Women & their participation in HIV Research in South Africa

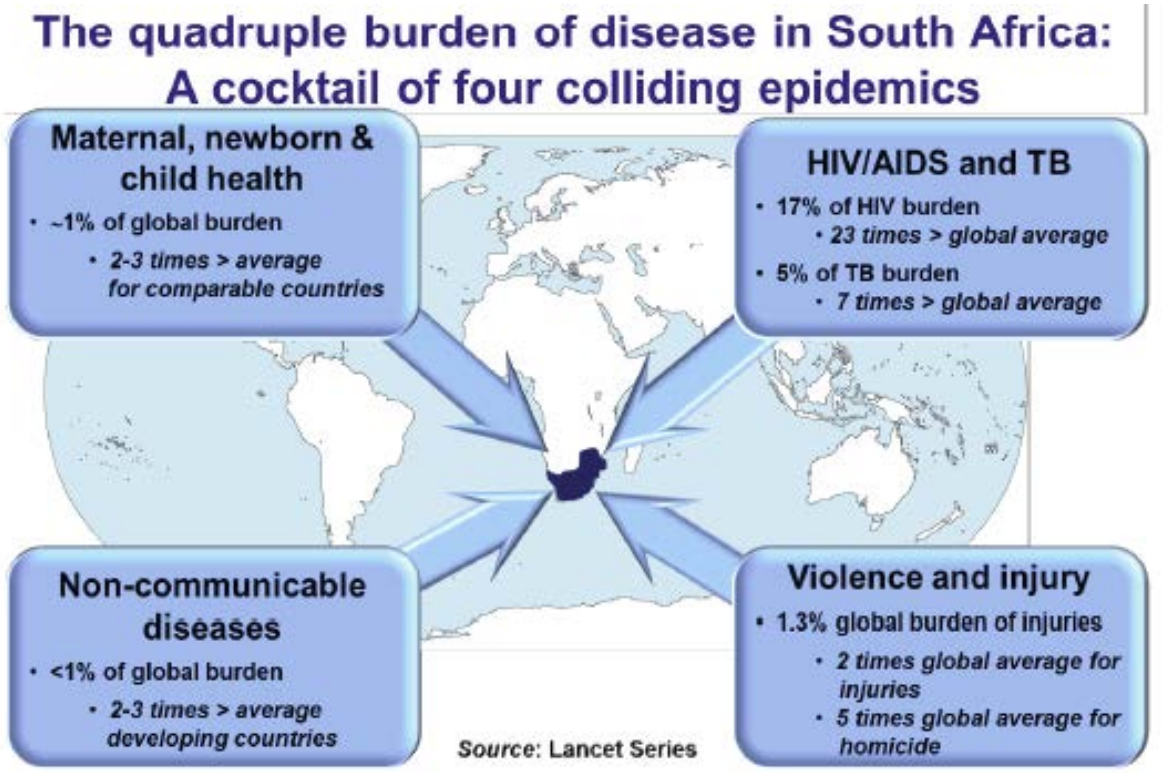
Glenda Gray
President & CEO of SA MRC

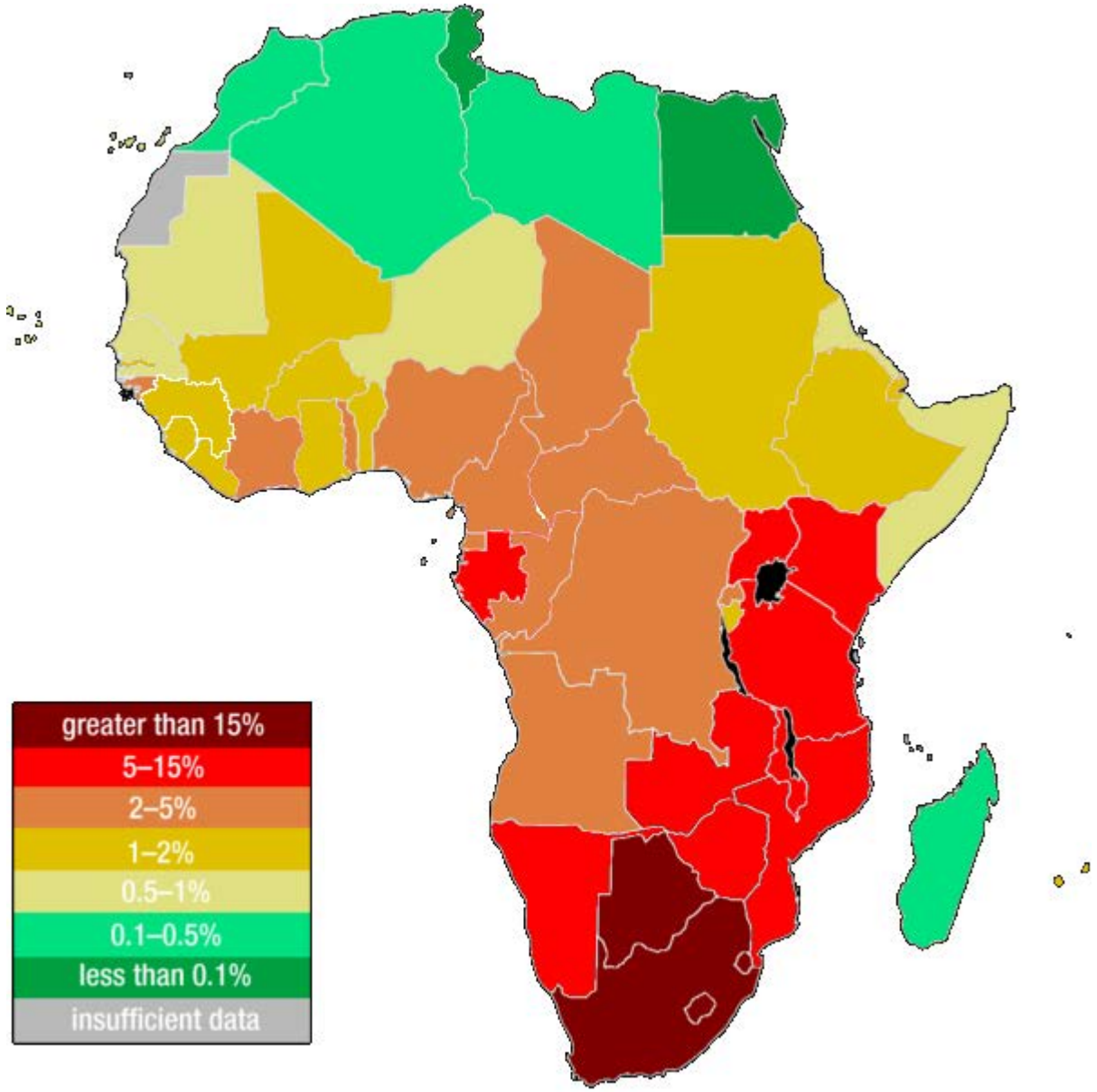
Gender Summit 5 Africa
28-30 April 2015

South African Medical Research Council
BUILDING A HEALTHY NATION THROUGH RESEARCH

SA's Burden of Disease – women bear the brunt

SA MRC is committed to addressing the burden of disease that impacts health		
Cause of death	**Deaths**	**%**
HIV/AIDS	180,870	29.4
Hypertensive heart disease	39,272	6.4
Lower respiratory infections	38,576	6.3
Cerebrovascular disease	37,913	6.2
Tuberculosis	37,519	6.1
Diarrhoeal diseases	26,564	4.3
Ischaemic heart disease	24,510	4.0
Interpersonal violence	20,155	3.3
Road injuries	18,166	3.0
Diabetes mellitus	13,667	2.2
COPD	11,458	1.9
Nephritis/nephrosis	9,130	1.5
Top 12 causes	457,800	74.3
Total	615,788	100.0





HIV in young women aged 15-24 is twice the number than in young men of similar ages

Map-of-HIV-Prevalance-in-Africa" by derivative work: Louis Waweru

PLOS ONE

RESEARCH ARTICLE

Impact of Exposure to Intimate Partner Violence on CD4+ and CD8+ T Cell Decay in HIV Infected Women: Longitudinal Study

Rachel Jewkes[1,2]*, Kristin Dunkle[1], Nwabisa Jama-Shai[1,2], Glenda Gray[3]

1 Gender & Health Research Unit, South African Medical Research Council, Pretoria, Gauteng, South Africa, **2** School of Public Health, University of the Witwatersrand, Gauteng, South Africa, **3** Office of the President, South African Medical Research Council, Western Cape, South Africa

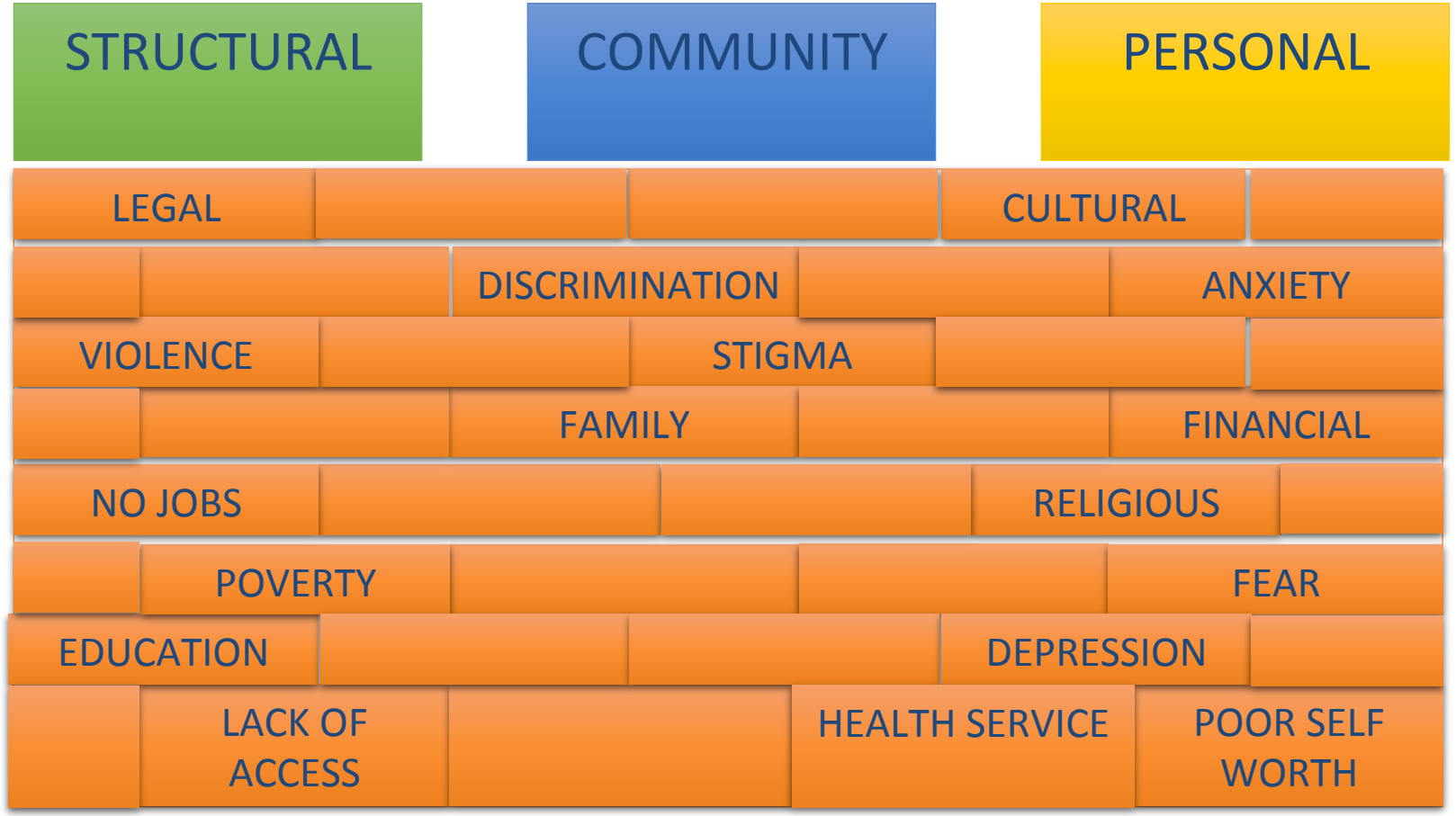
CD4 decline is associated with abuse

	CD4 change*			
	Coefficient	95% CI		P value
Experienced emotional abuse from current partner	-132.87	-196.37	-69.37	<0.0001
Ever experienced emotional abuse				
Ever used drugs	-129.90	-238.68	-21.22	0.019

HIV interventions for women

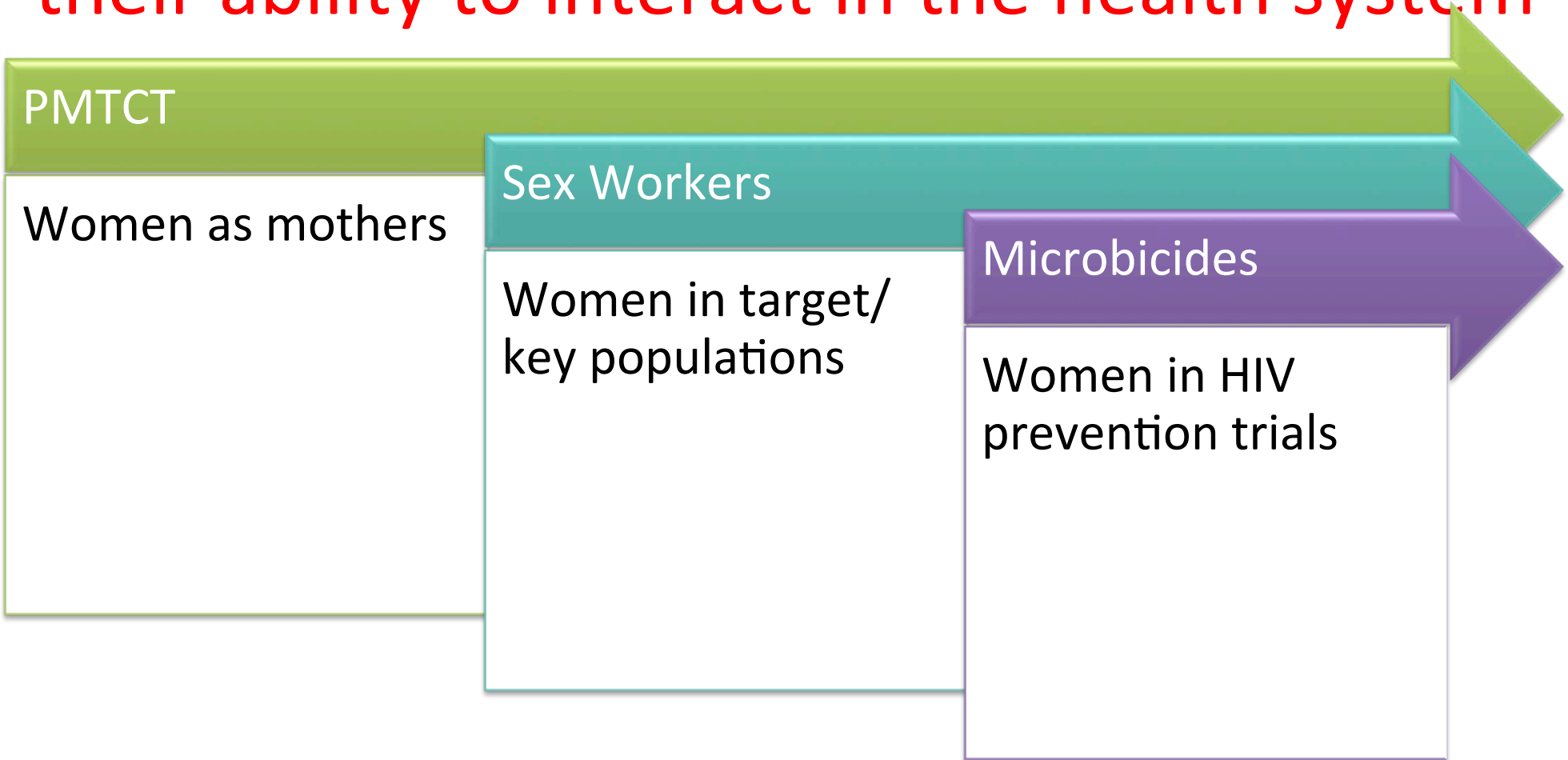
- We are faced with an HIV bio-medical intervention crisis for women in sub-Saharan Africa
- Despite biological plausibility for systemic & topical PrEP, we are unable to definitively establish how potent these interventions are in women
- We require a better understanding of the determinants of HIV acquisition in women
- Greater creativity in designing products women can use to reduce their vulnerability

Multiple barriers impact on Women who are HIV infected



Adapted from Tucker et al, 2012; MSMGF 2012

3 case scenarios that illustrate the context that make it difficult for women to be the beneficiaries of progress made in HIV research, or that restrict their ability to interact in the health system



PMTCT interventions

- PMTCT research has been incredibly effective in developing interventions that have driven perinatal transmission rates down to less than 2%
- HAART is being rolled out for all HIV infected pregnant women irrespective of CD4 count, initiated during pregnancy, continued throughout the period of lactation, and beyond with the promise to eradicate pediatric HIV and improve the health of women

Why don't HIV infected women want ARVs?

- **Women initiated on lifelong ARVs during pregnancy were five times more likely than women who started ARVs in WHO stage 3/4 or with a CD4 cell count 350 cells/ml or less, to never return after their initial clinic visit.**

- **Women initiating lifelong ARVs while breastfeeding were twice as likely to miss their first follow-up visit.**

- **Loss to follow up was highest in pregnant women who began lifelong ARVs at large clinics on the day they were diagnosed with HIV**

Tenthani L et al AIDS 2014

Conversations with mothers: Exploring reasons for prevention of mother-to-child transmission (PMTCT) failures in the era of programmatic scale-up in Soweto, South Africa

F Laher; A Cescon; E Lazarus; A Kaida;
M Makongoza; RS Hogg; CN Soon; CL Miller;
G Gray

AIDS Behav. 2012 Jan;16(1):91-8

Reasons for PMTCT failure

- 28 mother-infant pairs (62%) received no or inadequate PMTCT care
  - prenatal ARVs for <2 months,
  - improper length of infant AZT prophylaxis and/or
  - AZT instead of ART for mothers with CD4<200
- Reasons for inadequate care:
  - preterm delivery (n=13, 46%)
  - prescription errors for infant (n=10, 36%) and/or mother (n=6, 21%)
  - no or late attendance to antenatal care (n=6, 21%)
  - treatment refusal (n=5, 18%),
  - treatment delays (n=4, 14%).

Qualitative results

- **Delayed attendance of ANC**

"At my local clinic we book as from Thursday. They take 10. If ever you are number 13 or whatever, you are told to come back next Thursday. Still if you don"t wake up early, you will go back the following Thursday. You will find the clinic full because you did not wake up; come next Thursday."

- **Fear of stigma**

"When you get home [from the clinic] you are confronted straight away, "What did you get today?". This is not right and you get more stressed, contemplate suicide and stop thinking for your children. You even forget that if you get treatment, you will live." and treatment delays (n=4, 14%).

Women as Key/Target Populations: challenges to accessing services for sex workers in South Africa

Sex Work and HIV in South Africa

- Between 0,7-4,3% of South Africa's female population engage in sex work (SW).
  - With 5% of sex workers (SWs) are male and 4% transgender
- 60% of SWs are estimated to be HIV positive
  - Only 30% of SWs can access healthcare services
    - 40% have regular access to condoms
    - 5% of SWs have access to a comprehensive package of HIV services
    - In the absence of tailored SW projects, 37% have good HIV knowledge
    - 19,8% of new HIV infections are linked to SW (predominantly from bridging populations such as clients and partners, but also through SWs themselves)
- A systematic review of evidence has suggested that the decriminalisation of SW could avert 33- 46% of

In three separate studies spanning 1, 6 and 12 months respectively

- 65% of SW interviewed in Johannesburg had experienced one form human rights violations by police, including verbal, physical and sexual assault.
- 1 in 3 SWs reported being raped
- 57% of SWs nationally reported client violence, and 55% police violence

Accessing healthcare services is challenging, with enactments of stigma being underpinned by an unconstitutional legislative framework . Amplified by internalisation of shame around SW and a generalised fear of experiencing stigma at the hands of healthcare officials

When you reach there some they put their hand glove where they put their hands in you when they check you they say yah mmm even your discharge is smelling. It shows that you just sleep without condom. While it's not like that infection is infection. You don't know sometimes you got it in the toilets. So the nurse are not the same. Even show you looks how it looks but you are a lady it even smelling [she is holding up two fingers as if discharge is on it and it is being shoved into her face as if the nurse has done this to her] so I we we just keep quiet ... Sometimes you got infection but they don't give you stuff for infection they give you B-co and vitamin it don't help nothing mos.

I don't know or me I III don't know …that how is she going to react if she find out that me I am a sex worker and I need help.

Police harassment further compounds health concerns through the withholding of access to treatments, including ART, and acts of violence

*The police they found me inside I was busy with the client...So they take the pepper spray he pepper spray me my va my vagina! [starts crying]... Even after I wash it it BURNING! I stayed in the house...for 3 to 4 days! If I want to pee it was a problem...After they pepper spray me you get some snot clap so that you...cant see their faces and can't see their nametags...I didn't go to the clinic...I was scared that...I was confused that, hey maybe I go to the doctor go to the clinic maybe they will talk [*to*] me [*in the same way*]...So I was just scared .*

Designing interventions for women: the case of microbicides

FACTS
Follow-on African Consortium
for Tenofovir Studies

FACTS 001:
a multi-centred phase III randomised, double-blind, placebo-controlled trial of pericoital tenofovir 1% gel for HIV prevention in women

Primary Effectiveness Results
(mITT)

	TFV gel	Placebo gel
Person-years	1515	1521
Protocol-specified HIV endpoints	61	62
HIV incidence per 100 p-y (95% CI)	4.0 (3.1-5.2)	4.0 (3.1-5.2)

Incidence Rate Ratio (IRR) 1.0; 95% CI: 0.7-1.4 *

*stratified by site

FACTS
Follow-on African Consortium for Tenofovir Studies

Did women perceive themselves to be at risk for HIV?

I was not using a condom everyday and it was a risk because I don't know what he does when he is not with me. (109-02280)

- HIV is acquired through the actions of others
- Unstable partnerships:
  - Lacking in trust and commitment
- Stable partnerships:
  - Suspicions of infidelity
- Rape:
  - Narratives highlight the vulnerability of women

FACTS
Follow-on African Consortium for Tenofovir Studies

Baseline factors associated with HIV acquisition

Baseline variable	IRR* (95% CI)	p-value
Single	2.5 (1.0 - 6.3)	0.044
Lives with parents/siblings	2.7 (1.5 - 5.0)	0.001
Perceived HIV risk > than usual**	1.7 (1.1 - 2.6)	0.014
HSV-2 positive at baseline	1.5 (1.0 - 2.1)	0.034

No significant association between HIV incidence and age , partner characteristics, or other sexual behaviours at baseline

** Adjusted for arm and site*
***in the past 28 days*

FACTS
Follow-on African Consortium for Tenofovir Studies

Did using the gel change women's sense of HIV risk?

- Protective … but no disinhibition
- Narratives are hopeful of an effective product, but still uncertain of its effectiveness

I want something that will help us as women to protect us from HIV/AIDS (01-01698)

I think the gel can protect HIV because when I go to the party and then you find that HIV [positive] person rapes me while I have inserted the gel before going to the party, it will protect me from HIV (01-01301)

FACTS
Follow-on African Consortium for Tenofovir Studies

Was the gel acceptable?

- flow, cleansing, sexual pleasure, intimacy, lubrication

I think it just flows with my body and my blood that's what I think. (0400266)

…my vagina seems clean somehow, I feel like it cleans the dirt, I don't have dirty discharge anymore. (0302714)

[Laughs] *on my side it did help me a lot and it did improve my love life, ja* (04-03979)

(…) *after fighting he wanted to have sex with me even more (…) even if I was dry he wanted to have sex with me (…) the gels helped me because if he had sex with me by force I won't be hurt* (06-03270)

FACTS
Follow-on African Consortium for Tenofovir Studies

But … knowledge and acceptability do not necessarily lead to behaviour…

Even though my boyfriend knows but I didn't insert the second gel in front of him because I respect him and that's why I told him that I am going to the toilet to insert this gel (09-01070)

'I will have sex while it's inside there you see so that one after sex I don't see a reason' (0306383)

R: I [inserted the gel] waited for two hours and bathed so that I don't become too wet.
(…)
I: Did you remove it?
R: No just washing it to feel better. (07-0918)

…and everyday life and relationships are difficult

… it was easy to insert the first gel because I would still be at home but it will be difficult to insert the second gel if you didn't tell your partner [about being in the trial] (09—02314)

… it was easy to insert the first gel because I insert when I am at work or at home then I will go to him but for the second gel eish it was difficult because I must wakeup in the morning or wakeup at night so I didn't like to do that because I like sleeping (01-02045)

FACTS
Follow-on African Consortium for Tenofovir Studies

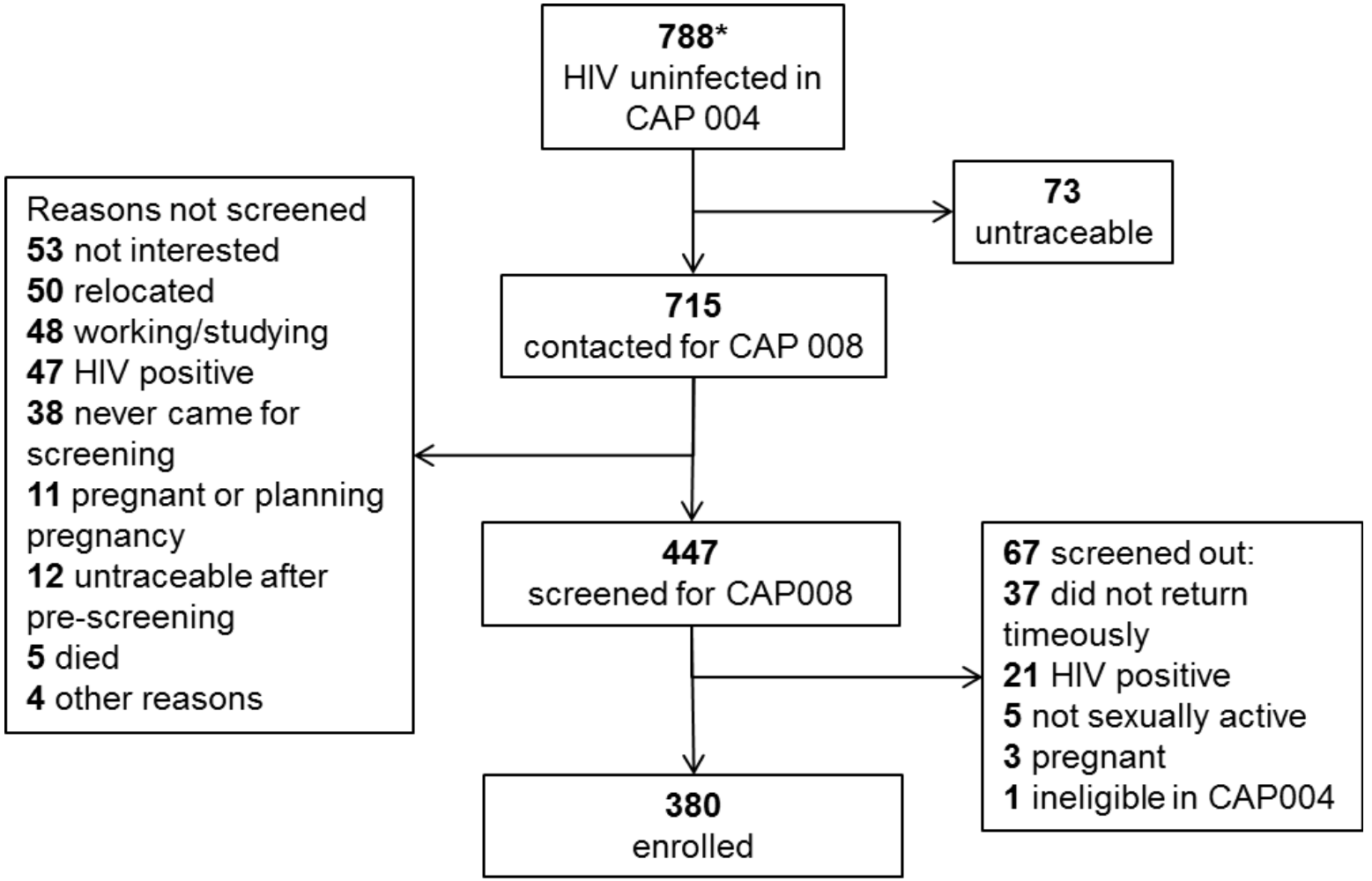
CAPRISA 008

- ***Purpose:*** **To assess the effectiveness of an implementation model which integrates tenofovir gel provision into existing family planning services (while simultaneously providing post-trial gel access to CAPRISA 004 women)**
- ***Design:*** **Open-label 2-arm randomized control trial**
- ***Population:*** **HIV-uninfected CAPRISA 004 participants**
- ***Control arm:*** **CAPRISA research clinics (Vulindlela & eThekwini) - monthly gel provision as if they are in CAPRISA 004**
- ***Intervention:*** **Public sector family planning services with 2-3 month provision of tenofovir gel. Quality improvement methodology for promoting reliable service delivery**
- ***Endpoint:*** **Applicator count adherence (Adherence)**

Karim S et al

Progress: CAPRISA 008 Trial Status

as per 15 September 2014



* 788 includes 3 participants enrolled in error as they were previously co-enroled in CAPRISA 004

Karim S et al

Lesson 1: Need early planning for post-trial access – 68 / 543 women (12.5%) acquired HIV between CAPRISA 004 and CAPRISA 008

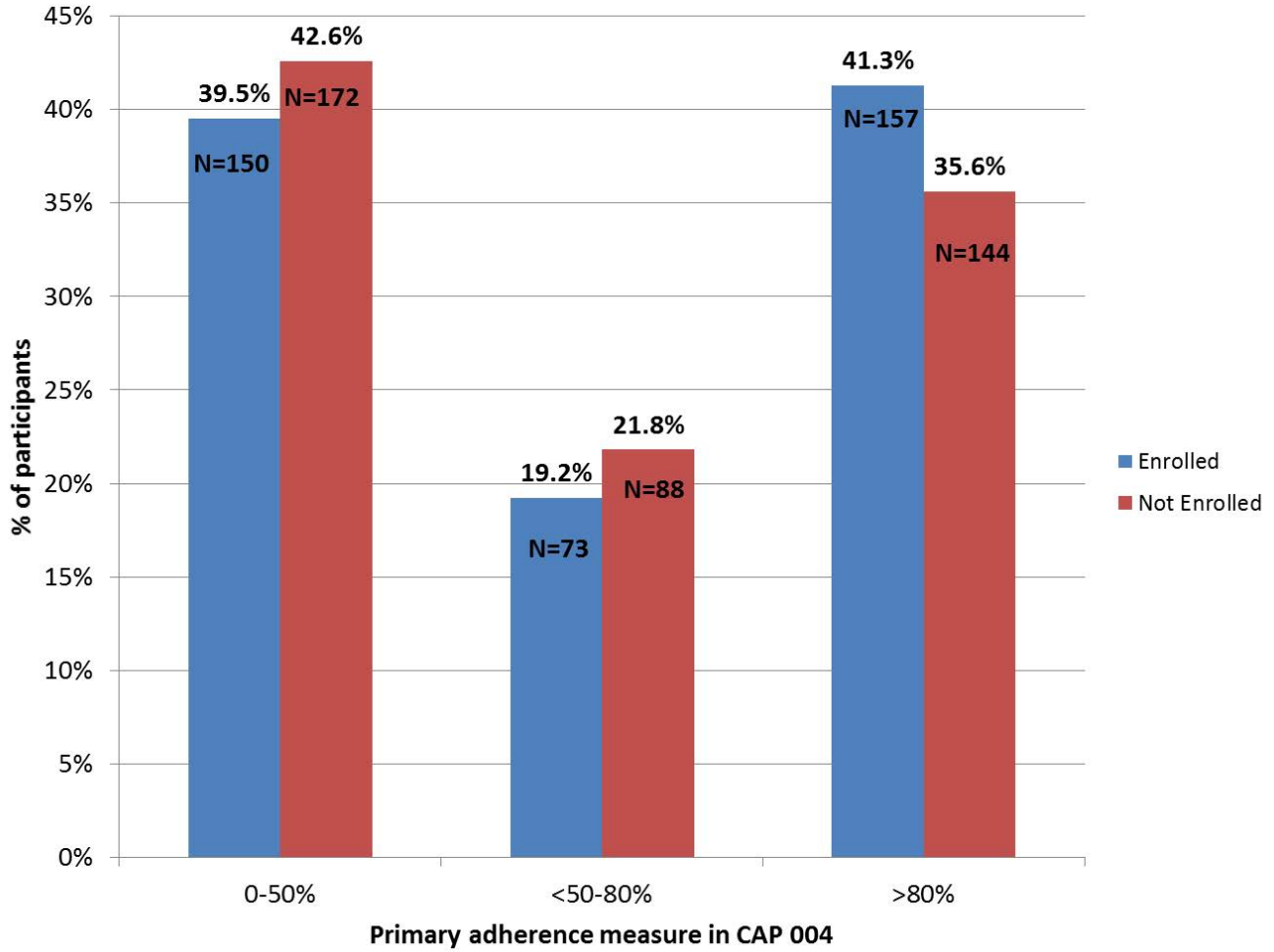
	Tenofovir gel	Placebo gel
No. of women pre-screened *	230	196
No. of women screened *	230	217
Infected between CAPRISA 004 and CAPRISA 008	34	34
% seroconverted †	12.1%	12.9%
HIV incidence rate (per 100 wy)	4.3	4.6
95% CI	3.0 – 6.0	3.2 – 6.4

*Pre-screened & screened groups are not mutually exclusive, as some women attended both screenings.

† Percentage calculated out of number of women who came for either screening: N=280 in tenofovir gel arm and N=263 in placebo gel arm.

Karim S et al

Lesson 2: High adherers from CAPRISA 004 agree more often to enrolment in CAPRISA 008 – 41.3% of women enrolled in CAPRISA 008 were high adherers (> 80% adherence) in CAPRISA 004



Karim S et al

Lesson 3: Link marketing research with post-trial access to enhance uptake

CAPRISA's TFV gel toolkit research was done in parallel. Hence, the marketing concepts generated through community participation, like these, were not available for CAPRISA 008

Karim S et al

How Should We Engage Women in Research?

Who needs to do what differently?

Using a theoretical framework, which barriers and enablers need to be addressed?

Which intervention components could overcome the modifiable barriers and enhance the enablers?

How will we measure behavior change of health care workers?

Enhancing our understanding of Women

- Design elements
- Process evaluations
  - Qualitative
  - Quantitative
  - Theory based
- Temporal evaluations

Development of methods to assess barriers and facilitators to implementation

Behavioural perspective

- Implementation depends on behaviour
  - Citizens, patients, health professionals, managers, policy makers
- To improve care, we need to change behaviour
- To change behaviour, it helps to understand determinants of current behaviour and how behaviour changes

Health worker attitudes determine health service access

Health workers do not exist in isolation but are part of the broader community

Approaches to implementation: need policies, clinical training and the need to address health care attitudes and practice.

Attitudes determined by their own belief systems, community norms and values, political statements and positions and religious guidance

Little to no education or training in pre-service curricula on sexual health or practices

Region	Supporting innovations and impact evaluations in 17 countries
Africa	DR Congo, Ghana, Kenya, Mozambique, Nepal, Rwanda, South Sudan, South Africa, Uganda, Zambia,
MENA	Occupied Palestinian Territories, Yemen
South Asia	Afghanistan, Bangladesh, India, Pakistan, Tajikistan

Acknowledgements

- James McIntyre
- Kenneth Mayer
- Scott Hammer
- Magda Sobieszcyk
- Larry Corey
- Susan Buchbinder
- Fatima Laher
- Rachel Jewkes
- Jared Baetan
- Salim Abdool Karim
- Quarraisha Abdool Karim
- Leila Mansoor
- Jenny Coetzee
- Erica Lazrus
- Jeremy Grimshaw