

Adherence counseling approaches utilized in prior HIV prevention trials

NSC (iPrEx) and VASP (VOICE)

NIH OPTIMIZATION OF ADHERENCE AFTER VOICE MEETING

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DISCLAIMER

Review of approaches -- from published work

Content/slides **not** reviewed by iPrEx or VOICE teams

Experiences and insights shared -- my own views and may **not** reflect those of either study team

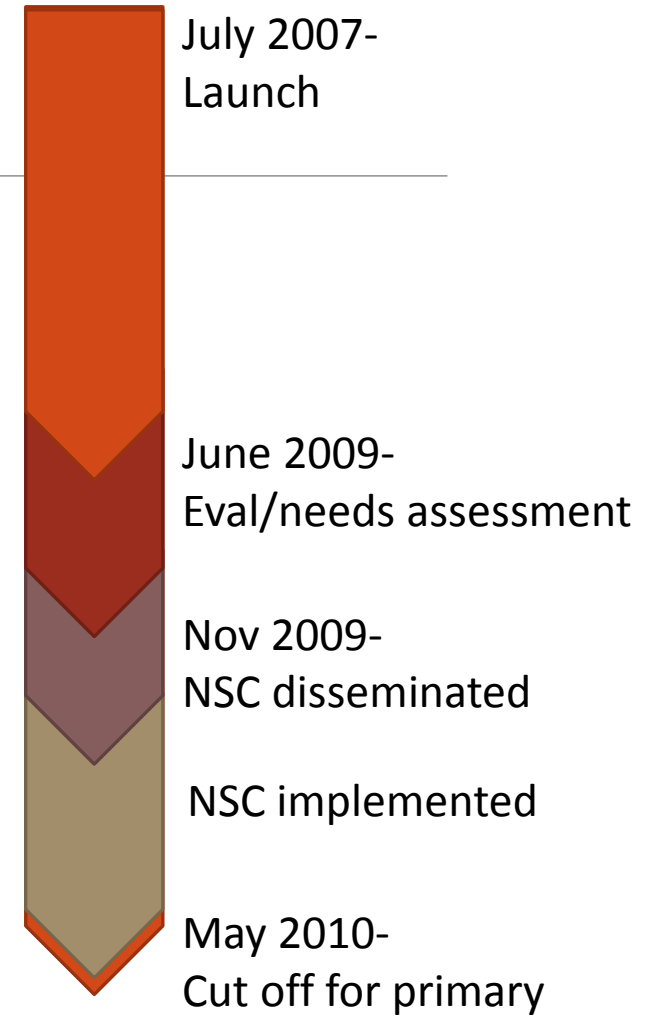


Supporting Product Use in RCTs

- **iPrEx NSC/NA**
 - **Description**
 - **Lessons Learned**
- **VOICE VASP**
 - **Description**
 - **Lessons Learned**
- **Hindsight**
- **Forward Progress**

iPrEx RCT

2499 MSM and transgender women

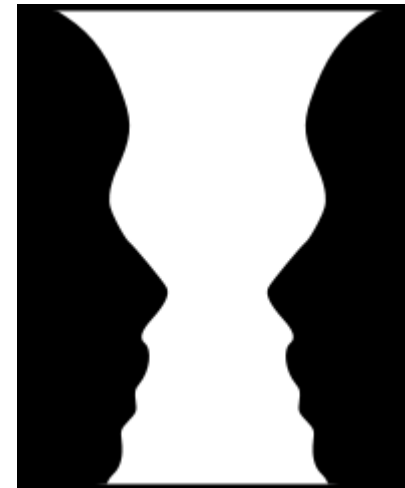


Early Approach to Supporting Product Use

Framing Product Use

- Critical to success of trial
- Messages of need for adherence at each visit
 - Often by multiple staff
- Barriers focused
 - Identify non-adherence
 - Ask about reasons
 - Reinforce adherence
 - Offer strategies
 - Variable by site- some used pill-count to identify non-adherence and trigger additional discussions
- Core team tracking of pill-count adherence
 - Sites reinforced for high rates

SOCIAL CONTRACT



Early Approach to Supporting Product Use

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Participants

- Priority is on trial success
- Staff want/need you to adhere
- Non-adherence is bad
- Reporting non-adherence makes people upset and visit longer
- Using drug does not protect you personally

SOCIAL CONTRACT



Study/Team

- Participants share drive for trial success
- Participants want to adhere but lose site of importance or lack skills
- Participants report non-adherence openly
- A good site has good sample adherence

REVISED Approach to Supporting Product Use

Try to change the social contract

Participants

- Priority is on ~~you~~ and ~~success~~ contributions
- Staff want/need you to ~~be honest~~
- Non-adherence is ~~okay~~
- Reporting non-adherence is ~~ok~~ makes people
- ~~Using and giving longer~~
- ~~bring you personally~~ protect you personally

SOCIAL CONTRACT



Study/Team

- Participants ~~have~~ drive ~~different~~ reasons for
- ~~Participants~~ want to
- ~~Participants~~ lose site of ~~important~~ take ~~back~~ skills
- ~~Participants~~ take ~~on~~ non-adherence ~~openly~~
- ~~A good site~~ had good ~~simple~~ adherence
- Participants *may not* report non-adherence
- A good site has good *open discourse around adherence*

REVISED Approach to Supporting Product Use

The Adherence Working Group developed Next Step Counseling and Neutral Assessment

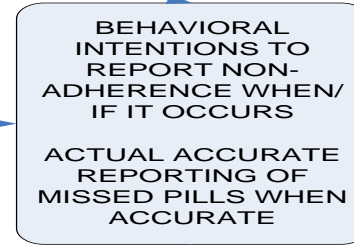
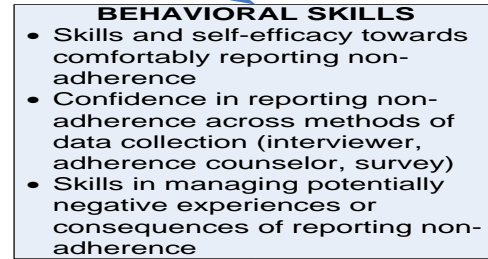
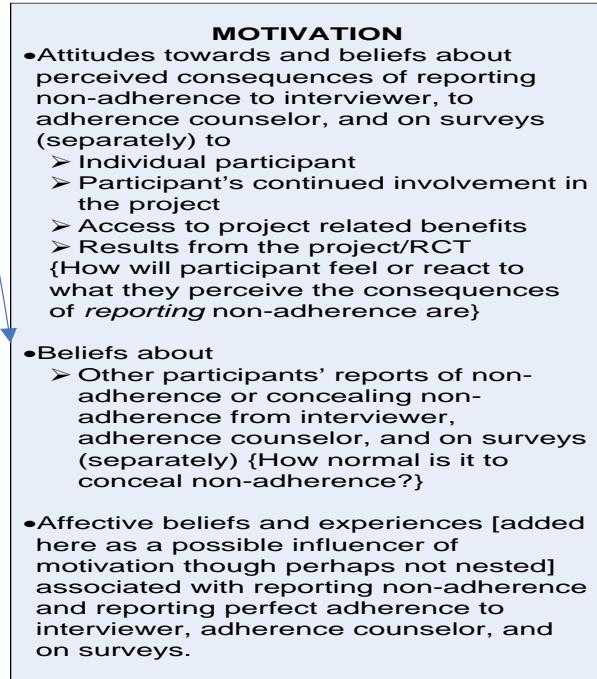
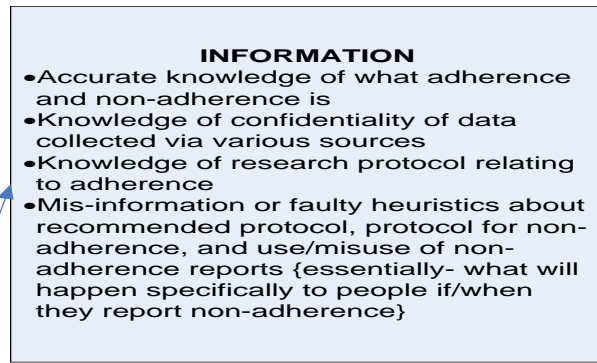
- A strategy to shift thinking about adherence globally
- Engaged all team members at all sites
- Included structural changes to procedures as well as efforts to promote buy in at all levels

.....the approach

Neutral Assessment

Next Step Counseling

REPORTING PILL-TAKING IMB

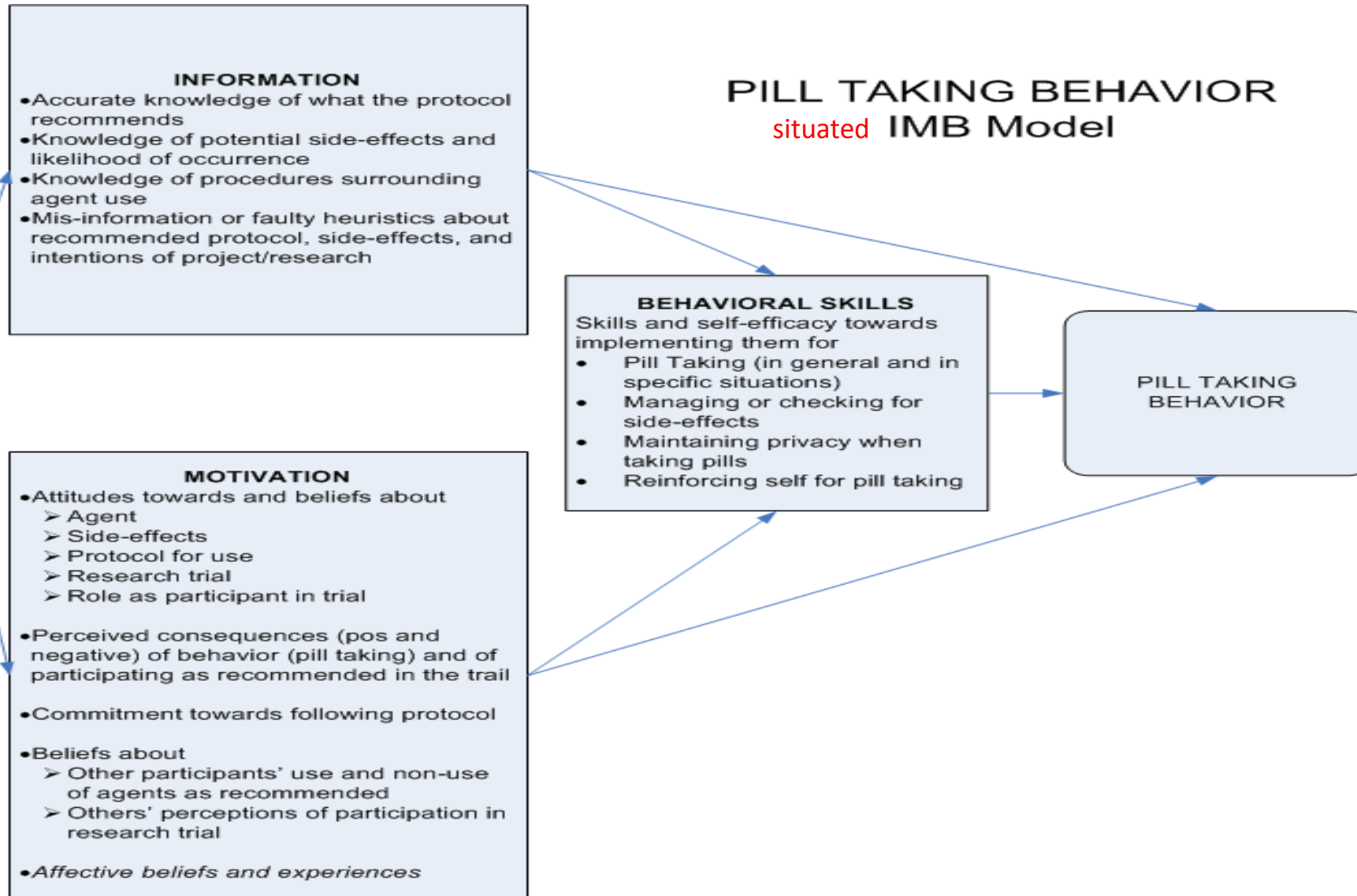


-
- **Separated counseling from assessment**
 - **Allowed participants to report non-adherence with no overt negative consequence**
 - **Trained interviewers on neutral data collection**

NEUTRAL ASSESSMENT

PILL TAKING BEHAVIOR

situated IMB Model



NEXT STEP COUNSELING

Next Step Counseling

A participant-centered discussion of ease and difficulty of pill-taking

Context driven

Focused on

- *forward progress/movement in small steps*
- *the experience of pill-taking*

NOT Focused on actual pill-taking behavior

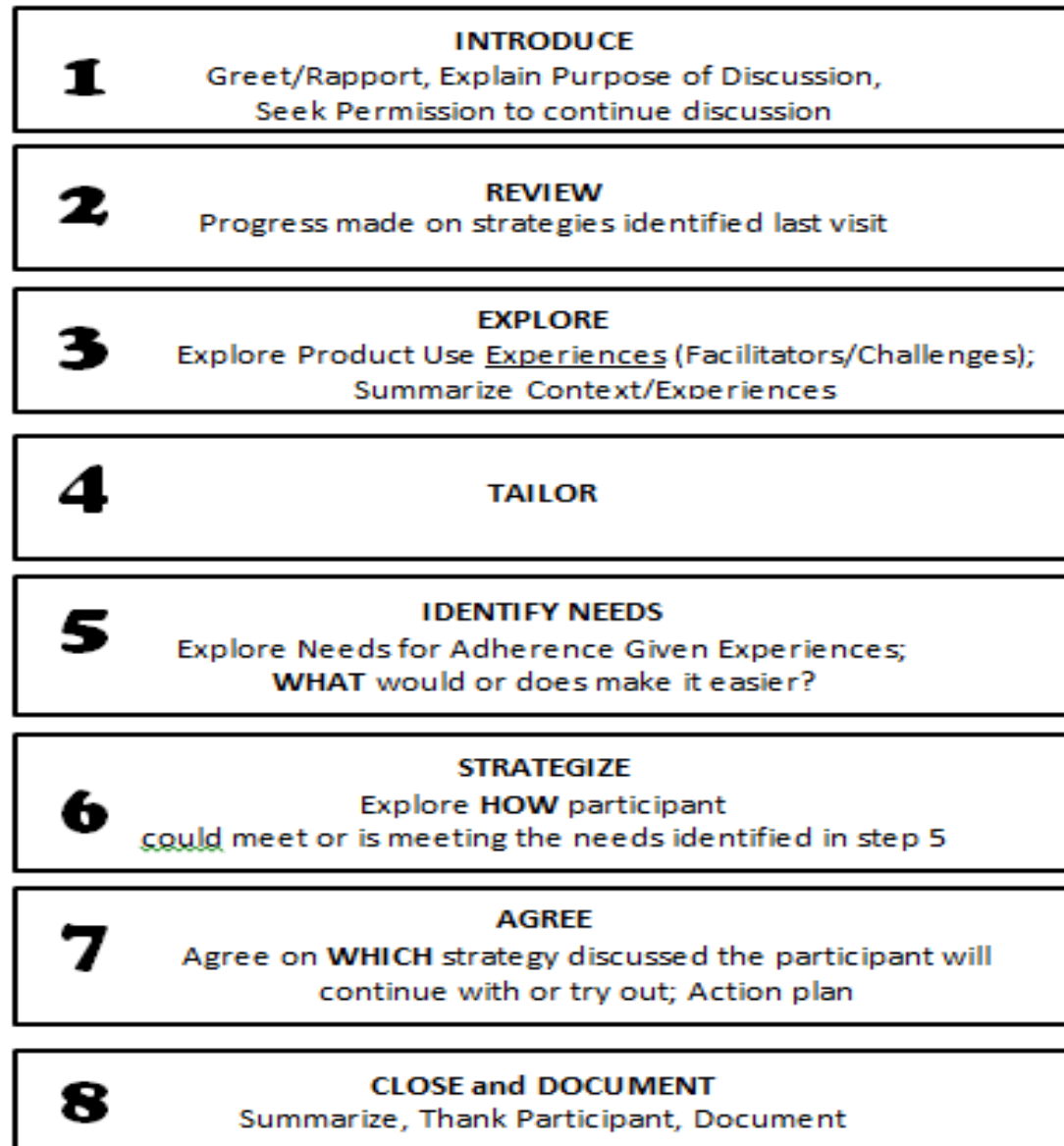
Repeated, cumulative exposures targeting small steps

Motivational Interviewing

Embedded several MI strategies to help counselors to work WITH participants

- Ambivalence
- Avoid righting reflex
- Collaboration
- Guiding
- Respect for autonomy

FIGURE 2: NSC Steps/Flow

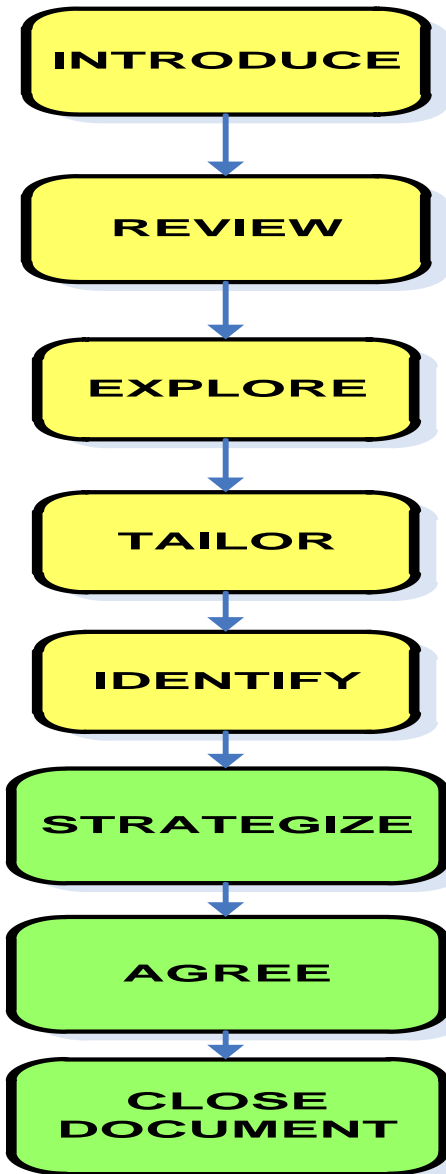


GOAL: Create a comfortable environment to talk about experiences with the product

CLIMATE: Supportive, non-judgmental, neutral, reinforcing of open discussion/efforts, avoidance of “fixing,” recognition of limited role, and emphasis on participant as a whole person.

METHOD: Exploration of context (experiences, thoughts, beliefs, feelings; information, motivation, skills) to identify needs and promote movement towards building a context that supports product use.

IMPLICIT ASSUMPTION: Participants choose whether or not, or how much, to use the study product. We cannot make them use it, but can support open frank discussions about it.



An 8 Step Counseling Approach

1: INTRODUCE . . . the counseling session.

2: REVIEW . . . previous experiences.

3: EXPLORE . . . facilitators and barriers.

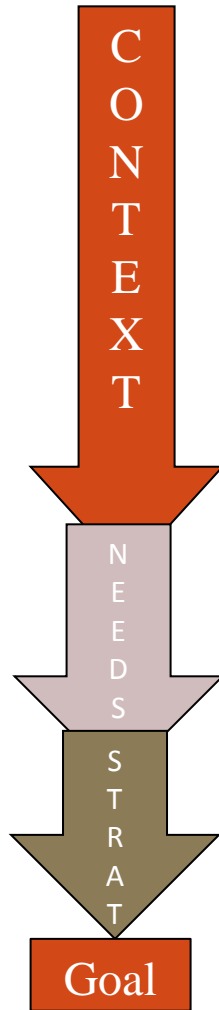
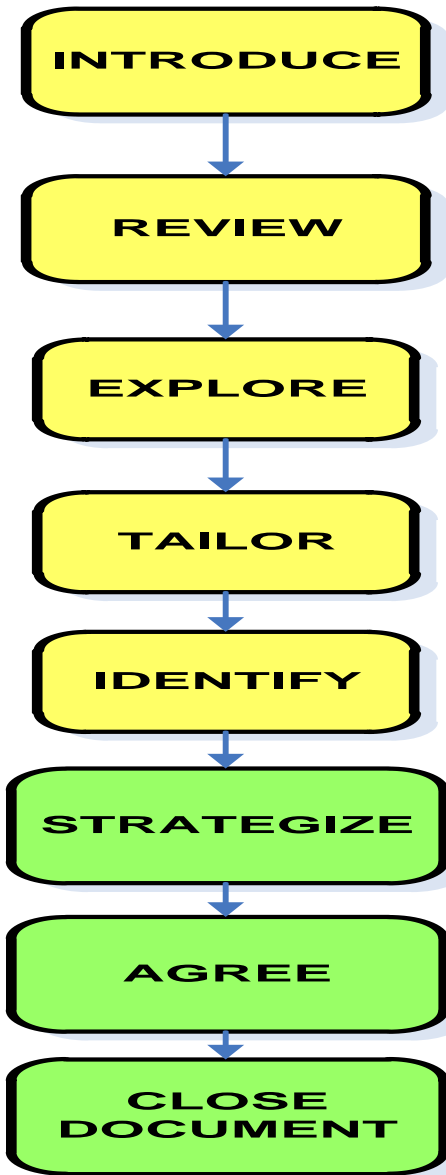
4: TAILORE . . . the discussion to the specific needs of the participant.

5: IDENTIFY . . . the next small step towards pill-taking-- *WHAT* ...

6: STRATEGIZE . . . on *HOW* that next small step could be made towards.

7: AGREE ON . . . *WHICH* of the strategies the participant will try and develop an **ACTION PLAN** for that strategy.

8: RECORD



I would like to spend a few minutes speaking with you about your experiences with the study pills. Is that OK with you?

Can you share with me what your experiences have been with the study pills?

What has made using the product feel easier? ...seem difficult? Regardless of whether or not you use the product?

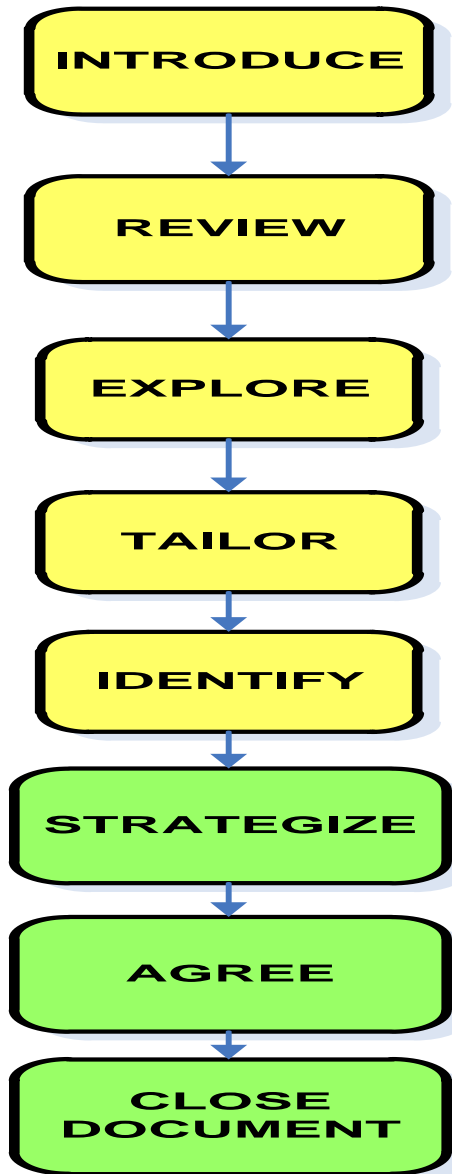
Counselor guides discussion towards what appears most relevant.

What would need to happen for....to feel a little easier/more manageable?

How could you see that happening?...How could you do that?

Of the things we have discussed, is there a strategy you are willing to try between now and the next time we meet?

Reiterate emphasis on easing use, empower, engage



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RECORD FORM

STEP 1: INTRODUCE the session – with Permission
Repeat, Define the problem; introduce the solution/approach; and foster engagement

STEP 2: REVIEW

STEP 3: EXPLORE– Facilitators (summarize) and Barriers (summarize)

Facilitators (Easier)	Barriers (Harder)

Facilitators
What are the times, situations, ways you feel, ways you think, ways others think or things you hear from others that help you to take the pill?

Barriers
What are the situations, times, ways you feel, things you think, or even things others think or tell you that make it hard to take the pill?

STEP 4: TAILOR (what did the discussion focus on) Increasing EASE of pill-taking Increasing pill-taking BEHAVIOR Other

Engagement level: Lo - Mod - High
Level of Pill-taking: Lo - Mod - High [Not Reported]
(self-report)

STEP 5: IDENTIFY a next-step (WHAT)
What would need to happen for...
...taking the pills to be a little easier
...you to be able to take the pill (in a given situation, more frequently, so on)

What:	

STEP 6: Strategize– List strategies to use to take the next-step (HOW)
How could that happen? What would that look like?

STEP 7: Agree on a strategy to try and develop an action plan

STRATEGY:	
ACTION PLAN:	

Strategy written down as next-step goal and handed to participant? YES No

STEP 8: RECORDED YES No

Comments:	
-----------	--

Write and then place a circle around the letters next to any step not implemented an NA for not applicable or NI for not implemented– DO NOT LEAVE ANY STEP BLANK!

Implementation

2-3 day workshops

Practice through role plays

Monthly team teleconference

Booster meeting

By the end of the study....

Over the final >15,000 NSC sessions with ~2000 participants

Lessons learned

- *Counselors found the approach feasible*
- *Moving away from assessment driven to conversational was liked...by most*
- *Conversations/discussions did not take more time in general (20m 1st, 12-14m follow-ups)*
- *PrEP adherence appeared similar and different from adherence to open-label or known medications*
 - *“Unintentional” non-adherence appeared similar to ARVs, while “intentional” adherence appeared more unique to PrEP trial and cultures.*

Lessons learned

- *Remains unevaluated formally...*
- *Adherence*
 - *was not dramatically changed pre/post*
 - *at end of study remained low in most non-US areas while extremely high in the US*
- *Not clear*
 - *If 'social contract' was successfully renegotiated*
 - *If reporting/openness changed*
 - *If implementation was with fidelity to spirit*

Lessons learned

HOWEVER...

iPrEx contributed substantially to the conversation about relationships between participants, studies and product use

The NSC and NA approach helped to advise the development of other support strategies in clinical trails (and open label applications)

NSC AS WELL AS OTHER APPROACHES (CARPISA ASP) HELPED RETOOL CONVERSATIONS...

SETTING SOME AGENDA

DEVELOP CONTEXT

...for experiences with product

IDENTIFY

...needs (what would need to happen to make that easier for you)...
...barriers (what are some things that made it difficult)...

STRATEGIZE

...to meet needs/address barriers identified

FOLLOW UP



VOICE

Adherence

Strengthening

Program



Adherence Counseling Manual

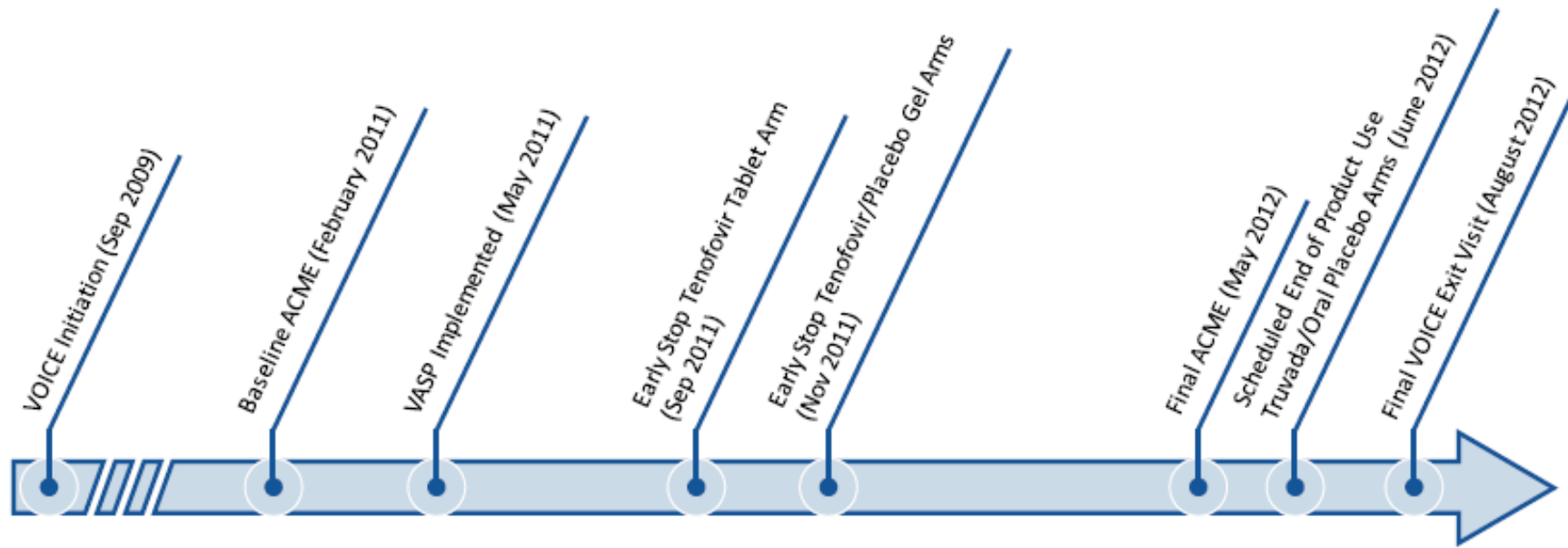


Fig. 1 Timeline of VOICE, VASP implementation and ACME assessments (not to scale) *ACME* Adherence Counseling Monitoring and Evaluation project, VASP VOICE Adherence Strengthening Program

Pre-VASP

Uses product count from pharmacist in counseling session; reconciled product count and self-reported adherence.

Asks participant how often she had been able to use the product and then based counseling on reported level of adherence.

Adherence plan/strategies is based on overcoming **barriers** to product use.

Uses reported adherence to determine the focus of the session (i.e. page 2 of the counseling worksheet options).

Reinforcement of product use instructions (10 key messages) by the adherence counselor.

Positive reinforcement of good adherence.

Goals focus on perfect adherence.

VASP

Counselors will **NOT** review product count prior to counseling session or probe about discrepancies in product count vs. self report.

Counseling will focus on participant's **experiences** using the product, and what makes using product easier or harder, regardless of how much she used it.

Adherence plan/strategies based on addressing adherence-related **needs**.

All sessions will follow the same 8 steps, regardless of how much the participant has been using the study product.

Product use instructions (10 key messages) will be reviewed by the pharmacist as needed.

Maintain a neutral counseling approach. Goals focused on making product use manageable.

1	WELCOME Greet/Rapport; Thank participant; Check-in	C O N
2	FRAME Explain purpose of discussion Seek permission to continue	
3	EXPLORE Explore product use <u>experiences</u> (f Discuss efforts on strategies f	
4	SUMMARIZE Summarize Context/Ex	
5	IDENTIFY NEED Explore needs for adherence gi What would make it	
6	STRATEGIZE Explore how partic could increase ease/comf	
7	NEGOTIATE Agree on a goal identified by	
8	CLOSE Summarize; Thank participa	

I would like to spend a few minutes speaking with you about your experiences with the study {gel/pills}. Is

Follow-up Adherence Counseling Worksheet

PTID:	Visit Code:
<input type="checkbox"/> 1. WELCOME: Greet and thank participant and establish rapport.	
<input type="checkbox"/> 2. FRAME: Explain the purpose of discussion and seek permission.	
<input type="checkbox"/> 3. EXPLORE: The context (experiences) in which the participant feels it is easiest and hardest to use the study product. Check in on how things went with the goals set at the last session; reinforce efforts and move on to exploring ease and difficulty <u>now</u> .	
CONTEXT (EXPERIENCES)	
... made it feel easier...	... made it seem difficult ...
CONTEXT AROUND EXPERIENCES WITH PRODUCT: REGARDLESS OF ACTUAL PRODUCT	
<input type="checkbox"/> 4. SUMMARIZE: The context (experiences) in which product feels easiest to use/hard use for this participant.	
<input type="checkbox"/> 5. IDENTIFY NEEDS: Help the participant to identify her specific adherence needs gi context explored. What does this participant feel she needs in order for adherence to manageable as possible? (Keep the focus on making use easier, rather than perfect).	
Adherence Related NEEDS:	

it?

it

(

:

your experiences have

to using

PTID:	Visit Code:
<input type="checkbox"/> 6. STRATEGIZE: Explore new strategies or continued use of established ones to address the needs identified.	
STRATEGIES:	
<input type="checkbox"/> 7. NEGOTIATE: A goal that the participant identifies. Ask the participant what she might be willing to try or continue to do between now and the next session (Goal).	
GOAL	
<input type="checkbox"/> 8. CLOSE THE SESSION: Summarize what was discussed; thank the participant for talking with you and contributing to the study; document the session (after participant leaves the room).	
CONTEXT → ADHERENCE RELATED NEEDS → STRATEGIES → GOAL	
Please show participant what you are writing if you write notes during the session	

1	WELCOME Greet/Rapport; Thank participant; Check-in
2	FRAME Explain purpose of discussion; Seek permission to continue discussion.
3	EXPLORE Explore product use <u>experiences</u> (facilitators/challenges); Discuss efforts on strategies from last session.
4	SUMMARIZE Summarize Context/Experiences
5	IDENTIFY NEEDS Explore needs for adherence given experiences; What would make it easier?
6	STRATEGIZE Explore how participant could increase ease/comfort/efficacy.
7	NEGOTIATE Agree on a goal identified by the participant.
8	CLOSE Summarize; Thank participant, Document

Dissemination and Implementation



Lessons learned

Adherence Counseling Monitoring and Evaluation (ACME) Project

Perceptions and Experiences with the VOICE Adherence Strengthening Program (VASP) in the MTN-003 Trial

**Ariane van der Straten · Ashley Mayo · Elizabeth R. Brown ·
K. Rivet Amico · Helen Cheng · Nicole Laborde ·
Jeanne Marrazzo · Kristine Torjesen**

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Lessons learned

ACME

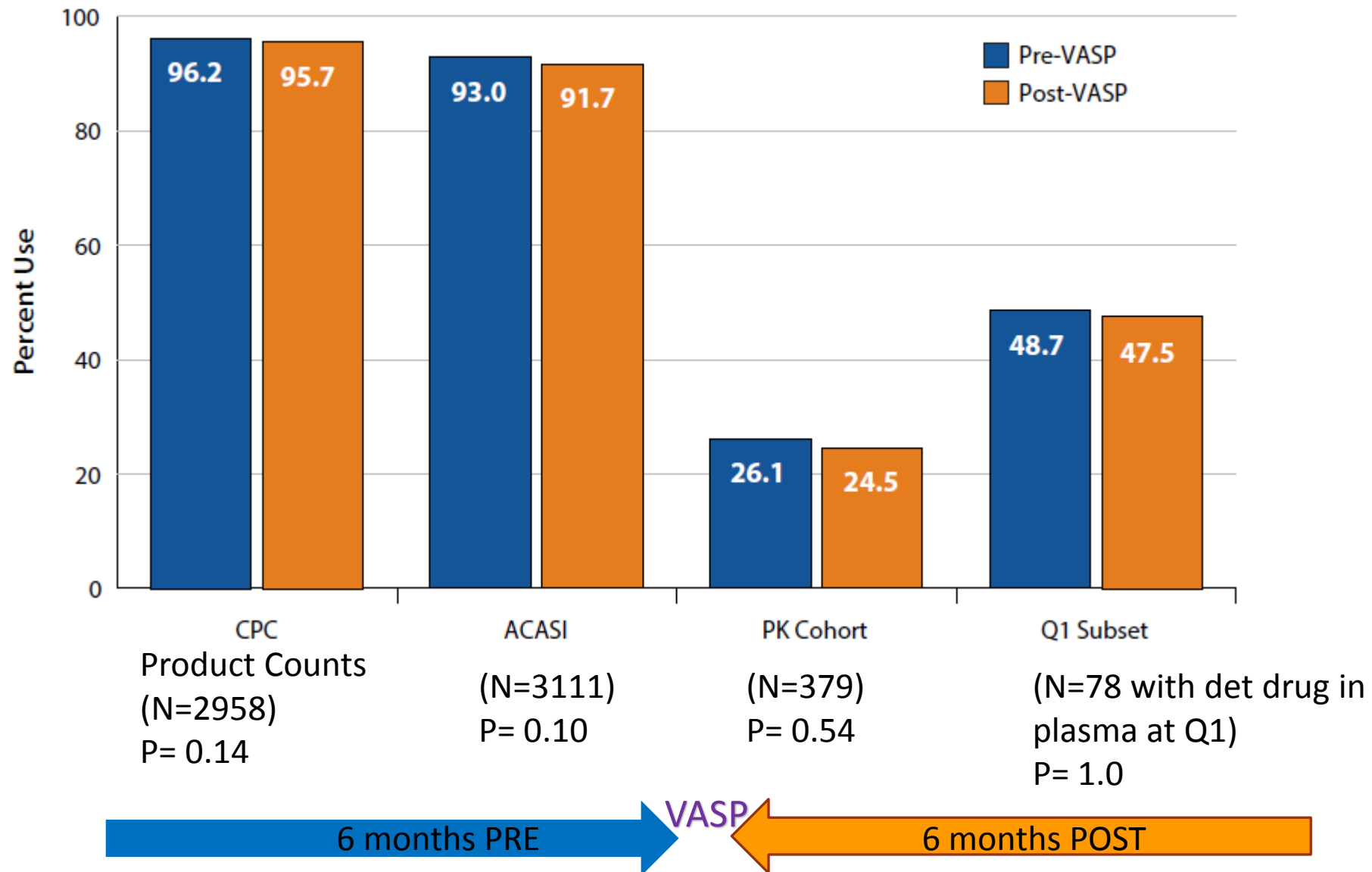
- Staff Surveys
- IDIs staff
- IDIs participants

Change to VASP not appear to be a remarkable, noticeable change



Counselors liked VASP, felt it promoted conversations and avoided lecturing, and preferred a problem solving approach

Pharmacists were not as supportive and felt not having product return counts diminished intervention



Lessons learned

- *Adherence*
 - *was not changed pre/post*
 - *Could have been derailed by DSMB/Study events*
 - *'Social Contract' did not appear renegotiated*
 - *No direct data on implementation*
- *Adherence is ONE PIECE of the puzzle*

Lessons learned

VOICE-C

Factors influencing participants:

- Preserving a healthy status (health)
- Managing social relationships (network, community beliefs)
- Ambivalence towards research and trust)

Social Ecological Factors

FEM PREP

Medical Anthropology Quarterly

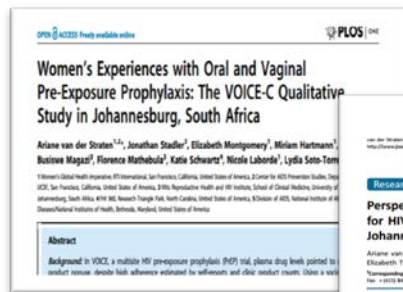
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Malicious Whites, Greedy Women, and Virtuous Volunteers

Negotiating Social Relations through Clinical Trial Narratives in South Africa

As clinical trial research increasingly permeates sub-Saharan Africa, tales of purposeful HIV infection, blood theft, and other harmful outcomes are widely reported by

MEDICAL ANTHROPOLOGY QUARTERLY, Vol. 27, Issue 1, pp. 103–120, ISSN 0745-5194, online ISSN 1548-1387. © 2013 by the American Anthropological Association. All rights reserved. DOI: 10.1111/maq.12018



Avoidance of being reminded to take the tablets

hind·sight /'hɪn(d),saɪt/ =

woulda + shoulda + coulda

Some of the things I wish I had appreciated more...

1. The difference between ART, or PrEP, adherence and study product use
2. The inter-team dynamics at site level
3. The vast range of approaches to study product use
4. The areas in which motivation-based counseling were not well-matched to participant needs
5. The need for supervision and true capacity building
6. The allure of checklists and forms
7. The tendency of our own research community to look for easy answers to complex situations

MI?

➤ Motivational Interviewing

Behavioural and Cognitive Psychotherapy, 2009, 37, 129–140

So What Is Motivational Interviewing?

Having differentiated MI from 10 things with which it is sometimes confused, we offer an updated definition of what it is. Motivational interviewing is a collaborative, person-centered form of guiding to elicit and strengthen motivation for change.

procedures with which MI should not be addled. **Results:** This article discusses 10 things that MI is not: (1) the transtheoretical model of change; (2) a way of tricking people into doing what you want them to do; (3) a technique; (4) decisional balance; (5) assessment feedback; (6) cognitive-behavior therapy; (7) client-centered therapy; (8) easy to learn; (9) practice as usual; and (10) a panacea. **Conclusion:** Clarity about what does (and does not) constitute MI promotes quality assurance in scientific research, clinical practice, and training.

Forward Progress

We are taking opportunities to gain understanding

Mixed methods

We are shifting our understanding of engaging participants

Looking closely at structural factors and community and action based research

New approaches are emerging

Thank you!

To participants and study teams around the globe for their amazing contributions towards ending the HIV epidemic.