

Optimization of adherence after VOICE
Rockville, Maryland

September
2015

Adherence Measurement and Optimization of Long-Acting ARV- Based Vaginal Rings

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Overview

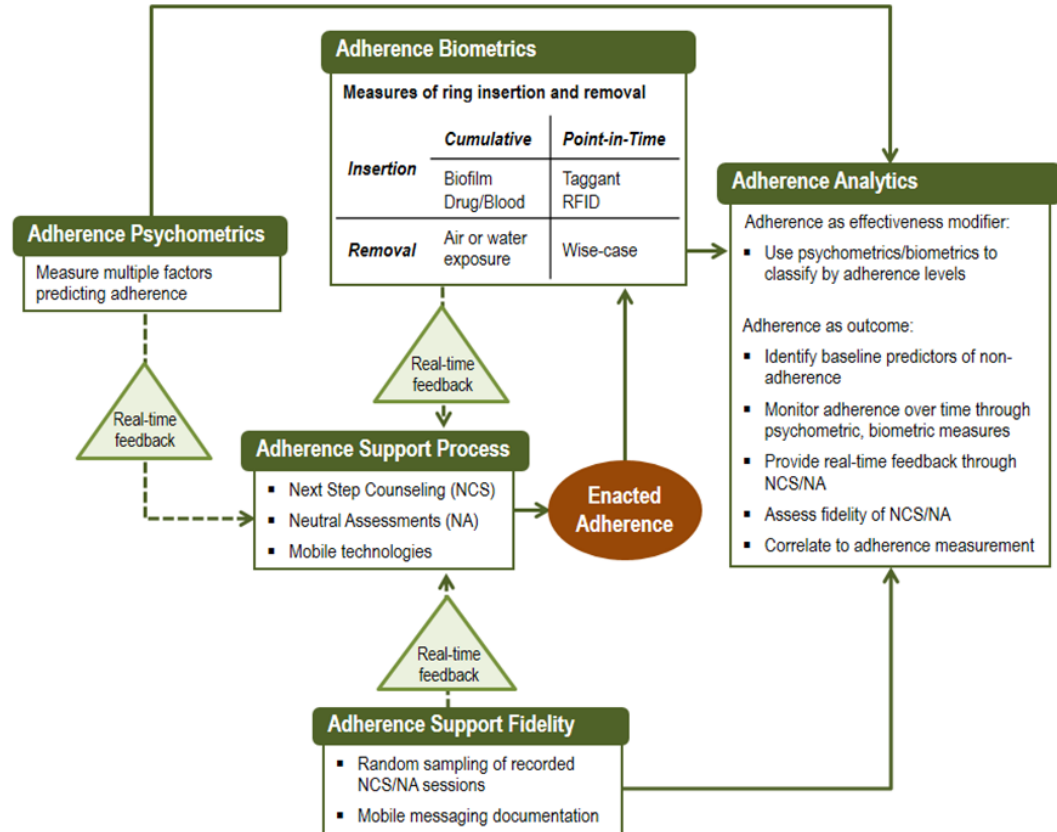
- Description of project
- Aim 1: adherence support
- Aim 2: psychometric measures of adherence

Project Goal: Overview

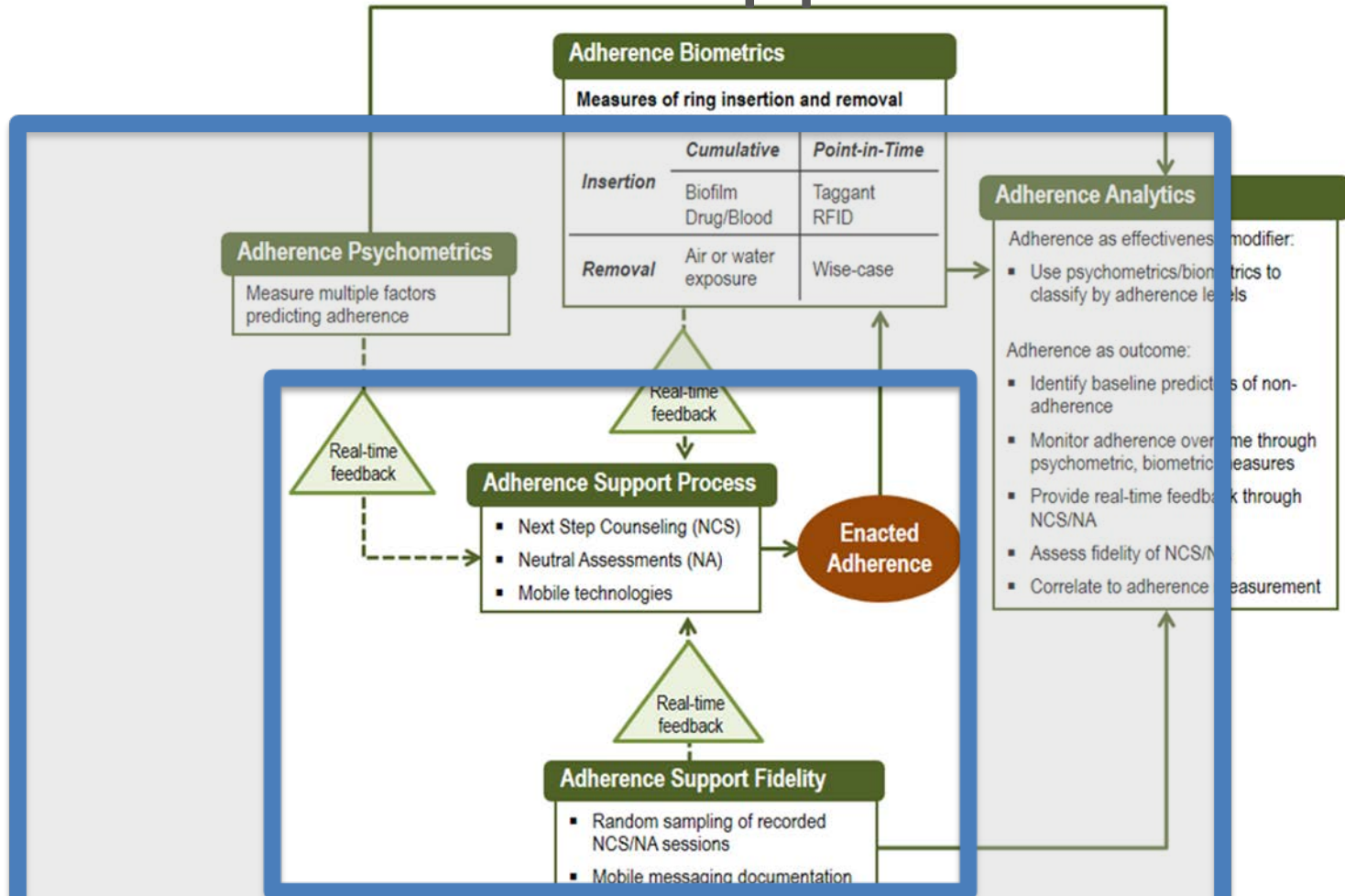
- Use an interdisciplinary framework to create a coherent, validated, and feasible adherence measurement and support package for use in ARV-based vaginal ring trials.
 - 3 year project (November 2013 – October 2016)
 - Includes social, behavioral & technological experts
 - Aligned with specific challenges of measuring and supporting ARV-based vaginal ring adherence in context of RCTs

Adherence Measurement and Optimization

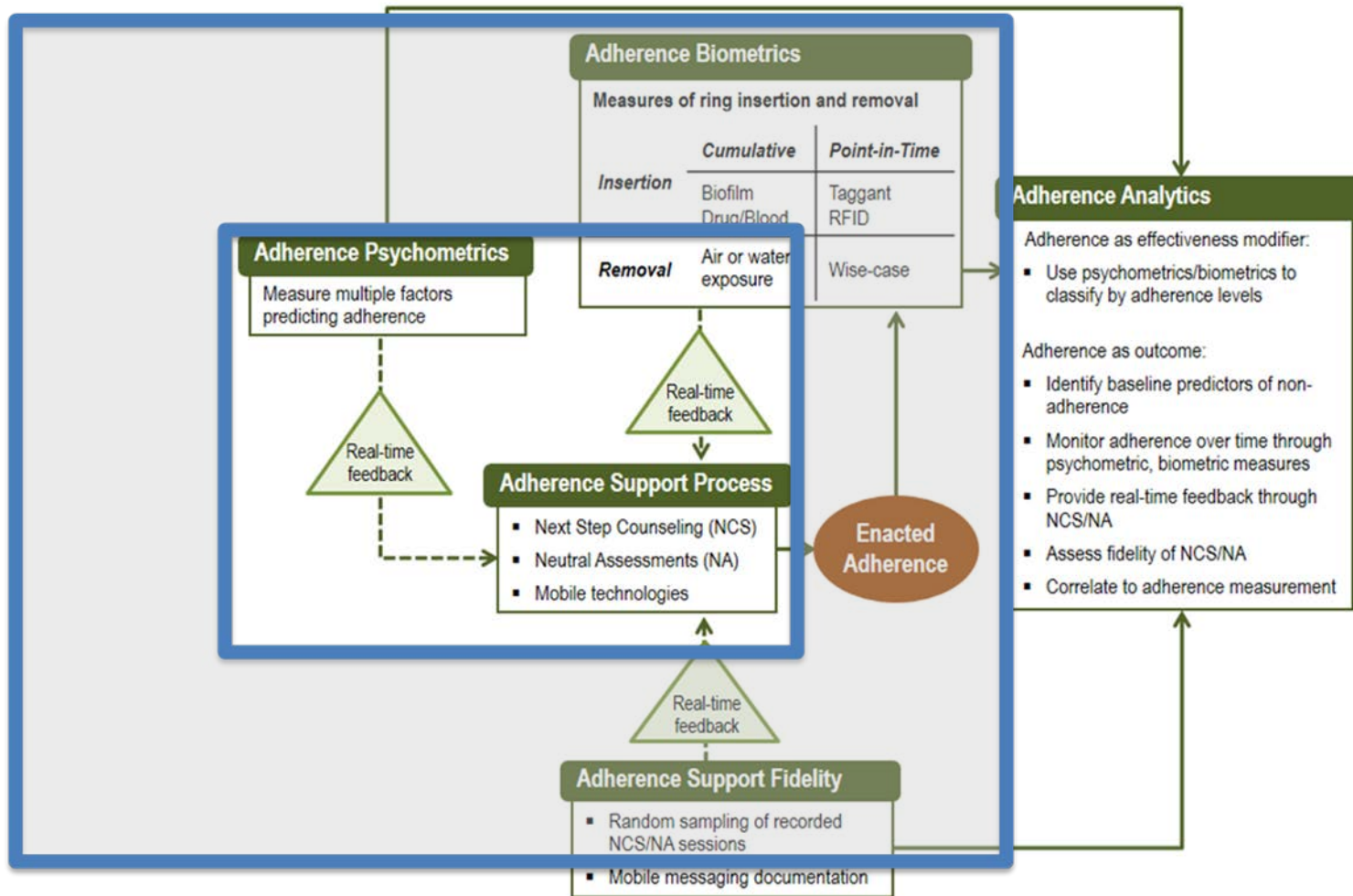
Interdisciplinary integration of adherence measurement and support.



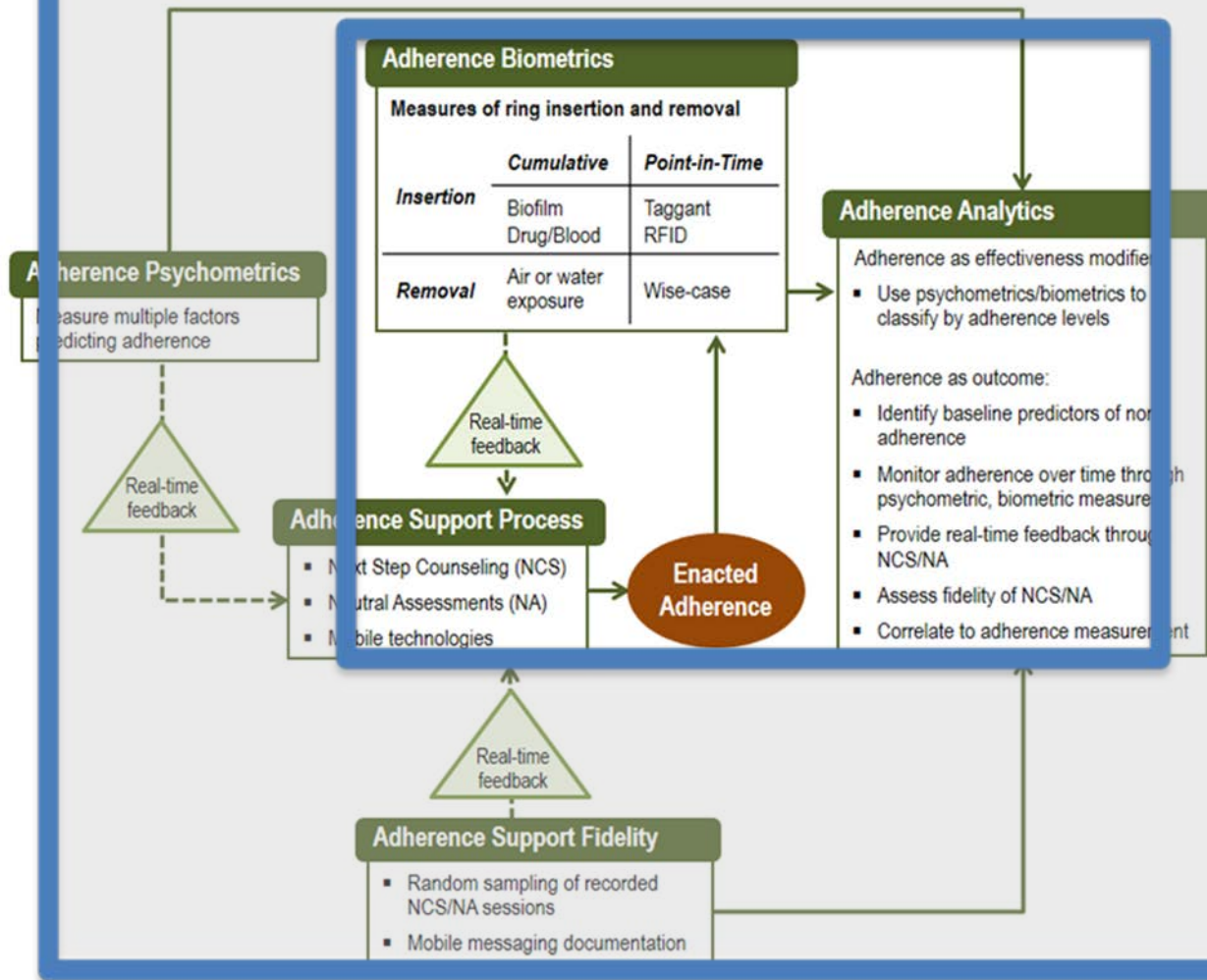
Aim 1: adherence support



Aim 2: psychometrics



Aim 3: biometrics



Internet survey: analysis in progress

- Identify key concepts related to adherence support where translation and comprehension are problematic
- Assess acceptability, feasibility, and perceived utility of:
 - Methods for assessing fidelity to adherence counseling protocols
 - Biometric technologies to detect adherence to ARV-based vaginal ring use
- Assess perspectives on trial participant characteristics and motivations potentially associated with:
 - Varying levels of product adherence (high, moderate, low, non-use of product)
 - Over-reporting of product use
- Assess perspectives on the ethical, statistical, and practical implications of:
 - Using psychometric measures to screen out participants
 - Disenrollment of non-adherent participants
 - Increasing incentives for continuously adherent participants

Internet survey: participation

894 emails sent

- 779 (87%) delivered

391 emails opened

- 50% of emails delivered

258 completed eligibility question

- 66% of emails opened

225 eligible

- 87% of those completing eligibility

219 consented

- 97% of those eligible

206 answered at least one question

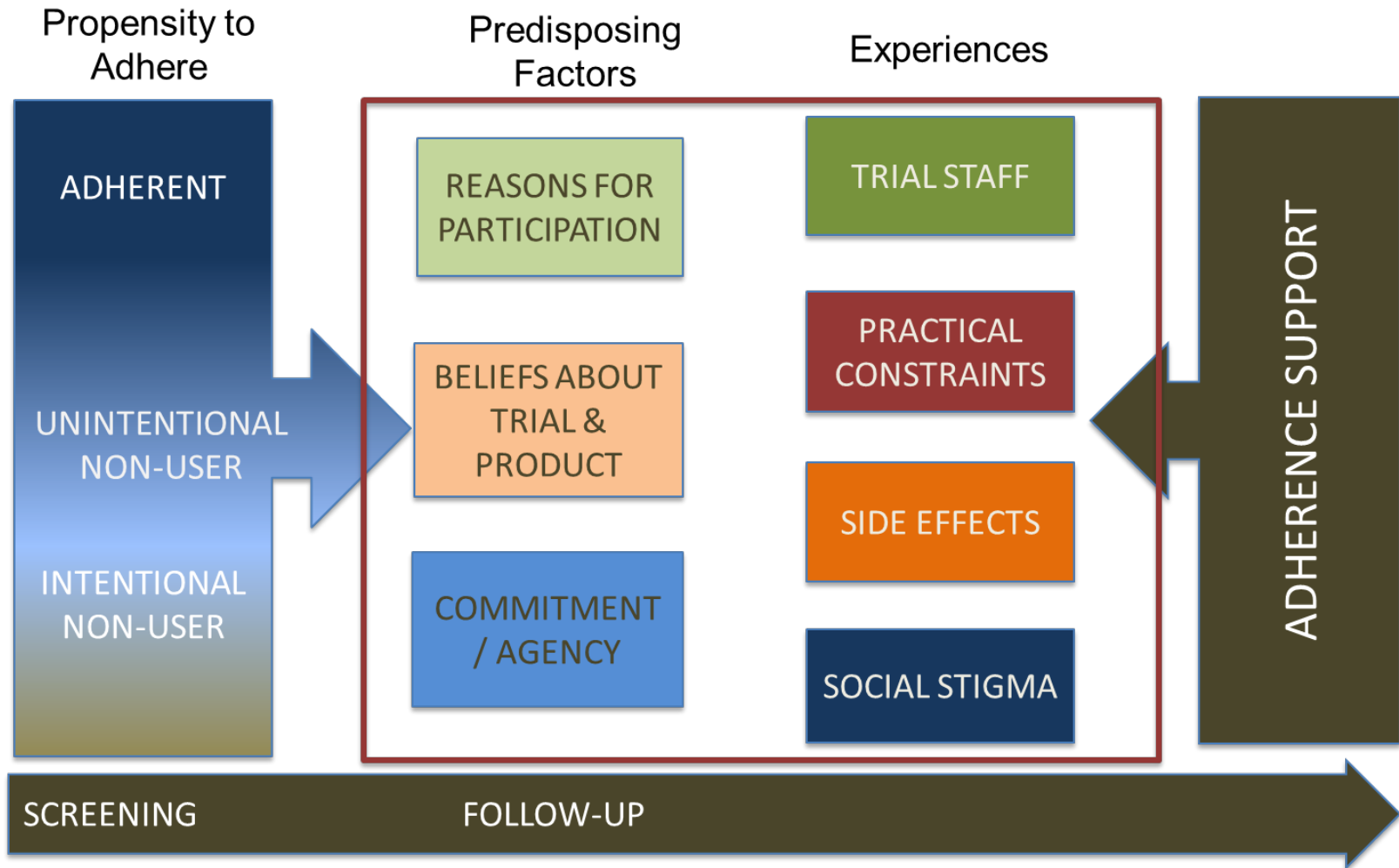
- 94% of those who consented

152 completed all eligible sections

- 69% of those who consented

Role	Survey respondents (n=206)
	n (%)
Protocol team member	100 (48.5%)
Trial implementation (e.g., investigator, manager, coordinator)	128 (62.1%)
Program officer at a funding organization	14 (6.8%)
Adherence and product use counselor	53 (25.7%)
Trial participant recruiter	40 (19.4%)
Trial monitor	7 (3.4%)
Community liaison officer, outreach worker, or educator	34 (16.5%)
Ethics review committee member or administrator	9 (4.4%)
Ethics consultant	5 (2.4%)

Adherence in prevention trials



Aim 1: adherence support

- FHI 360 lead: Kate MacQueen
- Rivet Amico
- Natasha Mack
- Rachel Scheckter
- Eunice Okumu

Adherence support manual

- A tool to help research teams think through options for supporting adherence
- Consideration of:
 - Women’s engagement in the trial
 - interactions between the study, the participant, and the community
- Site and trial context determines choice of strategies
 - Adapt or supplement as needed or appropriate.

Adherence support manual

- Bridging two approaches traditionally used in HIV-prevention trials: individual counseling and community engagement
 - Trust and belief in study product, study goals, and value of results for the community
 - Motivation and skills to reach high levels of adherence and sustain them over time

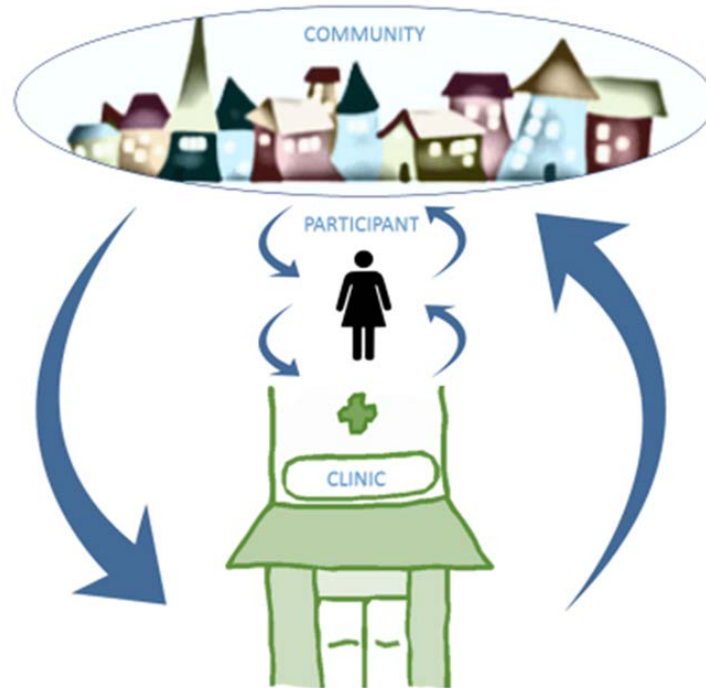
Pathways to adherence

- Reasons for participation
 - Level of commitment to HIV prevention
- Beliefs about the trial
 - Trial promotes the interests and goals of the community
- Beliefs about the study product
 - Safe, promising, acceptable
- Shared vision
 - Aligned across participant, her community, and the study
- Agency
 - Empowered to make her own choices

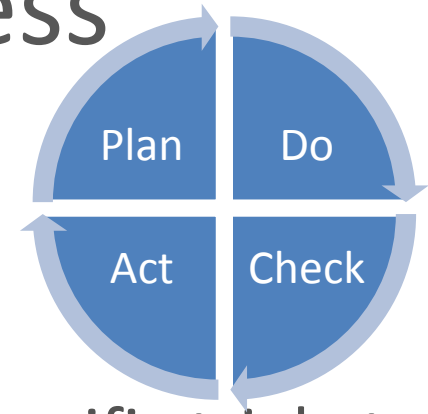


Participant journey

Participant's experience as she progresses through the trial from start to finish and post-trial



Adherence support process



- Plan, Do, Check, Act (PDCA) cycles
 - Identify pathways to adherence
 - Tailored to dynamic context of a specific trial at a specific site
 - Process is the same, strategies & approaches vary
- Activities vary over time
 - Pre-trial: community context
 - During trial: screening, enrollment, follow-up
 - Post-trial: access, fair benefits

Aim 1 adherence manual timeline

- 10/15: Initial draft sent out for stakeholder review & input
- 2/15/2016: Document revised based on stakeholder review & findings from Aim 2 psychometric analysis
- 5/1/2016: Final design & formatting completed for production

Aim 2: psychometrics

- FHI 360 lead: Betsy Tolley
- Kate Morrow
- Kate MacQueen
- Allison Pack
- Seth Zissette
- Monique Mueller

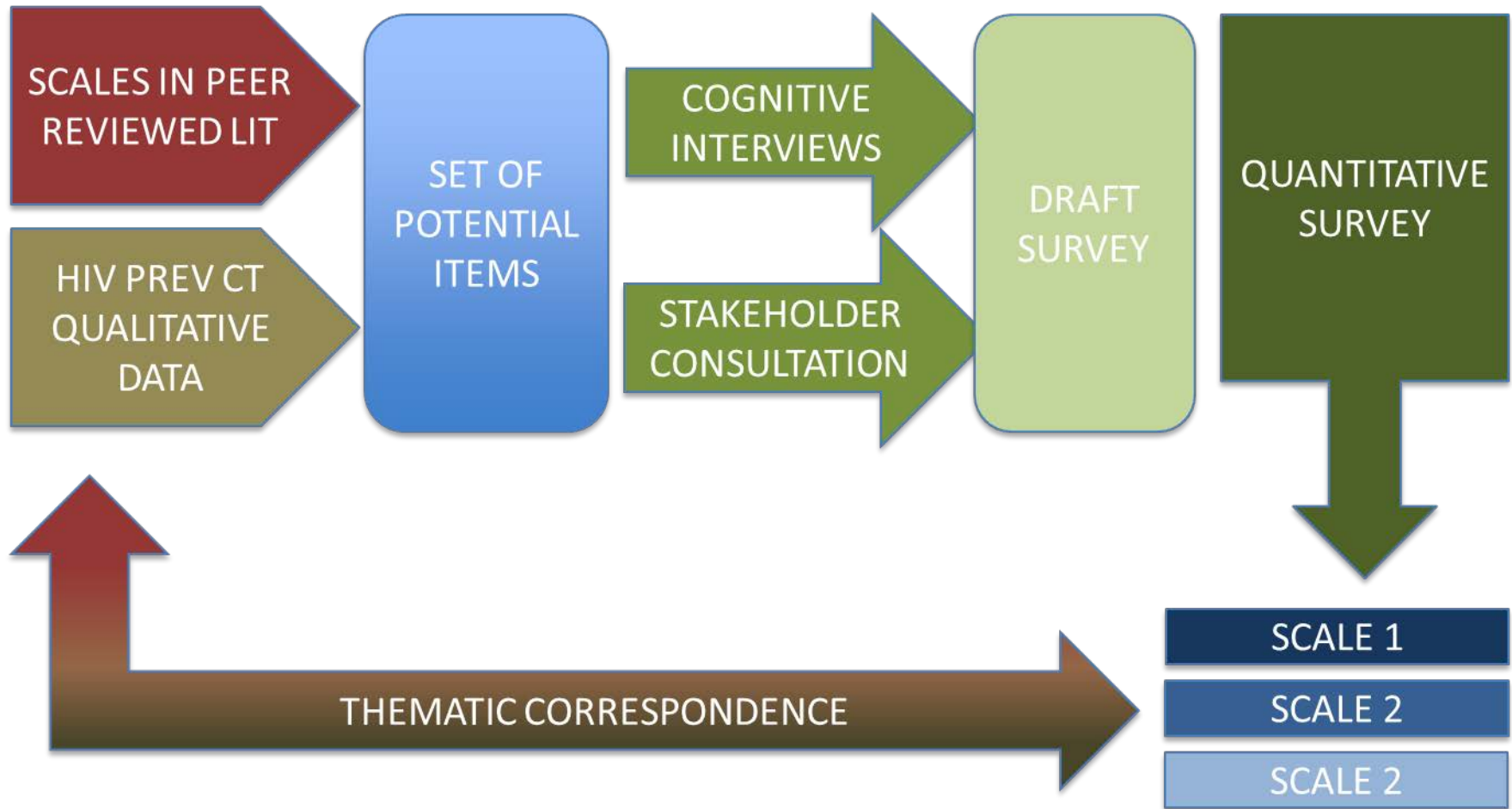
Why develop an adherence scale?

Benefits: Inexpensive, and easy to administer, may avoid biases of other self-report questions; **valid** scales increase power to detect differences between participants

Uses:

- **To screen** potential participants prior to study enrollment in an effort to identify those who are most likely to adhere;
- **To provide** participant **feedback** during adherence support sessions in order to revise adherence support tools/counseling in real time; and/or
- **To classify** participants **into adherence categories** for use in per product analyses of product efficacy.

Scale Development Process



Literature review

- 45 articles provided adherence scale items
 - Most assessed adherence to treatment (n=35) versus prevention (n=10)
 - Within prevention, most assessed contraception or HIV prevention/condom use
 - Within treatment context, most assessed adherence to HIV treatment (n=19) versus other disease areas
 - Several assessed adherence to any medication
- Several additional scales surfaced after the literature review
 - Beliefs related to Medications Survey, Beliefs about Medicines Questionnaire

Some examples of scales from review

- AIDS Clinical Trial Group Adherence Questionnaire (ACTG)
- Adherence Determinants Questionnaire (ADQ)
- Adherence Treatment Scale
- Antiretroviral General Adherence Scale (AGAS)
- Brief Medication Questionnaire 1 (BMQ1)
- Beliefs about Medicines Questionnaire (BMQ)
- Hill-Bone High Blood Pressure Compliance Scale
- HIV Self Efficacy Questionnaire
- HIV-ASES
- Medication Adherence Questionnaire (MAQ) – MMAS-4 and MMAS-8
- Medication Adherence Rating Scale (MARS)
- Self-efficacy for Appropriate Medication Use (SEAMS)
- Structural Barriers to Clinic Attendance
- HIV Stigma Scale
- Interpersonal Support Evaluation List
- Self-Efficacy for Condom Use

Adherence Determinants

- Constructs included:
 - Community-level characteristics (social support and/or stigma)
 - Characteristics of the clinical trial (perceptions of clinical trial requirements and of health provider support)
 - Product-related factors (ease of use, concerns about side effects)
 - Personal characteristics (perceived risk, locus of control, memory, internalized stigma)

Development and Psychometric Validation of Measures for Vaginal Ring Adherence: Sites

Desmond Tutu HIV Foundation (DTHF) / Cape Town, South Africa

Local PI: Dr. Katherine Gill

Trials recruiting from: MTN 020 (ASPIRE), FACTS 001 and previous IPM Ring studies

Madibeng Centre for Research (MCR) / Brits, South Africa.

Local PI: Dr. Cheryl Louw

Trials recruiting from: IPM 027 study

Qhakaza Mbokodo Research Clinic / Ladysmith, South Africa.

Local PI: Dr. Phillip L Kotze

Trials recruiting from: FACTS 001 and IPM 027 studies

Wits Reproductive Health & HIV Institute (RHI) / Johannesburg, South Africa.

Local PI: Ms. Krishnaveni Reddy

Trials recruiting from: MTN 020 (ASPIRE), FACTS 001, VOICE and IPM 011 (Safety and Acceptability Study) studies.



Overview of sampling framework

Activity	Site A	Site B	Site C	Site D	Maximum totals
Staff Consultation Clinical trial staff Community (CAB)	6-10 0-5	6-10 0-5	6-10 0-5	6-10 0-5	60
Cognitive Interviews	12-16	12-16	12-16	12-16	64
Survey (maximum)	200	200	200	200	800
<i>Illustrative breakdown:</i> <i>Former trial px</i> <i>Similar community px</i>	<i>100-150</i> <i>50-75</i>	<i>100-150</i> <i>50-75</i>	<i>100-150</i> <i>50-75</i>	<i>100-150</i> <i>50-75</i>	
Total maximum	231	231	231	231	924

Aim 2 study timeline

Key Tasks	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
IRB	X	X	X								
Training		X	X								
Conduct Collaborative Workshops			X								
Conduct cognitive interviews			X	X							
Revise draft scale items based on cognitive feedback			X	X							
Finalize structured survey				X	X						
Program tablets, using ODK				X	X						
Train then administer survey					X	X	X				
Analyze data and draft manuscript							X	X	X	X	X

Acknowledgments

FHI 360

- Betsy Tolley
- Derek Owen
- Natasha Mack
- Randy Stalter
- Monique Mueller
- Eunice Okumu
- Rachel Scheckter
- Jenae Tharaldson
- Seth Zissette
- Sonja Jerome
- Allison Pack

Consultants:

- Rivet Amico
- Kate Morrow
- Tom Moench

THANK YOU!

This work is made possible by the generous support of the American people through the United States Agency for International Development (USAID). Financial assistance was provided by USAID to FHI 360 under the terms of the Adherence Measurement and Optimization of Long-Acting ARV-Based Vaginal Ring Agreement, AID-OAA-A-14-00003. The contents are the responsibility of FHI 360 and do not necessarily reflect the views of USAID or the United States Government.



