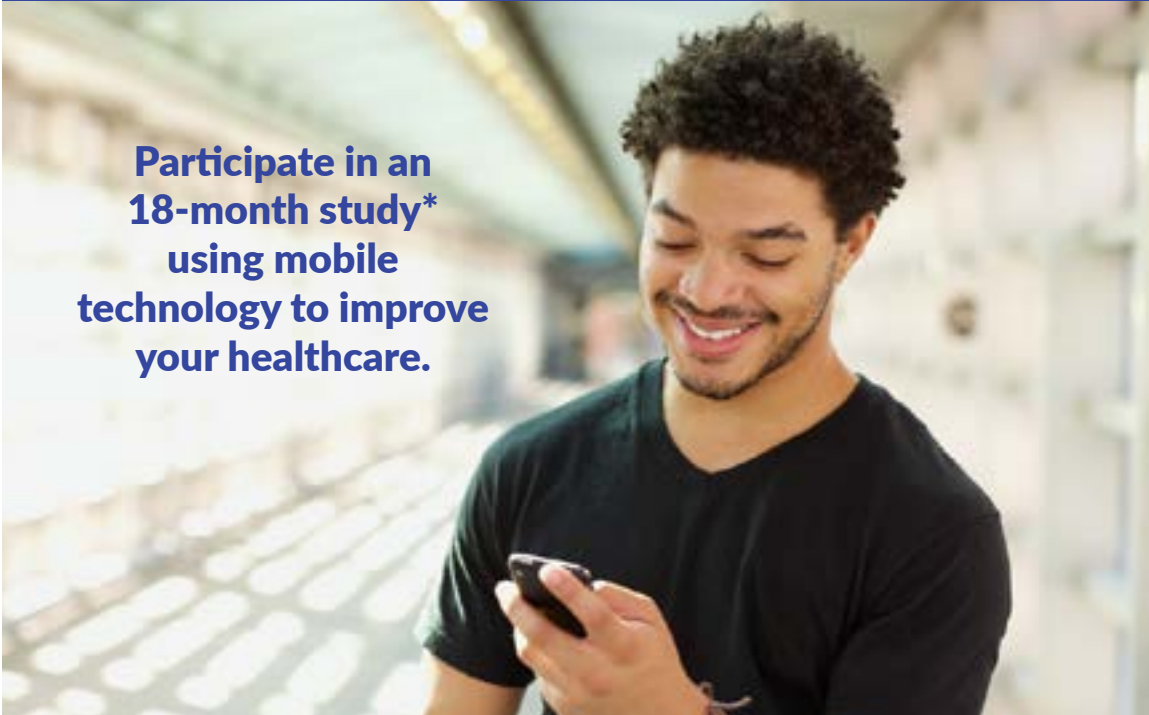
The Project ARK Leadership Team designed the specific in-reach strategy to identify potential candidates for the E-VOLUTION project. Reports created through use of the integrated medical record systems determined youth eligibility into E-VOLUTION. The program team approached potential participants during medical and case management visits. Additionally, medical case managers (MCMs) and clinical providers introduced the intervention to patients and referred patients to the program team. Primary recruitment occurred in the medical clinic setting and medical case management update appointments. During these in-person meetings, study team members were available to discuss the program and offer same-day enrollment.

In addition, promotional items were developed to promote client engagement. Focus groups helped develop the program brand including name (E-VOLUTION), logo and marketing tools for the project. 5 x 7 two-sided glossy postcards and 8.5 x 11 glossy posters were developed to promote E-VOLUTION. Posters were hung in clinical sites, electronic posters were incorporated into digital screens in clinic waiting rooms, and postcards were distributed by the MCM team to help recruit interested youth.



HELP US CONNECT WITH YOU!

Participate in an
18-month study*
using mobile
technology to improve
your healthcare.



HELP US CONNECT WITH YOU!

Participate in an 18-month study* using
mobile technology to improve your healthcare.

THE DETAILS

For people between the ages of 18 and 29 living with HIV
and receiving care from a Washington University clinic

THE PERKS

- Receive text reminders to take medications and come to appointments
- Securely get your health information at your fingertips
- Access to private online chat groups with other participants
- Receive up to \$100 in Walmart or Target Gift Cards for participation

THE REQUIREMENTS

- One in-person enrollment session
- Follow-up sessions every 6 months to complete a 30-45 minute survey

SIGN UP

Contact Jeff Glotfelty or Stacey Slovacek at (314) 565-2865.

*Katie Plax, M.D., Division Director of Adolescent Medicine, is conducting this study.

 Washington University in St. Louis

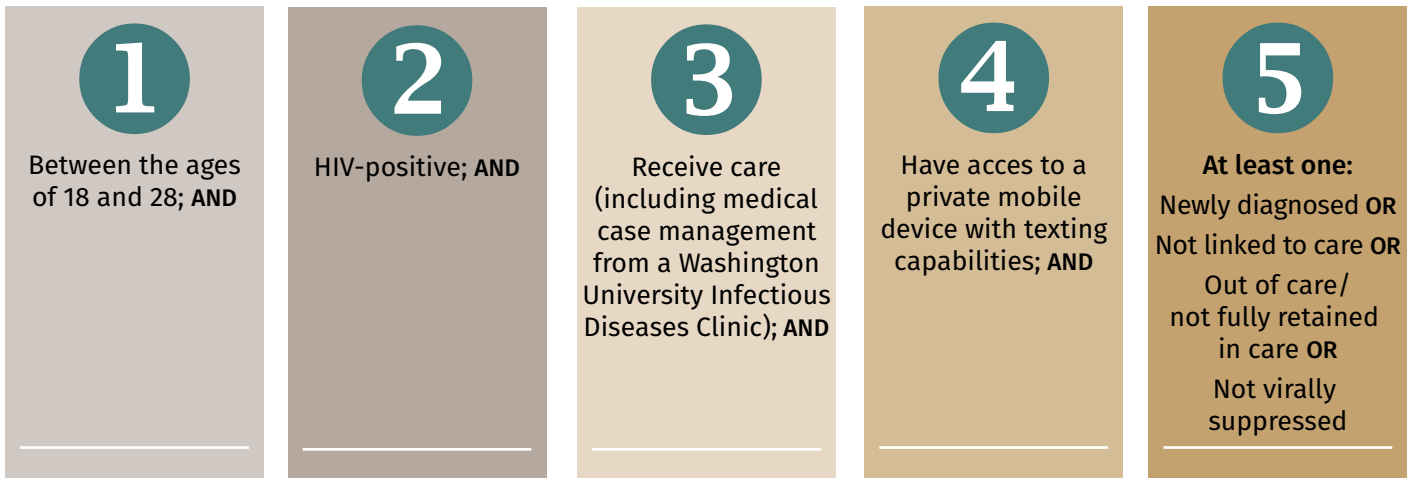


Implementation

TARGET POPULATION

E-VOLUTION was developed for youth aged 18–29 based on the disparities in the care continuum.

Inclusion criteria for participation in this project required the individual to:



And, met at least one of the following additional criteria:

- ▶ Newly diagnosed: tested HIV positive for the first time within the last 12 months; **OR**
- ▶ Not linked to care: aware of their HIV infection status but have never been engaged in HIV care (e.g. never having an HIV medical visit after being diagnosed with HIV); **OR**
- ▶ Out of care/not fully retained in care: diagnosed with HIV more than 12 months ago, but has a gap in HIV care greater than 6 months, within the last 24 months; **OR**
- ▶ Not virally suppressed: having a viral load >200 copies/mL at last lab test.

During E-VOLUTION's one-year recruitment cycle (February 2017–February 2018), staff enrolled 100 youth from the identified three clinical sites.



The primary marketing strategy, in-reach, produced referrals that were carefully documented in the already existing shared, electronic case management documentation system, SCOUT. Case managers were tasked to refer all eligible youth between the ages of 18–29 and record all recruitment efforts.

INTERVENTION DELIVERY

Upon completion of an informed consent form (appendix 5), enrollment, and the safety appraisal (appendix 3), participants received the E-VOLUTION texting intervention, which included two components:

- ▶ First, an automated two-way text message system;
- ▶ Second, person to person text messaging for follow-up of participant needs identified by the automated system and once a month, two-way exchanges

LOGIC MODEL

This section outlines the framework of E-VOLUTION. A comprehensive flowchart of the E-VOLUTION program can be found in appendix 6.

Resources	Activities Outputs		Short-Medium	
Medical case managers Experience with the targeted group for the intervention Program Coord & Asst Program Coord Funding Referring Providers Embedded w/in a one stop shop program	Automated Texting: <ul style="list-style-type: none"> ▶ Daily Med reminder ▶ Bi-weekly mood checks ▶ Appointment reminders ▶ Housing/ social services check in CM to youth texting: <ul style="list-style-type: none"> ▶ Resources for clients ▶ Respond to Alerts ▶ Provide new appointments 	Text messaging conversations Resources for clients to use # and kind of alerts identified Appointments kept Laboratory data to track	Improved viral load suppression rates Improved kept medical visits at 12 months Improved connection with MCM	Empower youth to engage with MCM Increased VLS rates decrease community risk for transmission and improve youth health outcome MCM operate more efficiently and meet the needs of clients

CORE ELEMENTS

Elements essential to the replication of E-VOLUTION includes:



Text Messaging: A text messaging delivery system that is mobile-based and agnostic of mobile provider. Texting reduces response time and is well received by young patients. Most mobile plans include an unlimited amount of sending and receiving text messages. Conversely, apps require either the use of data or access to a WIFI network, which may limit participation in the intervention.



Automation: An automated texting service that pushes out messages AND collects responses to questions. Automation of messaging facilitates greater efficiency for staff to communicate with clients and reduces the burden of repetitive, routine tasks, like drafting multiple individual text messages. The automated system allows staff to triage caseloads and highlights clients most in need of help and support.



Feedback to Care Team: A system that immediately provides real-time alerts to the care team allows a prompt response to client reported issues. Alerts monitored by a care team member provide an opportunity to help address issues in real time before it becomes a crisis and can efficiently support client health goals.




Human Connection: A two-way system fortifies a feeling of human connection between care provider and client. Improved communication supported a patient's ability to self-manage needs and allowed them to be more informed and activated.





KEY STAFF ATTRIBUTES

Title/Duties	Education/ Experience	Requirements	Successful Attributes
Project Manager/ Financial Administrator	<ul style="list-style-type: none"> ▶ Master's Degree 	<ul style="list-style-type: none"> ▶ Experience managing federal funded projects, including contracts, budget, and reporting. ▶ Experience supervising multi-disciplinary teams. 	<ul style="list-style-type: none"> ▶ Manage multiple activities simultaneously and a commitment to the development and success of team members. ▶ Knowledge of Ryan White HIV/AIDS Program Service administration and funding sources
Project Coordinator/ Champion	<ul style="list-style-type: none"> ▶ Bachelor's degree ▶ Master's Degree preferred 	<ul style="list-style-type: none"> ▶ Minimum of 3 years of HIV programing experience ▶ Lead or supervisory experience 	<ul style="list-style-type: none"> ▶ Manage multiple activities simultaneously ▶ Sensitivity about the needs/issues of various minority populations ▶ Research experience ▶ Knowledge of the impact of HIV ▶ Strong customer service ▶ Attention to detail
Field Staff/ Manager of client responses to automated system	<ul style="list-style-type: none"> ▶ RN or Bachelor's degree in a health related field, social work, counseling, sociology, or psychology 	<ul style="list-style-type: none"> ▶ Case management assistance and support experience ▶ Knowledge of community resources ▶ Computer skill 	<ul style="list-style-type: none"> ▶ Good organization ▶ Strong customer service ▶ Sensitivity about the needs/issues of various minority populations ▶ Strong crisis intervention skills ▶ Knowledge of HIV care

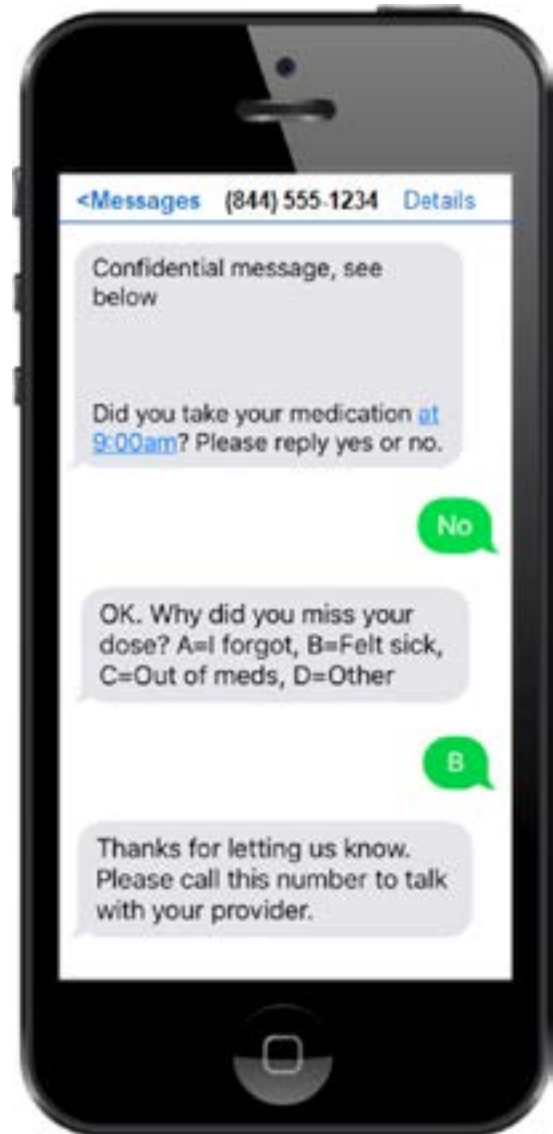
Automated System Administration



Built bi-directional mHealth HIV-specific modules which include:

-  Medication Reminders (Daily)
-  Appointment Reminders (As Needed)
-  General Mood Check-Ins (Twice Weekly)
-  Housing/Bills Needs (Monthly)

Clients' identified needs trigger alerts



Source: Epharmix, Inc.

Program staff uploaded appointment reminders for participants a week prior to the scheduled medical appointment. Participants received an appointment reminder five (5) days and one (1) day before all scheduled appointments for HIV care.

Self-reported missed appointments were triaged through the automated system and participants were directed to their clinic scheduling hub to re-schedule an anticipated missed appointment. The system collected reasons for missed appointments and generated alerts on the dashboard. The appropriate staff member was notified of the anticipated missed visit.

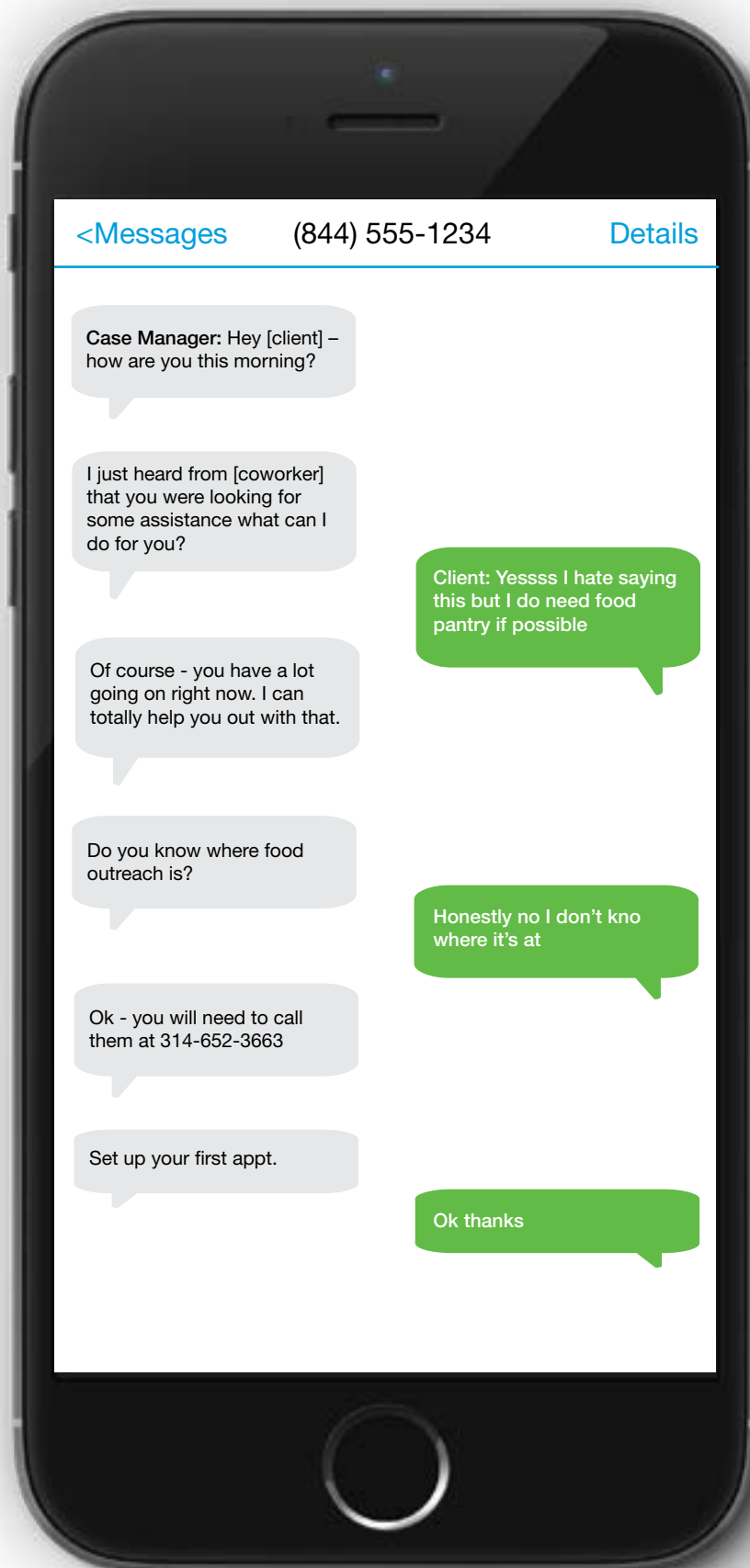
FEEDBACK TO CARE TEAM

All team members had access to a dashboard that monitored participation with the automated text messages. The dashboard allowed staff to log into the system and review client engagement in real-time. A designated staff member logged into the dashboard at least one time per week to review client status and resolve outstanding alerts and keep in mind alerts were most often first addressed via the staff's cell phone.

The automated system offered the ability to alert members of the care team in real-time when issues arose that may impact client care. For the E-VOLUTION intervention, responses that indicated a challenge for the participant generated an alert directly to the staff member's phone, who was expected to intervene within 24 hours.

PERSON-TO-PERSON TEXT MESSAGING

To supplement the automated two-way text message system, case managers communicated with clients on their work cell phones via text message. Medical case managers were tasked to text, at minimum, monthly with enrollees and all communications were downloaded and collected as part of our exposure data and qualitative evaluation.



Adaptable Characteristics

Elements of this program that can be adapted by sites that wish to replicate a similar intervention include:

- ▶ **Service Provider:** The option of which service provides two-way messaging. There are multiple service providers developing this type of technology and finding the right one for the institution is important.
- ▶ **Staff Oversight:** The staff person who fields text responses does not need to be a medical case manager. It could be a dedicated nurse, medical assistant or other staff member who can pass the incoming information on to the correct clinical team member.
- ▶ **Language:** The language used in information gathering and the message frequency can all be adapted to be appropriate for the target audience. These modifications should be driven by feedback from members of the target audience.
- ▶ **Audience:** The two-way text messaging system can be utilized with other target audiences, medical diagnoses, or medical/clinical settings. The two-way text messaging system can be adapted to any audience and can be a helpful tool for client reminders, staff triage, and medication monitoring. For example, other organizations have used the two-way text-messaging system for opioid management, suicide prevention, diabetes, post-partum depression, seizure tracking, mood tracking for clients living with bipolar disorder and depression, and substance use.^{xiii}



Outcomes

The E-VOLUTION program

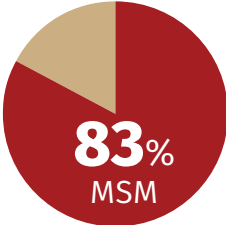
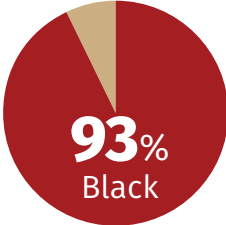
- ▶ Recruited a total of 100 youth
- ▶ 87 were retained for at least 6 months and
- ▶ 78 were retained for at least 12 months.

The majority of participants were Black (93%), MSM (Men who have Sex with Men) (83%), and the average age was 22.87 years (SD=2.30).

The E-VOLUTION program

100 youths recruited

22.87 years was average age



87% retained for at least 6 months



78% retained for at least 12 months



These young people faced a tremendous amount of adversity including high rates of experiencing intimate partner violence, jail time and sexual assault. Many reported symptoms of depression and used substances.

Intervention Participant Risk Factors at Enrollment (n=100)

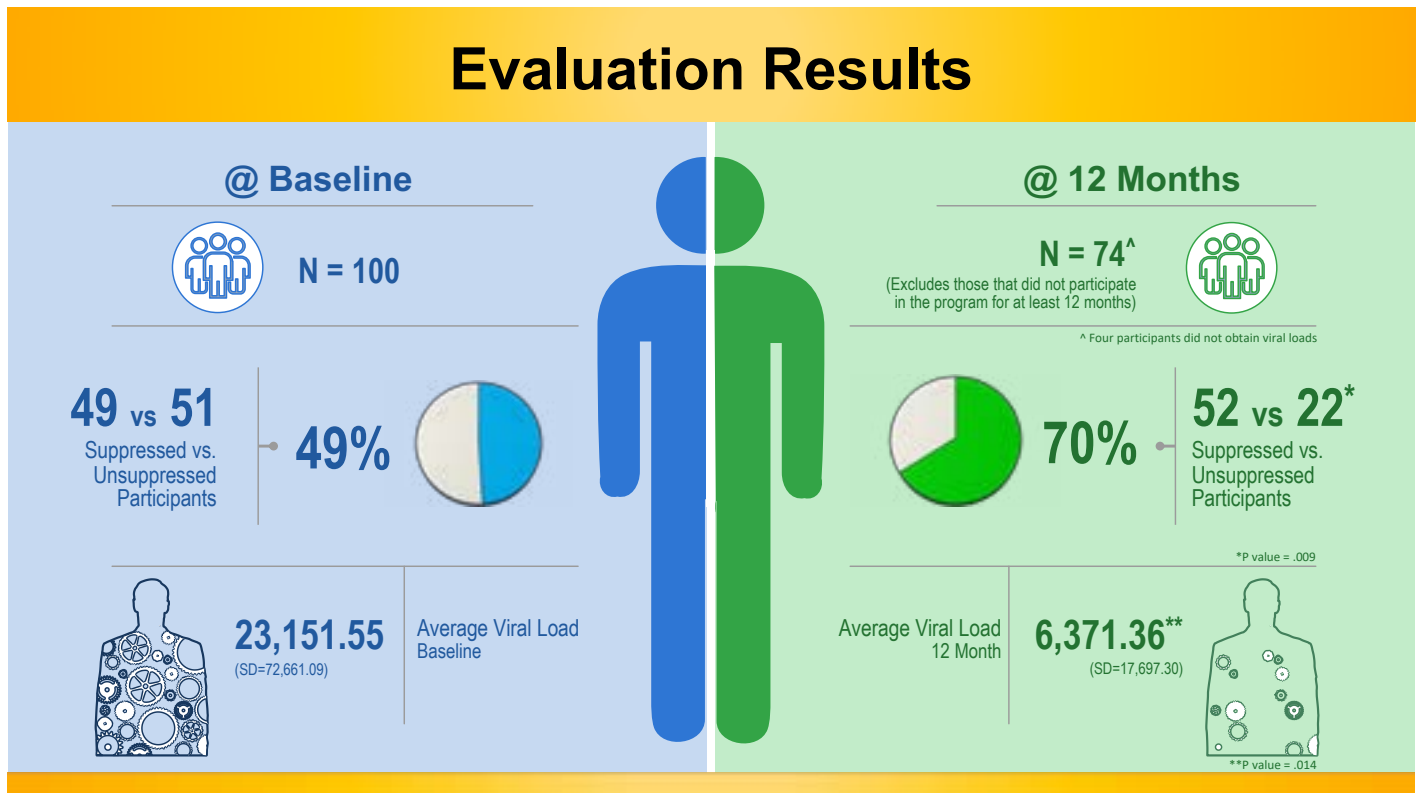
Psychosocial Risk Factors	M (%)
Depression (PHQ-2 \geq 3)	26 (26)
Experienced Physical Intimate Partner Violence	28 (28)
Used Alcohol Several Times a Week (last 6 months)	18 (18)
Used Marijuana Several Times a Week (last 6 months)	44 (44)
Used Tobacco Daily (last 6 months)	28 (28)
Misused Prescription Painkillers/Opioids (ever)	13 (13)
Used Methamphetamine (ever)	9 (9)
Experienced Sexual Assault	34 (34)
Traded Sex	22 (22)
Received Payment for Sex	28 (28)
Paid for Sex	6 (6)
Spent Time in Jail or Prison	47 (47)

“ The intervention resulted in **450** triggered alerts. ”

Alerts

The intervention resulted in 450 triggered alerts. The most common alerts were missed medication doses for the day (n=162), requests to discuss housing (n=94) and missed appointments (n=83). Most intervention participants (n=98) engaged in live text-message conversations with their case managers. McNemar exact tests determined a significant difference in the number of participants with suppressed viral loads at both 6 and 12-months compared to participants

VL at enrollment. Results indicated that a significantly greater proportion of participants were virally suppressed at both 6 (p=.003) and 12-month (p=.038) follow-ups.

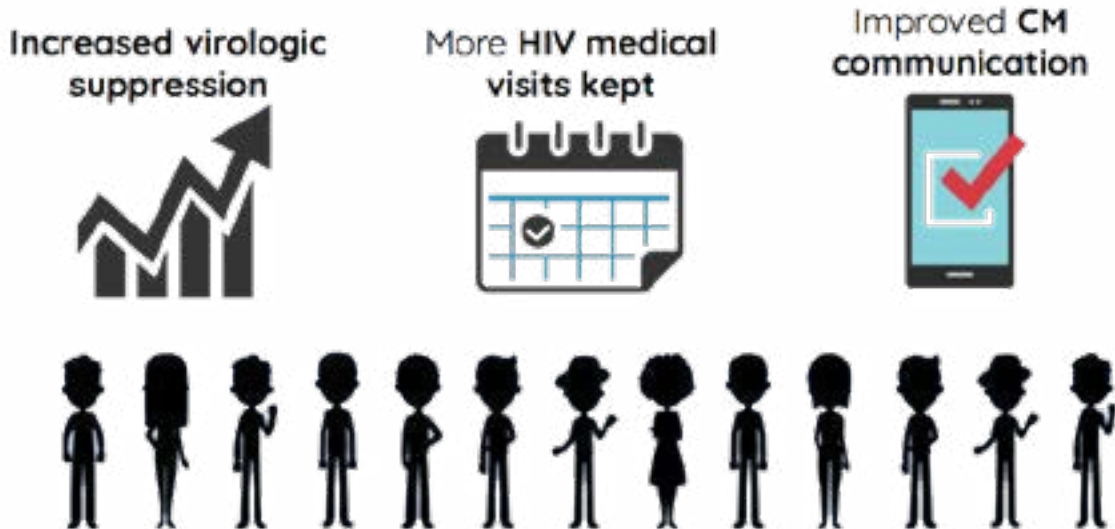


There was a significant positive association between texting frequency and medical visit attendance in which those who texted with their case manager at least once per month were more likely to attend their 12-month medical appointment.

Outcome/Impact Indicators

Outcomes indicators used to determine the success of this project are specific to performance measures along the HIV Care Continuum and were specifically defined by the HIV/AIDS Bureau. See the Performance Measure Portfolio on the HAB website for definitions for viral suppression, <https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/coremeasures.pdf>.

Outcomes



- ▶ **Viral Load Suppression Improvement:** Automated and live two-way text messaging with a case manager improved and sustained HIV viral load suppression rates at 6 months and at 12 months in a population of young, mostly black, MSM with high rates of significant social risk factors of depression, substance use, trauma and time in jail.
- ▶ **Attendance at Medical Visits:** Those who texted with their case manager at least once per month were more likely to attend 12-month medical visits.
- ▶ **Text Messaging Improved Case Managers and Clients Communication:** Case managers reported improved work effectiveness and participants felt supported as a result of implementing text messaging. Texting access ameliorated barriers to care including arranging appointments, transportation providing community resources and managing real time logistics. With the time saved, case managers were able to engage more intensively with clients, providing more support and resources and helping them solve problems in real-time.



Conclusions and Recommendations



Successes

OVERCOMING PROGRAMMATIC CHALLENGES

- ▶ **Recruitment:** Important to the success of enrollment was developing clinic-specific strategies to educate medical staff about the program and inform them of patient eligibility. This included getting clinical leadership buy-in for the program. Having project staff present in clinic to interact with the clinical team and potential participants led to successful enrollment opportunities.
- ▶ **Staff Technical Support:** Purchasing necessary equipment was another critical component to programmatic success. E-VOLUTION provided iPhones to all case management staff involved with implementation. Additionally, staff trainings specific to phone utilization helped define important boundaries for staff. Identifying phone “hours of operation”, emergency procedures, and HIPAA regulations helped staff successfully manage healthy boundaries with phone technology.



Successes

OVERCOMING IMPLEMENTATION CHALLENGES

► *Interruption of Phone Services*

– Many youth changed phone numbers, lost their phones, or experienced periods of interruption of cell phone service usually linked to lack of funds to cover services. For

some youth, this was a barrier to receiving automated and personal text messages within the program or completing E-VOLUTION updates.

- #### ► *Verifying “STOPS” to Prevent Early Exit*
- Eight (8) participants texted “STOP” to the automated system, an action that automatically withdraws them from the program. However, upon follow-up, five (5) of these participants texted “STOP” that still wanted to be part of the E-VOLUTION program. These youth texted “STOP” because their phone number was about to change and they wanted to ensure that the old number did not receive more messages from the study; not because they wanted to exit the program. To prevent this from continuing, the study staff added language into the follow-up survey sessions that explained how to alert a staff member when a phone number changed and appropriate times to utilize the “STOP” feature.

- #### ► *Automated Limitations*
- Appointment reminders were loaded into the two-way automated text messaging system weekly by staff. Any last-minute changes to a clinic schedule did not receive an updated automated appointment reminder. Also, youth reported that automated messages felt too sterile and reminded them they were not talking to a “real” person which led to feelings of dissatisfaction. Recommendations to meet with vendors to personalize messages was recommended by youth as a way to improve services.





Barriers

BARRIERS TO RECRUITMENT

Case management-specific recruitment challenges that make it difficult to enroll youth.

- ▶ **Staff turnover** – New hires had to learn the full scope of the MCM program in addition to E-VOLUTION protocols. Some new staff were hesitant to recruit youth on their caseload as they had not established relationships with these clients and other duties were prioritized before the E-VOLUTION project.
- ▶ **Programmatic barriers** – Case management clients were regularly transferred between medical case managers due to aging out of youth-specific services or graduating from time-limited intensive case management services (like lost to care or early intervention case management). Staff in these transitional roles were hesitant to recruit youth if they believed the youth would be transferred to a non-E-VOLUTION case manager at the end of the time-limited program.
- ▶ **Potential selection bias** – Some case managers were hesitant to recruit some clients for E-VOLUTION because of challenging social situations such as unstable housing or emotional instability. Alternatively, some case managers avoided recruitment of potential participants who they deemed as “too stable” to need the service to assist with medical adherence.



BARRIERS TO RETENTION

Similar to issues during recruitment, the project experienced challenges in retention.

- ▶ **Lost to Care** – Case management was a mandatory component to this project. Some youth missed required updates with medical case managers that made them ineligible for Ryan White HIV/AIDS Program services. When youth were closed to case management services, they were no longer eligible for E-VOLUTION services.

- ▶ **Change in Services** – Transfer processes between case management programs became a significant program barrier. For example, when young adults were transferred to adult care, adult case managers did not have capacity to work with the E-VOLUTION program. Therefore, these transferred clients were no longer eligible for the project.
- ▶ **Re-Location** – Youth and young adults are often transient due to changes in life situations. Some youth moved out of state or moved to another clinic site outside of the Washington University system after E-VOLUTION enrollment. This re-location made them ineligible to continue services.



Lessons From the Field

Several lessons were learned during program implementation. Below is a list of activities that were incorporated into E-VOLUTION that aided successful program deliver:



- ▶ It is crucial to have engagement and support from the case management and medical teams for the success of the program.
- ▶ Work closely with case managers and support staff to maintain updated contact information for the participants. Collect a second method of contact in case phone is out-of-service.
- ▶ Establish a thorough informed consent process that clearly explains the risks associated with text messaging and application use to ensure information security and legal reviews go well.
- ▶ Allow for nonspecific labeling of sensitive topics, for example in the message “did you take your *medication* today” allow the participant to choose an alternative, innocuous word to it saying “medication,” for example “vitamins” or “walk.”

- ▶ Provide staff with thorough training opportunities on incorporating new technology with clients to include topics such as emergency procedures, self-care, boundaries, and safety.
- ▶ Promptly follow-up on alerts and provide feedback on utilization of the messaging application. Knowing there is a real person following texts and alerts increases accountability. Participants may even be surprised and say things like “Someone really checks these?!”
- ▶ Addressing challenges to daily living such as access to transportation and food insecurity provides an opportunity to change existing care structures and allowed youth to become successful in attending clinic appointments, updating appointments, and managing their health.
- ▶ Establishing a good working relationship with the vendor(s) allows teams to address changes in the program (update messages, optimize feedback loops, customize product functions to meet program needs), implement reporting mechanisms for program monitoring, and receive prompt technical support when needed.



Considerations For Replication

A set of replication considerations were identified that may help in future implementation:

- ▶ Two-way text messaging necessitates an evolution of staff practice, such as:
 - » Defining crisis intervention protocols and ethical boundaries
 - » Identifying best practices for resource sharing via text message, self-care, and guarding clients’ privacy.



- ▶ Suggestions for improving automated medication reminder and check-in text messages.
 - » Offer a more comprehensive list of response options for clients to indicate reasons why they have not taken their medications.
 - » Clarify that automated appointment reminder messages are not coming from health care providers' offices and note that clients must contact their providers to cancel appointments.
 - » Create functionality to more easily identify and document that an alert has been resolved.
 - » Give messages a more relatable, warmer feel.
 - » Give messages a more supportive tone and make them feel like someone cares.

Appendices

Authorization For Electronic Communication	42
Text Messaging Policy	43
Safety Appraisal	46
Authorization For Automated Text Messages	48
Informed Consent Form	50
E-VOLUTION Flow Sheet	59

Appendix 1. Authorization For Electronic Communication



AUTHORIZATION TO UTILIZE UNENCRYPTED EMAIL/ TEXT MESSAGING TO COMMUNICATE PROTECTED HEALTH INFORMATION*

Electronic mail (email) and text messaging are forms of communication that may be used between you and the providers. We want to make sure you know that unencrypted email and text communications are not secure communications. Washington University Physicians is not able to encrypt text messages. We do have the ability to encrypt email communication of protected health information. Encryption is the process of making information unreadable unless you have the password or key to decrypt the information. We will encrypt email communications unless you tell us that you prefer us to use unencrypted email. If it is your preference that we not encrypt our email communications with you, please initial here: _____

If you elect to communicate from your workplace computer, you should be aware that your employer and its agents might have access to email communications between us. Email and text communications may become a part of your patient medical record and be accessible to my clinical support staff as needed for our operations.

Incoming email communications will be reviewed and answered as soon as possible. If you have not heard from your provider's office with a response and are concerned that your message was not received, please call the office during regular business hours. EMAIL COMMUNICATION SHOULD NEVER BE USED IN THE CASE OF AN EMERGENCY OR FOR URGENT REQUESTS FOR INFORMATION.

Washington University Physicians may use text messaging to remind you of upcoming appointments and/or care coordination activities if you have elected to receive reminders in this manner. We will limit information sent via text message to the minimum necessary. Washington University Physicians does not encourage text messaging for other purposes.

This authorization may be revoked at any time and must be done in writing. It is understood that the revocation will not apply to information that has already been released based on this authorization.

Authorization is valid while in a treatment relationship with Washington University Physicians and any of its associated providers or in the event of: _____

If you agree to the foregoing terms, please indicate your acceptance by your signature that you accept the terms and conditions outlined herein.

ACCEPTED: Signature of Individual _____ Date _____

Printed Patient Name _____ DOB ____/____/____

Authorized E-mail of Individual _____

Department of origination of authorization _____

*Please note, this form is valid for all entities and providers comprising Washington University Physicians.

Appendix 2. Text Messaging Policy

WUSM Ryan White Part C/D Standard Operating Procedure

Title:	Medical Case Management Texting Guidelines
Date:	9/6/16
Authors:	Julia Schlueter, Jeff Glotfelty, Stacey Slovacek

Purpose:

To provide guidance to medical case management staff regarding utilizing SMS text messaging for client outreach and retention purposes.

Background:

Ryan White Medical Case Managers (MCM) regularly provide intensive outreach services to clients, including appointment scheduling, follow up on missed appointments, reminders of benefit enrollment deadlines, and other outreach as necessary. The goal of this outreach is to link and retain clients in medical care.

Through receipt of funding from the HIV/AIDS Bureau's Special Projects of National Significance (SPNS) Washington University School of Medicine (WUSM) is implementing digital media interventions that target youth and young adults ages 18–29. One of the interventions is texting. Some clients respond via text that would normally not respond to voice calls. Many clients do not retrieve their voicemail messages and would prefer an informative text message. We believe that texting is an efficient and effective way to reach many clients.

MCM will implement texting to expand their outreach capabilities. MCM will use texting to reach clients who prefer this mode of communication. Targeted groups that may benefit the most from this expanded outreach service include: hearing impaired clients, clients under 30, and clients who have insufficient voice plans, and clients who specifically enroll in the SPNS project.

Procedure:

To ensure HIPAA compliance and client data safety, the following requirements will be followed:

- An agency issued smartphone with built-in encryption must be used for texting.
- The smartphone must have the built-in encryption enabled by IT at WUSM and a passcode. Passcodes for all MCM cell phones will be the same.
- The smartphone must have Mobile Device Management (MDM) software installed by Department of Medicine IS staff. This will enforce a PIN on the phone and will enable remote wiping of the phone in case it is lost or stolen.
- Prior to using the texting function with a client, the MCM must obtain explicit, in-person, consent from the client indicating they agree to receive text messages. The MCM must document client consent in SCOUT and upload the signed consent form to the documents module using the header "Email/Text Consent – 1ECONSENT"

- If the smartphone is lost or stolen, the MCM must report the loss immediately to their supervisor and the SPNS Project Coordinator.
- Leave your phone at work in a locked drawer.
 - There will be times when you are at a home visit or offsite and will not return to the office before going home. This is understandable. If you take the phone home, turn off your phone.
 - Extra keys for locked drawers will be kept in a key binder with the supervisor, so cell phones can be accessed if a MCM is unexpectedly out of the office and the cell phone is covered by another MCM.
- Respond to texts only during your normal work hours.
 - The maximum amount of time to respond to a text is by the end of the next business day.
 - A minimum of one text per month should be made to all active clients on the MCM caseload.
- Full client names should not be stored in the phone's contacts/address book — use first name and last initial. If you have multiple clients with the same first name and last initial, then expand into the second letter of the last name (ex: David Bo for David Bowie).
 - For those enrolled in SPNS, put the word "SPNS" after the last initial.
- Coverage while out
 - The MCM that covers the caseload will also cover the cell phone. Please remember to give your cell phone to the person that is covering for you prior to leaving.
- Text messages should not include sensitive information including:
 - Client full name
 - Client date of birth
 - Client medical record number
 - Client social security number
 - Client diagnosis (or any information indicating that client is HIV positive)
 - Client address
 - The name of any medications.
 - The name of any HIV-specific location of medical clinic where client receives care (ex. cannot say Project ARK, EFA, or other agencies with specific diagnosis in name).
- Text messages should not include sensitive information, such as information that would disclose that the client is HIV positive. Use "white label" information instead (examples: medication/meds vs. complera, CD vs. CD4, VL vs. Viral Load)
- Only text your client, do not text family members or partners.
- NEVER send a group text
- Staff will not store protected client information or documents on the smartphone:
 - Text Messages must be deleted from phone after 1 week max
 - Pictures deleted from phones after 24 hours max
- Clients may NOT text documents (can email to wustl email account)
- To save pictures from staff phone, must be sent wustl email to wustl email [SECURE] (no texting to self)

- MCM or Washington University staff may send a client community referral information in a text message as long as the referral is not HIV-specific or may identify the health care diagnosis of a client.
- Crisis Mental Health Event
 - Follow the internal protocol for Mental Health High-Risk
 - Call the client, stop texting
 - Keep the client on the phone while alerting another staff member to call 911 and contact Huey (Youth MH Specialist).
 - » The 911 call should include all pertinent information and a request to the 911 dispatcher to have the responding officer call staff back with a disposition.
 - » Contact Behavioral Health Specialist at 314-747-2717; pgr 314-469-6644; or by email
 - » An alphanumeric page can be sent from a computer to multiple MH Specialists at once by emailing [pager#]@myairmail.com — include the details (who/what/where) about the crisis and “911” in the page so the MH Specialist knows it is an urgent situation.
- Outgoing voicemail greeting should include the following information:
 - Staff name
 - This phone is only checked during business hours.
 - If this is a medical emergency, please contact 911.
 - If this is an urgent mental health crisis, please contact the BHR at 314-469-4908
 - If this is during business hours and you wish to speak with me please call [insert phone number for desk at MCM office location].

Appendix 3. Safety Appraisal

E-volution (SPNS): Safety Assessment

Objective: Ensure that candidate understands and can evaluate his personal safety if someone finds messages on his phone or surveys on the computer. This document is intended to serve as a guide, as the discussion will be dynamic based on candidate responses.

Sample Discussion:

- *“We might send text messages about some sensitive stuff – like coming to clinic, reminding you to take medications, and how you are feeling. If someone saw these messages, like a partner, friend or family member, it may give them information you did not want to share. For some people, it might actually put them in danger. The person reading the text messages might ask questions, get angry or lash out physically or saying mean things.*
- *The goal of this project is to give you a tool to have the best health possible. We don’t want to put anyone in danger. If you think this could be unsafe for you if someone were to read these messages, it’s really important to think about it before you to agree to join the program.”*
- *What do you think about the possibility of someone else (friend, partner, parent, etc) seeing messages about your healthcare?*
- *What would happen if someone (friend, partner, parent, etc) saw these kinds of messages (how are you feeling today, reminders for appointments, medication reminders, discussions with your case manager)?*

If seems unsafe:

- *It seems like texting with members of your healthcare team may not be a safe decision for you. If it helps, we can talk you through ways to make your phone more safe such as making sure your phone is password protected. Even with this step, someone may guess your password or demand that you give them the password. Your safety is important to me. What do you think?”*

If participant agrees it’s unsafe:

- *“Ok. Thank you for thinking about this project. If you would like to join at a later time when it feels more safe, just let me know.”*

Additional Questions for Processing:

- Who has access to your phone — who can read your messages?
- Do you have the ability to read your text messages in a private space?
- Is your phone password protected?
 - How often do you change your password?
 - Do you need help learning how to put a password protection on your phone?
- Email Apps – there are Apps that can be downloaded that can give someone else access to your text messages. Sometimes partners, parents, or friends have been known to do this.
 - Do you know what app to look for on your phone to see if this has been downloaded?
- Push Notifications – some phones have the ability to send you a preview of your email or text message without opening up your email or text message box.
 - Do you know how to turn this off? Do you need help learning how to do this?

Resource for Helpful Technical Tips:

- <http://projectg2g.com/technical-guides/>

References:

- Ybarra, M. L., Prescott, T. L., Phillips, G. L., 2nd, Bull, S. S., Parsons, J. T., & Mustanski, B. (2015). Iteratively Developing an mHealth HIV Prevention Program for Sexual Minority Adolescent Men. *AIDS and Behavior*, In Press. doi:10.1007/s10461-015-1146-3
- Ybarra, M. L., Prescott, T. L., Phillips, G. L., 2nd, Parsons, J. T., Bull, S. S., & Mustanski, B. (2016). Ethical Considerations in Recruiting Online and Implementing a Text Messaging-Based HIV Prevention Program With Gay, Bisexual, and Queer Adolescent Males. *Journal of Adolescent Health*, 59(1), 44–49. doi:10.1016/j.jadohealth.2016.03.020

Appendix 4. Authorization For Automated Text Messages

AUTHORIZATION TO UTILIZE AUTOMATED AND OTHER TEXT MESSAGES TO COMMUNICATE PROTECTED HEALTH INFORMATION

In connection with your care at _____ [*name of clinic*], you have the option to receive text messages from your case manager as well as regular automated text messages from a software application that will send you reminders and ask you questions that are important to your healthcare team. **These text messages may contain your protected health information that identifies you, such as the name of the clinic or clinical program in which you are a patient, or the name of your healthcare provider or case manager.**

The purposes of sending these messages is to improve your care by simplifying communication between you and your healthcare team, and by assisting you and your healthcare team in keeping track of your care and wellbeing. The types of messages you would receive are appointment reminders, reminders to take your medication, check-ins to see how you are feeling, and check-ins about any housing issues. Your responses to these messages are accessible by your healthcare team and clinic personnel involved in your care.

In order to utilize the messaging software application, your healthcare team will need to disclose the messages that contain your protected health information to the software vendor. Washington University has obtained satisfactory assurances from the vendor that the vendor will use the information only for the purposes for which Washington University engaged the vendor and that the vendor will safeguard the information from misuse. The software application encrypts messages during transmission to your phone. Encryption is the process of making information unreadable unless you have the password or key to decrypt the information. Still, once messages are received by and stored on your phone or texting application, the messages are no longer encrypted and can be accessed by your texting service provider and any individuals who have access to your phone plan, devices, or texting application account.

We will take measures to reduce the chance of a breach of information while text messaging. Automated text messages will be formatted with a blank space before the message to reduce the chance of someone seeing your personal information. Additionally, all text messages about medication will only provide your information as “white label” meaning we will use general terms that do not indicate the medical condition we are discussing (example: saying “medication” vs. naming a specific prescription by name). You can take steps on your own to lower the danger of someone seeing your information from text messages on your phone, including setting more strict security settings.

There is always a risk that a message could be intercepted or sent to the wrong phone number. To avoid sending messages to the wrong phone number, the first text message we send you will be a test message to ensure we have the correct phone number. If you text message us from a phone number that we do not have on file for you, we will need to speak with you over the phone to verify your identity before continuing text messaging. It is important to update your healthcare team if there are any changes to your phone number.

We will only send you these text messages if you chose to sign this authorization. If you choose not to sign this authorization, you can still work with your healthcare team to create a strategy for achieving the best health activities for you. Your healthcare team may not condition your treatment, payment, or enrollment in or eligibility for benefits on whether you sign this authorization.

This authorization will expire when you are no longer a patient at _____
_____ [*clinic name*] as long as you have informed your healthcare team and received your team’s acknowledgment that you no longer wish to receive care.

At any time prior to expiration, you may stop automated text messages to your phone or messaging application by texting 'STOP'. This will stop automated messages to your phone. However, your case manager will still be able to text you, so you will still need to take steps to revoke this authorization, as described below. A member of your healthcare team will reach out to confirm that you intended to end automated messaging.

At any time prior to expiration, you may also revoke all further uses or disclosures of your protected health information described in this authorization by revoking this authorization in writing and sending the writing to Washington University's HIPAA Privacy Office at hipaa@wustl.edu or Campus Box 8098, 660 S. Euclid Ave., St. Louis, MO 63110. You should send this written authorization even if you have already requested a stop to text messages, as this will ensure no further use or disclosure of your protected health information. Please note that your revocation will not affect any action Washington University has already taken in reliance on your authorization.

Please check one of the following boxes and sign below.

I have read and I agree to the foregoing terms and I **do authorize** _____ [clinic name] to use and disclose my protected health information in the manner described above to send me automated and other text messages at the following phone number: _____ .

OR

I **do not authorize** _____ [clinic name] to use or disclose my protected health information in the manner described above to send me automated and other text messages.

Signature of Individual: _____ Date: _____

Printed Name: _____

Date of Birth: _____

Appendix 5. Informed Consent Form

INFORMED CONSENT DOCUMENT

Project Title: E-VOLUTION: A Special Project of National Significance on the Use of Social Media to Improve Engagement, Retention & Health Outcomes along the HIV Care Continuum

Principal Investigator: Kathryn Plax

Research Team Contact: Jeff Glotfelty
(314) 535-7275
glotfelty_j@kids.wustl.edu

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are between the ages of 18–29 and have received care from a doctor, therapist, health coach, and/or case manager associated with Washington University in St. Louis' School of Medicine's Department of Infectious Diseases.

The purpose of this research study is to see if the use of digital technologies like text messaging and patient portals within the medical care setting will improve health outcomes for young adult patients.

WHAT WILL HAPPEN DURING THIS STUDY?

During this study, you will:

- Take a survey.
 - Today you will take a 35–45 minute survey about you and your health-related behaviors.
 - Every six months, you will retake the survey to see if there has been any change in your answers.
 - You are free to skip any questions that you would prefer not to answer.
- Continue to take part in your care services as directed by your doctor or other care providers at the clinic that you attend.
 - We will collect information from your health care record.

- Utilize digital technologies that are offered which may include one or all of the following:
 - Receiving and responding to text messages that come directly to your phone including:
 - Communication from your case manager (or a study staff member) via text message when possible
 - Regular automated text messages from a software application called Epharmix that will ask you questions that are important to your care team, for reminders about taking your medicine, appointment reminders, and general check-ins. Your responses will be accessible to your case manager and they may respond if they feel they need to talk with you
 - Every week, text message conversations between you and your case manager will be collected from the case manager's phone and reviewed to identify themes and trends in conversation topics.
 - Signing up (with the help of study staff) for the patient portal, which is provided by Washington University for you to access and manage your own electronic health information. You can access the portal on a computer or a mobile phone application.
- Every six months (2 times per year), your medical chart will be reviewed to obtain your HIV viral load, CD4 count and other medical indicators, which are taken as part of your regular medical visits.
- The questions you answer using the computer along with your medical information will be sent electronically using a code (without any information that could identify you) to the evaluation team at the University of California in Los Angeles (UCLA).

Completing the surveys, every 6 months, must be done in person at one of the Washington University School of Medicine Infectious Disease Clinics. Using the digital technologies can take place wherever you feel comfortable taking part in them.

Will you collect my social security number?

You will be asked to provide your social security number for the "Consented Participant Tracking Database" that is used track your process through the intervention, monitor your medical outcomes, and document your information that is important to this study. Your social security number will not be shared outside of Washington University for research purposes. The reason for collecting your social security number is to verify your identity to protect your personal information and to connect your medical records with your case management records. Collecting your social security number for this purpose is required for participation in the study.

HOW MANY PEOPLE WILL PARTICIPATE?

Up to 300 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last up to a total of 18 months.

- Today, you can expect to spend up to two hours to get enrolled in the study.
- Going forward, there will be up to three other visits (every 6 months) to complete the survey, which should take up to 45 minutes for each visit.
- Responding to text messages will take no longer than a minute each time and conversations with your case manager can last as long as you choose.
- The time you spend interacting with your patient portal is up to you.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Overall, experiencing potential risks (physical, psychological, social or economic) associated with participation in this study is unlikely. You will be asked to provide information about your physical and mental wellbeing, housing stability, and incarceration, as well as the barriers to care that you have personally experienced. These questions may make you feel stress, embarrassment, or guilt.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *“How will you keep my information confidential?”* for more information.

Breach of confidentiality is the highest likelihood of risk with text messaging. Communication via text message is unsecured and potentially non-confidential. The information stored on your phone is outside the control of the research study team and there is a risk that anyone who has access to your phone may see the private information being shared by your medical team.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. Possible benefits for you may be improved communication via text messaging with your care team.

However, we hope that, in the future, other people might benefit from this study because other doctors may be able to use the tools developed in this study to help people successfully manage their health.

WHAT OTHER OPTIONS ARE THERE?

If you choose not to participate in this study you can still work with your case manager and care team to create a strategy for achieving the best health activities for you.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You may have costs for being in this research study. Standard texting and data rates may apply when using your mobile phone for some study activities.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be asked to provide your social security number (SSN) in order for us to pay you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

Payment for participation in the study will be provided at the enrollment session and each of the follow-up 6 month sessions. The amount of compensation provided will be as follows:

1. Enrollment Session — \$25 Walmart or Target Gift Card
2. 6-month Follow up — \$25 Walmart or Target Gift Card
3. 12-month Follow up — \$25 Walmart or Target Gift Card
4. 18-month Exit — \$25 Walmart or Target Gift Card

The total compensation for participating in the study will be \$100 in Walmart or Target Gift Cards.

If needed, you can be provided with Metro (bus/train) tickets for travel to and from the study site — at the value of six dollars for round trip.

WHO IS FUNDING THIS STUDY?

The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, is funding this research study. This means that the Washington University is receiving payments from HRSA to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from HRSA for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- HRSA
- University representatives, to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

To help protect your confidentiality, we will collect information from you in a private space using a computer-administrated survey that creates a private setting for sensitive information and limit information sent via text message to the minimum necessary. Also, we will discuss with you how we can make your mobile phone more secure from other people accessing your information.

We will take measures to reduce the chance of a breach of information while text messaging. Automated text messages will be formatted with a blank space before the message to reduce the chance of someone seeing your personal information. Additionally, all text messages will only provide your information as “white label” meaning we will use general terms that do not indicate the medical condition we are discussing (example: saying “medication” vs. naming a specific prescription by name). We will also work with you to lower the danger of someone seeing your information from text messages on your phone. We can show you ways to protect your phone, including setting more strict security settings.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

To further protect your privacy, the investigator has obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). This Certificate may prevent the investigator from being forced (for example by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. However, a Certificate of Confidentiality does not prohibit the investigator from disclosing information about you or your involvement in this research that you have agreed to disclose or make available. For example, if you request in writing that information about you or your participation in the research be released to an insurance company, the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family should actively protect your own privacy. Finally, the investigator is not prevented from disclosing, including reporting to appropriate authorities, information concerning abuse, neglect or harm to others or yourself.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, “How will you keep my information confidential?”

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University’s Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
 - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.
 - If you revoke your authorization:
 - » The research team may only use and share information already collected for the study.
 - » Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
 - » You will not be allowed to continue to participate in the study.

Can we contact you by text message?

We would like to contact you by text message for the purposes listed below. Some of these texts may contain health information that identifies you.

- Prescription reminders
- Appointment reminders and scheduling
- Wellness check-ins
- Case management service referrals and communication
- General announcements

Only the research team and your care team will have access to your text message communications. We will only communicate by text message to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via text message.

- There is always a risk that the message could be intercepted or sent to the wrong phone number. To avoid sending messages to the wrong phone number, the first text message we send you will be a test message to ensure we have the correct phone number.
- If you text message us from a phone number that we do not have on file for you, we will need to speak with you over the phone, to verify your identity, before continuing text messaging.
- When using any phone you should be careful to protect your password. Make sure you lock your screen before leaving your phone.

If your parents or employer pays for your phone plan, they will have access to any text message communications sent or received on devices attached to that phone plan.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study. You may also text "STOP" in response to an automated text message to withdraw yourself from receiving text messages from the automated system, which will lead to your withdrawal from the study. You will still be able to receive text messages generated from your medical case manager. To stop case manager text messages, you would need to reach out directly to your case manager or the study team to revoke consent for electronic communication.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because you changed your clinical care location or the study or clinical team judges that it would not be safe for you to continue.

If you stop responding to text messages or to calls about the study, your assigned Medical Case Manager (or the project assistant if you are not enrolled in case management) will make three contact attempts by phone and via any other contact information provided by you. If, in three contact attempts, the MCMs/PA fails to contact you, you will be deemed no longer enrolled.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please call or text Jeff Glotfelty or Stacey Slovacek at (314) 565-2865. If you feel that you have been harmed in any way by your participation in this study, please contact Dr. Kathryn Plax at (314) 454-4101 or email plax_k@wustl.edu.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 07/10/18.

(Signature of Participant)

(Date)

(Participant's name — printed)

Statement of Person Who Obtained Consent

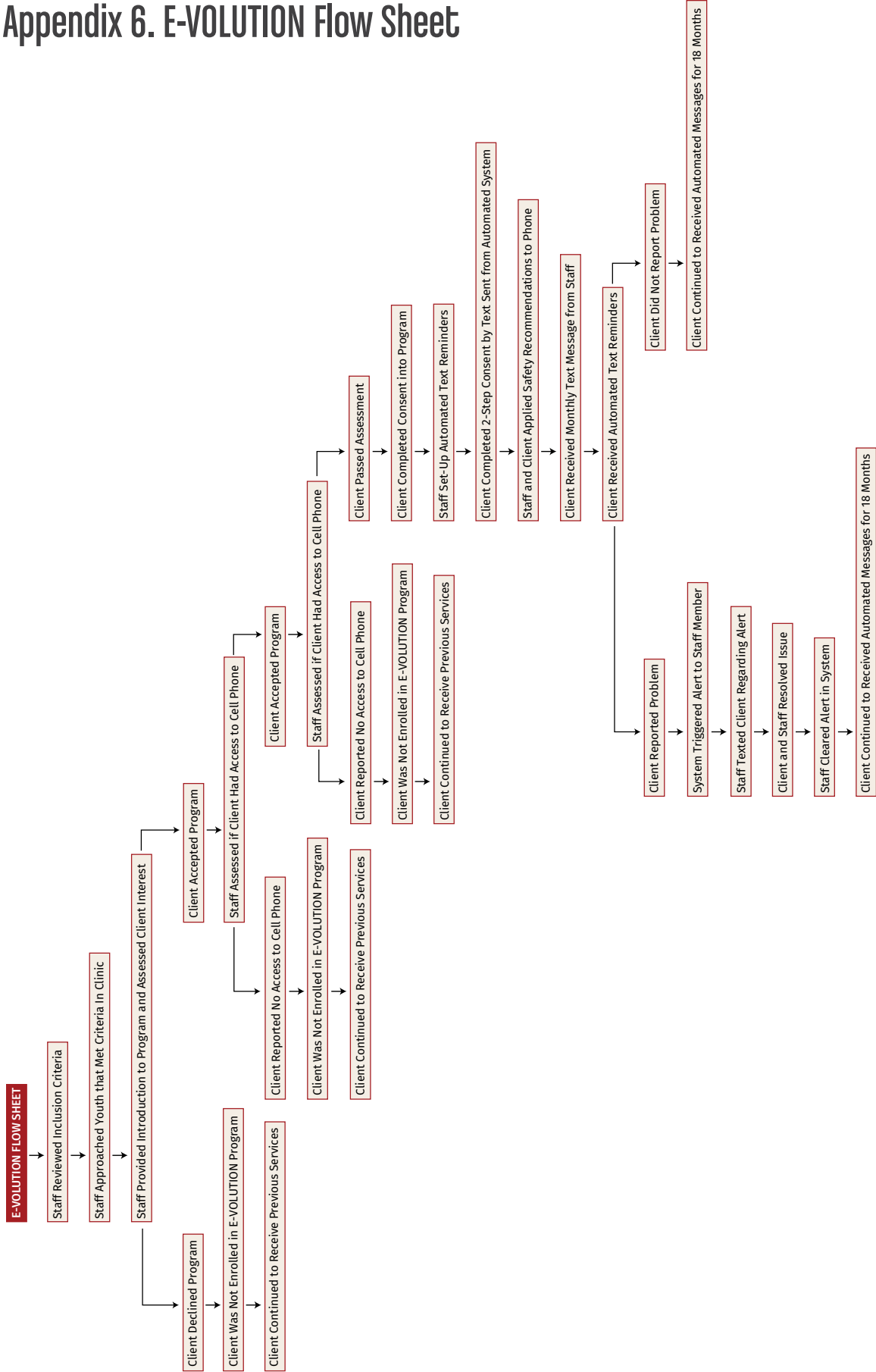
The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent)

(Date)

(Name of Person who Obtained Consent — printed)

Appendix 6. E-VOLUTION Flow Sheet



Works Cited

- ⁱ Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention. (2019). <https://www.cdc.gov/hiv/statistics/overview/atagance.html>
- ⁱⁱ Griffith DC & Agwu AL. Caring for Youth Living with HIV across the Continuum: turning gaps into opportunities, *AIDS Care*. 2017 Feb. 29:10, 1205–1211.
- ⁱⁱⁱ Lester RT, Ritvo P, Mills EJ, Kariri A, Karanja S, Chung MH, Jack W, Habyarimana J, Sadatsafavi M, Najafzadeh M, Marra CA, Estambale B, Ngugi E, Ball TB, Thabane L, Gelmon LJ, Kimani J, Ackers M, Plummer FA. Effects of a mobile phone short message service on antiretroviral treatment adherence in Kenya (WelTel Kenya1): a randomized trial. *Lancet* 2010 Nov; 376 (9755):1838–45.
- ^{iv} Da Costa TM, Salomão PL, Martha AS, Pisa IT, Sigulem D. The impact of short message service text messages sent as appointment reminders to patients' cell phones at outpatient clinics in Sao Paulo, Brazil. *Intl Med Informatics* 2009 Sept; 79 (2010):65–70.
- ^v Ingersoll K, Dillingham R, Reynolds G, Hetteema J, Freeman J, Hosseinbor S, Winstead-Derlega C. Development of a personalized bidirectional text messaging tool for HIV adherence assessment and intervention among substance abusers. *J Subst Abuse Treat*. 2014 Jan; 46(1):66–73.
- ^{vi} Murray MC, O'Shaughnessy S, Smillie K, Van Borek N, Graham R, Maan EJ, WelTel BC1 Study Team. Health care providers' perspectives on a weekly text-messaging intervention to engage HIV-positive persons in care (WelTel BC1). *AIDS Behav* 2015 Oct; 19(10):1875–1887.
- ^{vii} Saberi P, Johnson MO. Technology-based self-care methods of improving antiretroviral adherence: a systematic review. *PLoS One* 2011; 6(11):e27533.
- ^{viii} Lenhart, A, Smith, A, Anderson, M., Duggan, M, Perrin, A. Teens, Technology and Friendships. *Pew Research Center*, 2015 August. <http://www.pewinternet.org/2015/08/06/teens-technology-and-friendships/>
- ^{ix} Schnall R, Okoniewski A, Tiase V, Low A, Rodriguez M, Kaplan S. Using Text Messaging to Assess Adolescents' Health Information Needs: An Ecological Momentary Assessment. *J Med Internet Res*. 2013 Mar; 15(3): e54.
- ^x Uhrig JD, Harris J, Furberg R, et al. Communication-Focused Technologies: Health Messages for HIV-Positive Men Who Have Sex with Men – Final Report. (Prepared by RTI International, under Contract No. HHS290200600001 #7). *AHRQ Publication No. 11-0063-EF*. Rockville, MD: Agency for Healthcare Research and Quality. June 2011.
- ^{xi} Mohr D, Cuijpers P, Lehman K. Supportive Accountability: A Model for Providing Human Support to Enhance Adherence to eHealth Interventions. *J Med Internet Res* 2011; 13(1):e30
- ^{xii} Shiffman S, Stone AA, Hufford MR. Ecological Momentary Assessment. *Annu Rev Clin Psychol* 2008; 4:1–32.
- ^{xiii} Epharmix, Inc. (2017). Retrieved from <https://www.epharmix.com/product>