VOICE Adherence Counseling

The Development of the VOICE Adherence Strengthening Program VASP

VOICE Adherence Working Group

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

Amico KR, Liu A, McMahan V, Anderson PL, Lama JR, Guanira J, Zheng JH, Goicochea P, Vargas L, Glidden D, Grant RM for the iPrEx investigators. *Adherence Indicators and Pre-exposure Prophylaxis (PrEP) Drug Levels in the iPrEx Study.* Presented at the 18th Conference on Retroviruses and Opportunistic Infections (CROI); February 27th – March 2nd, 2011; Boston Massachusetts, USA.

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%
      - >=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)	

Mansoor L. *Adherence Support Program- CAPRISA 004.* (2010, September). Invited presentation. Microbicide Trials Network. Washington DC, USA.

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

Bartholomew K, Parcel GS, Kok G, Gottleib NH: *Planning Health Promotion Programs: An intervention mapping approach*. San Francisco: Jossey-Bass; 2006.

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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	VASP
Uses product count from pharmacist in counseling session; reconciled product count and self-reported adherence.	Counselors will ***NOT*** review product count prior to counseling session or probe about discrepancies in product count vs. self report.
Asks participant how often she had been able to use the product and then based counseling on reported level of adherence.	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 is based on overcoming ***barriers*** to product use.	Adherence plan/strategies based on addressing adherence-related ***needs***.
Uses reported adherence to determine the focus of the session (i.e. page 2 of the counseling worksheet options).	All sessions will follow the same 8 steps, regardless of how much the participant has been using the study product.
Reinforcement of product use instructions (10 key messages) by the adherence counselor.	Product use instructions (10 key messages) will be reviewed by the pharmacist as needed.
Positive reinforcement of good adherence. Goals focus on perfect adherence.	Maintain a neutral counseling approach. Goals focused on making product use manageable.

4. Development of a revised program

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1	**WELCOME** Greet/Rapport; Thank participant; Check-in
2	**FRAME** Explain purpose of discussion; Seek permission to continue discussion.
3	**EXPLORE** Explore product use experiences (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

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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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?

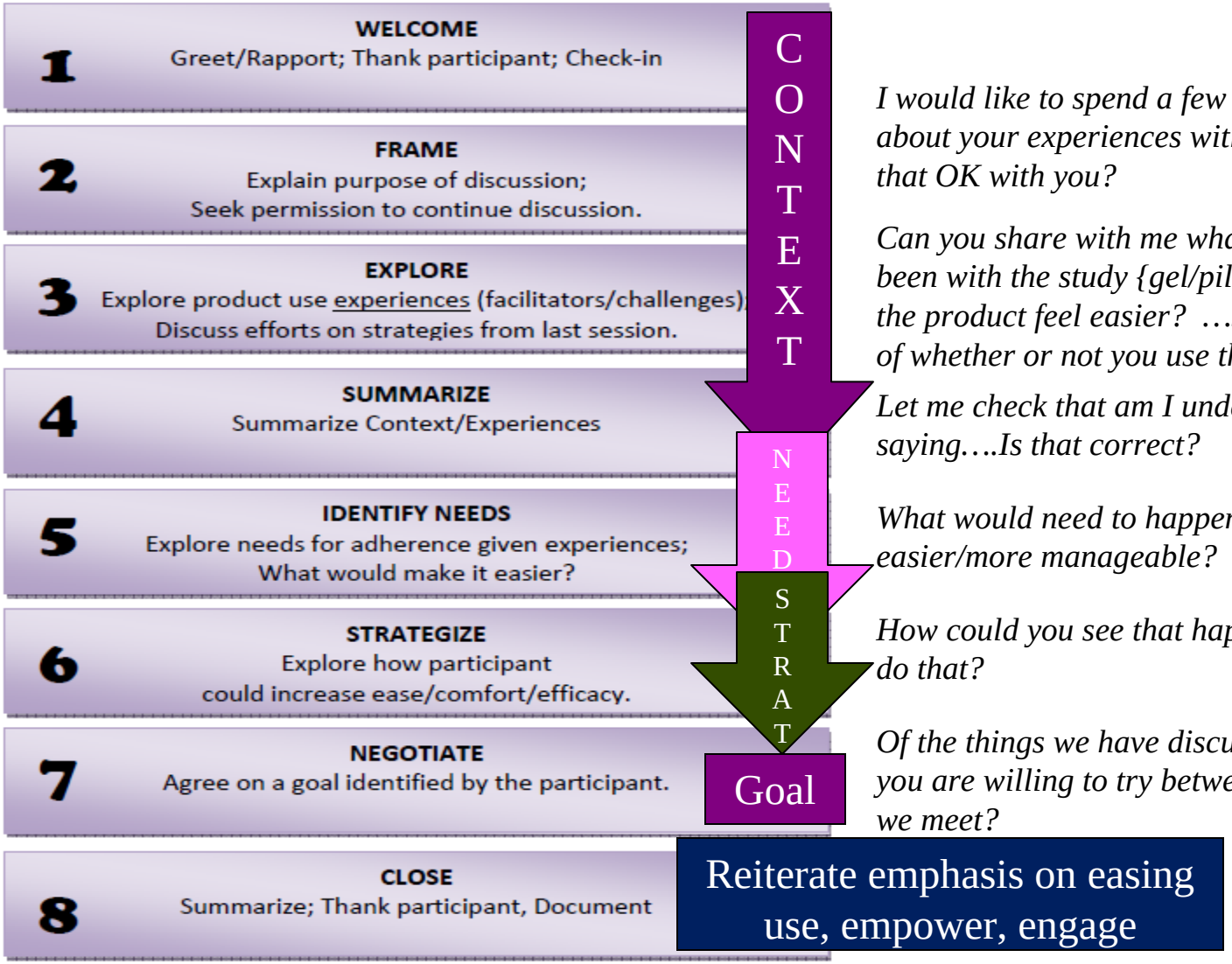
Let me check that am I understanding, I hear you saying….Is that correct?

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

How could you see that happing?...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



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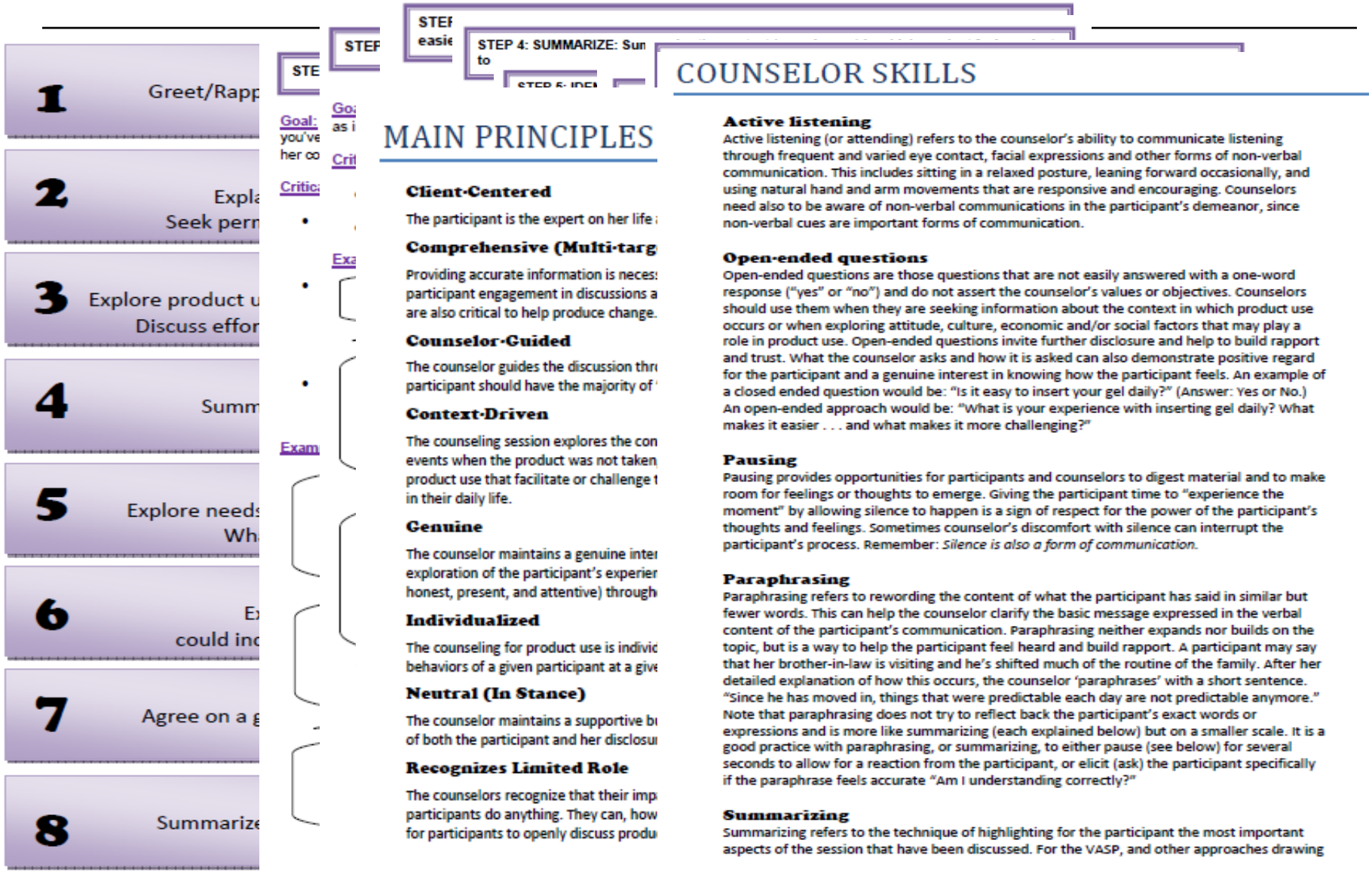
Reiterate emphasis on easing use, empower, engage

4. Development of revised program
5. Adoption and implementation plan



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Follow-up Adherence Counseling Worksheet

PTID:	Visit Code:

❒ 1. WELCOME: Greet and thank participant and establish rapport.

❒ 2. FRAME: Explain the purpose of discussion and seek permission.

❒ 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 now.

CONTEXT (EXPERIENCES)	
... made it feel easier...	*... made it seem difficult ...*

CONTEXT AROUND EXPERIENCES WITH PRODUCT: REGARDLESS OF ACTUAL PRODUCT USE

❒ 4. SUMMARIZE: The context (experiences) in which product feels easiest to use/hardest to use for this participant.

❒ 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 *easier*, rather than *perfect*).

Adherence Related NEEDS:

PTID: Visit Code:

❒ 6. STRATEGIZE: Explore new strategies or continued use of established ones to address the needs identified.

STRATEGIES:

NEGOTIATE: A goal that the participant identifies. Ask the participant what she might be g to try or continue to do between now and the next session (Goal).

GOAL

E SESSION: Summarize what was discussed; thank the participant for talking with uting to the study; document the session (after participant leaves the room).

CONTEXT → ADHERENCE RELATED NEEDS → STRATEGIES → GOAL

participant what you are writing if you write notes during the session**

5. Adoption and Implementation

1 **WELCOME**
Greet/Rapport; Thank participant; Check-in

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TRAINING APPROACH

One Day

Mixed Education and Practice

and lots and lots of practice…

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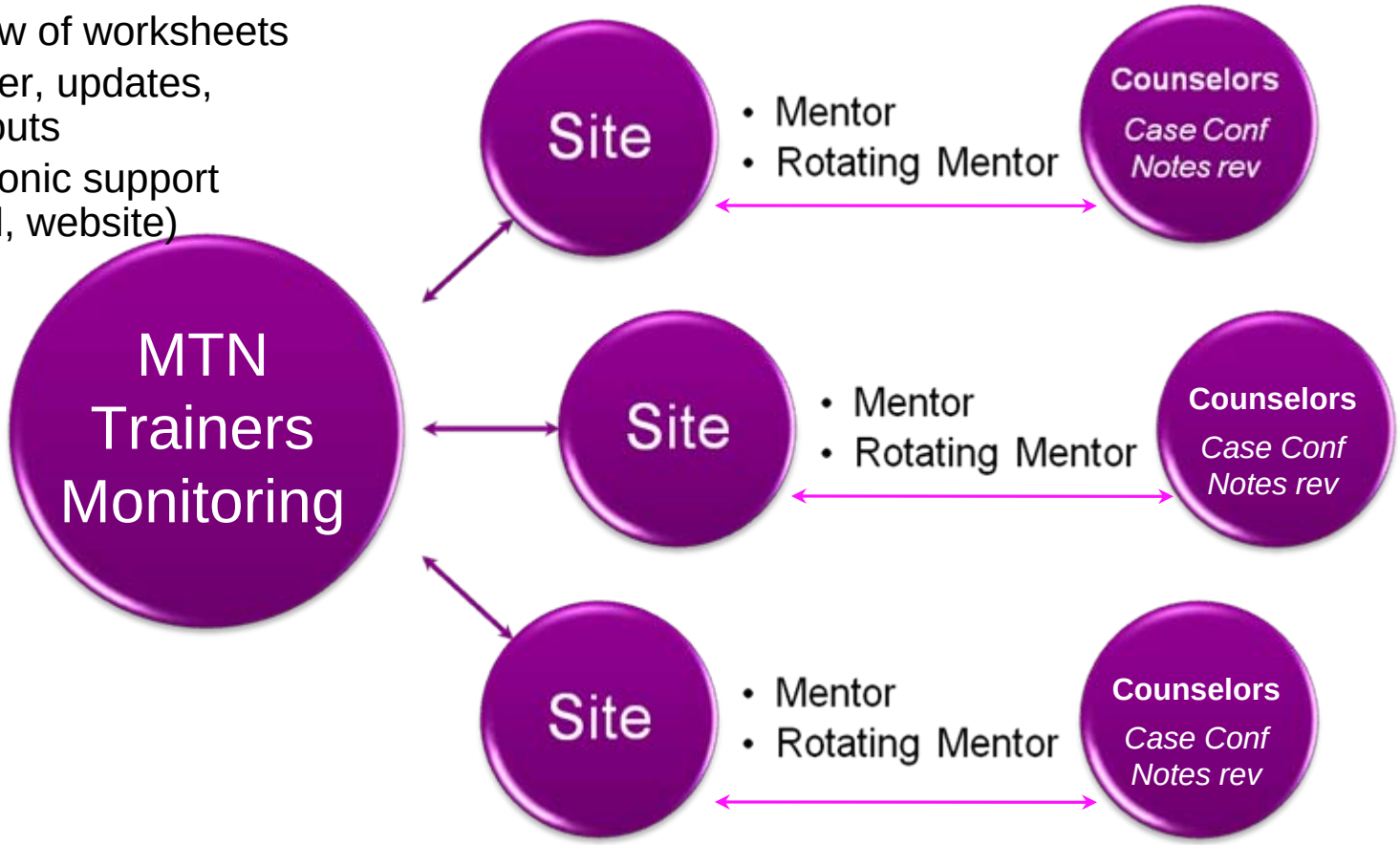
MPLEMENTATION SUPPORT APPROACH

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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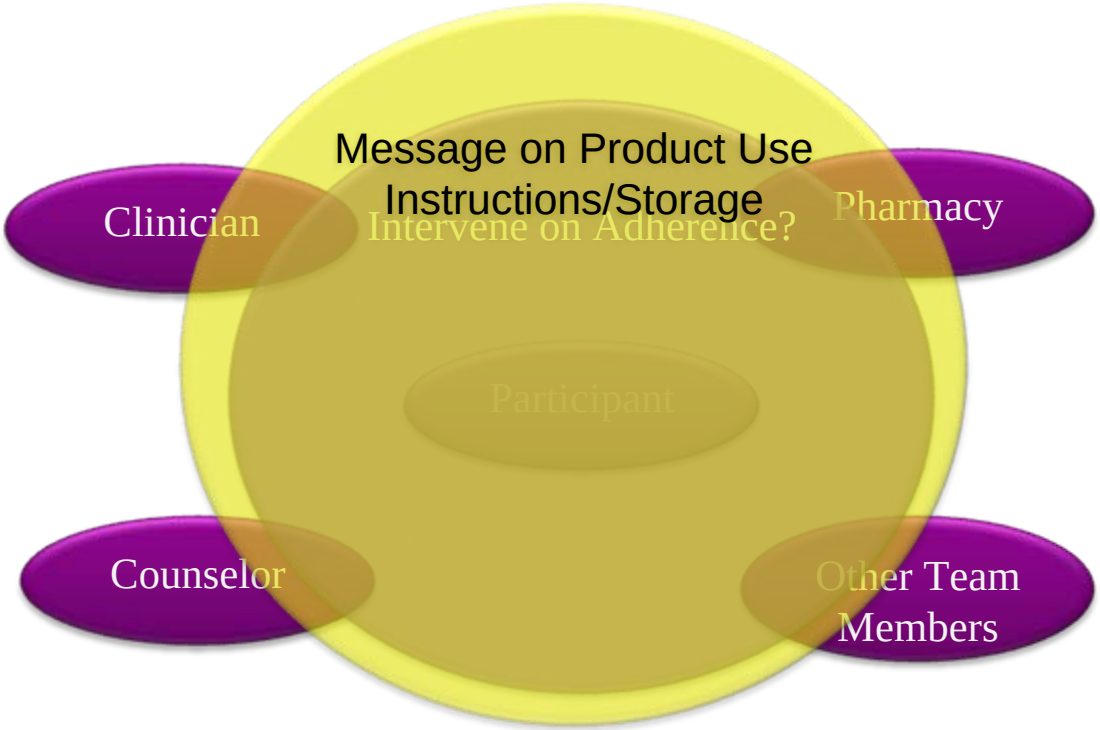

- Intervention mapping
  - Summary
    1. Needs assessment
    2. Identification of outcomes and change objectives
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VOICE Adherence Counseling Monitoring & Evaluation (ACME)

Developed and implemented by the Adherence Working Group

MTN
microbicide trials network

2. Identification of outcomes and change objectives

OUTCOMES	CHANGES OBJECTIVES
Acceptability/Feasibility	**Promote high levels of adoption**
Counselors/Pharmacists (IDIs, surveys)	high approval rate & positive attitude
VOICE-C participants (EI; IDIs, FGD)	Increase level of engagement in VOICE Increase sense of contribution to VOICE
Adherence	**Increase rate of product use**
Counselors/Pharmacists (IDIs, surveys)	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 eThekwini
  - 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