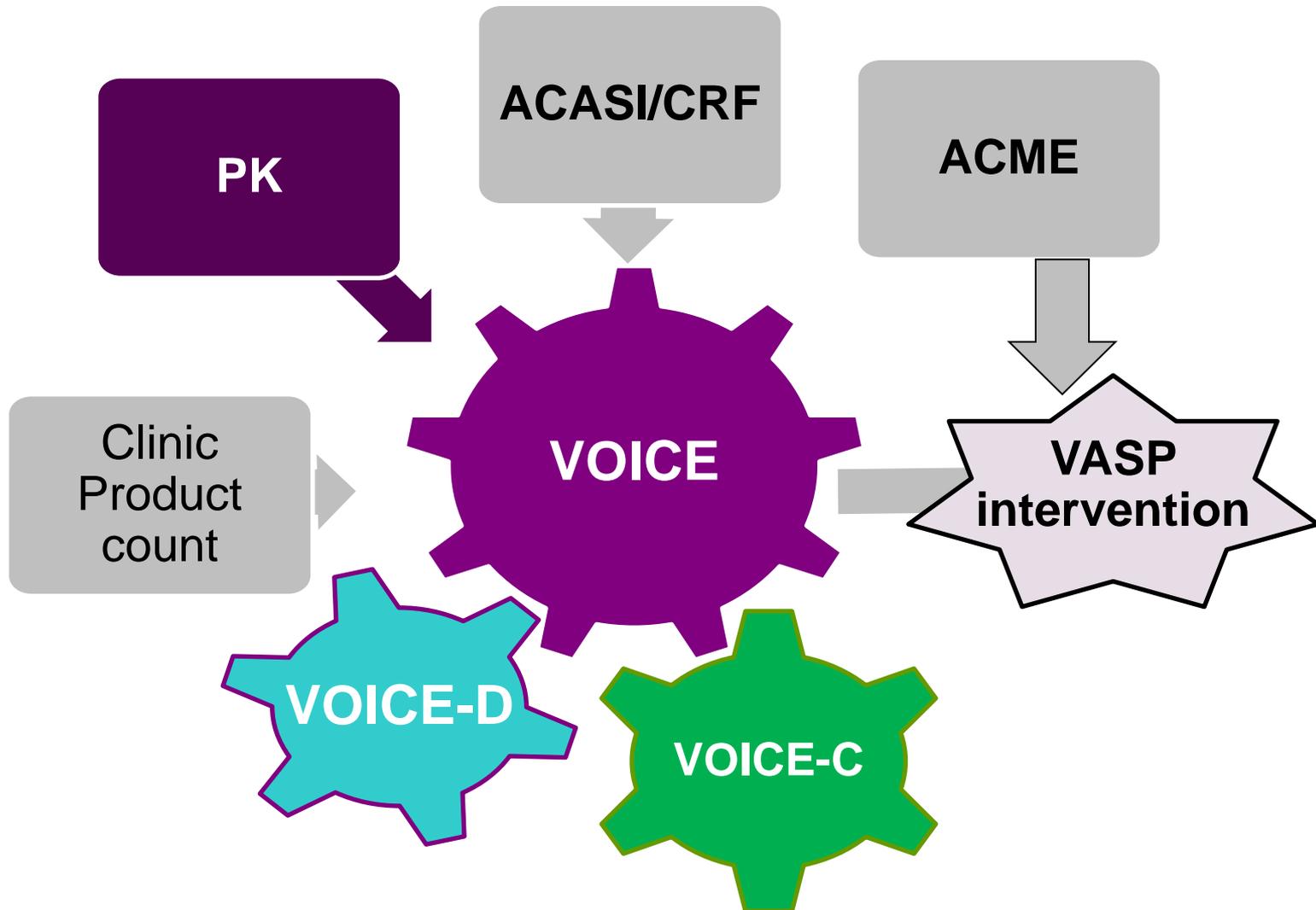


Understanding (non-) adherence: VOICE-C & -D Ancillary Studies

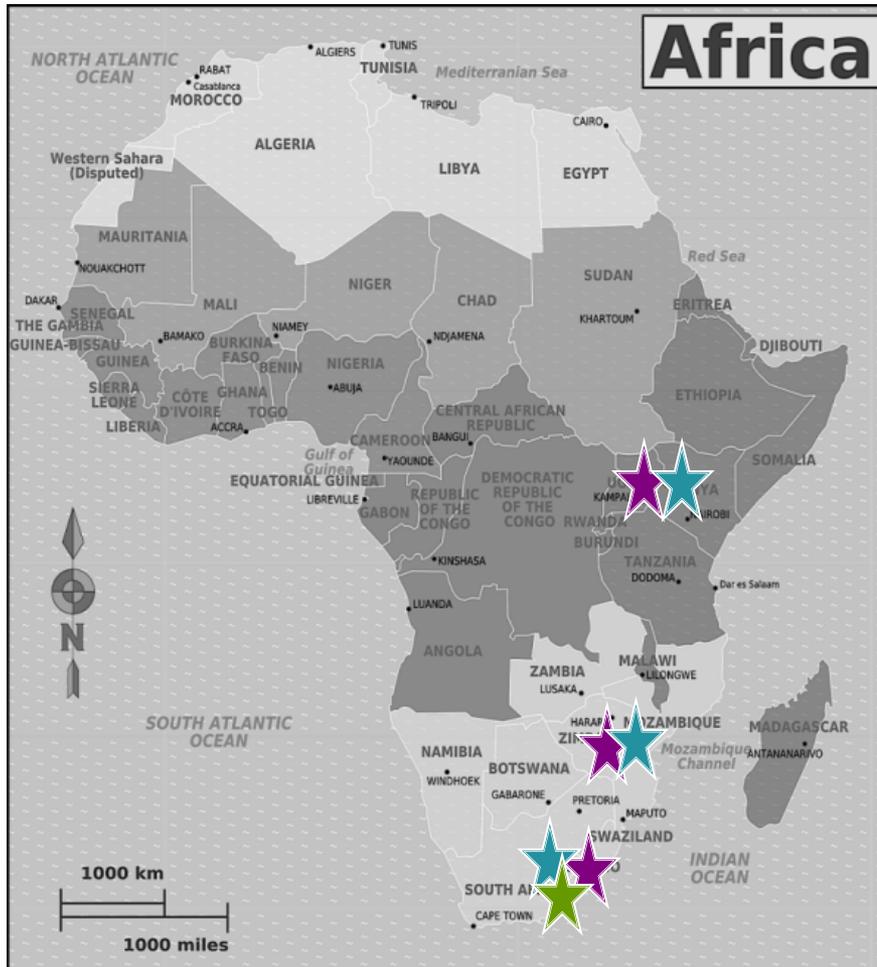
Ariane van der Straten, PhD, MPH
Women's Global Health Imperative
RTI International
San Francisco, CA, USA



VOICE: Approaches to Assessing Use

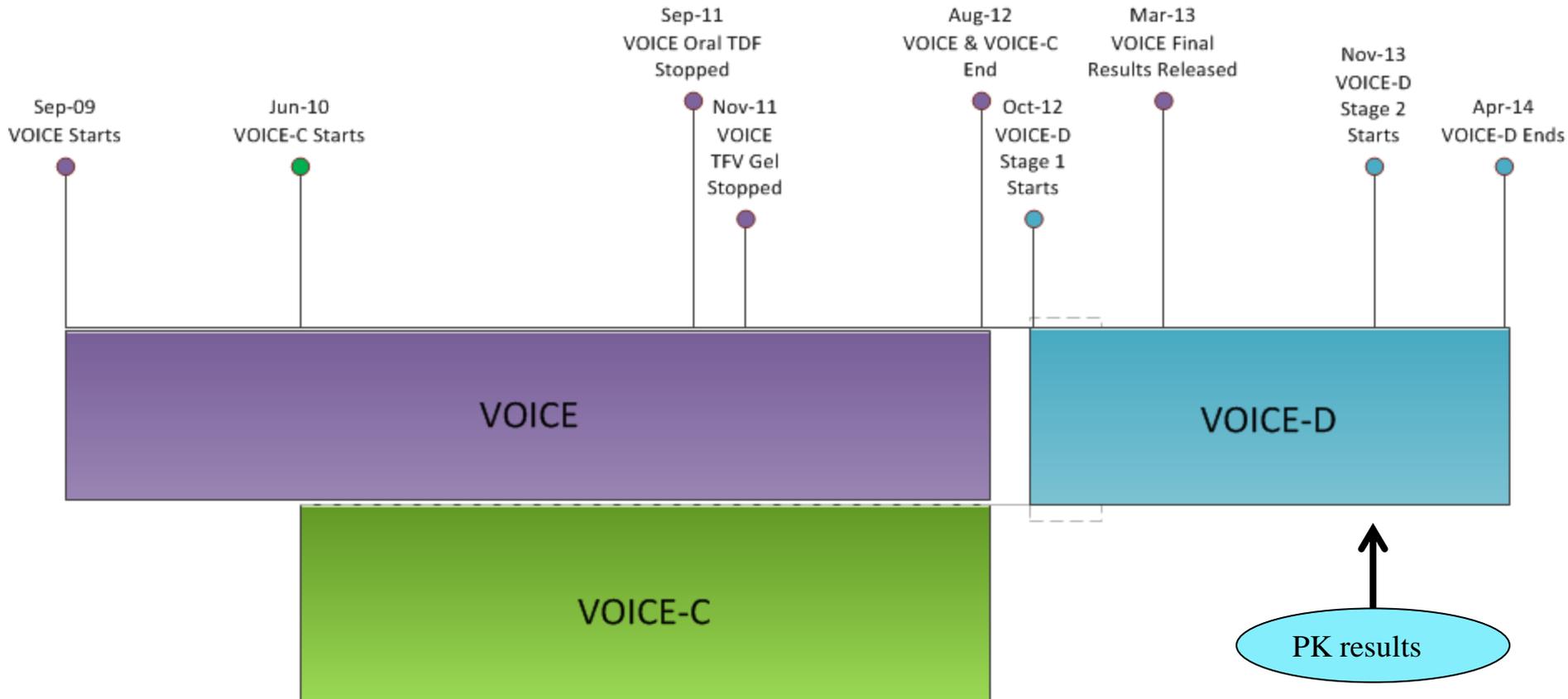


VOICE, VOICE-C, and VOICE-D



- **VOICE:**
 - N=5029 ♀
 - 3 countries, 15 CRS (sites)
- **VOICE-C:**
 - N=102 ♀, 22 ♂, 17 CAB, & 23 community stakeholders
 - 1 country, 1 CRS (Joburg)
- **VOICE-D:**
 - Stage 1, N=88 ♀
 - Stage 2, N=131 ♀
 - 3 countries, 5 CRS (Kampala, Chitungwiza, Durban)

Timelines: VOICE, -C and -D



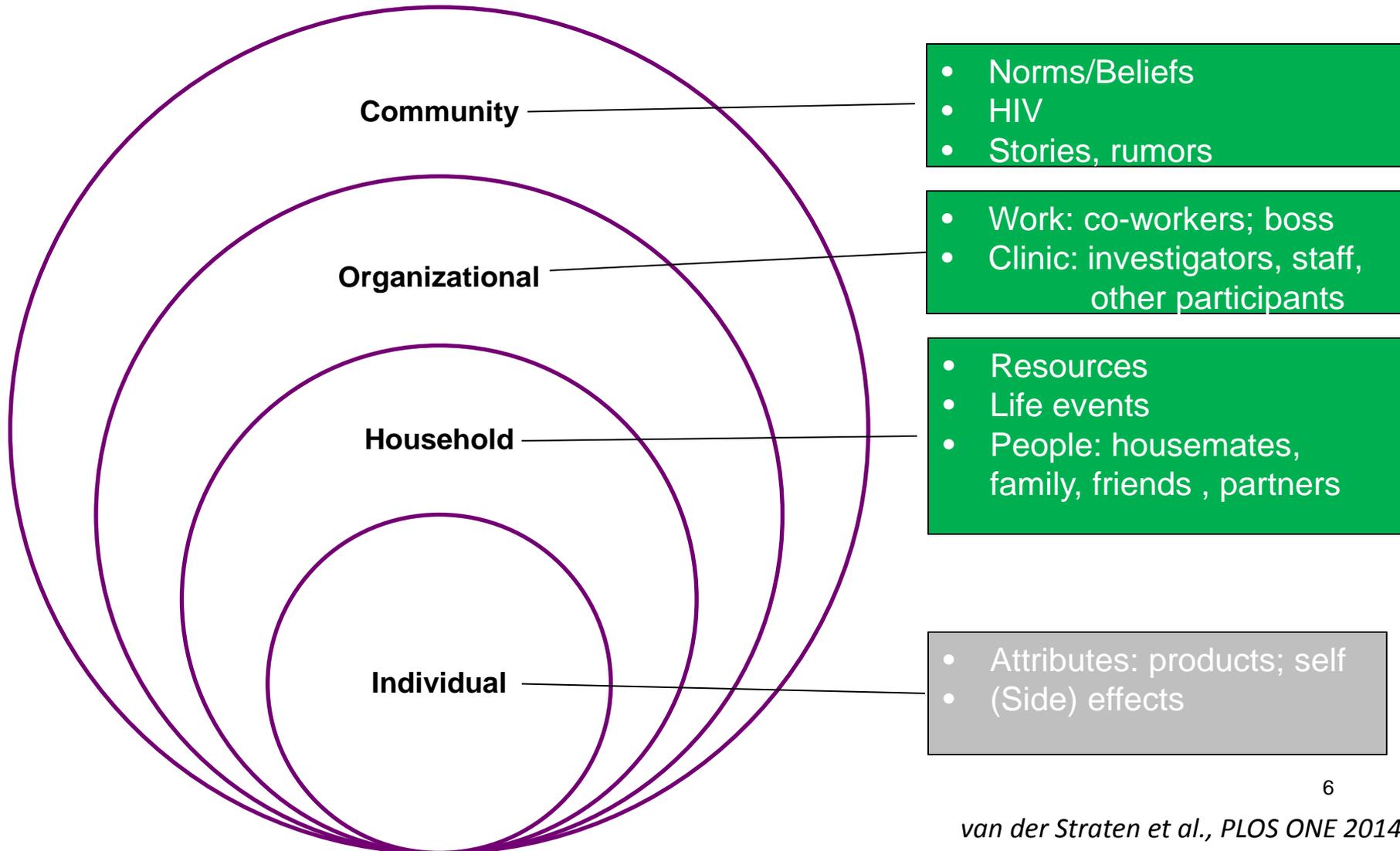
VOICE: Adherence estimates from 3 different measures

VOICE	TDF	FTC/TDF	TFV Gel
Total percent of doses reportedly taken*			
Returned Product Counts	87%	92%	86%
Self Report (7 days)	90%	91%	90%
Adherence based on plasma TFV detection			
Percent of <i>samples</i> with TFV detected averaged across women (mean)	30%	29%	25%

* Mean across all women's proportion of adherence estimated by these measure

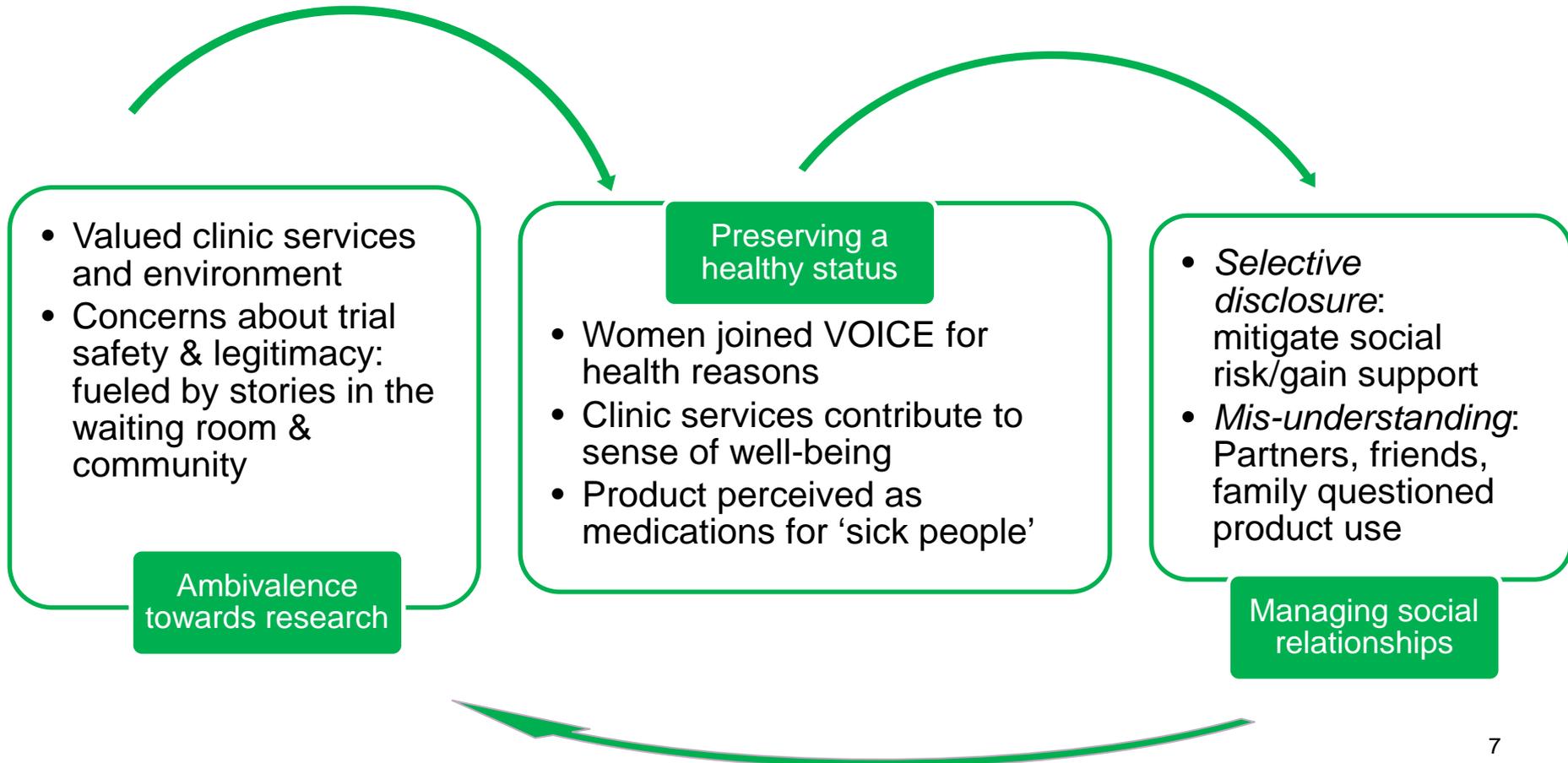
VOICE-C :

Levels of Influence on Adherence



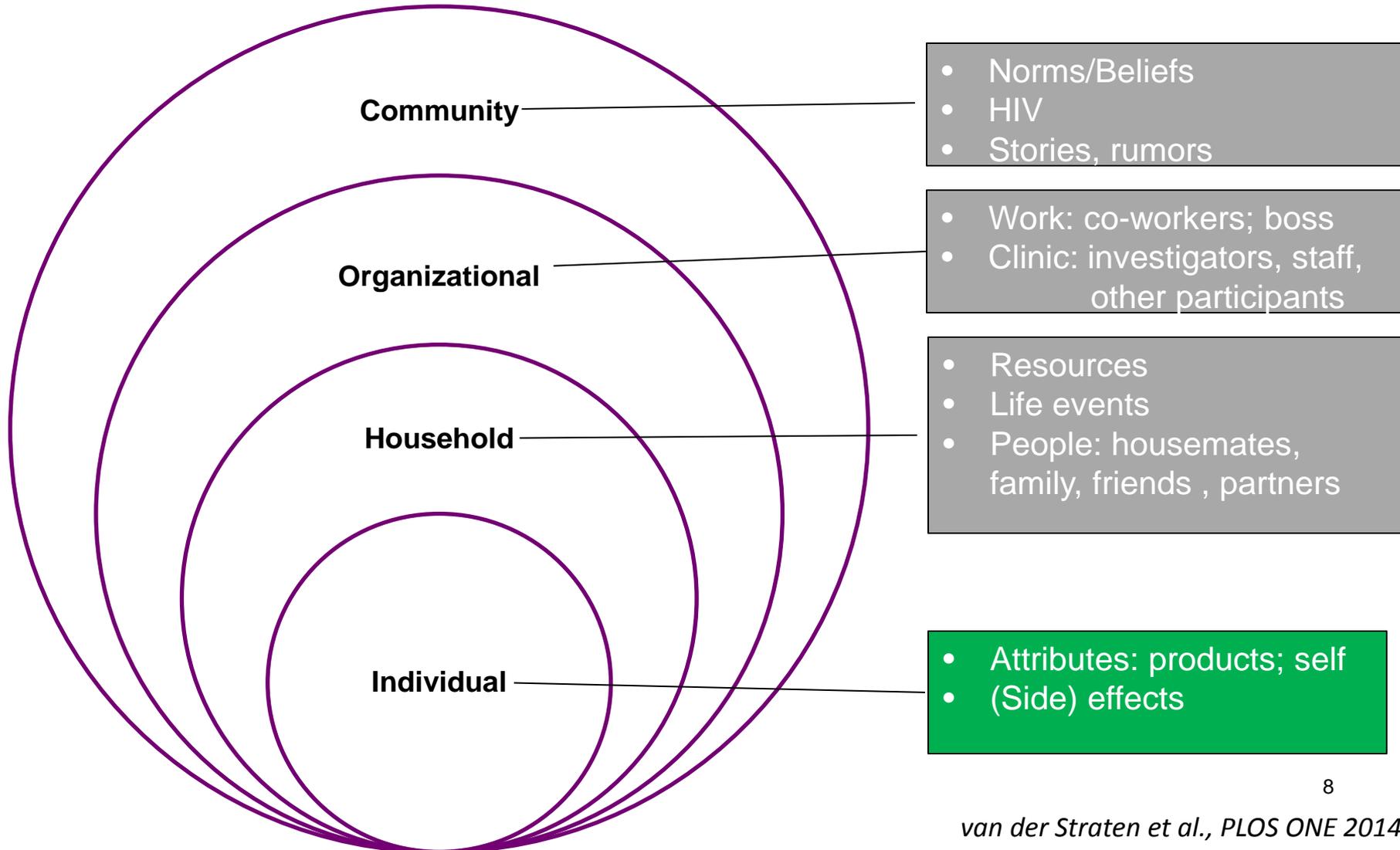
VOICE-C:

Themes influencing product experience



VOICE-C :

Levels of Influence on Adherence



Negative Attributes: Gel

Wetness:

I hate the fact that gel will make your panty wet as if you have urinated. I think the pill is better because it will just be once, not that I will have to take a bath again.

(Mango, FGD 103)

Harmfulness:

I said to him 'no nothing will happen' but I did have my concerns with these things since well it is part of the ARVs and you know the ARVs does in your body; that was his main concern. Even today I know that ARVs can react badly in your body so this [inserting the gel in the vagina] in the long run will it not affect me? (IDI 113)

AIDS

As time goes on, people said those gels have HIV & AIDS. So then people ..most people started to doubt... (FGD 103)

Negative Attributes: Tablets

Physical appearances:

*When started here full of energy and thinking, “Hey, we are going to take ARVs and they were saying we are going to look **beautiful**, and they were saying that they do this and that. You know that thing. So, the majority of us were talking when we started – you see we talk when... I won’t mention names but the majority of people, we were not taking the tablets. You would hear people saying I have stored mine away, and another would say I don’t take them and they are at the house. I don’t take them, they make me **fat**.*

You know stuff like that. (DK FGD 106)

Side effects

When I took them then I realized they [tablets] were not treating me well, even at home they would see me having changed and having a running stomach and they also made me to lose weight and each time I ate them they loosened my stomach and I ended up not taking them and no longer coming to the study as well. (IDI 139)

Negative Attributes: Users

Seropositive

The area that I live in has a bad influence because they like to gossip about people. If they could see these tablets, obviously they are going to gossip [...] If they could see me taking the tablets they will say that I have AIDS. They would not listen to my explanation about these tablets. (Tablet IDI 107)

Promiscuous

Well sometimes it's not easy for a woman to just come and implement that and "let's use the gel" it's going to be a lot of questions:, "why are we using this gel, are you cheating? .. why now why not 12 years back?" (Male FGD Gel)

Guinea pigs

What I know is that ARVs are for people who are sick, why would they [researchers] give them to us even though we are not sick? (EI11b, gel)

Positive attributes: Gel

Improves sex

He is just surprised about what is going on. He wonders what changed after such a long time of me not having the oomph for sex, and I tell him it's the gel that I got from the clinic. (IDI 114)

Protects

I have protected myself with the gel that contains the same ingredients they use in ARVs. I feel protected. I have a feeling that the particles in it will fight HIV if ever I can meet with an HIV positive person, it will help me fight this virus (IDI 115)

Positive attributes: Tablets

Potent

ARVs are taken by positive people, they get fat isn't it? That thing encourages me because I live with positive people in my community. I see how the ARVs are working on them. So that thing encourages me to want to take them (FGD106)

Strong

the tablets are also working because they have some reaction on us like some of us have headaches and become nauseous and stuff like that, so you would believe that means that these tablets have a certain possibility of reducing the risk of contracting HIV you know. (E1106)

Beautifying

[The tablets were] making my skin to be beautiful, and that thing encouraged me to keep on taking them. (FGD 106)

Positive attributes: Users

Hero

Yes, like once in a lifetime, I was dedicated to something, yeah I told myself that I am dedicated to this thing maybe if that gel was working then I would know that I am the one who began this study and we discovered that the gel is working; yeah I was very happy (IDI 135)

Volunteer

And they asked me how and why they chose us to use these things while we have nothing [HIV negative]. I told them that we are just volunteering with our health to help other people outside [of the trial]. (IDI 105 gel)

Contributing to knowledge

It is important for us to know that they [tablets] can help women to protect them from HIV or not. (FGD 107 tablet)

VOICE-D Design & Approach

□ *Design:* Qualitative exploratory study

Sample Stage 1 (N=88)	Selection	Data Collection Method
Former VOICE participants on product >3 months	Pre-selected based on: <ul style="list-style-type: none">• Anal sex report (ACASI)• HIV status (+ and -)• Study product (tablets & gel)	<ul style="list-style-type: none">• IDI
Sample stage 2 (N=131)		
Former VOICE participants on product >3 months	Pre-selected based on: <ul style="list-style-type: none">• Plasma drug PK detection (low, inconsistent, high)• HIV status (+ and -)• Study product (tablets & gel)	<ul style="list-style-type: none">• IDI• FGD (only with HIV-, low / inconsistent PK results)

Stage 2 Study Tools



Aids pills not taken

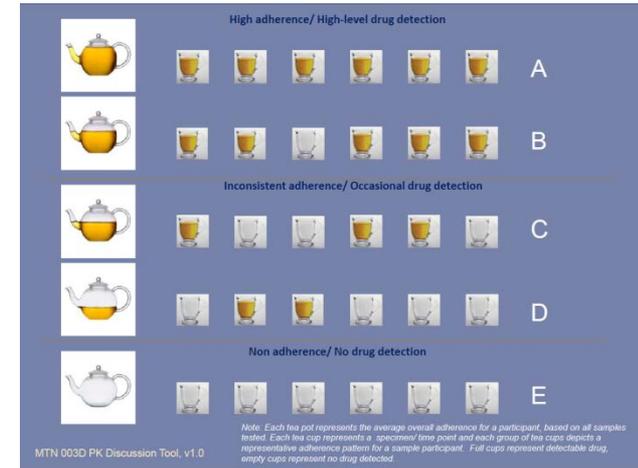
March 5 2013 at 09:11am
By LIZ CLARKE

Related Stories
 → HIV trial tests fail after participants shun regimen

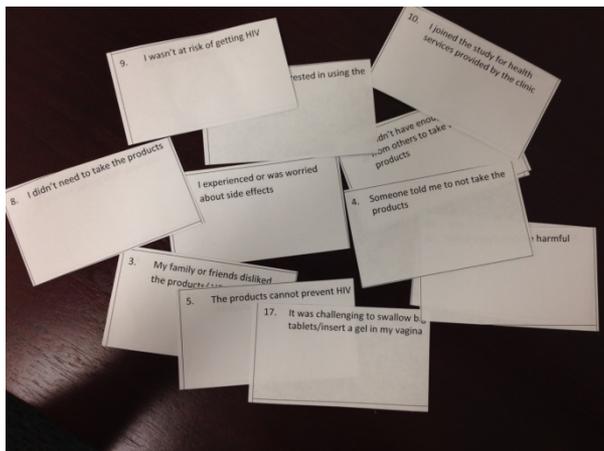
It was hoped that it would be the solution to one of the world's worst pandemics and the end to a global scourge of death and disease.

But the study failed because most of the women participating in the trials, including at sites in KwaZulu-Natal, did not take the medication.

Disappointment and dismay have come in the wake of the announcement that one of the largest HIV prevention trials did not find the answer to contain



Local press clippings



Theme identification cards

PK results 'Teapot' tool



Potential Product Formulations

Stage 2 Participant Background

Characteristic	Percent (N=131)
Site	
Durban (MRC)	24% (32)
Kampala (MU-JHU)	39% (51)
Chitungwiza (UZ-UCSF)	37% (48)
PK result group	
Low	65% (85)
Inconsistent	20% (26)
High	15% (20)
HIV Positive	13% (17)
Enrolled in Stage 1	34% (45)
Age (mean, range)	28 (29.2, 21-41)
Completed secondary school or more	39% (50)
Married	55% (72)
Same partner as in VOICE	79% (95)

Adherence Challenge Themes- IDIs (N=72)

Themes Selected as Relevant (ordered by weighting score)

I experienced or was worried about side effects

I joined the study for health services provided by the clinic

The products may be harmful

I didn't have enough support from others to take the products

It was boring to take the products daily

I was too busy to take products every day

Others would think I have HIV if I took the products

The products cannot prevent HIV

Someone told me to not take the products

[I heard that] other participants were not taking their products

It was challenging to swallow big tablets/insert a gel in my vagina

I had to hide when taking my products

My family or friends disliked the products/ VOICE

My partner disliked the products/ VOICE

I wasn't at risk of getting HIV

The place where I lived made it hard to take the products

I was not interested in using the products

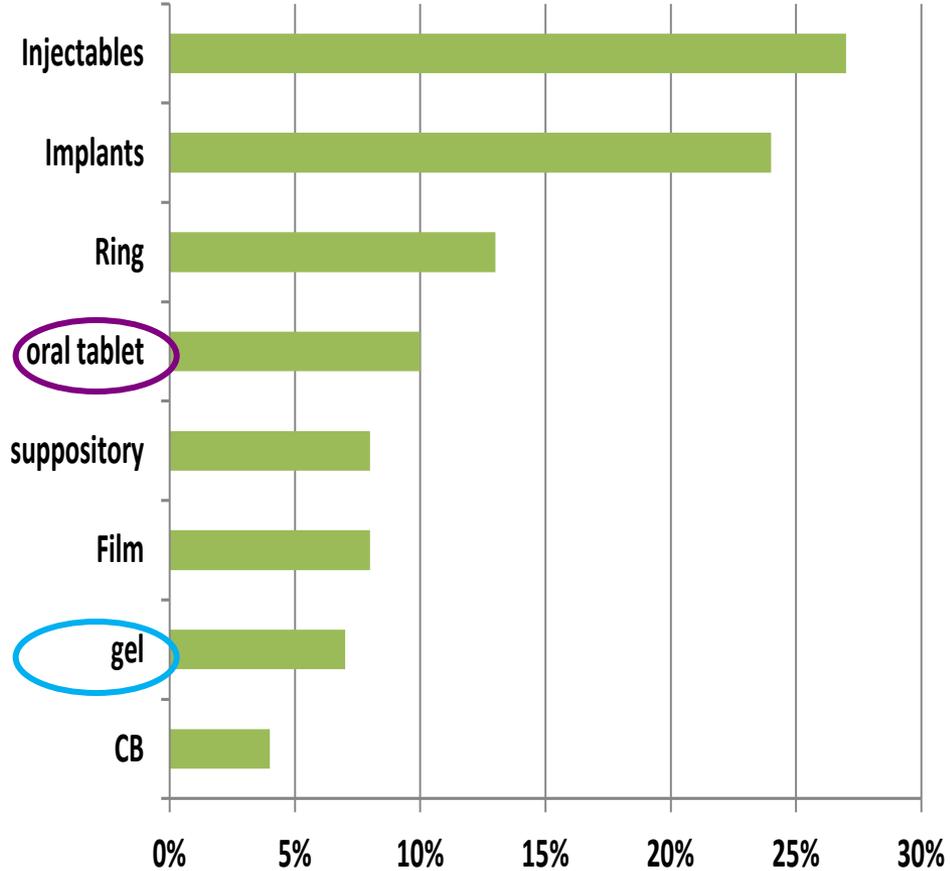
I didn't need to take the products

The products decreased sexual pleasure

I joined the study for the reimbursements

Products preferred* (IDIs)

HIV Prevention – Potential Product Formulations



MTN-H003D Stage 2: Pictures of Possible Prevention Products

1

* Multiple selections allowed



Final remarks

- RCT/clinic environment: taint women's perspectives (e.g. "test" products; side effects warnings; unknown efficacy)→ Fear
- Many social actors influence women's attitudes & ability to use
- Same product attributes viewed as attractive or repulsive:
 - Side effects: sign of product potency vs harmful or unpleasant
 - Wetness: improves lubrication/sex vs produce discomfort or worsen sex
 - Weight gain: improves or degrades physical appearance
- Challenge with products: potential harm, side effects, sickness
- Dosing regimen: burdensome → forgetfulness
- Reasons evoked for selecting tablets or gel:
easy to use, familiarity, no side effects

Study Teams and Key Roles

VOICE-C

- **Chairs:** Ariane van der Straten, Jonathan Stadler
- **Wits RHI:** Sello Seoka, Florence Mathebula, Busisiwe Magazi
- **FHI 360:** Katie Schwartz, Kat Richards, Rhonda White
- **RTI/WGHI:** Elizabeth Montgomery, Miriam Hartmann, Helen Cheng, Catie Magee
- **MTN Core:** Beth Galaska Burzuk
- **DAIDS:** Lydia Soto-Torres

VOICE-D

- **Chair:** Ariane van der Straten
- **Co-chairs:** Elizabeth Montgomery, Barbara Mensch
- **MRC:** Sarita Naidoo, Kubashni Woeber, Funeka Mthembu, Nozipho Vilakazi
- **UZ-UCSF:** Nyaradzo Mgodhi, Petina Musara, Imelda Mahaka, Otilia Munaiwa
- **MU-JHU:** Clemensia Nakabiito, Juliane Etima, Josephine Nabukeera, Teopista Nakyanzi
- **DTHF:** Zoe Duby, Thola Bennie
- **FHI 360:** Lisa Levy, Kristy Alston
- **RTI/WGHI:** Miriam Hartmann; Helen Cheng
- **MTN Core:** Beth Galaska Burzuk, Sonia Gor
- **DAIDS:** Jeanna Piper
- **NIMH:** Cynthia Grossman



THANKS!
