

VOICE Adherence Counseling

*The Development of the
VOICE Adherence
Strengthening Program
VASP*



Background

- Adherence in blinded biomedical trials tends to be lower than desired
 - Self-report tends to produce high estimates of adherence (with interview or ACASI)
 - Clinic based pill counts tend to be high
 - But, drug detection suggests adherence is lower than any of these indicators

Adherence is critical

- Differential effectiveness in as treated analyses based on adherence suggest adherence is critical ... *and lower than desired*

- CAPRISA 004

- Overall end study effectiveness: 39%
- >80% Adherence 54%
- 50-80% Adherence 38%
- <50% Adherence 28%



38% of participants

- iPrEx

- Overall end study effectiveness: 44%
- $\geq 90\%$ Adherence 68%
- 50-90% Adherence 34%
- <50% Adherence 16%



49% of visits

Promoting adherence

- How should we promote and support adherence in blinded biomedical trials?
 - Standard of Care for adherence support
 - Dominated by information provision
 - Emphasis on achieving high adherence
 - Evidence suggests this may not produce the levels of adherence desired
 - We lack evidence based alternatives
 - Several approaches have been developed but few have been evaluated

CAPRISA 004's ASP-MI approach

	Adherence before MI % (N)	Adherence after MI % (N)	p-value
High gel use (>80%)	29.9 (221)	42.3 (341)	<0.0001
Moderate gel use (50-80%)	21.2 (157)	21.3 (172)	
Low gel use (<50%)	48.8 (361)	36.4 (294)	



Evidence of need for alternatives

- ...does support a movement away from prescriptive information-dominated approaches.
 - ...may foster environments where recorded adherence is high; while actual adherence is low

Objectives

- The VOICE adherence working group (ADW) was brought together to consider:
 - How adherence is presently monitored and supported in general?
 - Identify areas of strength
 - Identify potential revision opportunities
- Develop a semi-standardized revised adherence support approach: VOICE Adherence Strengthening Program (VASP)

Methods

□ Intervention mapping

■ 6 key stages:

- 1. Needs assessment
- 2. Identification of outcomes and change objectives
- 3. Selection of theory based methods and practical strategies
- 4. Development of a program plan
- 5. Adoption and implementation plan
- 6. Evaluation plan

Methods

□ Intervention mapping

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1. Needs Assessment

Identify areas of strength and revision opportunities.

- Review existing training material for enrollment and follow-up sessions
- Counseling Worksheet reviews
- Observations on site by ADW team members
- Notes from MTN meetings
- Face to face meeting at FHI January 6th 2011
- Conversations with site personnel



Strengths

- ❑ Accurate recognition of adherence as critical to trial outcomes among all staff
- ❑ Strong commitment to convey importance of adherence to participants
- ❑ Strong commitment to conveying accurate product (use and storage) information to all participants
- ❑ Willingness/commitment to reinforce and support participants



Strengths

- Normalization of the female body (helping participants to increase comfort with their bodies)
- Recognition/incorporation of how sex is culturally negotiated
- Involvement of partners and communities



Revision Opportunities

- Positive consequences for reporting perfect adherence to counselors and other staff
 - Reporting adherence as “perfect” brings praise
 - Especially when consistent with product count
 - Sessions are more brief with consistent perfect adherence



Revision Opportunities

- Approach places high emphasis on use and non-use
 - Discussion quickly becomes dominated by rates of non-use

Revision Opportunities

- Focus is largely on identification of concrete barriers to use and their resolution
 - May lead to prescribing strategies that are uniformly applied (one size fits all- take the tablets with breakfast; use gel at night)
 - Focus on participant and her experiences may be overshadowed by actively hunting for barriers and offering solutions
 - Product-use Police

Revision Opportunities

- Reiteration of 10 key messages at each visit
 - Limits counselor responsiveness and flexibility
- Over-reliance of worksheets
 - Limits counselor responsiveness and flexibility
- Flow for session is directed by reports of adherence
 - Bases counseling on estimated rates of adherence- which are difficult to validate and often “inaccurate”



Revision Opportunities

- Reconciliation of discrepant product count and self-report estimates of adherence
 - We don't have much evidence to support clinic-based product count as being accurate
 - Needing to reconcile takes away from the process and neutrality of counseling



Revision Opportunities

- Diffusion of adherence messaging
 - Participants can be instructed to adhere to their product several times by several different staff over the course of a visit
 - Adherence counseling at the end of the visit may be one of several times the participant has been asked to talk about their product use which limits potential novelty and impact of the counseling discussion



What to draw from for revisions?

- Strengths
- Use current literature, theories, and models....

3. ...theory ...and practical strategies

- Review/comparison of VOICE and approaches used in iPrEx (NSC) and CAPRISA 004 (ASP-MI)
- Pull from promising strategies
- Review and draw from communication and counseling approaches
 - client-centered counseling
 - motivational interviewing
 - other intervention packages (Options, RESPECT)

3. ...theory ...and practical strategies

■ ***Theoretical Model:***

- Information Motivation Behavioral Skills model of product adherence situated to blinded biomedical prevention trial context

■ ***Practice Models (Practical Strategies):***

- Person-centered
- Motivational Interviewing
- Next Step Counseling (iPrEX)
- Adherence Support Program (CAPRISA)



4. Development of a revised program

- Use strengths, available literature, and innovations to address revision opportunities
 - Preserve aspects that work well
 - Modify aspects of the current approach that raised concern
 - Promote a clinical trial climate that is streamlined and envisions adherence as ultimately a participant's decision- which can be promoted and supported but not demanded or “enforced”



4. Development of a revised program

Current Approach

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.

4. Development of a revised program

Current /

Uses product count from counseling session; record and self-reported adherence

Asks participant how often to use the product and then on reported level of adherence

Adherence plan/strategy overcoming *barriers* to product use

Uses reported adherence as focus of the session (i.e. counseling worksheet or

Reinforcement of product key messages) by the advisor

Positive reinforcement of goals. Goals focus on perfect adherence

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

product count prior to session vs. self report.

participant's product use, and what makes it easier, regardless of

based on addressing

same 8 steps, but participant has more control.

10 key messages) will be consistent as needed.

more engaging approach. Goals are more use manageable.

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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) 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.

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STRATEGIZE

6

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could increase ease/comfort/efficacy.

NEGOTIATE

7

Agree on a goal identified by the participant.

CLOSE

8

Summarize; Thank participant, Document

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

Can you share with me what your experiences have been with the study {gel/pills}? What has made using the product feel easier? ...seem difficult? Regardless of whether or not you use the product?

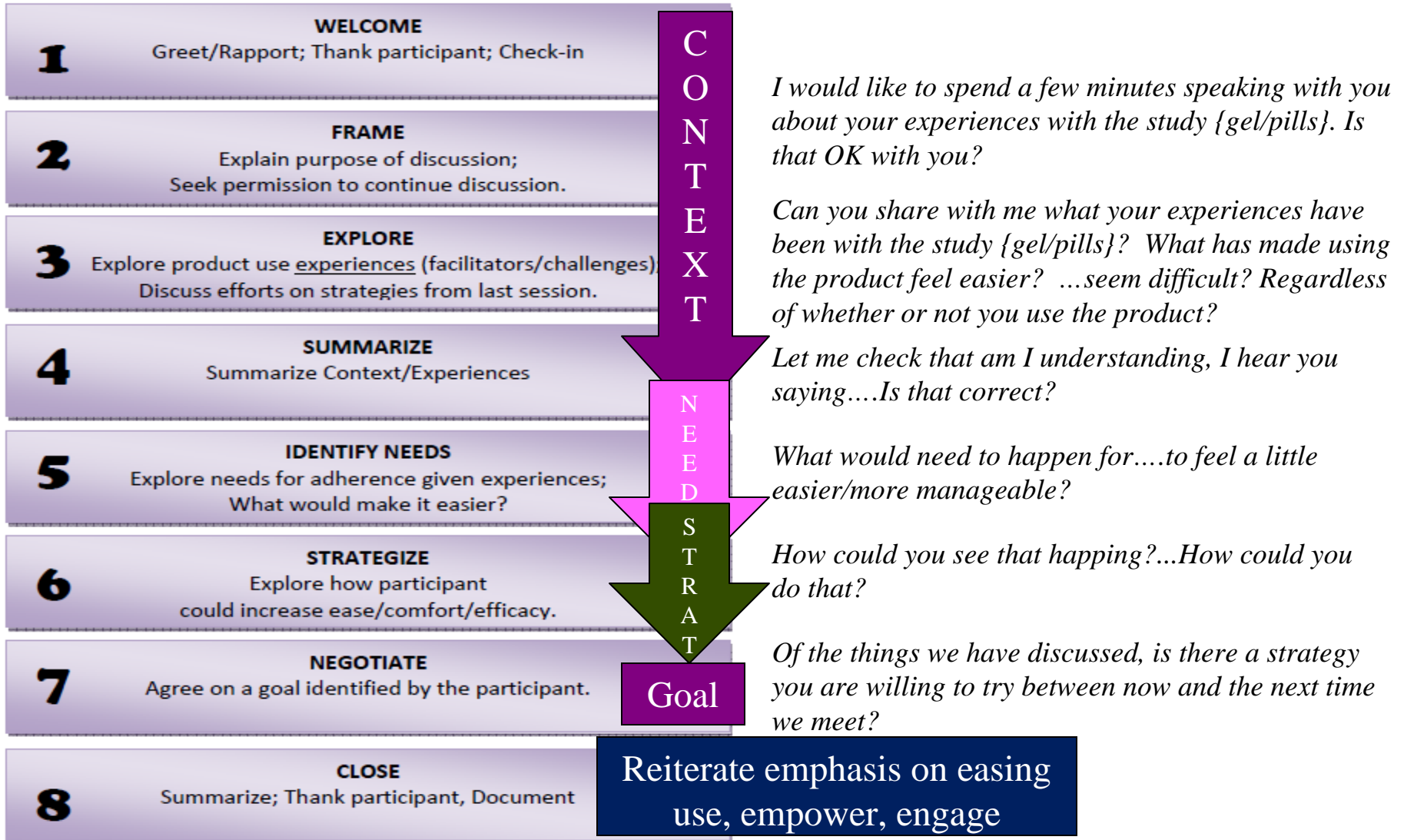
Let me check that am I understanding, I hear you saying....Is that correct?

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?

4. Development of a revised program



4. Development of revised program

5. Adoption and implementation plan

1 Greet/Rapp

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8 Summarize

STEP

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COUNSELOR SKILLS

MAIN PRINCIPLES

- Client-Centered**
The participant is the expert on her life :
- Comprehensive (Multi-targ**
Providing accurate information is neces participant engagement in discussions a are also critical to help produce change.
- Counselor-Guided**
The counselor guides the discussion thri participant should have the majority of '
- Context-Driven**
The counseling session explores the con events when the product was not taken product use that facilitate or challenge t in their daily life.
- Genuine**
The counselor maintains a genuine inter exploration of the participant's experier honest, present, and attentive) through
- Individualized**
The counseling for product use is indivi behaviors of a given participant at a giv
- Neutral (In Stance)**
The counselor maintains a supportive bi of both the participant and her disclosur
- Recognizes Limited Role**
The counselors recognize that their imp participants do anything. They can, how for participants to openly discuss produ

- Active listening**
Active listening (or attending) refers to the counselor's ability to communicate listening through frequent and varied eye contact, facial expressions and other forms of non-verbal communication. This includes sitting in a relaxed posture, leaning forward occasionally, and using natural hand and arm movements that are responsive and encouraging. Counselors need also to be aware of non-verbal communications in the participant's demeanor, since non-verbal cues are important forms of communication.
- Open-ended questions**
Open-ended questions are those questions that are not easily answered with a one-word response ("yes" or "no") and do not assert the counselor's values or objectives. Counselors should use them when they are seeking information about the context in which product use occurs or when exploring attitude, culture, economic and/or social factors that may play a role in product use. Open-ended questions invite further disclosure and help to build rapport and trust. What the counselor asks and how it is asked can also demonstrate positive regard for the participant and a genuine interest in knowing how the participant feels. An example of a closed ended question would be: "Is it easy to insert your gel daily?" (Answer: Yes or No.) An open-ended approach would be: "What is your experience with inserting gel daily? What makes it easier . . . and what makes it more challenging?"
- Pausing**
Pausing provides opportunities for participants and counselors to digest material and to make room for feelings or thoughts to emerge. Giving the participant time to "experience the moment" by allowing silence to happen is a sign of respect for the power of the participant's thoughts and feelings. Sometimes counselor's discomfort with silence can interrupt the participant's process. Remember: *Silence is also a form of communication.*
- Paraphrasing**
Paraphrasing refers to rewording the content of what the participant has said in similar but fewer words. This can help the counselor clarify the basic message expressed in the verbal content of the participant's communication. Paraphrasing neither expands nor builds on the topic, but is a way to help the participant feel heard and build rapport. A participant may say that her brother-in-law is visiting and he's shifted much of the routine of the family. After her detailed explanation of how this occurs, the counselor 'paraphrases' with a short sentence. "Since he has moved in, things that were predictable each day are not predictable anymore." Note that paraphrasing does not try to reflect back the participant's exact words or expressions and is more like summarizing (each explained below) but on a smaller scale. It is a good practice with paraphrasing, or summarizing, to either pause (see below) for several seconds to allow for a reaction from the participant, or elicit (ask) the participant specifically if the paraphrase feels accurate "Am I understanding correctly?"
- Summarizing**
Summarizing refers to the technique of highlighting for the participant the most important aspects of the session that have been discussed. For the VASP, and other approaches drawing

4. Development of revised program

5. Adoption and implementation plan

- 1** Greet/Rapport;
- 2** Explain purpose; Seek permission
- 3** Explore product use experience; Discuss efforts on
- 4** Summarize
- 5** Explore needs for adherence; What would help?
- 6** Explore strategies; could increase adherence?
- 7** Agree on a goal
- 8** Summarize; Thank participant, Document

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 USE	
<input type="checkbox"/> 4. SUMMARIZE: The context (experiences) in which product feels easiest to use/hardest to use for this participant.	
<input type="checkbox"/> 5. IDENTIFY NEEDS: Help the participant to identify her specific adherence needs given the context explored. What does this participant feel she needs in order for adherence to be as manageable as possible? (Keep the focus on making use <i>easier</i> , rather than <i>perfect</i>).	
Adherence Related NEEDS:	

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"/> 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	
<p>SESSION: Summarize what was discussed; thank the participant for talking with you; document the session (after participant leaves the room).</p> <p>CONTEXT → ADHERENCE RELATED NEEDS → STRATEGIES → GOAL</p> <p>participant what you are writing if you write notes during the session**</p>	

5. Adoption and Implementation

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TRAINING APPROACH

One Day



Mixed Education and Practice



and lots and lots of practice...

5. Adoption and Implementation

IMPLEMENTATION SUPPORT APPROACH

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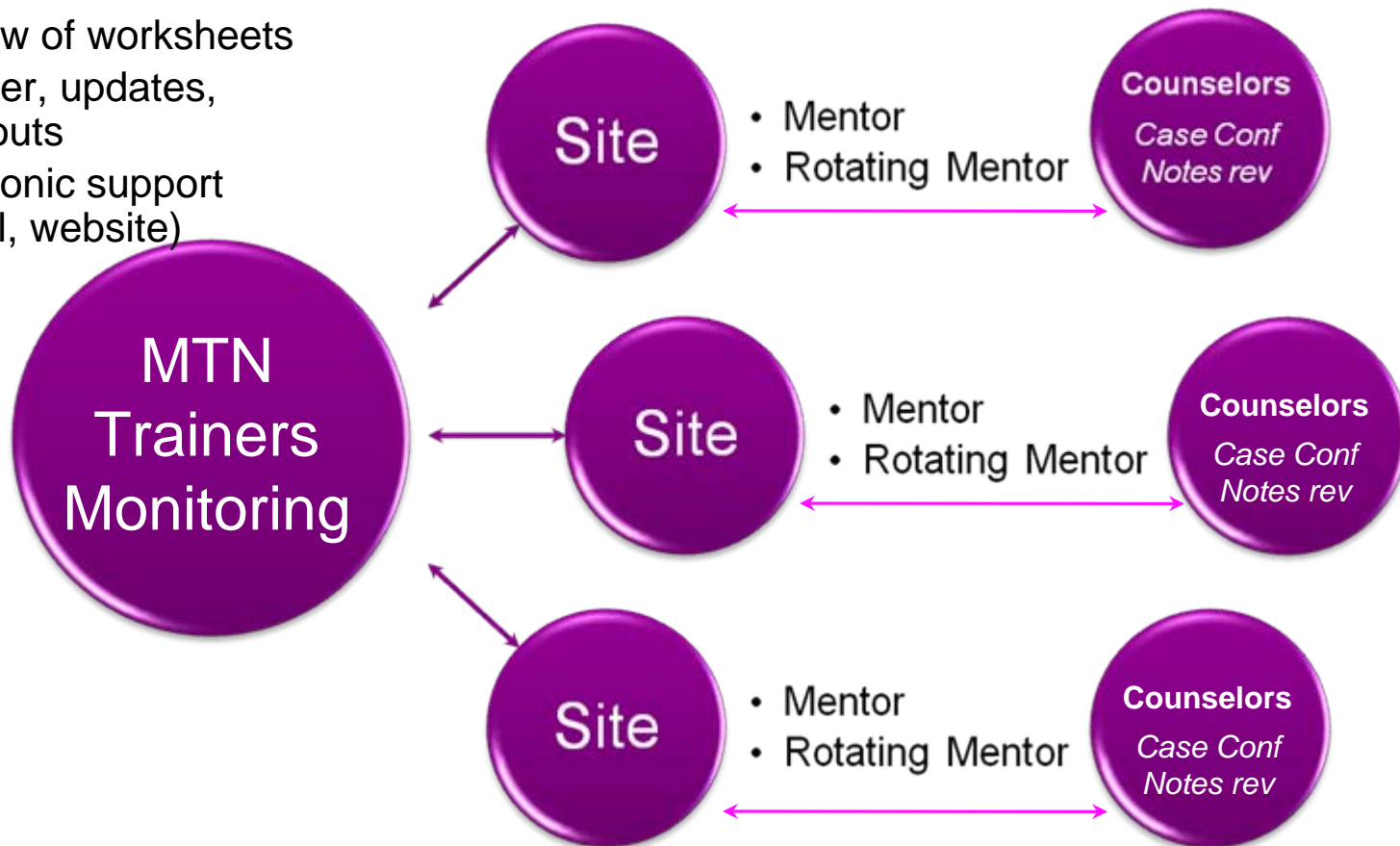
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5. Adoption and Implementation

IMPLEMENTATION SUPPORT APPROACH

- Mentors conference call
- Review of worksheets
- Booster, updates, handouts
- Electronic support (email, website)



5. Adoption and Implementation

FULL TEAM APPROACH



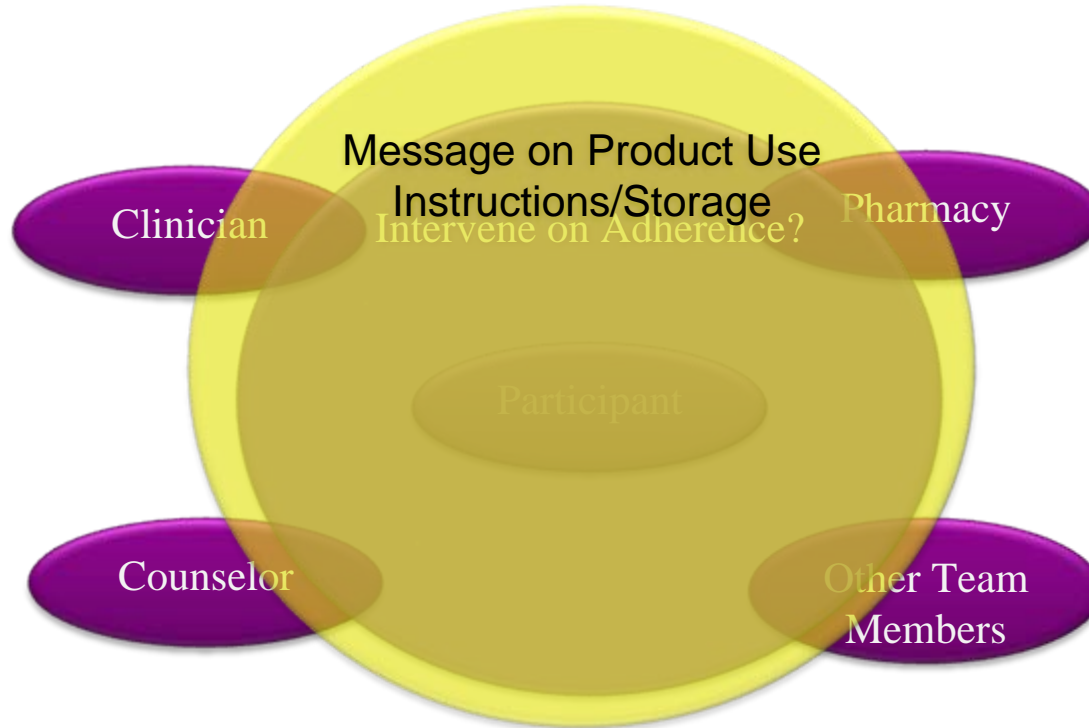
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FULL TEAM APPROACH



5. Adoption and Implementation

FULL TEAM APPROACH





□ Intervention mapping

■ Summary

- 1. Needs assessment
- 2. Identification of outcomes and change objectives
- 3. Selection of theory based methods and practical strategies
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□ Intervention mapping

■ Remaining pieces...

- 1. Needs assessment
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VOICE Adherence Counseling Monitoring & Evaluation (ACME)

*Developed and
implemented by the
Adherence Working Group*



2. Identification of outcomes and change objectives

OUTCOMES	CHANGES OBJECTIVES
<u>Acceptability/Feasibility</u>	<u>Promote high levels of adoption</u>
<u>Counselors/Pharmacists (IDIs, surveys)</u>	high approval rate & positive attitude
<u>VOICE-C participants (EI; IDIs, FGD)</u>	Increase level of engagement in VOICE Increase sense of contribution to VOICE
<u>Adherence</u>	<u>Increase rate of product use</u>
<u>Counselors/Pharmacists (IDIs, surveys)</u>	Perceived effectiveness of approach on increasing product use
BIOMARKERS: Plasma [oral arm] ?PBMC, vaginal swabs?, hair?	Increased drug levels
Product count, self-report (ACASI; CRF)	Increase reported adherence levels

6. ACME: Evaluation Plan

- Assessments with counseling team (ongoing):
 - Prior to VASP training (Feb-March 2011)
 - Post evaluation: planned for ~ Oct 2011
 - Quantitative component (anonymous survey)
 - Qualitative component (In-depth Interviews)
- VOICE-C participants' experience (ongoing)
- Adherence analysis (@ end of trial):
 - Compare plasma levels Pre/Post VASP
 - Compare Product Counts Pre/Post VASP
 - Self-reported adherence measures Pre/Post VASP

ACME: IDI interviews

- Pre-assessment completed
- 18 IDIs at 5 CTUs* (10 nurse-counselors and 8 counselors) to explore attitudes towards current counseling approach
 - 6 at UZ-UCSF
 - 2 at CAPRISA eThekweni
 - 7 at MRC
 - 2 at PHRU
 - 1 at RHRU
- Transcription and analysis in progress



ACME: Counseling Team Survey

- Pre-assessment ongoing (14-25 March)
- 15' anonymous web-based survey (30 items)
 - Perceived role as counselor
 - Stress/ Burnout
 - Experience/attitudes with counseling session
 - Perceived Counselor-Participant relationship
 - Perceived effectiveness of counseling approach
- Status: 80/120 completed as of 3/25/11

QUESTIONS

