## PEER REVIEW HISTORY

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## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | A nationally-representative survey of health care provider counseling and provision of the female condom in South Africa and Zimbabwe |
| **AUTHORS** | Harper, Cynthia; Holt, Kelsey; Blanchard, Kelly; Chipato, Tsungai; Nhemachena, Tazaadza; Blum, Maya; Stratton, Laura; Morar, Neetha; Ramjee, Gita |

## VERSION 1 - REVIEW

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| **REVIEWER** | Dr Mags Beksinska<br>Technical Advisor<br>Maternal Adolescent and Child Health<br>Dept of O&G<br>University of the Witwatersrand<br>South Africa |
| **REVIEW RETURNED** | 04-Nov-2012 |

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| **THE STUDY** | The criteria above should have another column for N/a as there were no patients however when I say no for some It is more a case of bing unsure as explained in my review I would like to know if providers were asked about counseling and provision in clinics where no FCs were available and staff were not trained and some of these are probably represented in the non-responders but its not clear. I do not feel that SA and Zim can be directly compared unless the facilities are comprable in terms of curently able to offer FCs |
| **RESULTS & CONCLUSIONS** | I explain this in reviewers comments as it does not state in paper if clinics sampled actually had FC or the nurses had been trained in FCs so it would be more credible to breakdown the information by availability. |
| **REPORTING & ETHICS** | Above no to point one as it is not required, point 2 i have asked for DoH apporval information and how consent was gained from providers as does not say. |
| **GENERAL COMMENTS** | This paper describes a two-country survey among providers and is very interesting and important information. It is well written and I have commented on a few issues below firstly general ones and then specific edits.<br>This article talks of counseling and provision practices, therefore it is essential to know if the condom was “available” to be provided. In the discussion it says “we did not ask about availability or procurement cost” although Table 2 has a category which states currently offers FCs. This study was in the field in 2009 and although In South Africa the FC programme has expanded over the years FCs are not available in every clinic. The government policy is that facilities should not be distribution sites unless staff have been trained. Sites that do not have stock can refer to those that do. However in 2009 although training was not limited to those dedicated sites but those with stock are most likely to be trained first. The question is therefore were the clinics in the sampled sites in the survey official FC distribution sites/referral sites? This is very |

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| | important to know as if staff are untrained and have no stock they may be unlikely to counsel as they may be concerned that they cannot give women any FCs or have to refer them to other fcailities.<br>It was recommended that each sub district has at least one site but I do not think this is evenly applied across the provinces. The information is available from provinicial and district offices who can provide the information to the researchers. Zim has a different distribution system where all facilities aim to have FCs and this may explain the greater proportion of responses. As you are comparing SA to Zim and in Table 2 data shows that providers are significantly more likely to counsel and provide FCs it would be important not to compare them unfairly.<br>It would be important to compare those who have and those who do not have FCs In South Africa. It may also be why the response rate in SA was low.<br>Of the 40% who did not respond was there any attempt to find out why? Was it that the clinic when phoned told the interviewer that they had no FCs? Or were not part of the programme? Were the non responders clustered in clinics for instance?<br><br>Introduction: I think the introduction should have more information about the programmes in both countries specifically on the training programmes ( coverage etc)<br>Maybe useful to add that the FC has been recently identified by The Reproductive Health Supplies Coalition as one of several "underused" reproductive health technologies.<br>Page 7- social marketing of FCs is no longer available in SA and has not been available for some time.<br>Methods: Can you explain a bit more about the sampling when you say probablility proportional to size do you mean population size/district size or number of clinic in that district?<br>FP vs FC training in the results you present FP training but did this include FC training? Most of FC training to date in SA has been with male condom training, some with HIV prevention training so was it actually asked if they had been trained in FC counseling and distribution specifically?<br>Did the Department of Health give permission for the survey in their facilities at national? Provincial level? I assume so and this should be added to the approval paragraph.<br>How was consent gained? From individuals? From Clinics? Verbal or written<br>Results: in the methods it says if clinic was sampled all providers were included. For Zim it was 7 per clinic on average and in SA it was 10. In the results can you add aside from providers what proportion of the initial site sample participated in any way. Of the 116 in SA and 130 fcailities in Zim how many were represented.<br>Add reason for non response for the telephone interviews<br>Table 1<br>Under type of facility sub heading for Urban rural could be added to indicate these are two categories?.<br>Discussion<br>Page 13 para 2 "did not ask about availability or procurement cost" maybe worth noting here that there are no procurement costs for FC in clinics in SA. FCs are provide free to clients in SA and Zim in public sector.<br>As above it maybe worth discussing the results in light of the country training programmes. For instance in SA most PHC clinics rely on nurses with limited use of doctors who may not be full time or available every day and so often far fewer were trained and this explains the findings on page 10. |

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| | The discussion last para should also expand on the sentence "providers noted that FCs are expensive and not always available in clinics" in the light of the "who pays" clinics in SA and ZIm do not pay for the stock and they are free to women but the programme is restricted by cost and rather than "not always available" should be for SA are available in some where stock should always be there and not available in others where stock has never been available. There maybe more stock outs however.<br>The response rate is noted as "high" in strengths and limitations and in discussion but the SA response rate was only 60% which is not that high?<br>I am surprised that the Zim response rates are so much higher seeing that this was self- administered compared to telephone administered. |

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| **REVIEWER** | Anny Peters<br>PhD researcher<br>RutgersWPF, Utrecht.<br>The Netherlands.<br><br>I have no competing interests. |
| **REVIEW RETURNED** | 08-Nov-2012 |

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| **THE STUDY** | The participants of the study are not cleary defined. At this moment it is said to be providers (physicians and nurses) in HIV/STI clinics and in family planning clinics. Are these clinics always separate? Never integrated? Government or private? Who takes care for the stock of the products? Are male or female patients visiting? Etc. etc.<br><br>The research question is not very clear and therefore the resutls. "We examined female condom counseling and provision among providers". The main question for me is: can you expect counsellers to counsel on a product which is not available or not provided? So what is first? First provision (stability in availablity of the product) or first counselling. When you counsel and the product is quickly out of stock (as reported): what is than the main issue?<br>So the research question should be more precise and should already state the starting point: there is not any family planning clinic nor STI/HIV clinic with ensured stock of female condoms. This has big consequences for the level of counselling and for the level of take up of the method. |
| **RESULTS & CONCLUSIONS** | Because the research question is not very clear, the results do not answer it. (see above)<br><br>I think the discussion could be more elaborated. for example also including studies which show that a health providers power: they can "make or break" a new product. Also include health providers studies researching attitudes towards condoms. |
| **GENERAL COMMENTS** | **A nationally-representative survey of health care provider counseling and provision of the female condom in South Africa and Zimbabwe**<br><br>**Short title: Provider counseling and provision of female condom in South Africa and Zimbabwe** |

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**Words: 2,914**

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**Keywords:** HIV; prevention; condoms, female; health care providers; Africa, southern

**Article summary**

1) Article focus:

- Cross-sectional study examining current female condom counseling and

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provision practices among a nationally-representative sample of health care providers in South Africa and Zimbabwe

- Assessment of whether providers view female condoms as more appropriate for certain types of patients
- WHY PATIENTS? FEMALE CONDOMS ARE FOR PREVENTION. PEOPLE ARE NOT ILL, WHO USE THE FEMALE CONDOM. SO NO PATIENT, YOU HAVE TO REACH THE GENERAL POPULATION, WHO ALL MIGHT USE THEM TO PREVENT STI,AIDS OR PREGNANCY,
- and how their FC practices varied compared to those for male condoms
- This is very relevant question. Do providers view female condoms in a different way than male condoms and why?

2) Key Messages:

- Most providers reported offering female condoms (more so in Zimbabwe than in South Africa) but perceived a need for novel female barrier methods for HIV/STI prevention, suggesting female condoms do not meet all patient/provider needs or are not adequately well-known or accessible .
- THIS IS A KEY QUESTION.
- ARE PATIENTS NOT SATISFIED.
- Or ARE PROVIDERS NOT SATISFIED. ON BASIS OF WHAT CRITERIA ARE THEY NOT SATISFIED?
- OR ARE THE FEMALE CONDOMS NOT ADEQUATELY KNOWN AMONG PROVIDERS AND THUS PATIENTS?
- OR ARE THEY JUST NOT AVAILABLE, OR TO EXPENSIVE.
- FIRST THE WRITERS HAVE TO GIVE THEIR OWN VIEW ON THE FEMALE CONDOM. HOW DO THE WRITERS PERCEIVE THE PRODUCT?
- Providers reported less frequent female condom counseling of adolescents, women using hormonal contraception, and married women, compared to unmarried or HIV-positive women, suggesting the need for training emphasizing the importance of female condom counseling with all

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women

IMPORTANT FINDING THAT PROVIDERS DO NOT COUNSEL ADOLESCENTS ON THE USE OF THE FEMALE CONDOM. NOBODY HAS EVERY PROMOTED THE FEMALE CONDOM TO YOUNG PEOPLE. THIS IS THIS FIRST TIME IT IS STRESSED IN A STUDY THAT THIS IS ONE OF THE POSSIBILITIES, BUT NEVER GOT ANY ATTENTION. FEMALE CONDOM MIGHT BE A VERY GOOD PRODUCT FOR YOUNG GIRLS WHO START BEING SEXUALLY ACTIVE. THERE IS A LOT OF LUBRICANT ON THE PRODUCT (fc2) AND IT MIGHT PREVENT THE VULNERABLE INSIDE OF THE VAGINA FROM RUPTURES.

- Providers should be included in HIV training efforts to raise awareness of new and existing products
- PROVIDERS SHOULD BE AWARE OF THEIR OWN ATTITUDES TOWARDS PROMOTING CHANGES AND TOWARDS THE PRODUCT. WHAT THEY PREACH, PATIENTS WILL PRACTISE. THIS IS ALSO TRUE FOR THE RESEARCHERS WRITING THIS ARTICLE AND RESEARCHING THIS TOPIC: WHAT IS THEIR OWN ATTITUDE TOWARDS THE PRODUCT?

3) Strengths and Limitations:

Strengths: this is the first nationally-representative survey in South Africa or Zimbabwe examining female condom counseling and provision and we obtained high response rates; thus, we are able to generalize to the entire provider populations of these two high HIV prevalence countries

- Limitations: Potential social desirability bias may have influenced responses toward more comprehensive levels of prevention counseling.
- WAS THERE A DIFFERENCE BETWEEN MALE AND FEMALE PROVIDERS?

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**Abstract**

**Objectives:** Female condoms are the only female-initiated HIV and pregnancy prevention technology currently available. We examined female condom counseling and provision among providers in South Africa and Zimbabwe, high HIV-prevalence countries.

**Design:** Cross-sectional study using a nationally-representative survey.

**Setting:** All facilities that provide family planning or HIV/STI services in the two countries.

Who is coming to these clinics?

STI clinics mainly for men? And prostitutes only?

Please explain that in South Africa and Zimbabwe you have special STI clinics. Maybe a bit of the history of STI treatment in these two countries, likewise the family planning clinics. I think due to the name (family planning), unmarried people don't visit these clinics.

**Participants:** National probability sample of 1,444 nurses and physicians (male or female?) who provide family planning or HIV/STI services.

**Primary and secondary outcome measures:** Female condom practices with different female patients, including adolescents, married women, women using hormonal contraception, and by HIV status. Using multivariable logistic analysis, we measured variations in condom counseling by provider characteristics.

**Results:** Most providers reported offering female condoms (88%), but perceived a need for novel female barrier methods for HIV/STI prevention (85%). By patient type, providers reported less frequent female condom counseling of adolescents (55%), women using hormonal contraception (65%), and married women (66%), compared to unmarried (74%) or HIV-positive women (82%).

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Multivariable results showed providers in South Africa were less likely to counsel women on female condoms than in Zimbabwe (OR=0.48, 95% CI: 0.35-0.68, p≤ 0.001).

Zimbabwe is known to be the country with the best female condom availability and access. So maybe there is more counseling, because the availability has always been higher?

However, South African providers were more likely to counsel women on male condoms (OR=2.39, 95% CI: 1.57-3.65, p≤ 0.001).

Nurses counseled patients on female condoms more frequently than physicians (OR=5.41, 95% CI: 3.26-8.98, p≤ 0.001).

This is also a well known fact that physicians (or male?) are less likely to counsel on prevention in general, or talk about sex.

HIV training, family planning training, provider location (urban vs. rural), and facility type (hospital vs. clinic) were not associated with greater condom counseling.

And what about the variables:

1. age and 2. gender and 3. Provider's attitude towards (female) condoms?

**Conclusions:** Female condoms were integrated into provider counseling and care, although providers reported a need for new female-initiated multipurpose prevention technologies, suggesting female condoms do not meet all patient/provider needs or are not adequately well-known or accessible.

Important to know what it is. Due to the fact that the providers in Zimbabwe are more positive, I would say that it is due to the lack of the fact that the product is just not available and therefore not known. It is terrible expensive!

Providers should be included in HIV training efforts to raise awareness of new and

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existing products, and encouraged to educate all women.

I think this can reasonably be expected, when the product is well priced. At this moment it is far too expensive to be used by women in developing countries. If you encourage all women to use a product, you have to consider the price setting.

**INTRODUCTION**

There is growing recognition that no single intervention will be sufficient to halt the HIV epidemic and that combination prevention strategies tailored to the needs of specific populations have the most potential for decreasing HIV infection rates.(1) The female condom (FC) is the only available alternative to the male condom that provides protection from both HIV/STI infection and pregnancy, and it is a method that women can initiate. A review of research on the FC concluded that increased access to the method leads to an increase in protected sex acts in a population, and decreased STI incidence.(2) Though there have been promising results from recent clinical trials testing the effectiveness of novel woman-initiated methods, including microbicides(3) and pre-exposure prophylaxis,(4) conclusive proof of effectiveness and registration of a new product is unlikely for a number of years, and the FC continues to fill this important niche.

In sub-Saharan Africa, women are at increased risk of HIV/AIDS and heterosexual sex is the predominant mode of transmission.(5) HIV prevalence among women was estimated at 33% in the peak ages (25-29 years) in South Africa and 29% in Zimbabwe (30-39 years).(6, 7) Additionally, 24% of married women and 9% of never-married women in sub-Saharan Africa have an unmet need for contraception—rates higher than elsewhere in the developing world.(8) In South Africa and Zimbabwe, reported use of the FC is less than 1% compared to 4-6% use of male condoms among married women in peak ages.(7, 9)

Since the United States Food and Drug Administration (USFDA) approved the first available product—the FC1—in 1993, there has been a lack of

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commitment and resources to expand access to the FC among the international policy community.(10) In 2009, the USFDA approved a second-generation FC called FC2 made of synthetic latex rather than polyurethane. The FC2 is less expensive and makes less noise when used;(10) other new FC technologies are in development and could reduce costs further. In addition, the 2010 and 2011 U.S. PEPFAR *Fiscal Year Country Operational Plan (COP) Guidance* specifically mentioned the importance of FCs in country program plans.(11) These new products and policy developments are positive signs of increased support for the FC.

Health care provider participation, however, is essential to the success of FC programs. Even if countries procure significant supplies, women and men may have limited knowledge and access if providers do not discuss and provide FCs. Unlike the male condom, the FC is typically obtained through provider contact, not dispensers, in the public sector. Training and accurate information from providers could increase acceptability and sustained use of the FC.(10)

Yes. This is very important to mention. Well done. The male condom is marketed normally. The female condom not. It is only available through health care provider contact (or through social marketing, for example in Zimbabwe through hair salons).

Few studies have examined counseling and provision practices for FCs in sub-Saharan Africa. Three early case studies exploring family planning providers' attitudes about the FC in South Africa and Nigeria (where the FC was not yet introduced in the public sector), and the United States (U.S.) found that U.S. providers lacked knowledge on the FC despite product availability and saw the method as appropriate only for certain women, such as sex workers or HIV-positive women.(12)

Yes indeed, very important to mention. Many providers have biased attitudes towards the female condom, see also study of Amy Kahler, done in South Africa, among health providers.

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In the U.S. and South Africa, providers reported negative attitudes about the aesthetics and use of the FC, although providers in South Africa were more enthusiastic after receiving training. In a study of voluntary counseling and testing counselors in Kenya, many counselors recognized the need for a female-initiated prevention method but felt uncomfortable with FCs or expressed concern about counseling when FCs were not widely available.(13)

This is a great concern. There is no use to counsel on something which is not or only available to very rich people! These studies, albeit small and non-generalizable, suggest a need for further investment in supporting providers to counsel and offer women the FC.

As already said, at this moment, I fully understand why Zimbabwean and South African health providers don't counsel on the product, simple because it is too expensive or not available. There is no use to counsel on products which are not made available.

In this nationally-representative study of physicians and nurses, we examined FC counseling and provision practices in South Africa and Zimbabwe. The two countries have different histories of FC introduction that could impact provision at the health service level. Zimbabwe was one of the first countries to introduce FCs in 1997 through the public sector and innovative social marketing campaigns. Scale-up of male and female condoms in recent years has been based on a national comprehensive behavior change strategy to reduce sexual transmission of HIV.(14) FC distribution in the public sector in Zimbabwe increased from about 400,000 in 2005 to more than 2,000,000 in 2008 and social marketing sales have risen from about 900,000 in 2005 to more than 3,000,000 in 2008.(14) South Africa introduced the FC shortly after Zimbabwe in 1998 primarily through public-sector family planning clinics and community-based programs;(15) social marketing promotion efforts also exist. FC distribution in South Africa is among the highest in the world (4.3 million FCs distributed in public sector in 2008);(16) however, proportional to population size (the population of South Africa is

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approximately four times that of Zimbabwe), Zimbabwe has higher distribution rates.

Zimbabwe is indeed the so-far best country in introducing the FC. However, when talking to Zimbabweans (from time to time), they are not aware of it. So it might be still small scale, just because the product is not to be find through a normal, shop, retail system.

We investigated counseling and provision practices among a nationally-representative sample of providers to gauge the prevention services offered to a range of patients in varied clinical settings. We assessed whether providers view FCs as more appropriate for certain types of patients, and how their FC practices varied compared to those for male condoms. The results have the potential to inform efforts to prepare providers to expand access to this female-initiated prevention method for their patients.

**METHODS**

This study is part of a mixed-methods research project in Southern Africa investigating providers' pregnancy and STI/HIV prevention practices. We completed national probability surveys of physicians and nurses in South Africa and Zimbabwe in 2009. Participants answered a series of questions on female and male condom counseling and provision practices, as well as demographic and professional practice characteristics and patient population. The surveys were preceded by 60 in-depth interviews of providers serving female patients at risk of HIV, which revealed their views of FC use within their patient populations.

We used a multistage, facility-based approach to generate a national probability survey sample of providers. We randomly selected districts (with probability proportional to size), then facilities that provided family planning or HIV/STI services within those districts (stratified by type—hospital or clinic—and probability proportional to size), and recruited all providers from those facilities who

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provided family planning or HIV/STI services. The methodology has been described in detail elsewhere.(17) The final sample included 1,019 providers representing 116 facilities from South Africa and 953 providers representing 130 facilities from Zimbabwe.

Data were collected via self-administered questionnaires distributed in-person in Zimbabwe and telephone-administered questionnaires in South Africa (costs of in-person visits were prohibitive due to the large country size). The study was approved by the University of KwaZulu-Natal Biomedical Research Ethics Administration, the Medical Research Council of Zimbabwe, the Western Institutional Review Board, and the University of California, San Francisco Committee on Human Research.

Providers were asked whether they currently provide the FC and the male condom, and whether they would like to receive more training (yes/no). Providers were also asked about the frequency of female (and male) condom counseling, on a 4-point Likert scale (never, sometimes, usually, or always), with the following types of female patients: women in general, female teenagers, HIV-positive women, married women, unmarried women, and women using hormonal contraception. They were asked whether they believe FCs are appropriate contraceptives for women at risk of HIV infection (yes/no) and HIV-positive women (yes/no), whether they routinely talk to female patients about pregnancy and HIV/STI prevention in the same visit (yes/no), and how much of a need there is for more female barrier methods for HIV/STI prevention (on a scale of 1-10).

It is not clear what is done in the overlap of the female patients.

All women

Unmarried – married.

HIV+

Women using hormonal contraception.

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We assessed clinician practices by country for different types of female patients in these high HIV prevalence settings, using chi-square statistics for categorical variables and t-tests for continuous variables. We analyzed condom counseling practices with multivariable logistic regression to assess FC counseling by provider and practice-related characteristics. We also analyzed male condom counseling practices for comparison. The outcome variables were routine (usually/always) counseling on female and male condoms. We adjusted analyses for the facility-based sampling scheme to account for clustering at the facility level. We used Stata 11.0 (College Station, TX) for analyses. Significance was defined as $P<0.05$. We conducted thematic analysis of qualitative data to investigate open-ended provider responses about their counseling and provision practices.

**RESULTS**

A total of 614 providers from South Africa and 830 providers from Zimbabwe completed the survey (N=1,444) with an overall response rate of 73.2%. In South Africa, the response rate did not differ between hospitals (61%) and clinics (60%), though nurses were more likely to respond than physicians (66% versus 39%).

Important finding! Often physicians have more power than nurses in a health clinic. What does it mean to prevention and the importance given to prevention?

In Zimbabwe, providers in hospitals were more likely to respond than in clinics (92% versus 81%), and physicians were more likely to respond than nurses (100% versus 87%). Did you ask the gender of the nurses and physicians?

The majority surveyed in both countries were female (86%), nurses (91%) (Table 1).(17) Most reported prior training in HIV prevention (80%) and family planning (63%). Participants were split between hospital (55%) and clinic (45%) settings,

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and urban (48%) and rural (52%) areas. The majority (70%) reported that most or all of their patients are at risk for HIV.

Almost all (99%) providers reported currently offering male condoms to patients (Table 2).

So offering male condoms to male and female patients?

Why not asked why female condoms are not provided to male patients?

A large majority in both countries (88%) reported offering FCs, with a lower proportion in South Africa (80%) than Zimbabwe (94%) ($p \leq 0.001$). More providers in South Africa (28%) than Zimbabwe (14%) reported that they would like training on FCs ($p \leq 0.001$).

Seventy-one percent reported routinely counseling (usually or always) women on FCs; more providers reported FC counseling for HIV-positive (82%) and unmarried women (74%), and fewer reported counseling for married women (66%), women using hormonal contraception (65%), and female adolescents (55%). Most of these differences in counseling by patient type were due to large variations in Zimbabwe where counseling for HIV-positive women was 93%, but for adolescents was 50% (Table 2).

Important finding

In South Africa, there was a lower level of routine counseling in general (62%), with little difference among the patient types, ranging from 67% of HIV-positive women to 62% of adolescents. However, 90% of providers in South Africa reported routine male condom counseling with female patients compared to 80% in Zimbabwe. Similar within-country counseling patterns held true for male condoms, with 94% routinely counseling female adolescents in South Africa compared to 56% in Zimbabwe.

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| | Support for the FC as a contraceptive method for HIV-positive women or women at risk of HIV infection was high overall;<br><br>Important finding. It means that providers view male and female condoms very differently. Male condoms as to be used by all people who like to practice safe sex: the famous “condomize” campaigns in Zimbabwe and South Africa. While female condoms are perceived for “not normal” women instead of all women. In this way the providers are stigmatizing the product (and the users…).<br><br>in Zimbabwe there was near universal support for women at risk of HIV infection (98% versus 84% in South Africa; p≤0.001) or HIV-positive women (97% and 87%, respectively; p≤0.001) (Table 2). The large majority (89%) reported routinely talking to female patients about pregnancy and HIV/STI prevention in the same visit. About two-thirds of providers (68%) believed there is a very high (9 or 10 on a scale of 1-10) need for more female barrier methods for HIV/STI prevention.<br><br>Important finding that more female barrier methods, more types of female condoms are needed. It is strange because there is hardly any new technological developments on variations on the female condom.<br><br>In multivariable logistic regression, several provider characteristics were found to be significantly associated with routine condom counseling (Table 3). Providers in South Africa were significantly less likely to counsel female patients on the FC (OR=0.48; p≤0.001), and more likely to counsel on the male condom (OR=2.4; p≤0.001). Provider age was positively associated with FC counseling (OR=1.02; p≤0.001), and nurses were significantly more likely than physicians to counsel patients on both female (OR=5.4; p≤0.001) and male condoms (OR=2.6; p≤0.001). HIV prevention training and family planning training were not associated with FC counseling. HIV prevention training was associated with male condom counseling in bivariate models, but in the multivariable models including a variable for proportion of patients at risk of HIV (most/all), HIV training was no longer significant, although high proportion of patients at risk of HIV was (OR=1.6; |

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p≤0.001). HIV training was not significant for counseling on condoms. Was the attitude of the provider towards the product taken into consideration?

Condom counseling did not vary by urban versus rural clinical setting or in clinics or hospitals.

The in-depth interviews gave some insight into the reasons that some providers might include the FC in counseling, while others might not.

Where the in-depth interviews used before or after the survey?

Where they used to make the questionnaire?

Or where they used to find more in-depth answers, after the survey.

Many providers mentioned logistical factors in the interviews, as well as physical attributes, which might restrict use.

Providers noted that FCs are expensive and are not always available in clinics.

This is a very important finding. This restricts ofcourse the level of counseling. You can't counsel if the product is not there. So we don't need new products, we rather need more attention for existing products.

Several considered physical features as method limitations, including discomfort and being highly visible. Alternatively, many providers noted that some men who will not use a male condom will agree to a FC, since the women puts it on. Providers noted that the FC could help empower women since they could ensure it was used.

**Important findings.**

**DISCUSSION**

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| | The FC was integrated into provider practices in Southern Africa, but to a lesser extent than the male condom. Providers in Zimbabwe reported counseling patients on FCs significantly more than providers in South Africa, which is likely attributable to the larger public sector FC program in Zimbabwe, relative to population size. Providers across South Africa may have been less likely to have learned about the FC due to the geographic distance and smaller FC program per population. As in a previous study from Kenya,(13) providers from both countries noted in interviews that the FC was not always available in clinics even though it was distributed in the public sector. FCs, a basic technology, had counseling patterns that were similar in rural and urban areas and clinics and hospitals, unlike for more sophisticated technologies which in general are more available to urban populations or in hospital settings.<br><br>Variations in counseling by patient type were wide in Zimbabwe, with high levels of counseling for HIV-positive women. In Zimbabwe, providers were much less likely to report female and male condom counseling with adolescents than with women in general, suggesting the need for provider training emphasizing the importance of education of adolescents on safe sex, perhaps even prior to sexual initiation; less thanhalf of Zimbabwe adults in the 2010-2011 DHS, however, supported condom education for 12-14year olds.(7) Zimbabwe providers were also less likely to report condom counseling with women using hormonal contraception, signaling the need for emphasis on dual protection of STIs and pregnancy. In both countries, providers were less likely to counsel married women than unmarried women on FCs, although it is essential to give all women information in these high-prevalence settings. Condom use is less common among married women, although one study of a condom intervention (female and male) showed increased use among HIV-positive married women.(18) There were some signs in the qualitative data that providers thought FCs might be more acceptable in marriage than male condoms in some cases where the woman would be willing to make the effort and ensure use was consistent. Another early study from the U.S. identified similar training needs among providers who saw FCs as appropriate for only |

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certain groups of women, such as HIV-positive women.(12)

A number of providers reported a desire for more FC training, signaling the need for continued investment in programs and policies to support access to the FC in both countries. Previous research from South Africa has demonstrated the positive impact of training on provider attitudes.(12) Our results showed that neither having previous HIV training nor serving a high proportion of at-risk patients significantly increased likelihood of provider counseling on FCs. Efforts should be made to ensure that HIV and family planning training in both countries include FCs, given the wider availability of supplies in recent years. This is incorrect. As most providers said, the availability is inconsequent. This is the worst condition, when you promote a new product! The product should be easily available. The finding that nurses were significantly more likely than physicians to report counseling women on both male and female condoms reflects the prominent role that nurses play in prevention counseling; however, physicians should also be prepared to counsel women and men about their options for dual protection against pregnancy and STIs.

Providers reported a strong need for new female-initiated barrier methods for prevention In other part of the article it is said that providers wanted new female barrier methods (you can also say more variations in the female condom) and, similar to prior research from the U.S. and South Africa,(12) several providers demonstrated negative attitudes about the aesthetics and use of the FC during qualitative interviews. That is why we need the development of new female condoms, more varieties. This finding suggests that current technologies may not meet all their patient needs or are not adequately well-known or accessible, though it is important to note that this research was conducted just before the new FC2 was approved by the USFDA.

The reported desire for training suggests that even as we work to develop new technologies, we must also invest in programs and policies that ensure the potential for available existing technologies is achieved.

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These findings must be considered in light of study limitations. We did not ask providers about availability or procurement cost of FCs in their health care systems. These factors might influence their ability to provide them and thus the likelihood that they counsel patients. Since providers are reporting on their counseling practices, it is likely that social desirability bias influenced responses toward more comprehensive levels of prevention counseling; therefore patients for whom we measured low levels of counseling are likely to be in even greater need of FC education. Our study also has important strengths. Our nationally representative surveys (with relatively high response rates) allow us to generalize about providers' counseling and provision practices in these two countries; this is the first research on FC counseling and provision in Southern Africa to include representative national samples of providers. Further, very few data existed previously on FC counseling and provision in sub-Saharan Africa overall and our study contributes significantly to the literature on this topic by providing information on current provider practices in two high HIV-prevalence countries.

Provider practices and support are essential to the successful integration of the FC into HIV and family planning services, and ultimately to ensuring women can protect themselves from both STI infection and unintended pregnancy. Our findings revealed provider support for the FC as a dual-protection method, and a significant need for further work promoting provider counseling in particular with adolescents, married women, and women using hormonalcontraception.

**TABLE 1: Provider and Practice Characteristics**

| | **Zimbabwe (n=830)** | **South Africa (n=614)** | **Total (N=1444)** |
|---|---|---|---|
| **Gender**, n (%) | | | |
| Female | 674 (82) | 547 (90) | 1221 (86) |
| Male | 145 (18) | 62 (10) | 207 (15) |
| **Provider type**, n (%) | | | |
| Nurse | 792 (95) | 528 (86) | 1320 (91) |

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| | | | |
|---|---|---|---|
| Physician | 38 (5) | 86 (14) | 124 (9) |
| **Age**, median years (range) | 39 (20-74) | 43 (23-69) | 41 (20-74) |
| **Previous training**, n (%) | | | |
| HIV Prevention | 629 (77) | 510 (84) | 1139 (80) |
| Family Planning | 503 (61) | 399 (66) | 902 (63) |
| **Type of facility**, n (%) | | | |
| Hospital | 484 (59) | 309 (50) | 793 (55) |
| Clinic | 342 (41) | 305 (50) | 647 (45) |
| Urban | 375 (45) | 315 (51) | 690 (48) |
| Rural | 451 (55) | 299 (49) | 750 (52) |
| **Proportion of patients at risk for HIV**, n (%) | | | |
| None/Some | 175 (22) | 46 (8) | 221 (16) |
| Half | 112 (14) | 92 (15) | 204 (14) |
| Most/All | 524 (65) | 470 (77) | 994 (70) |

**TABLE 2: Condom Counseling and Provision Practices and Female Condom Beliefs**

| | **Zimbabwe (n=830)** | **South Africa (n=614)** | **Total (N=1444)** |
|---|---|---|---|
| **Currently offers condoms**, n (%) | | | |
| Female condoms*** | 756 (94) | 483 (80) | 1,239 (88) |
| Male condoms | 796 (99) | 599 (99) | 1,395 (99) |
| **Would like training on condoms**, n (%) | | | |
| Female condoms*** | 112 (14) | 165 ( | |

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11. CHANGE.

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| **REVIEWER** | Alexandra Minnis, PhD<br>Senior Research Epidemiologist<br>RTI International - San Francisco<br>USA |
| **REVIEW RETURNED** | 09-Nov-2012 |

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|---|---|
| **GENERAL COMMENTS** | This manuscript is extremely strong and was enjoyable to read. The writing is clear, the questions well-defined and the analysis carefully conducted and presented. The data are unique, being both population-based in two countries with persistently high HIV epidemics and derived from a national sample of providers.<br><br>The question of whether and how to promote female condom use has surfaced a number of times since its availability and apparent comparable effectiveness to male condoms as an STI prevention tool. Despite recent advances in oral PrEP and treatment for prevention, highlighting the opportunity to promote an existing prevention device to at-risk women stands as an important contribution of this paper.<br><br>One limitation of the data is minimal information about the content and quality of the counseling offered, which could have a bearing on whether female condoms are ultimatley used by women. That is, was female condom counseling interactive, didactic, did it address perceived barriers to use and partner reactions? There was likely tremendous variability but I wondered whether any of this was explored through the qualitative interviews. Earlier FC studies conducted in the US demonstrated that uptake was higher among women who had had an opportunity to insert the condom during a clinic visit and to troubleshoot problems/barriers with their clinician. Protocols for vaginal ring microbicide trials and other HIV prevention barriers now regularly include insertion of the first dose/product while at the clinic for this reason. A bit of consideration of this issue in the Discussion seems worthwhile. And, the degree to which you can use the qualitative data to explore this issue when you present some qualitative findings would enrich the results.<br><br>A second issue to consider further is the use of the qualitative data. Currently there is one paragraph of results from the in-depth interviews and I would either do more to enrich the findings that are shared or consider not including it in this paper if you do not have the space to use the qualitative data to explore themes related to key quantitative findings. It just seemed a bit thin given you have |

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| | conducted 60 interviews.<br><br>Minor comments:<br>INTRODUCTION<br>1) Page 5, line 24: I would note that oral PrEP, deemed an effective HIV prevention approach in some populations, including sero-discordant couples, is now recommended and approved for use. This could also be female-initated so I would modify this last sentence of the first paragraph a bit.<br><br>2) Page 5, line 34: note the year for this HIV prevalence estimate given the phrasing of the sentence.<br><br>3) Page 5, line 43: simply state the age range from which these condom use proportions are estimated rather than "in peak ages". Also, while most readers will know that adolescents have high rates of HIV, you might highlight that here given your finding that counseling is happening least often among youth, despite their high incidence and the dramatic increase in prevalence between 15 and 20 years of age. There are plenty of data from South Africa on this that would be relevant to cite here.<br><br>4) Page 6, line 16: I was somewhat puzzled by the statement that female condoms are typically obtained through provider contact, yet the practice in Zimbabwe is broader distribution. Since Zim is one of the two countries included in this study I would reconcile this statement with the study setting, even if it just means you state that there are several exceptions. I suspect that PSI, which has done some of the FC distribution in Zim and social marketing campaigns may operate similar programs in other Southern African countries -- perhaps they are more recent.<br><br>5) Page 7, line 31: insert "counseling" between FC and practices.<br><br>METHODS: Page 9, Line 7: a minor point, but I would just clarify that you have two outcomes for which you examined the same set of predictors. I wasn't sure at first read of the text whether you were considering a combined outcome of female AND male condom counseling.<br><br>RESULTS:<br>Analysis of in-depth interviews (last paragraph of results): Do you have anything to report on your quantitative finding that providers counseled some types of women (e.g., adolescents) more than others (in Zim, anyway)? I felt this paragraph could be strengthened, especially since you conducted 60 in-depth interviews. Likely these findings will be (or have been) reported elsewhere, but I wanted to see these data used a bit more to explicate some fo the quantitative findings. Twice the physical attriutes are noted and there isn't much depth to the results presented.<br><br>DISCUSSION:<br>Page 12, line 14: I would emphasize here the considerable HIV risk among women from their marital partner. And, then, I would address the apparent inconsistency between the qualitative finding that providers though FC use might be more acceptable in marital relationships but counseled married women less often on FC use. Limitations (see initial comment). |

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## VERSION 1 – AUTHOR RESPONSE

Reviewer: Dr Mags Beksinska
Technical Advisor
Maternal Adolescent and Child Health
Dept of O&G
University of the Witwatersrand
South Africa

I would like to know if providers were asked about counseling and provision in clinics where no FCs were available and staff were not trained and some of these are probably represented in the non-responders but its not clear. I do not feel that SA and Zim can be directly compared unless the facilities are comprable in terms of curently able to offer FCs
I explain this in reviewers comments as it does not state in paper if clinics sampled actually had FC or the nurses had been trained in FCs so it would be more credible to breakdown the information by availability.

Thank you for your thoughtful comments. While we do not have data that directly answers all your questions, we are able to address some of them with additional analyses. In the manuscript, we had the provider variable “current offers female condoms” (Table 2), which gives a nationally representative estimate of the large proportion of providers in each country who are offering patients female condoms. We do not have a direct measure, however, on who does not have the female condom, but we do have an indirect measure about availability that we are now adding to the manuscript. We have added data on the proportion of providers who said they would offer female condoms if they were more easily available to the Results, and we have also shown the estimate who would among those who are not currently offering female condoms (page 11 in manuscript and Table 2)

“Availability is an important factor in being able to offer a method, and 27% of providers reported they would offer female condoms if more easily available. Among the small proportion currently not offering female condoms (13% n=169), 68% in South Africa reported they would if it were more easily available and 54% in Zimbabwe.”

We also added these points on availability to the Discussion section on page 13.

“In the South African qualitative data, many providers commented that availability in the clinic is still a problem, although the majority reported in the national survey that if female condoms were more easily available, they would offer them.”

We have added an analysis of the routine counseling of different types of patients on female condoms among the providers who currently offer the method (Table 2). While the frequencies that show overall how many providers counsel the patients is valuable to see how much progress needs to be made broadly for patient well-being, it is also instructive, as you point out, to look at counseling patterns among those offering condoms, to discern whether those who have condoms are counseling patients routinely. In all instances, as you might think, the proportion of providers counseling is far higher, except for the female teen patients in Zimbabwe, which remains at the same low level. We have added more data from the qualitative interviews in the manuscript on page 13 that shows that for teens, providers emphasize abstinence counseling over condoms in Zimbabwe, and tend to include both in South Africa.

This paper describes a two-country survey among providers and is very interesting and important information. It is well written and I have commented on a few issues below firstly general ones and then specific edits.

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This article talks of counseling and provision practices, therefore it is essential to know if the condom was “available” to be provided. In the discussion it says “we did not ask about availability or procurement cost” although Table 2 has a category which states currently offers FCs. This study was in the field in 2009 and although In South Africa the FC programme has expanded over the years FCs are not available in every clinic. The government policy is that facilities should not be distribution sites unless staff have been trained. Sites that do not have stock can refer to those that do. However in 2009 although training was not limited to those dedicated sites but those with stock are most likely to be trained first. The question is therefore were the clinics in the sampled sites in the survey official FC distribution sites/referral sites? This is very important to know as if staff are untrained and have no stock they may be unlikely to counsel as they may be concerned that they cannot give women any FCs or have to refer them to other fcailities. It was recommended that each sub district has at least one site but I do not think this is evenly applied across the provinces. The information is available from provinicial and district offices who can provide the information to the researchers. Zim has a different distribution system where all facilities aim to have FCs and this may explain the greater proportion of responses. As you are comparing SA to Zim and in Table 2 data shows that providers are significantly more likely to counsel and provide FCs it would be important not to compare them unfairly.
It would be important to compare those who have and those who do not have FCs In South Africa. It may also be why the response rate in SA was low.

The surveys were national probability samples of physicians and nurses in family planning and HIV prevention care (largely primary care providers), so it gives a view over the whole country of provider practices, but unfortunately we cannot tell whether clinics were official FC distribution/referral sites. We have added your relevant commentary about stocking and distribution in South Africa to our Discussion section on page 13.

“In South Africa, the government has focused on reaching certain designated clinics with supplies and training, so availability is not yet ubiquitous.”

Of the 40% who did not respond was there any attempt to find out why? Was it that the clinic when phoned told the interviewer that they had no FCs? Or were not part of the programme? Were the non responders clustered in clinics for instance?

The national probability surveys were part of a large multi-country study on pregnancy and HIV prevention, and questionnaire items on female condoms formed part of a comprehensive survey of many different services. The response rate was unrelated to female condom availability, as providers were not aware that there were questions on the female condom before taking the survey. The principal reason for non-response among providers was that they were too busy or not at the clinic and we have added a note on this on page 10

“The most common reason for not responding was busy clinic load or that the staff was not at the clinic.”

Introduction: I think the introduction should have more information about the programmes in both countries specifically on the training programmes ( coverage etc) Maybe useful to add that the FC has been recently identified by The Reproductive Health Supplies Coalition as one of several “underused” reproductive health technologies.

We have added clarifications to the paragraph on programmes in both countries (on page 7) to specify that in contrast with Zimbabwe, South Africa does not yet have female condoms available in all public sector facilities.

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In addition we have added to the limitations in the Discussion section (p.15) the fact that we did not ask directly about prior female condom training .

[Zim]: “Scale-up of male and female condoms in recent years has been based on a national comprehensive behavior change strategy to reduce sexual transmission of HIV and FCs are now offered in all public-sector facilities.”

[RSA]: “FC distribution in South Africa is among the highest in the world (4.3 million FCs distributed in public sector in 2008);(16) however, FCs are not yet available in all public-sector facilities in South Africa and proportional to population size (the population of South Africa is approximately four times that of Zimbabwe), Zimbabwe has higher distribution rates.”

“We did not ask providers directly about stocking of FCs in their health care systems or whether they had prior training in FC counseling.”
Thank you for pointing out the Reproductive Health Supplies Coalition – we have also added this to a sentence earlier in the introduction (page 6):

“In addition, the 2010 and 2011 U.S. PEPFAR Fiscal Year Country Operational Plan (COP) Guidance specifically mentioned the importance of FCs in country program plans and the Caucus on New and Underused Reproductive Health Technologies recently named the FC as one of several “underused” reproductive health technologies.”

Page 7- social marketing of FCs is no longer available in SA and has not been available for some time.

Thank you for that information-we have removed the phrase on social marketing.

Methods: Can you explain a bit more about the sampling when you say probablility proportional to size do you mean population size/district size or number of clinic in that district?

The probability proportional to size was based on numbers of physicians and nurses, which we have added to the Methods section on page 8.

FP vs FC training in the results you present FP training but did this include FC training? Most of FC training to date in SA has been with male condom training, some with HIV prevention training so was it actually asked if they had been trained in FC counseling and distribution specifically?

The family planning training is a general measure, and does not ask about specific services.

Did the Department of Health give permission for the survey in their facilities at national? Provincial level? I assume so and this should be added to the approval paragraph.

We have added approval information in the Methods section on page 9; the necessary approvals varied in each country. South Africa, for example, required provincial, not national approval, since the provinces were randomly selected and not all were in the study. However, in Zimbabwe, national approval was needed.

“Approvals were granted as required in each country, at the national, provincial, district and facility levels. In South Africa, provincial approval was granted, as well as district-level approval where required by the facility. In Zimbabwe, approval was granted at the national level, and either the provincial or district level, as needed.”

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How was consent gained? From individuals? From Clinics? Verbal or written

Verbal permission was given from facilities (although in some cases written) to recruit clinicians. Implied consent was given by individuals. In South Africa verbal consent was obtained for interviewer-administered surveys (most surveys), while consent was implied for self-administered surveys in South Africa and Zimbabwe. Prospective participants were given a cover letter describing study and inviting participation, along with the paper, self-administered questionnaire. Return of the survey implied consent to participate.

Results: in the methods it says if clinic was sampled all providers were included. For Zim it was 7 per clinic on average and in SA it was 10. In the results can you add aside from providers what proportion of the initial site sample participated in any way. Of the 116 in SA and 130 fcailities in Zim how many were represented.

We added the number of facilities selected and the proportion participating into the Methods section (page 8). We changed the order of the citation for additional details on methodology, so that it was more prominent where to look for more information.

“The final sample included 1,019 providers representing 116 facilities (or 89% of the total 130 selected facilities) from South Africa and 953 providers representing 130 facilities from Zimbabwe (94% of the total 138 facilities selected).” The methodology has been described in detail elsewhere.(17)

Add reason for non response for the telephone interviews Table 1 Under type of facility sub heading for Urban rural could be added to indicate these are two categories?.

We added the Location header for Urban and rural on Table 1– thank you for the suggestion. We added the following on page 10 of the results in the paragraph on non-response:

“The most common reason for not responding was busy clinic load or that the staff was not at the clinic.”

Discussion
Page 13 para 2 “did not ask about availability or procurement cost” maybe worth noting here that there are no procurement costs for FC in clinics in SA. FCs are provide free to clients in SA and Zim in public sector.

We have clarified this sentence to make clear our main focus in this section on availability of the FC in the public sector. Thank you for your point on procurement costs for clients; we have added a phrase to the 4th paragraph of the introduction section with this information (p.6).
We have also changed the Discussion section (p. 15)

“These findings must be considered in light of study limitations. We did not ask providers directly about stocking of FCs in their health care systems or whether they had prior training in FC counseling. Expense to the health system and availability at the clinic level (in addition to whether they have had prior training on FC provision) would influence their ability to provide them and thus the likelihood that they counsel patients.”

“Unlike the male condom, the FC is typically obtained through provider contact (not dispensers) in the public sector with no cost to the user, although in some settings there is also a strong presence of social marketing campaigns.”

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As above it maybe worth discussing the results in light of the country training programmes. For instance in SA most PHC clinics rely on nurses with limited use of doctors who may not be full time or available every day and so often far fewer were trained and this explains the findings on page 10.

In the Discussion section we have added emphasis that the nurses should be a priority for training as they deliver much of the primary care (page 15):

“The finding that nurses were significantly more likely than physicians to report counseling women on both male and female condoms reflects the prominent role that nurses play in prevention counseling; nurses therefore should be a priority for training as they deliver much of the primary care.”

The discussion last para should also expand on the sentence “providers noted that FCs are expensive and not always available in clinics” in the light of the “who pays” clinics in SA and ZIm do not pay for the stock and they are free to women but the programme is restricted by cost and rather than “not always available” should be for SA are available in some where stock should always be there and not available in others where stock has never been available. There maybe more stock outs however.

Yes, this is a good point. We have amended our Discussion section on the expense and availability to the following on page 15.

“We did not ask providers directly about stocking of FCs in their health care systems or whether they had prior training in FC counseling. Expense to the health system and availability at the clinic level (in addition to whether they have had prior training on FC provision) would influence their ability to provide them and thus the likelihood that they counsel patients.”

The response rate is noted as “high” in strengths and limitations and in discussion but the SA response rate was only 60% which is not that high?

60% is still very respectable for a clinician survey. This kind of a nationally representative probability survey of clinicians in Africa is rare and we don’t have direct comparisons, but can provide citations in US (Lawrence RE, Curlin FA. Physicians’ beliefs about conscience in medicine: a national survey. Acad Med 2009;84:1276-82; DesRoches, C.M., Rao, S.R., Fromson, J.A., Birnbaum, R.J., Iezzoni, L., Vogeli, C., & Campbell, E.G. Physicians' perceptions, preparedness for reporting, and experiences related to impaired and incompetent colleagues. JAMA, 2010;304(2),187-193; Henderson, JT, Harper CC, Gutin S, Saraiya M, Chapman J, Sawaya G. Routine bimanual pelvic examinations: Practice and beliefs of US obstetrician-gynecologists. American Journal of Obstretrics & Gynecology (in press) 2012).

I am surprised that the Zim response rates are so much higher seeing that this was self- administered compared to telephone administered.

Zimbabwe is a far smaller country and easier to administer research throughout reaching clinicians, particularly with our partners in the University of Zimbabwe College of Health Sciences.

Reviewer: Anny Peters
PhD researcher
RutgersWPF, Utrecht.
The Netherlands.

I have no competing interests.

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The participants of the study are not cleary defined. At this moment it is said to be providers (physicians and nurses) in HIV/STI clinics and in family planning clinics. Are these clinics always separate? Never integrated? Government or private? Who takes care for the stock of the products? Are male or female patients visiting? Etc. etc.

We have added more information about the study participants on page 8 in the Methods. The providers are not necessarily in HIV/STI clinics or family planning clinics; many are in primary care clinics or general hospitals, for example, with a wide range of services available. Our criteria were to have facilities that provided family planning or HIV/STI services in the selected districts, and then all clinicians providing family planning or HIV/STI services within those clinics (page 8).

“The sample consists of public facilities in South Africa and Zimbabwe. Some non-governmental organizations are included in Zimbabwe as they deliver primary care, and specifically family planning, to low-income populations.”

We have added to the end of the first paragraph on the Results more information on patients served (see page 10):

“Virtually all providers served adult women of reproductive age (99.7%), female teens (98%), and the majority also saw male patients (86%). The majority (70%) reported that most or all of their patients are at risk for HIV.”

The research question is not very clear and therefore the resutls. "We examined female condom counseling and provision among providers". The main question for me is: can you expect counsellers to counsel on a product which is not available or not provided? So what is first? First provision (stability in availablity of the product) or first counselling. When you counsel and the product is quickly out of stock (as reported): what is than the main issue?
So the research question should be more precise and should already state the starting point: there is not any family planning clinic nor STI/HIV clinic with ensured stock of female condoms. This has big consequences for the level of counselling and for the level of take up of the method.
Because the research question is not very clear, the results do not answer it. (see above)

Yes, these are important points, also brought up by Reviewer 1. As we responded above to Reviewer 1 comments, we have added the primary role of availability and stocking of supplies to the manuscript in the Introduction (page 7), data in Results (page 10), the Discussion section (page 13), and Table 2.

Introduction (page 7):
“Given these distribution efforts to increase stocking and availability in both countries, we still lack national estimates of how many providers are able to offer female condoms to patients.”

Results (pages 10 & 11)
“Availability is an important factor in being able to offer a method, and 27% of providers reported they would offer female condoms if more easily available. Among the small proportion currently not offering female condoms (13% n=169), 68% in South Africa reported they would if it were more easily available and 54% in Zimbabwe.”
“Providers noted that FCs are more expensive than male condoms and are not always supplied to clinics, especially in South Africa, where availability was frequently mentioned as a problem.”

Discussion (page13)
“In South Africa, the government has focused on reaching certain designated clinics with supplies and training so availability is not yet ubiquitous. In the South African qualitative data, many providers commented that availability in the clinic is still a problem, although the majority reported in the national

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survey that if female condoms were more easily available, they would offer them."

I think the discussion could be more elaborated. for example also including studies which show that a health providers power: they can "make or break" a new product. Also include health providers studies researching attitudes towards condoms.

Thank you for these suggestions. We have added a sentence addressing the role of health care providers as gatekeepers (page 16):

"As discussed in Mantell et al. (2000), a number of previous studies have documented the influence that provider acceptance of new prevention methods can have on their successful introduction and uptake."

There are very few studies on provider attitudes towards FCs and these are the ones reviewed in the 5th paragraph of the introduction section and referred to throughout the discussion section (for example in these places:p. 14:

"Another early study from the U.S. identified similar training needs among providers who saw FCs as appropriate for only certain groups of women, such as HIV-positive women.(12)"

p. 14: "Providers reported a strong need for new female-initiated barrier methods for prevention and, similar to prior research from the U.S. and South Africa,(12) several providers demonstrated negative attitudes about the aesthetics and use of the FC during qualitative interviews."

Congratulations.
See my comments (between minor and major).
Please see attached file.

Thank you for the Kahler reference-we have added this sentence in the introduction section, 5th paragraph:

"In another small qualitative study of provider FC opinions in Kenya, several health care providers reported believing that FCs give women "choice" and "control."

Reviewer: Alexandra Minnis, PhD
Senior Research Epidemiologist
RTI International - San Francisco
USA

This manuscript is extremely strong and was enjoyable to read. The writing is clear, the questions well-defined and the analysis carefully conducted and presented. The data are unique, being both population-based in two countries with persistently high HIV epidemics and derived from a national sample of providers.
The question of whether and how to promote female condom use has surfaced a number of times since its availability and apparent comparable effectiveness to male condoms as an STI prevention tool. Despite recent advances in oral PrEP and treatment for prevention, highlighting the opportunity to promote an existing prevention device to at-risk women stands as an important contribution of this paper.
One limitation of the data is minimal information about the content and quality of the counseling offered, which could have a bearing on whether female condoms are ultimatley used by women. That is, was female condom counseling interactive, didactic, did it address perceived barriers to use and partner reactions? There was likely tremendous variability but I wondered whether any of this was

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explored through the qualitative interviews. Earlier FC studies conducted in the US demonstrated that uptake was higher among women who had had an opportunity to insert the condom during a clinic visit and to troubleshoot problems/barriers with their clinician. Protocols for vaginal ring microbicide trials and other HIV prevention barriers now regularly include insertion of the first dose/product while at the clinic for this reason. A bit of consideration of this issue in the Discussion seems worthwhile. And, the degree to which you can use the qualitative data to explore this issue when you present some qualitative findings would enrich the results.
A second issue to consider further is the use of the qualitative data. Currently there is one paragraph of results from the in-depth interviews and I would either do more to enrich the findings that are shared or consider not including it in this paper if you do not have the space to use the qualitative data to explore themes related to key quantitative findings. It just seemed a bit thin given you have conducted 60 interviews.

We have reviewed the interview data and included more analysis of the counseling and the perceptions of the providers of their patients' reactions to the female condom. While we did not find exact answers to all the interesting questions above about the counseling, we did find more results to complement the survey findings. The new section on the interviews reads as follows (pages 11 and 12):

"The in-depth interviews gave some insight into the reasons that some providers might include the FC in counseling, while others might not, and what they think the best approach is to encourage use. Many providers mentioned logistical factors in the interviews that would restrict access to the method. Providers noted that FCs are more expensive than male condoms and are not always supplied to clinics, especially in South Africa, where availability was frequently mentioned as a problem. Several considered physical features as method limitations, including discomfort and being highly visible.

Alternatively, many providers noted that some men who will not use a male condom will agree to a FC, since the women puts it on. Providers noted that the FC could help empower women since they could ensure it was used, although they also mentioned that trust issues related to marriage and condom use arise with the female and male condom. Many providers thought that husbands might be more willing to try female condoms if they came with their wives to the clinic and were shown by the provider how to use it. As a Zimbabwe physician said: "…the method is a bit awkward. It's quite difficult to use, so it really remains for us to encourage the partner to accompany the lady to the surgery for consultation so that we can have some kind of counseling between myself and the couple." While counseling the couple was frequently brought up by providers, in one clinic the provider also mentioned clinic support groups with peer counseling to help women to initiate condom use.

In the interviews most providers explained that in counseling adolescents, they discussed abstinence and saying no to sex before marriage, which may explain the finding in the survey data of lower counseling of adolescents on condom use in Zimbabwe. Some, however, also mentioned condoms, after abstinence, and in South Africa, most providers in the interviews reported they counseled adolescents on abstinence and condoms."

Minor comments:
INTRODUCTION
1) Page 5, line 24: I would note that oral PrEP, deemed an effective HIV prevention approach in some populations, including sero-discordant couples, is now recommended and approved for use. This could also be female-initated so I would modify this last sentence of the first paragraph a bit.

Excellent point-thanks very much. We have modified the end of the first paragraph:

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“There have been promising results from recent clinical trials testing the effectiveness of novel woman-initiated methods of HIV prevention, including microbicides(3) and pre-exposure prophylaxis, which was recently endorsed by the Centers for Disease Control and Prevention (CDC) in the United States (U.S.) for use by heterosexual women at very high risk for HIV infection (e.g., women with HIV-positive sex partners). (4) However, conclusive proof of effectiveness and registration of a new woman-initiated HIV-prevention product recommended for widespread use is unlikely for a number of years, and the FC will remain an important option for women who desire pregnancy prevention and STI protection from a single product.”

2) Page 5, line 34: note the year for this HIV prevalence estimate given the phrasing of the sentence.

Good idea-we have amended.

“HIV prevalence among women was estimated at 33% in the peak ages (25-29 years) in South Africa in 2008 and 29% in Zimbabwe (30-39 years) in 2010-2011.(6, 7)”

3) Page 5, line 43: simply state the age range from which these condom use proportions are estimated rather than "in peak ages". Also, while most readers will know that adolescents have high rates of HIV, you might highlight that here given your finding that counseling is happening least often among youth, despite their high incidence and the dramatic increase in prevalence between 15 and 20 years of age. There are plenty of data from South Africa on this that would be relevant to cite here.
We have added the relevant age ranges per the first part of this comment.

We have added a new sentence on HIV prevalence among young people:

“Among young people ages 15-24, HIV prevalence was 8.6% in South Africa in 2008 and 5.5% in Zimbabwe in 2010-11. (6,7)”

4) Page 6, line 16: I was somewhat puzzled by the statement that female condoms are typically obtained through provider contact, yet the practice in Zimbabwe is broader distribution. Since Zim is one of the two countries included in this study I would reconcile this statement with the study setting, even if it just means you state that there are several exceptions. I suspect that PSI, which has done some of the FC distribution in Zim and social marketing campaigns may operate similar programs in other Southern African countries -- perhaps they are more recent.

We have revised the below sentence to indicate that social marketing campaigns often have a strong presence; in addition, further down in the Introduction section we provide more information on FC programs in RSA and Zim.

“Unlike the male condom, the FC is typically obtained through provider contact (not dispensers) in the public sector with no cost to the user, although in some settings there is also a strong presence of social marketing campaigns.”

5) Page 7, line 31: insert "counseling" between FC and practices.
We have made this edit.

METHODS: Page 9, Line 7: a minor point, but I would just clarify that you have two outcomes for which you examined the same set of predictors. I wasn't sure at first read of the text whether you were considering a combined outcome of female AND male condom counseling.

Thank you. The section on page 10 now reads:

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"We also analyzed male condom counseling practices for comparison using the same set of predictors. The two outcome variables were routine (usually/always) counseling on female condoms and routine counseling on male condoms."

RESULTS:
Analysis of in-depth interviews (last paragraph of results): Do you have anything to report on your quantitative finding that providers counseled some types of women (e.g., adolescents) more than others (in Zim, anyway)? I felt this paragraph could be strengthened, especially since you conducted 60 in-depth interviews. Likely these findings will be (or have been) reported elsewhere, but I wanted to see these data used a bit more to explicate some fo the quantitative findings. Twice the physical attriutes are noted and there isn't much depth to the results presented.

Thank you for the suggestion of adding to the qualitative findings. We have now included data on the different methods for counseling that is used (couple's counseling, peer counseling) and the perceptions of providers in Zimbabwe about adolescents, compared to those in South Africa, as well as more results on married women and condoms (see Results pages 11 & 12).

DISCUSSION:
Page 12, line 14: I would emphasize here the considerable HIV risk among women from their marital partner.

Thank you. We have amended this sentence:
"In both countries, providers were less likely to counsel married women than unmarried women on FCs, although it is essential to give all women information in these high-prevalence settings as many married women are at risk of acquiring HIV from their marital partner."

And, then, I would address the apparent inconsistency between the qualitative finding that providers though FC use might be more acceptable in marital relationships but counseled married women less often on FC use.

We added to the results and then the discussion on page 14 that providers also noted that trust issues arise for female condom use as well in marriage. This is likely a reason why counseling on condoms, female or male, is lower for married women.

"However, providers noted trust issues may also arise with female condoms."

**VERSION 2 – REVIEW**

| | |
|---|---|
| **REVIEWER** | Dr Mags Beksinska<br>Technical Advisor<br>Maternal Adolescent and Child Health<br>Dept of Obstetrics and Gynaecology<br>University of the Witwatersrand<br>South Africa<br><br>No competing interests |
| **REVIEW RETURNED** | 18-Dec-2012 |

| | |
|---|---|
| **THE STUDY** | Although I am very happy with the discussion of limitations and I think this is an improtant and well written paper in my own personal opinion i feel the results are flawed by the fact that they have sampled in clinics or rathe dont know if clinics had female condoms/staff were trained and i think they need to go back to the clinics and find out if at the time they were in the programme. |

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|---|---|
| **GENERAL COMMENTS** | I think this is an important study and I feel it needs to be published and I am very happy that it was conducted. The sampling of clinics from sites in 2009 unfortunately makes the results uncredible where there is unknown status of whether they were a. In the FC programme (should have FC supply even if stocked out), had nurses trained or were a sub distribution site (got supplies from another clinic in same sub district. I feel stronlgly that if these results are published they would not truly represent the correct situation. We need to know if the clinics had FC and nurses trained as the primary sampling base and although the limitations have addressed this I feel stronly that the researchers need to go back and contact all the clinics samples and ask them if they were in the programme. If this is done the results will present a true picture of the situation and I am really sorry to have to ask for this revision as I do truly feel this paper needs to be published. I feel strongly that data cannot comment on a situation of a provision of a service when that service was not there to be provided. I note reviewer 2 mentions the same issue. This maybe because we know the nitty gritty of the SA programme. |

## VERSION 2 – AUTHOR RESPONSE

We have added on page 15 in the Discussion an explanation of the limitations of the sampling scheme, and how it would affect our results:
"These findings must be considered in light of study limitations. We did not ask providers directly about stocking of FCs in their health care systems or whether they had prior training in FC counseling. Consequently, results do not shed light on how many providers in stocked clinics are providing patients with FC; rather, we only know how many providers overall, in both stocked and unstocked clinics, are offering the method. Provision in stocked clinics, especially with trained providers, is likely to be higher. Expense to the health system and availability at the clinic level (in addition to whether they have had prior training on FC provision) would influence their ability to provide them and thus the likelihood that they counsel patients. "

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