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

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%

- **iPrEx**
  - Overall end study effectiveness: 44%
    - >=90% Adherence 68%
    - 50-90% Adherence 34%
    - <50% Adherence 16%
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

<table>
<thead>
<tr>
<th></th>
<th>Adherence before MI % (N)</th>
<th>Adherence after MI % (N)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td><strong>High gel use (&gt;80%)</strong></td>
<td>29.9 (221)</td>
<td>42.3 (341)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Moderate gel use (50-80%)</strong></td>
<td>21.2 (157)</td>
<td>21.3 (172)</td>
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<tr>
<td><strong>Low gel use (&lt;50%)</strong></td>
<td>48.8 (361)</td>
<td>36.4 (294)</td>
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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

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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 Approach: VASP

Uses product count from pharmacist in counseling session; reconciles 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 has been able to use the product and then bases counseling on reported level of adherence.

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

Uses reported adherence to determine the focus of the session (i.e. product use experiences) on the counseling worksheet options.

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Positive reinforcement of good adherence.

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The same 8 steps, regardless of how much the participant has been using the product, and what makes using the product easier or harder, regardless of how much she used it.

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Maintains a neutral counseling approach. Goals are focused on making product use manageable.
4. Development of a revised program

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.
4. Development of a revised program

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

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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
4. Development of revised program

5. Adoption and implementation plan

**COUNSELOR SKILLS**

**MAIN PRINCIPLES**

**Client-Centered**
The participant is the expert on her life.

**Comprehensive (Multi-targ)**
Providing accurate information is necessary for participants in discussions as it can help to produce change.

**Counselor-Guided**
The counselor guides the discussion in a way that the participant should have the majority of the conversation.

**Context-Driven**
The counseling session explores events when the product was not taken into consideration.

**Active listening**
Active listening (or attending) refers to the counselor’s ability to communicate by listening through frequent and varied eye contact, facial expressions, and other non-verbal forms of 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 communication in the participant’s demeanor, since non-verbal cues are important forms of communication.

**Open-ended questions**
Open-ended questions are those 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 attitudes, 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 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 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 it 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.”

**Neutral (In Stance)**
The counselor maintains a supportive stance where he maintains their responsibilities and their involvement in open discussions.

**Recognizes Limited Role**
The counselors recognize that their impact on the session is minimal. They can, however, help participants to openly discuss their experiences.
4. Development of revised program
5. Adoption and implementation plan

Follow-up Adherence Counseling Worksheet

1. Greet/Rapport;
2. Explain purpose; Seek permission;
3. Explore product use experience; Discuss efforts on product use;
4. Summarize;
5. Explore needs for other product use;
6. Explore what could increase adherence;
7. Agree on a goal in product use;
8. Summarize; Thank participant, Document.
## 5. Adoption and Implementation

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

### TRAINING APPROACH

**One Day**

- Mixed Education and Practice

and lots and lots of practice…
5. Adoption and Implementation

**IMPLEMENTATION SUPPORT APPROACH**

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
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**

- Message on need for adherence
- Message on Product Use
- Instructions/Storage
- Intervene on Adherence?
- Pharmacy
- Participant
- Counselor
- Other Team Members
- Clinician
5. Adoption and Implementation

FULL TEAM APPROACH

- Message on need for adherence
- Message on Product Use
- Instructions/Storage
- Intervene on Adherence?
- Participant
- Clinician
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- Other Team Members
5. Adoption and Implementation

**FULL TEAM APPROACH**

- Clinician
- Pharmacy
- Counselor
- Other Team Members

- Intervene on Adherence?
- Message on Product Use
- Instructions/Storage

Participant
Intervention mapping

Summary

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
 Intervention mapping

- Remaining pieces...
  - 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
VOICE Adherence Counseling Monitoring & Evaluation (ACME)

Developed and implemented by the Adherence Working Group
## 2. Identification of outcomes and change objectives

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