# Implementation of Evidence-Based Counseling Interventions in Biomedical HIV Prevention Studies

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Behavioral Working Group

Columbia University

# Overview of Presentation

- Why? (Ivan)
- How? (Rebecca)
- Raters' Experience

# The Ring

**Product**

- Silicone matrix polimer
- Flexible
- No sharp edges
- Slow Release

**Active Ingredient**

- 25 mg Dapivirine

**RCT:** QA processes ensure that one group receives a defect-free product with active ingredient while the other uses a placebo or other condition

# Behavioral Interventions

**Product**

- Counselor
- Counseling Interaction
- Estimated duration

**Active Ingredient**

- Cog-Beh Therapy
- Behavioral Therapy
- Motivational Interviewing
- etc

**RCT:** Fidelity processes ensure that one group receives the product as designed, and with active ingredient, while the other receives delayed treatment or other condition

# Sustaining Treatment Fidelity in Studies

(Bellg, et al., for NIH Behavior Change Consortium, 2004)

- Design of Study
  - Consistency within and across intervention conditions
- Monitoring and Improving Provider Training
  - Consistency in training and ongoing assessment for decay of skills
- Monitoring and Improving Delivery of Intervention
  - Consistency in the way the intervention is delivered
- Monitoring and Improving Receipt of Intervention
  - Ensure that participants understand and can do what is included in intervention
- Enactment of Intervention Skills
  - Ensure that participants use skills they received in intervention

# Implementation

The integration of evidence-based interventions into practice settings

Limited Resources

Must retain the active ingredient of the intervention

# Learning new interventions

(Herschell, et al., 2010)

- **Treatment Manuals and Written Materials**
  - Reading treatment manuals and materials may be necessary, but not sufficient, for skill acquisition and adoption of a psychosocial treatment

(e.g., Dimeff et al., 2009; Ducharme & Feldman, 1992; Kelly et al., 2000; Rubel, Sobell, & Miller, 2000)

- **Self-Directed Training (online)**
  - Rated favorably by learners; cost effective

(e.g., Worrall & Fruzzetti, 2009; National Crime Victims Research & Treatment Center, 2007; Sholomskas et al., 2005)

  - Works only for some therapists and was only slightly more effective than reading written materials at improving knowledge

(e.g., Suda & Miltenberger, 1993; Miller et al., 2004; Sholomskas et al., 2005)

# Learning new interventions-continued

- **Workshops**
  - Often resulted in increased knowledge, but not significant changes in attitude, application of knowledge, or clinical skills when assessed by behavioral observation

    (Anderson & Youngson, 1990; Byington et al., 1997; Freeman & Morris, 1999; McVey et al., 2005; Rubel et al., 2000)
  - In studies that found initial improvements in therapist skills after a workshop, skills decreased by follow-up to show no difference from the untrained group.

    (Miller, et al., 2004; Moyers, et al., 2008; Chagnon, et al., 2007; Baer, et al., 2009).
- **Additional Components**
  - active, behaviorally-oriented training techniques (e.g., feedback, behavioral rehearsal/role-play, coaching) were found to be effective in improving adoption of the intervention, particularly when used in combination (Miller et al., 2004; Kelly et al., 2000).
  - Others found no additional benefit to providing feedback and up to six consultation calls after providers had participated in a two-day workshop (Moyers, et al., 2008).

# MTN-017

√ Fidelity Criteria Met

● Fidelity Criteria Not Met

— Switched roles in study

| | PRACTICE | | | | | STUDY VISIT | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 1 | √ | √ | | | | √ | √ | √ | √ | ● | ● | ● | ● | ● | √ |
| 2 | √ | √ | | | | ● | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| 3 | √ | √ | | | | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| 4 | √ | √ | | | | — | — | — | — | — | — | — | — | — | — |
| 5 | ● | ● | ● | ● | √ | — | — | — | — | — | — | — | — | — | — |
| 6 | √ | ● | | | | — | — | — | — | — | — | — | — | — | — |
| 7 | ● | √ | | | | √ | ● | √ | ● | √ | √ | √ | √ | √ | √ |
| 8 | ● | ● | ● | √ | | ● | ● | √ | ● | ● | ● | ● | ● | ● | ● |
| 9 | ● | ● | √ | | | √ | √ | √ | √ | √ | √ | ● | √ | √ | ● |
| 10 | √ | ● | | | | ● | ● | ● | √ | ● | √ | √ | ● | ● | ● |
| 11 | √ | √ | | | | — | — | — | — | — | — | — | — | — | — |
| 12 | √ | √ | | | | √ | √ | √ | ● | √ | √ | √ | √ | ● | √ |
| 13 | √ | √ | | | | √ | ● | ● | ● | √ | √ | √ | ● | ● | ● |
| 14 | √ | √ | | | | √ | √ | √ | √ | √ | √ | √ | ● | √ | √ |
| 15 | √ | √ | | | | ● | √ | √ | √ | √ | √ | √ | √ | √ | √ |
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| 17 | √ | √ | | | | √ | √ | √ | — | — | — | — | — | — | — |
| 18 | √ | √ | | | | √ | √ | √ | √ | √ | √ | √ | √ | ● | — |
| 19 | ● | √ | | | | √ | ● | ● | √ | √ | √ | √ | √ | ● | √ |
| 20 | √ | ● | | | | √ | √ | √ | ● | √ | √ | √ | √ | √ | √ |
| 21 | √ | √ | | | | √ | √ | √ | √ | ● | √ | √ | — | — | — |
| 22 | √ | √ | | | | √ | √ | √ | √ | ● | √ | ● | ● | ● | ● |
| 23 | √ | ● | | | | √ | √ | ● | ● | ● | √ | ● | ● | ● | ● |
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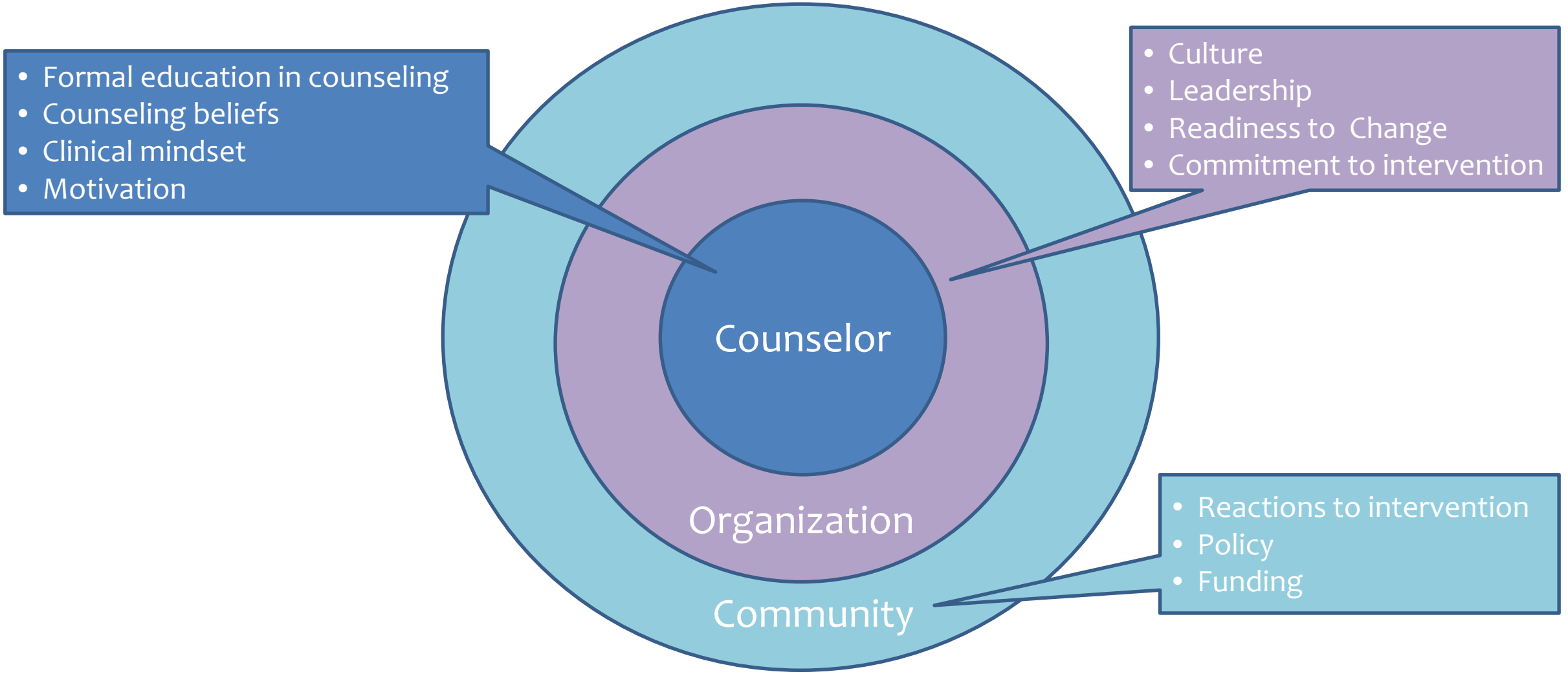
| 25 | √ | √ | | | | ● | √ | ● | ● | ● | √ | ● | ● | ● | ● |

- 25 counselors trained, post-training
  - 58% met criteria in both sessions
  - 27% in one session
  - 15% in neither session.
- 18 counselors who completed ten visits
  - 44% met criteria on ≥80% of sessions
  - 50% met criteria on ≤50% of sessions
  - Fidelity ratings fluctuated over time
- 64% of the 199 study sessions reviewed met fidelity criteria.

# Implementation is complex



# Why monitor fidelity?

- Not all counseling approaches are equally effective
  - We owe it to our participants, communities, and funders to provide the most effective counseling possible
- Difficult to adopt new counseling approaches
  - Monitoring and coaching allow for ongoing skills development
- Careful monitoring and feedback allow us to assess how counselors and participants respond to the interventions
  - Allows for subtle adaptations to better tailor to community


# The Session Ratings Process

Rebecca Giguere, MPH

# Development of Materials: Ratings Forms

## MTN - 025 Participant Centered Counseling Ratings Form: Follow-up Visit

Counselor: PTID: Site: Date of Session: Visit #:

Date of Review: Reviewer: Duration:

**FOLLOW-UP VISIT**

*Please make a note if a session task was covered out of order, at a different point in the session.*

| | |
|---|---|
| 1. Welcome participant and set structure for session<br>☐ Welcomes or greets ppt OR mentions that the visit will now shift to the counseling portion of the visit<br>☐ Affirms ppt's attendance<br>☐ Informs ppt of what will occur during session<br>☐ Normalizes difficulties with implementing HIV prevention approach<br>*Notes:* | ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 |
| 2. Present information on drug level results (DO THIS SECTION ONLY FOR PARTICIPANTS WHO CHOSE THE RING)<br>☐ Asks permission to share information about Ring drug levels<br>☐ Clearly explains meaning of drug levels in the Ring in terms of level of HIV protection<br>☐ Asks for participant's feedback after sharing information<br>*Notes:* | ☐ ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 NA |

# Development of Materials: Ratings Forms

**Global Ratings:**

| | |
|---|---|
| Collaboration<br>➢ Degree to which counselor sees ppt as an equal partner, working together to develop an HIV prevention plan | ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 |
| Respectful<br>➢ Degree to which counselor clearly acknowledges the ppt's right to make decisions about their choice of HIV prevention approach and how to implement it and asks permission before giving info or advice | ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 |
| Evocative<br>➢ Level of curiosity about the ppt's interest and plan to use the HIV prevention approach chosen; counselor speaks less than ppt and uses open questions to invite discussion | ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 |
| Direction<br>➢ Degree to which session focuses on the goals as stated in the manual, without a lot of discussion unrelated to HIV prevention | ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 |
| Empathy<br>➢ Degree to which the counselor demonstrates interest in ppt's perspectives and understands her experiences, reflecting what ppt says | ☐ ☐ ☐ ☐ ☐<br>1 2 3 4 5 |
| | **GLOBAL MEAN:** |

# Development of Materials: Fidelity Ratings Guide

**2. Present information on drug level results (DO THIS SECTION ONLY FOR PARTICIPANTS WHO CHOSE THE RING) (Slide 23)**

1. Not done

2. The counselor briefly presents the information on drug level results, but does not explain what the results mean or ask the participant for her thoughts about them.

3. Counselor briefly explains the information on the residual drug level results and what they mean but does not link level of use to level of protection, and does not ask the participant for her thoughts about this.

4. Counselor gives a brief explanation of what the residual drug level results mean in terms of HIV protection, and asks the participant for her thoughts about them.

5. Counselor gives a clear and detailed explanation of how the amount of drug released affects protection level. The information is presented in a neutral manner, making it clear to the participant that it is not about her use of the Ring. She asks for the participant's thoughts about this information with an open-ended question.

# Development of Materials: Fidelity Ratings Guide

**Collaboration: This is the degree to which the counselor sees the participant as an equal partner in the session, working together to develop an HIV prevention plan (whether or not that includes use of the Ring).**

1. Counselor actively assumes the expert role for the majority of the interaction with the client. Collaboration is absent. What you might hear in these kinds of sessions is a lot of "something you should do…" or "something you can do…" without getting permission to share information/advice beforehand.

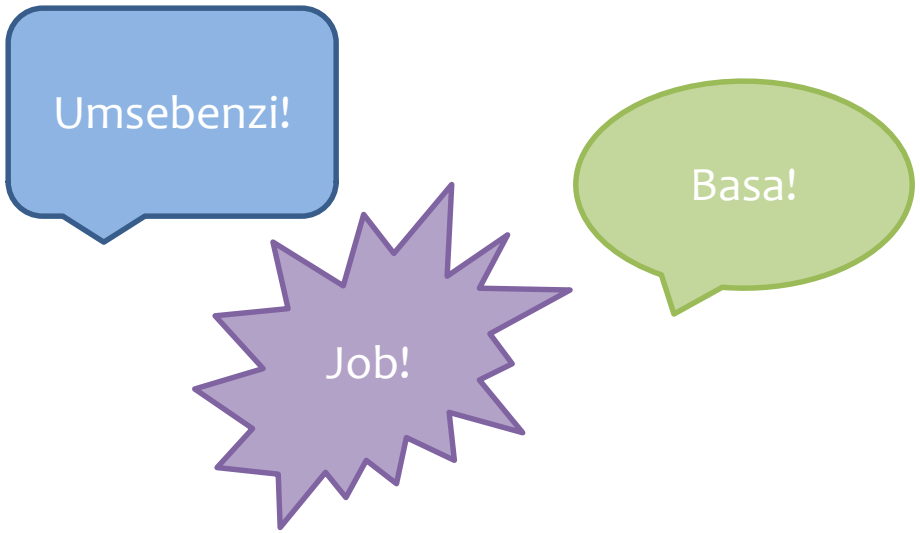
2. Counselor responds to opportunities to collaborate superficially. So, they might say that a participant's idea is good, but may then offer other suggestions, not really paying attention to what the participant said.

3. Counselor incorporates participant's ideas, but does so in a so-so manner, not inquiring further. For example, if they have used the Ring regularly in the past, the counselor may not recognize that as an opportunity to explore how the participant has done that and how that can apply to this study. What you will hear is more of a question and answer interaction than a counselor who is really interested in getting the active participation of the participant.

4. Counselor actively tries to create a collaboration and get the participant's ideas on all aspects of the session so that the session becomes a mutual conversation.

5. Counselor actively works to create and encourage an interaction where the participant's ideas and contributions to the discussions lead the session. What you will hear in this type of session is the counselor guiding the discussion and asking questions that help the participant think through the plan, but it's really the participant who comes up with the plan. For this rating, the counselor really makes the participant the expert in the interaction, with the counselor there to assist if necessary.

# Hiring the Rating Team




- Advertisements placed on online job search websites
- Job announcement sent to African student organizations, embassies, UN missions
- Word-of-mouth

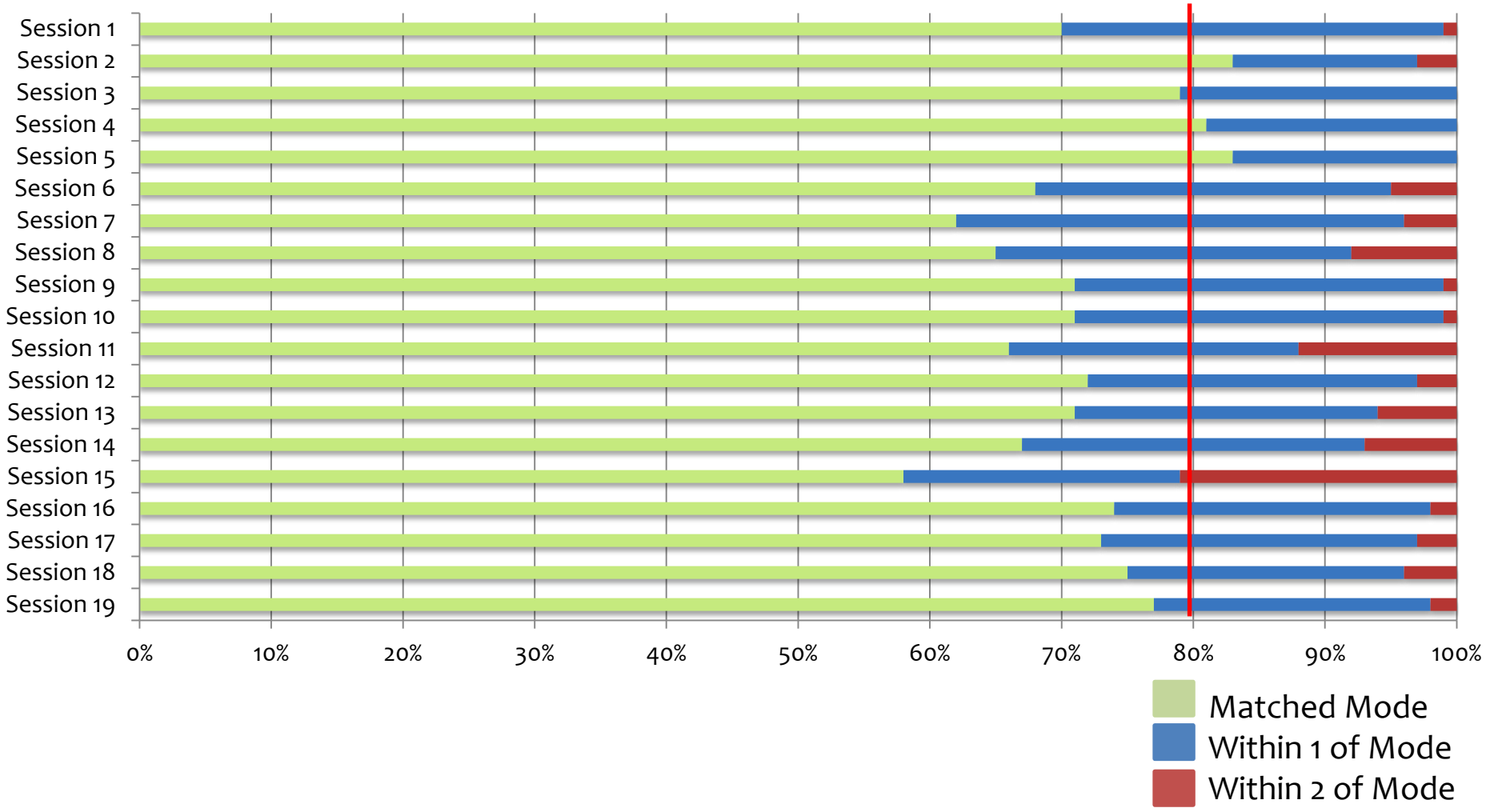
# Training the Rating Team

- Two initial training sessions
  - Client-centered counseling concepts
  - HOPE Study counseling tasks
  - Fidelity Rating Guide/Forms
  - Interrater Reliability
- Three enrollment sessions rated
  - Rated independently
  - Group discussion
- Two follow-up sessions rated
  - Rated independently
  - Group discussion

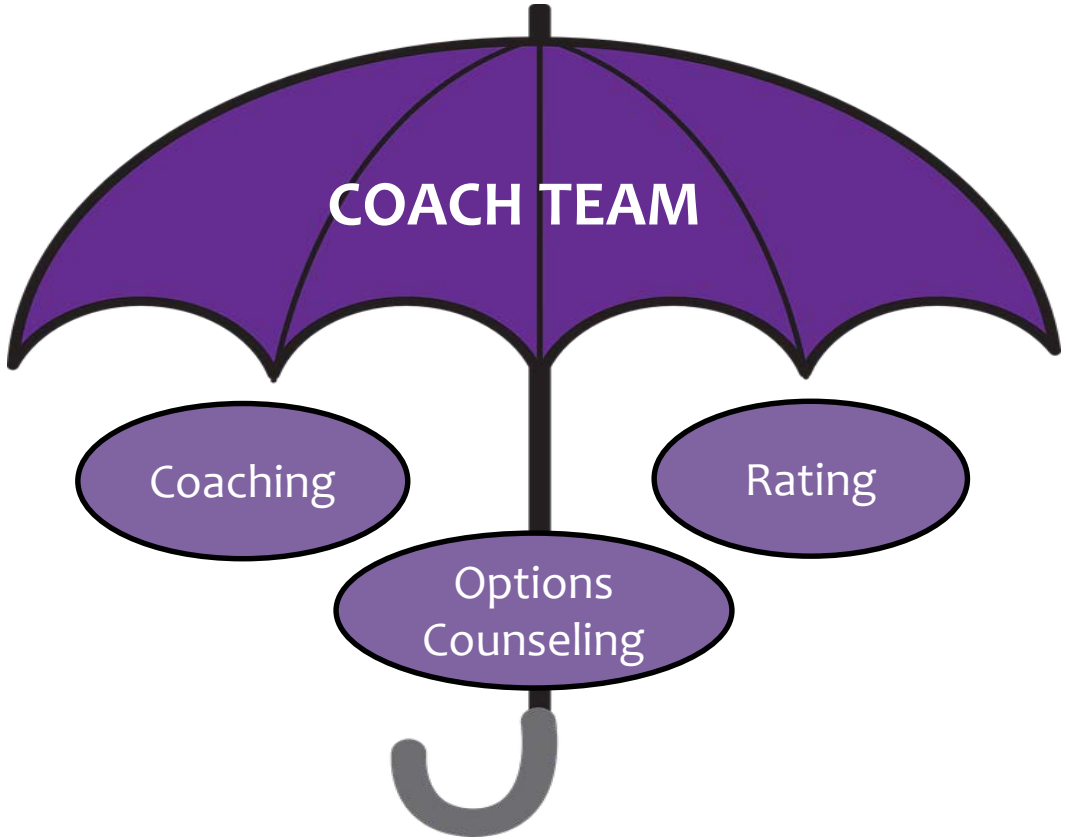
# Assessing Interrater Reliability

| Reviewer | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | Mean | Coll | Resp | Evoc | Dire | Emp | Mean |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A | 5 | 4 | 5 | 5 | 5 | 5 | 4 | 5 | 5 | NA | 5 | 4.80 | 5 | 5 | 4 | 5 | 5 | 4.8 |
| B | 5 | 3 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | N/A | 4 | 4.50 | 4 | 5 | 4 | 5 | 4 | 4.4 |
| C | 5 | 5 | 5 | 4 | 5 | 4 | 3 | 5 | 3 | N/A | 3 | 4.20 | 4 | 4 | 3 | 5 | 4 | 4.0 |
| D | 5 | 4 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | N/A | 4 | 4.60 | 5 | 4 | 4 | 5 | 5 | 4.6 |
| E | 5 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | N/A | 4 | 4.70 | 4 | 4 | 4 | 5 | 4 | 4.2 |
| F | 5 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 4 | NA | 4 | 4.60 | 4 | 4 | 4 | 5 | 5 | 4.4 |
| G | 5 | 5 | 5 | 5 | 4 | 1 | 4 | 5 | 5 | N/A | 4 | 4.30 | 4 | 4 | 5 | 5 | 5 | 4.6 |
| H | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | N/A | 5 | 5.00 | 4 | 5 | 5 | 5 | 5 | 4.8 |
| | | | | | | | | | | | | | | | | | | |
| | 5 | 5 | 5 | 4 | 5 | 5 | 4 | 5 | 5 | | 4 | | 4 | 4 | 4 | 5 | 5 | |
| | 8 | 5 | 8 | 4 | 7 | 6 | 6 | 8 | 6 | | 5 | | 6 | 5 | 5 | 8 | 5 | |
| | 100% | 63% | 100% | 50% | 88% | 75% | 75% | 100% | 75% | NA | 100% | N/A | 75% | 63% | 63% | 100% | 63% | |
| | 800% | 700% | 800% | 800% | 800% | 700% | 800% | 800% | 700% | | 800% | | 800% | 800% | 800% | 800% | 800% | |
| | 100% | 88% | 100% | 100% | 100% | 88% | 100% | 100% | 88% | NA | 100% | N/A | 100% | 100% | 100% | 100% | 100% | |

# Interrater Reliability

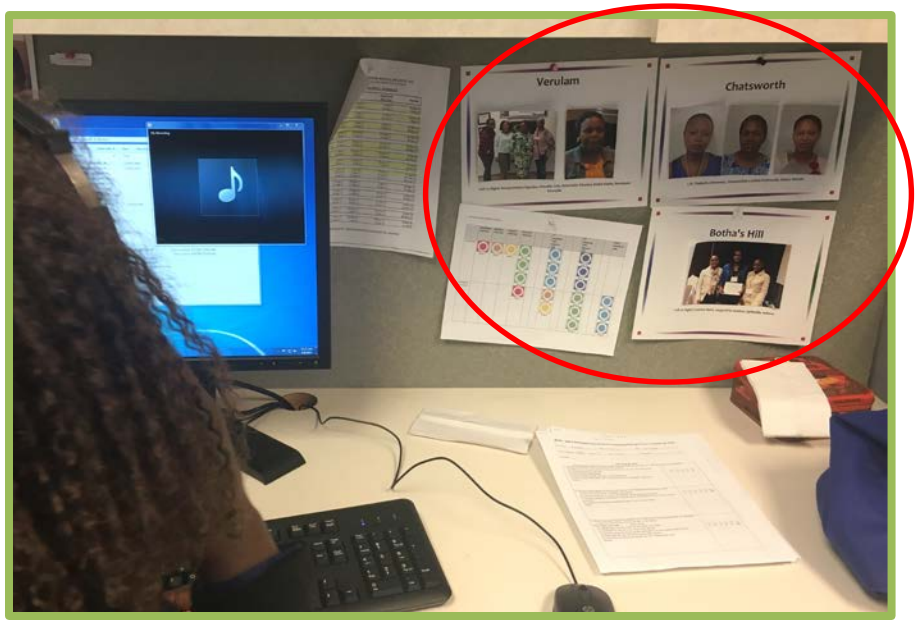


# Counselling to Optimize Adherence, Choice and Honest Reporting

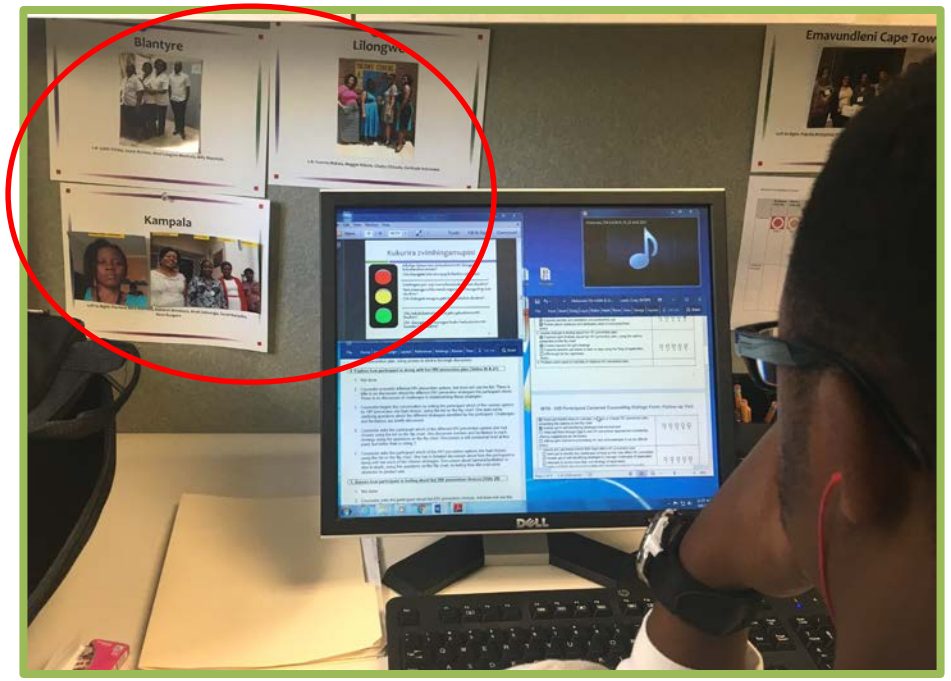



GOAL:
To create a client-centered team that fully supports the counselors' delivery of the COACH Options Counseling Intervention

# Becoming a client-centered team




Raters' work space at Columbia University with photos of counselors



# Becoming a client-centered team

## COACH Team Newsletter

*Counselling to Optimize Adherence, Choice, and Honest Reporting*

*December 2016*

**In this issue:**

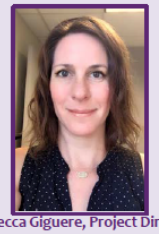
- An introduction from Ivan
- Meet the COACH session raters
- "What else would you like to discuss about the Ring or the other HIV prevention approaches you selected?"
- Link to the demonstration videos

Hello COACH Team!!

I am very excited to share with you our first COACH Team Newsletter. We plan on sending a newsletter to you each month with information and updates that are important to our COACH Team. We will also use the newsletter to highlight some key aspects of the counseling sessions that emerge as we review sessions for all of the sites.

I am also very excited about introducing you to my team here in New York. You have heard me speak about them during our time together in Durban and Cape Town as well as during our calls. But it is always nice to put a face to a name and to learn something about them. You may remember that in Durban, I took pictures of the teams from the different sites. We plan to print those pictures and display them on a board in the HOPE team office! So, although we may be separated by an ocean, we are all one team, working together to help women remain HIV negative!

### *Meet the COACH Session Raters!*



**Rebecca Giguere, Project Director**
**English Session Rater**

Grew up in Chapel Hill, North Carolina. Holds a Master's degree in Public Health. Currently, a Project Director at the HIV Center, with 8 years of experience on several MTN studies including MTN-017 (rectal tenofovir gel with MSM) and MTN-027 (vaginal ring with young women in the US). Responsible for training and supervising the US-based rating team.

**Lonely Kachenjera**
**Chichewa Session Rater**

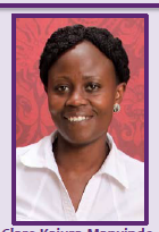
From Zomba, Malawi. Holds a Bacherlor's degree in Mathematical Sciences Education, majoring in Statistics, from the University of Malawi, Polytechnic. Currently, pursuing a Master's degree in Pure Mathematics and Lehman College, City University of New York.

**McLoddy Kadyamusuma**
**Shona Session Rater**

Born in Harare, Zimbabwe, lived in Chitungwiza until the age of 23, when he left Zimbabwe. Earned a Ph.D. in Linguistics at the University of Potsdam in Germany. Currently an assistant professor at the State University of New York at Fredonia.



COACH Team Newsletter



**Clare Kajura-Manyindo**
**Luganda Session Rater**

Born in Wakiso, Uganda, with family in Entebbe, Kampala, and Fort Portal. Attended Makerere University for a Bachelor's Degree in Education and Bishop Magambo Counselor Training Institute for a Diploma in Counseling, and Mercy College, NY for a Master's in Counseling. Prior to moving to NY, she taught high school, was a counselor, and facilitated counseling trainings for service providers working with HIV patients. Currently teaches Psychology.

**Cody Lentz, Project Coordinator**
**English Session Rater**

From New Oxford, Pennsylvania. Completed a Bachelor's degree in Psychology at Fordham College in New York. Currently, a Research Coordinator at the HIV Center for Clinical and Behavioral Studies, coordinating all audio files and preparing them for rating, in addition to rating session in English.

**Zanele Ndlovu-Ford**
**Zulu Session Rater**

Born and raised in Esikhawini, Kwa-Zulu Natal, South Africa. Lived in Lamontville for two years after graduating from high school and in Johannesburg for three years before moving to the US in 1997. Attended the university at Medgar Evers College in New York, with a degree in Computer Science. Currently works as a translator, translating scripts between English and Zulu.

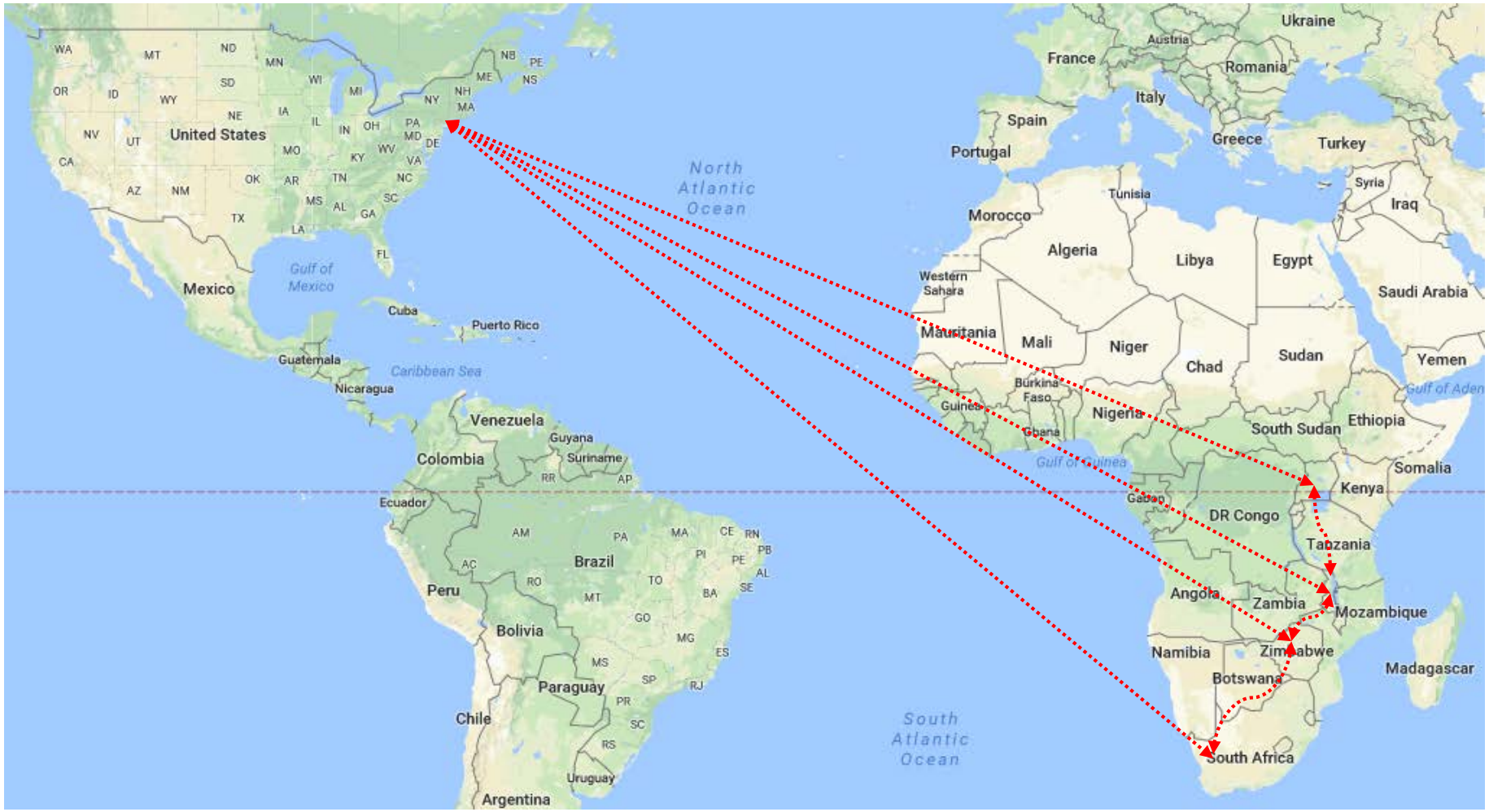
**Christine Rael**
**English Session Rater**

Originally from Rochester, New York. Holds a Ph.D. in Health and Behavioral Science from the University of Colorado at Denver. Currently, a post-doctoral fellow at the HIV Center for Clinical & Behavioral Studies, where her work focuses on expanding access to HIV prevention and care via mobile technology for stigmatized populations.

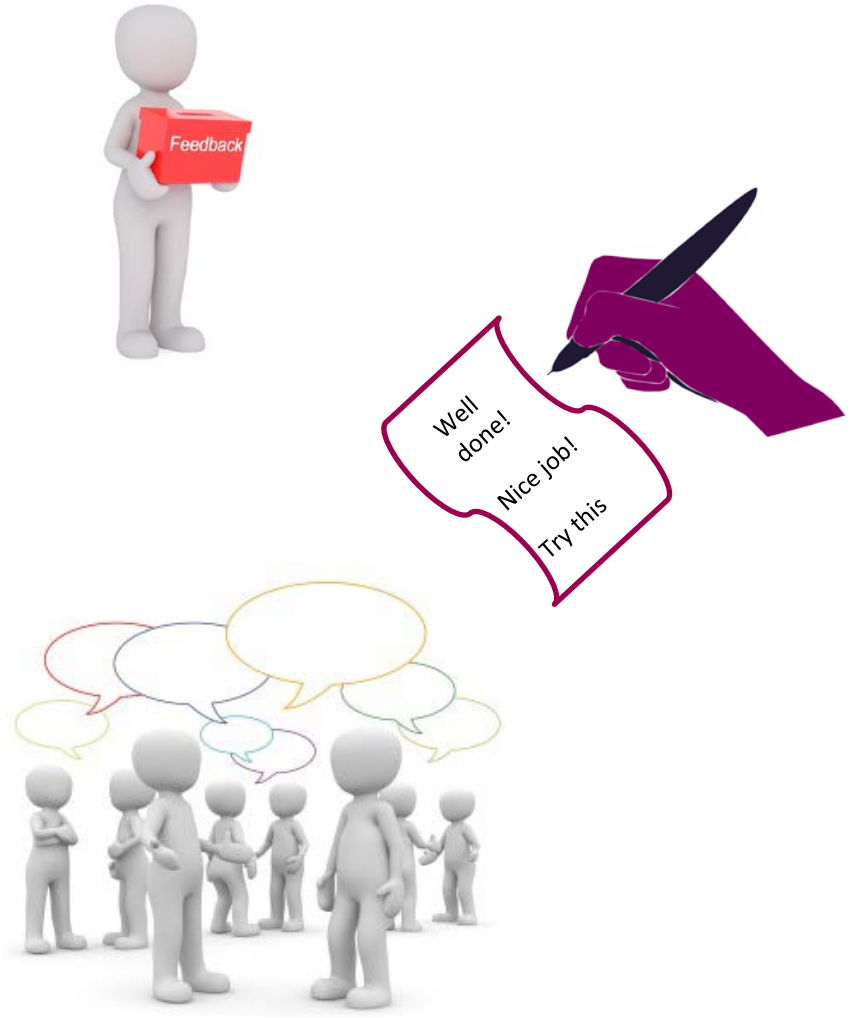
**NoCamagu Tuswa-Haynes**
**Xhosa Session Rater**

Born and raised in Umtata, Eastern Cape, South Africa. Moved to the US in 1981. Earned a degree in Pharmacy and currently works as a community pharmacist, specializing in public health, harm reduction, & HIV prevention.

# Becoming a client-centered team



# Becoming a client-centered rater




- Getting feedback on IRR sessions
- Including client-centered comments on ratings forms
- In-person feedback from counselors

# Next generation of raters

# Acknowledgements


- MTN-025 Counselors, raters, and protocol team
- MTN-025 Leadership: Jared Baeten, Nyaradzo Mgodi, Thesla Palanee
- MTN Leadership: Sharon Hillier & Jared Baeten
- The Microbicide Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the *Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health.*


# Thank you! Zikomo kwambiri!
# Webale! Mazviita!
# Enkosi! Ngiyabonga!

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