Vaginal Delivery Forms for HIV Prevention:
End User Perspectives

Petina Musara
UZCHS-CTRC
(on behalf of the Quatro Study Team)

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UZCHS-CTRC
University of Zimbabwe College of Health Sciences - Clinical Trials Research Centre
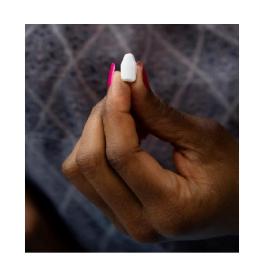Saving Lives Through Innovative Research Strategies

Background

- The attributes of an HIV microbicide may affect its acceptability, uptake and use.

- Quatro, a clinical study with a qualitative component, was conducted in Durban, South Africa and Zengeza, Zimbabwe, between June 2016 and June 2017.

- To elicit input from end users and key informants on four different placebo vaginal microbicide delivery forms; fast-dissolve insert, ring, film and gel.

Quatro Study Goals

To find out which of four products – a vaginal ring, a vaginal film, a vaginal insert, or a vaginal gel – young women prefer and use.

To learn what characteristics young women like and dislike about each of these products, so that they can be improved.

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Who and how many participated in Quatro?

- ***Clinical study, where women used placebo products:***
    - 200 young women (100 from each country) joined and 176 stayed in the study for all five months.

    - 41 of those women took part in focus group discussions (five groups total)

- 17 male partners (who took part in 2 focus groups and 4 individual interviews)

- 24 health care providers

- Another 222 young women (1/2 from each community) took part in the tablet computer survey only, and did not use placebo products

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What did women do in Quatro?

Stage1: try all
(4 months)

Stage 2: choose
and use
(1 month)

Final opinion +
survey

- The ring was to be worn monthly, the other three products were designed for pre-coital use.
- Vaginal swabs were self collected to measure product use throughout the study

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Who were the participants in the Clinical Study?

Average age: 23 (range 18-30)

Most (92%) were married in Zimbabwe

Only 4 out of 100 were married in South Africa

Nearly all (97%) had a primary sex partner & 2% reported more than one partner in the past month

Over two thirds (70%) completed secondary school or higher
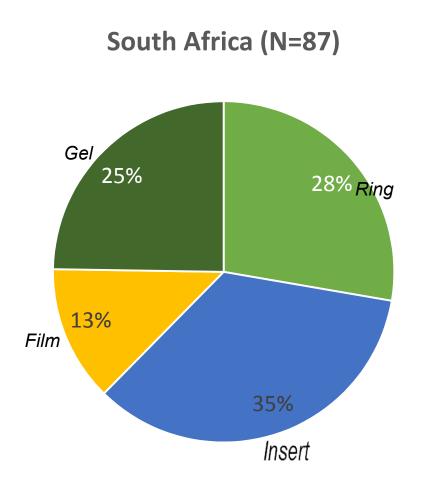
QU4TRO

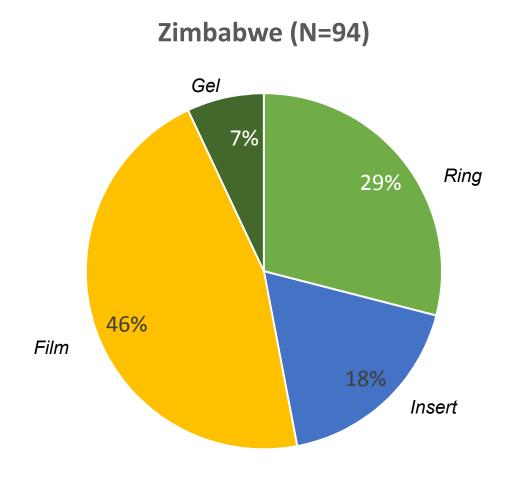# What were women's opinions of the Quatro products?

Choice at month 4 visit in each country

South Africa (N=87)

Gel 25%
Ring 28%
Film 13%
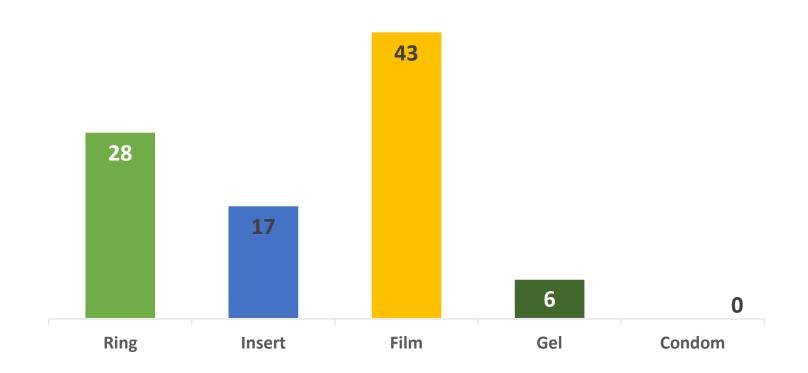Insert 35%

Zimbabwe (N=94)

Gel 7%
Ring 29%
Film 46%
Insert 18%

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Month 4 ranking preference of Quatro products & condoms: Product ranked as number one

Among Zimbabwean participants

	Ring	Insert	Film	Gel	Condom
	28	17	43	6	0

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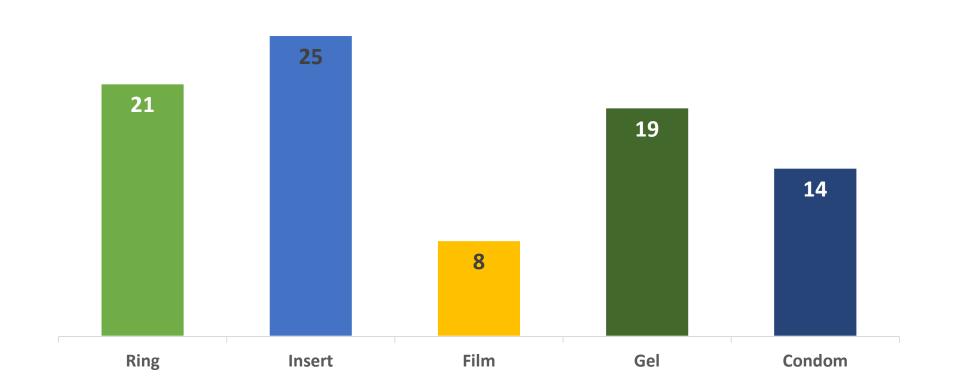
Month 4 ranking preference of Quatro products & condoms: Product ranked as number one

Among South African participants

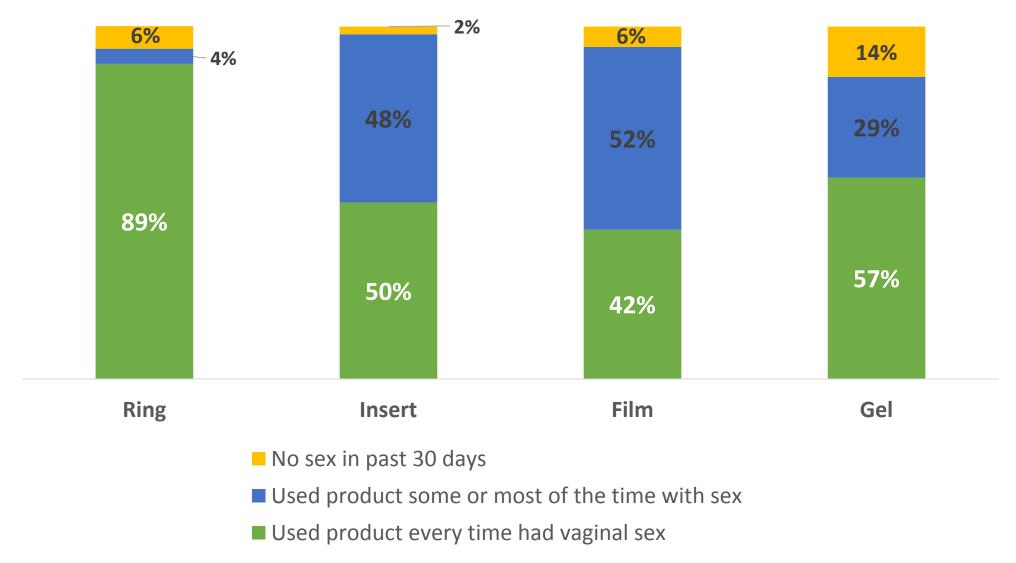| Ring	Insert	Film	Gel	Condom
21	25	8	19	14

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Did women try the products in stage 1?

	% of women who used product at least 2 weeks (in first 4 months), by product and site		
	South Africa	Zimbabwe	Total
Gel	83	94	89
Film	80	96	88
Insert	64	86	76
Ring	72	82	77

- Based on analysis of swabs and returned rings
- Bottom line: product use was higher in Zimbabwe than in South Africa, and higher for the gel and film than for the insert and ring.

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What women said about their chosen product during sex

Ring: 6% No sex in past 30 days, 4% Used product some or most of the time with sex, 89% Used product every time had vaginal sex

Insert: 2% No sex in past 30 days, 48% Used product some or most of the time with sex, 50% Used product every time had vaginal sex

Film: 6% No sex in past 30 days, 52% Used product some or most of the time with sex, 42% Used product every time had vaginal sex

Gel: 14% No sex in past 30 days, 29% Used product some or most of the time with sex, 57% Used product every time had vaginal sex

■ No sex in past 30 days

■ Used product some or most of the time with sex

■ Used product every time had vaginal sex

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Willingness to use products in the future

- After trying all four products, 125 (69%) women named one product they would not consider using in the future
  - 32% would not use rings
  - 17% would not use gel
  - 14% would not use film
  - 8%   would not use inserts

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Common pros and cons about the film: Qualitative findings

- **Pros:**
  - Perceived effect on vaginal state
    - tightened the vagina
    - enhanced sexual pleasure

- **Cons:**
  - Difficult to insert

So the film is good because if you insert it, you shrink back to having that vaginal tightness that is being followed up by men, one. Two, it dries all the waters, you become the cream tape [his favourite] such that he will not go anywhere.
(Zimbabwe, Female Participant, FGD2)

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Common pros and cons about insert

Pros:

Easy to use- small size and shape

- ease of use defined as not causing pain during insertion, quick to insert   or dissolving completely
- made the vagina dry
- enhanced sexual pleasure

Ay, the insert is alright...It doesn't waste any time, it's nicely small, it's quick to insert, it is quick to dissolve. (South Africa, Female Participant, FGD2)

Cons: some women complained of the vaginal wetness

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Common pros and cons about the gel

Pros:

- provided vaginal lubrication which improved sex
- Use of gel applicator made insertion smart and easy

So, gel increases wetness, which causes you to think, if you are someone who thinks a lot, you might think that my wife -- if you had not seen her applying the gel. You might suspect that your wife might have wanted to have sex with someone else… Because she will be already wet… At one point I asked why her vagina was now always wet when it's supposed to get wet when we are about to have sex. (Zimbabwe, Male Partner, FGD2)

Cons:

- excess vaginal wetness caused infidelity concerns

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Common pros and cons about the ring

Pros:

- Long acting

- Despite preference for the long-action, on-demand products were the most liked by women

(film in Zimbabwe and insert in South Africa)

Cons:

- Felt it during sex, it disturbed sex
- Too hard, big
- Difficult to insert

I also didn't like the ring but what I liked about it is that you insert it once and it stays. **(South Africa, Female Participant, FGD2)**

Mmm, it was bad because it was here like in the front you know, you end up not reaching [penetrating] far. (South Africa, Male Partner, IDI)

Participants recommended that the ring be modified to make it more acceptable

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Conclusion

- Data from Quatro study provided rich feedback on specific attributes important to the acceptability of four HIV prevention product platforms currently in development, enabling more informed and guided product development efforts moving forward.

- A product that is long-acting, easy to use and non-interfering with sex could be more likely to be accepted and used.

- Participants' different experiences with and perceptions about the four products further justify the need to expand the options available for women to protect themselves against HIV.

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Acknowledgements

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