MEASURING AND ASSESSING VARIABILITY OF DATA ON SELF-REPORTED SEXUAL BEHAVIOUR COLLECTED USING DIFFERENT METHODS

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Declaration

I the undersigned, hereby declare that the work contained in this assignment is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

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Abstract

This study investigated the variability in self-reported sexual behavior data collected using different methods. The motivation for the study was to better understand sexual behaviour as a means of reducing HIV incidence among women. Respondents for the study were women enrolled in the Microbicides Development Programme pilot study at the Africa Centre for Health and Population Studies in the Umkhanyakude district of KwaZulu Natal, South Africa. These 51 women were asked to use a placebo vaginal gel before sex for 4 weeks. Three methods of sexual behaviour data collection were used in order to evaluate the accuracy of data collected. A coital diary was kept for all 4 weeks, a sexual behaviour questionnaire was administered at the end of 4 weeks and then an in-depth interview was conducted within the following week. Variations in reporting were subsequently probed regarding reporting of the number of sex acts, condom usage, and gel usage. There was a variance in individual reports – using different data collection tools – of numbers of sexual acts, condom use, and gel use. The majority of discrepancies were reported by the women to be due to misunderstandings or recall bias.

The study concludes that using multiple methods of sexual behaviour data collection methods adds value in terms of being able to report on the level of variance thereby improving the confidence with which the data can be interpreted. Further analysis of the in-depth interviews is necessary to assess the level of social desirability bias. Variability does exist among data collection methods, but case record forms could be used as a substitute for in depth interviews in large scale microbicides clinical trials since this variability is not major.

Opsomming

Hierdie studie het die afwyking in self-aangemelde seksuele gedrag deur verskillende metodes bestudeer. Die motivering vir die studie was om seksuele gedrag beter te verstaan en die kennis aan te wend as ‘n metode om MIV infeksie by vroue te verminder. Respondente vir die studie was ingeskrewe vroue in die ‘Microbicides Development Programme’ loods navorsingsprojek by die ‘Africa Centre for Health and Population Studies’ in die Umkhanyakude distrik van KwaZulu-Natal, Suid-Afrika. Hierdie 51 vroue is gevra om vir 4 weke ’n *placebo* jel te gebruik voordat hulle seksueel verkeer. Drie metodes is gebruik om data te versamel oor seksuele gedrag om die akkuraatheid van die data te evalueer. Respondente is gevra om dagboek van hul seksuele aktiwiteite vir die 4 weke te hou, om ’n seksuele gedrag vraelys aan die einde van die 4 weke voltooi, en 'n diepte onderhoud binne die volgende week te voer. Afwykings in verslaggewing is verder bespreek met betrekking tot die aantal seksuele dade, gebruik van kondome en gebruik van jel. Daar was afwyking in individuele rapportering – deur verskeie data insamelings gereedskap te gebruik – van aantal seksuele dade, kondoom gebruik, en die gebruik van jel. Die meerderheid van hierdie afwykings wat gerapporteer is, was as gevolg van misverstande en onewewigtige herroepping.

Die gevolgtrekking van hierdie studie is dat die gebruik van veelvuldige metodes om inligting oor seksuele gedrag te versamel die waarde verhoog in terme van die vermoë om te rapporteer oor die vlak van afwyking en daardeur verhoog dit die akkuraatheid waarmee die inligting verklaar kan word. Verdere analise van die in-diepte onderhoude is nodig om die vlak van sosiale aanvaarbaarheid te bepaal.

Daar bestaan veranderlikheid tussen die verskillende data insamelingsmetodes, maar ‘n siekteverslag kan in-diepte onderhoude in grootskaalse kliniese eksperimente vervang, aangesien die veranderlikheid nie groot is nie.

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CHAPTER 1

1.1 Background to Study

When used properly and consistently, condoms are the most effective method of protection against HIV and STI's. However, despite considerable efforts by numerous agencies and an overall increase in condom sales over the past decade, only a small proportion of the sexually active population in many countries use condoms, and those who do may do so irregularly and only with selected partners (Mayaud & Mabey, 2004). Lack of condom use in sub-Saharan Africa contributes to the high prevalence of HIV in this region (WHO, 2000). Lurie et. al. (2002), found that condom use was very low in rural South Africa; fewer than 20% of men reported that they ever used a condom.

Many women are not able to negotiate condom use with their sexual partners, and are at increased risk of HIV infection. To address this problem, the Microbicides Development Programme (MDP) aims to develop and implement an acceptable alternative prevention method to decrease the spread of HIV. To this end, the MDP has commissioned a multi-site randomized double-blind clinical trial to evaluate the efficacy of the PRO 2000 microbicide gel in reducing the risk of vaginally acquired HIV infection. Prior to this clinical trial, a pilot study to evaluate the acceptability of gel use during sexual intercourse and trial procedures using a placebo gel (HPTN 035) was conducted in all six sites of the MDP: Uganda; Tanzania; Zambia; Johannesburg, South Africa; Durban, South Africa; and Africa Centre for Health and Population Studies in Mtubatuba, KZN, South Africa.

Because the majority of vaginally acquired HIV infections are due to heterosexual intercourse (MDP 301 Pilot Protocol), there is a growing emphasis on understanding sexual behaviour as a means to reducing HIV incidence among women. The most common methods of collecting sexual behavior data include questionnaires/surveys, coital diaries, and in-depth interviews, all of which rely on self-reporting (Devon et al,

2005; Minnis et al, 2001; Hays et al, 2001; Ramjee et al, 1999; Kurth et al, 2004). Computer-assisted interviews have also been used to obtain sexual behaviour data, but are not a viable method of data collection in many populations (Kurth et al, 2004) due to limited technological resources and low levels of computer literacy.

Despite increasing use of sexual behavior data collection methods, limited research has been conducted regarding the accuracy and reliability of self-reporting for each independent method and across different methods. Some studies indicate that the reliability of self-reported sexual behavior data is questionable (Lagarde 1995). Accurate measures of sexual behaviour are crucial for informing interventions aimed at mitigating the impact of HIV/AIDS, and so a key challenge for all sexual behavior-related research is to generate unbiased and precise measures of individual and population sexual behaviour patterns. Methods are needed to minimize measurement error that may be introduced by participation bias, recall bias, social desirability and participant's willingness to report sensitive sexual behaviour (Fenton, 2000).

Prior research suggests that self-reported sexual behavior will vary depending on the method used to collect the data (Obermeyer, 2005). Pool et al (1995) cited by Obermeyer (2005) have shown that convergence between survey data and in-depth interviews are uneven, with interviews sometimes validating survey results and sometimes contradicting them. Ramjee, Leigh and Webb found that there is a significant level of agreement between data collected through questionnaires and coital diaries. However, for questions that required numerical responses (i.e. number of partners, number of condoms used), higher mean numbers were reported in coital diaries in all cases except for oral sex with partners, in which there was no significant difference between questionnaire responses and coital diary responses.

Previous studies suggest that the in-depth interview provides the most accurate reflection of the participant's true experiences (Obermeyer, 2005). However, it is difficult to draw global conclusions about bias in methods from small numbers of studies, especially if the

sample populations were quite different. For this reason, it is important to evaluate discrepancies within the same population, and to increase the number of studies available for comparison.

The Africa Centre pilot study provides an excellent opportunity to explore variability between methods of sexual behavior data collection within the same population. Triangulation of data regarding gel use and sexual practices can be conducted using data from questionnaires, coital diaries, and in-depth interviews. During in-depth interviews, participants are asked to explain reasons for discrepancies between self-reported sexual behavior among these three data collection methods. The following is a secondary analysis of the secondary objective of the Microbicide Pilot study, whose protocol was approved by the University of KZN ethics committee.

Established in 1997, the Africa Centre for Health and Population Studies is a joint project of the University of KwaZulu-Natal and the Medical Research Council of South Africa. The Centre conducts research on population and health issues of importance to developing countries; develops local research capacity; and identifies ways to overcome the health challenges facing sub-Saharan Africa. Based near Mtubatuba in rural Kwa-Zulu Natal and with a virology laboratory in the Nelson R. Mandela Medical School in Durban, the Centre has a staff of 400 and an annual budget of $4,200,000. The main focus of Africa Centre research is quantitative data. This is supported by qualitative ethnographic surveillance. Research covers three integrated areas:

- Population Studies: the Africa Centre Demographic Information System (ACDIS) collects demographic, socio-economic and health data from 11,000 households in a 435 square kilometre area of the Hlabisa District in KwaZulu-Natal. The total population surveyed is 90,000. The Demographic Surveillance System (DSS) is the most comprehensive in Africa. Data collection began in February 2000, with homesteads visited every six months to register new individuals and households, update demographic variables, and record all births, deaths and migrations. Since 2001, the DSS has also collected socio-economic data, and since 2003 the Centre

has offered every adult in the demographic surveillance area the opportunity to be tested for important health problems including HIV. HIV testing is enabling researchers to discover how many people are living with the virus as well as finding ways in which HIV-negative people can avoid infection and HIV-positive people can remain healthy for longer.

- Child Health: studies focus on critical health issues among mothers and children, including comparing the effect on child health of breastfeeding or formula-feeding in a context of high HIV infection rates; testing the effectiveness of Nevirapine in preventing mother-to-child HIV transmission; and identifying ways of improving child health through the provision of inexpensive micronutrient supplements.

- HIV Prevention and Treatment: the Africa Centre's Durban-based virology laboratory is genotyping strains of HIV and sexually transmitted diseases (STDs) and studying vaccines and microbicides for HIV prevention. In 2004, the Centre will begin offering anti-retroviral treatment to approximately 600 people living with AIDS in the Demographic Surveillance Area.

Longitudinal studies such as the ACDIS benefit from being able to track changes over time and build up a robust picture of communities. Longitudinal data provide the most comprehensive answers to questions regarding, for example, the role of temporary migration in community life, the impact and cost-effectiveness of health interventions, links between economic well-being and health status, and the effect of government policy on the wealth of rural households. Demographic trends, too, can be more closely monitored by longitudinal studies.

Research on HIV/AIDS demonstrates the benefits of the Demographic Surveillance System. The DSS allows researchers to measure the burden of disease in the surveillance area; highlight new trends in HIV infection; describe patterns and determinants of health service utilisation and their impact on demographic and health outcomes; assess the

ongoing effect of different intervention strategies on the spread of the epidemic; and, potentially, monitor resistance levels to anti-retroviral drugs.

As well as measuring core variables such as household structure, migrations and key events, the DSS also allows for the inclusion of add-on modules. These include sections on household socio-economic status and women's reproductive health. Like the core data, these are collected over time and over the entire eligible population. Short-term modules, moreover, have answered questions regarding child grants and cholera. Separate studies, such as those related to Child Health and HIV Prevention and Treatment, also involve the DSS population but may be initiated by investigators outside the population studies research group.

The Africa Centre aims to make the ACDIS data as widely available as possible while balancing the interests of data subjects, data controllers and data users. Access to ACDIS analytical datasets is provided on the basis of analysis plans submitted by prospective data users to the ACDIS Principal Investigator. Investigators will be able to obtain the data they wish to work with from a website, subject to access control.

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1.2 Research objectives and hypotheses

The Microbicide Pilot study conducted at the Africa Centre site in Mtubatuba, South Africa sought to assess gel acceptability and optimize the trial procedures developed for the proposed phase III randomized double-blind placebo-controlled trial. The Pilot study was designed to ensure that key procedures and methods were to be correctly implemented and be effective. One of the study aims was to assess the validity and reliability of sexual behavior data from a questionnaire compared to the more detailed methods of the coital diary and in-depth interview. Sexual behaviour data obtained through case record forms, coital diaries and in-depth interviews was analyzed to evaluate the extent to which data reported using the different methods varies.

For the purposes of this study, I evaluated discrepancies among data collected from IDI's vs. coital diaries and questionnaires. I also assumed that the use of three different methods may influence the reporting in each. The research questions were therefore:

1) *Is there variability in sexual behaviour data collected using multiple techniques?*
2) *What are the reasons for this variability (qualitative)?*

In this study, the Null hypothesis was that there is no variability of sexual behavior data collected by different methods. The alternative hypothesis was that sexual behavior data varies according to type of data collection method.

The scientific hypotheses to be assessed were as follows:

- There is variability of sexual behavior data collected through different methods
- Variability differs according to time frame of sexual behavior being queried (sex in the last week vs. sex in the last 4 weeks)
- Variability of reported condom use across methods will differ from variability of reported gel use across methods

1.3 Operational definition of concepts

1.3.1 Case record forms (CRF)

Case record forms are structured sexual behaviour questionnaires administered by the HIV counselors. The CRF's were completed at the final visit to the clinic. If a participant reported having sex in the previous week, detailed information of sexual behavior in the previous week was collected. On the other hand, if a participant reported no sexual acts during the previous week, detailed information concerning sex acts from the previous four weeks was collected.

1.3.2 Coital Diaries (CD)

Coital Diaries are written text and pictorial sexual behaviour questionnaires, which are participant self-administered with each sex act. Participants were issued these, along with the gel, at the enrollment visit, and asked to complete the CD and bring them back after two weeks for review. The coital diaries provided another tool to trace product use over

the course of the month and quantify it in conjunction with other practices such as condom use and the use of vaginal inserts.

1.3.3 In-depth interviews (IDI)

In-depth interviews were conducted with all participants who completed the CRF and the CD. The interviews were twofold, with the first part focusing on independent data collection and the second part probing about reasons for inconsistencies in the IDI vs. CRF and CD. At the end of the IDI, triangulation of data obtained using all three different methods of data collection was conducted. The data used depended on whether a participant had reported sex acts in the week prior to the final visit to the clinic. If a participant stated that she had no sex acts during that time period, the sexual behavior data pertained to sex acts occurring in the four weeks prior to the final clinical visit.

1.3.4 Variability (outcome measure)

For the purposes of this study, variability was defined as the difference in sexual behavior data across methods, using the in-depth interview as the gold standard. Variability of data from the CRF, coital diary and in-depth interview was assessed for number of sex acts, condom use and gel use. Reasons for variability were obtained through the qualitative probes about inconsistencies within data collected.

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CHAPTER 2

2.1 Sexual Behaviour Data Collection

2.1.1 Introduction

In the late 1990s, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) introduced second-generation surveillance to strengthen and improve national HIV surveillance systems (UNAIDS, 2000). Tailoring the surveillance system to the specific needs of the epidemic was done by amongst other things supplementing the biological data with behavioral trend data to gain insights into the extent to which behavioral changes are responsible for HIV trends (Zaba et al, 2005).

Zaba et al (2005), further stress that the behavioral component of the surveillance system should contribute significantly to the ability to predict changes in the HIV incidence rate, to assess the potential for the spread of HIV in specific risk population or in the general population and to the evaluation of the impact of the programmatic efforts.

2.1.2 Sexual Behaviour Reporting Biases

Analysis of the quantity of self-reported sexual behaviour have found evidence of several problems including underreporting of ever having had sex among young unmarried respondents, underreporting of the number of partners (particularly by women), possible exaggeration of the number of partners by some young unmarried men (Curtis & Sutherland, 2004). Many behaviors that carry a high risk of HIV infection are also socially proscribed, and there is evidence that it is difficult to get individuals to disclose such behaviour, especially if it is current or recent (Zaba etal, 2005). Very few studies have tried to assess changes in the bias in sexual behaviour reporting overtime, including the tendency of the respondents to provide the answer he or she thinks the interviewer wants to hear, the social desirability bias. This is a particular source of concern in the behavioral surveillance in the context of interventions that promote safer sexual behaviors.

An important principle in collecting data on sensitive sexual behaviour topics is to use standard survey instruments that have been tested in a variety of populations and maintained the same quality of implementation. Huygens et al cite a few more areas of concern in collecting sexual behaviour data:

- Influence of gender, age and social status of he interviewer
- Influence of the duration of the interview
- Risks of misclassification due to translation
- Research models used

2.1.3 Sexual Behaviour Collection Methods and Biases

2.1.3.1 Self-administered questionnaires (SAQs)

Self-administered questionnaires are thought to enhance privacy under appropriate conditions. Also one person can administer SAQs to many respondents simultaneously, SAQs tend to be very inexpensive to use in a group of respondents too. Catania et al (1990), argue that SAQs are limited by respondents' level of education, reading ability and the investigator's ability to employ terminology understandable to a wider range of respondents, and because there is no opportunity for probing ambiguous responses. Catania et al (1990), further stress that respondents may feel less threatened by SAQs than by Face-Face-Interviews when answering questions.

SAQs, however, have not always resulted in higher levels of reporting. A study by DeLamater and Mac Corquodale (1975) quoted by Catania found that young adult women were less likely too report vaginal intercourse on SAQs than in Face-to-Face interviews. Although not unequivocal, current evidence suggests that SAQs reduce measurement error related to respondents' privacy concerns, though one might expect that language comprehension difficulties would increase measurement error. Therefore SAQs provide a useful but limited tool for conducting AIDS-related sex research.

Biases associated with SAQs are response bias and item-order effects bias. The latter can be categorized onto placement effects sand sequencing effects. Catania et al (1990)

defines placement effects of the item-order effect as the response bias produced wherein the questionnaire item occur relative to the total number of items assessed. For example, items occurring in the questionnaire may be unanswered due to respondent's fatigue. Sequencing effects occur when, for instance, the content of earlier items influence the later items.

2.1.3.2. Face-Face Interviews (FTFIs)

FTFIs involve both visual and auditory social contexts, thus one might expect that self-presentation bias would be highest on FTFIs, relative to telephonic interviews and SAQs. This is the notion that arises from the fact that people wish to present themselves in a positive light, thus self-presentation bias may lead to either over-or underreporting of a particular sexual behaviour, depending on whether that behaviour has a positive or negative social value.

People vary in the degree to which they will bias reports of some or all of their sexual activities. Therefore, some people will be generally threatened by questions concerning their sexual behaviour and may refuse to answer or may substantially underreport any and all activities (giving zero responses). Others may be threatened only by questions concerning very specific behaviors that they believe were socially deviant. Bradburn etal (1978), found that subjects who rated themselves as very uneasy about sexual questions were more likely to refuse to answer vaginal intercourse items. Similarly Catania etal (1990), found that the frequency of refusing to answer sexual questions correlated significantly with self-reported willingness to disclose sexual information. Although these studies support the assumption that presentation bias is a concern in assessing sexual behaviour, they do not identify which behaviors are most sensitive to presentation bias.

Respondents perceive FTFIs as having greater credibility and may trust the interviewer more than in the telephone interviews and SAQs, factors that serve to reduce measurement error in sex surveys. Moreover, in FTFIs, interviewers can assist respondent

in the use of different response scales and correct their misconceptions about questions. Also interviewers may bring into the interview room a calendar to help the respondents remember the dates during which they had sex.

2.1.3.3 Diaries

The diary method has been used as an appropriate method for collecting sequential and time-linked data on sexual behaviour since 1982, and has proved to be a realistic tool for the study of sexual behaviour in a number of pioneering studies, resistant to interview and retrospective bias and yielding detailed and often unique information (Coxon,1999). It is undoubtedly a demanding method both for respondents and researchers, subject to selection bias and it is unlikely to be a substitute for survey methods.

Coxon (1999) who studied discrepancies between self-report and recall measures found that the sexual diary method is likely to be more accurate than retrospective questionnaire data but they are strongly related. In particular:

- Diarist attribute highest certainty in their questionnaire estimates of sexual behaviour to the less common sexual acts, and in particular for the higher-risk acts which involve anal sex. This is confirmed in the smaller relative discrepancies associated with these same acts.
- At the individual level, post factum questionnaire estimates also yield much the same aggregate profile as diary counts, but they consistently yield average frequencies.
- Most individuals have a consistent pattern of over-identical/under-reporting estimates across different sexual acts.
- The main important exception occurs for the highest-risk sexual activity; anal sex without a condom which differs markedly according to whether it refers active or passive variants. The discrepancies may in part reflect a sort of 'social desirability' effect.

Catania et al (1990), also cite that greater precision of diaries suggest that the concordance of estimates from SAQs and coital diaries would be sufficient to validate each method, and allow the strengths of each to be capitalized upon.

Although diaries are subject to a number of shortcomings, especially potential selection bias and difficulties in use for large populations, the advantages of diaries are also very considerable (Catania et al,1990; Coxon, 1999). Most importantly, the short time period between the sexual act and its recording makes for greater precision and minimizes retrospective error, and diaries also allow more detailed, contextually-specific and naturally expressed accounts of behaviour.

2.2 Theoretical Framework Associated with sexual behaviour reporting

Many of the most familiar theories of health behaviour like the theory of reasoned action; theory of planned behaviour; health belief model; protection motivation theory and subjective expected utility theory can be called continuum theories (Weinstein et al, 1998). Their approach is to identify variables that influence action (such as perception of risk and precaution effectiveness) and to combine them in a prediction equation. It is reasonable to assume that behaviour change can be described by a single prediction equation but many natural phenomena pass through qualitative different stages.

Stage theory ideas are helpful in reaching the goals of understanding and influencing behaviour. The idea that if people at one stage have to address similar issues before they can progress to the next stage, the third feature of the stage theory is the requirement that people at a stage face similar barriers and, consequently, that they can be helped by similar interventions.

Most women in the Microbicides study faced the problem of a partner who does not want to use condoms when having sex with them. The accessibility of the nurses and

counselors, that offer them condom education; negotiation skills help them realize that they can overcome the barriers to the sexual health.

Weinstein et al (1998), call the seven stage model the Precaution Adoption Process Model (PAPM). The stages are:

Stage1: At some initial point, people are unaware of the health issue.

Stage2: When people first learn something about the issue, they are no longer unaware, but they are not necessarily engaged by it either.

Stage3: People who reach the decision-making stage have become engaged by he issue and are considering their response.

Stage4: This decision-making process can result in one of two outcomes. If the decision is made not to the action, the precaution adoption process ends, at least for the time being.

Stage5: But once the people have decided to adopt the precaution;

Stage6: The next step is to initiate the behaviour.

Stage7: The last stage, if relevant, indicates that the behaviour has been maintained over time.

Reporting sexual behaviour is scary and if the participant does not understand the reasons for scientists to ask for sexual behaviour data; the likelihood is that they will decide to offer untrue reports or decline to report. With ongoing education about sexuality, condom use and safe sex they begin to realize that they are being helped and some may be triggered to give truths about their behaviour. This is likely to happen during the In-depth interviews which happen during the last visit when the participant knows that she is not going to meet the study staff after all. Thus for this study the IDI has been used as the gold standard.

CHAPTER 3

MATERIALS AND METHODS

3.1 Introduction

The Africa Centre Microbicides Pilot Study was conducted from July to October 2005 in the Umkhanyakude district in rural KwaZulu-Natal. This section describes the materials and methods used to collect and analyse data from the Microbicides Pilot Study.

3.1.1 Study Area and Population

The Africa Centre pilot study enrolled 51 female participants from primary health care facilities at three clinics: KwaMsane; Mtubatuba and Madwaleni. These are government clinics in rural KwaZulu Natal at the Umkhanyakude district, in the Mtubatuba area, and primarily provide family planning and immunization services. Women were recruited from these clinics through talks about microbicides by HIV/AIDS counselors at the clinic's waiting room. Interested women were invited to receive further information about the study on a one-on-one basis. Flip charts and information sheets were used to explain details and procedures for the study. This information session formed part of the informed consent procedure. After giving informed consent, the participant was taken through the screening process which included completion of some case record forms, blood test and general examinations.

3.2 Sampling design and enrolment criteria

The study population consisted of women aged 18 years and above who were sexually active and visited Africa Centre clinic sites in Kwa-Zulu Natal, South Africa. To join the pilot study, women had to be sexually active, willing to undergo HIV testing and receive their result, use study gel as instructed, undergo regular speculum examinations and a genital infection screen, have regular urine pregnancy tests, receive health education about condoms and be able to give informed consent. Women were ineligible if they

were unable or unwilling to provide a reliable method of contact for the field team, likely to move permanently out of the area within the next year, likely to have sex more than 14 times a week over the next month, using spermicides regularly, pregnant or within 6 weeks postpartum, had grade 3 clinical or laboratory abnormalities, had a known latex allergy, participating in any other microbicide study or clinical trial, and/or considered unlikely to be able to comply with the study protocol.

The study staff screened 147 women for the microbicides pilot study, of whom 76 were eligible and 51 provided consent to enroll in the study. 62 women were excluded from participation due to HIV positive status, 6 women were excluded due to pregnancy, and 3 women were excluded due to sexual inactivity. Fifty participants who completed the study were included in the current analysis (systematic convenient sampling design).

3.3 Research Design

The study employed a cross-sectional, non- randomized, open label design (Christensen, 2004); where female participants were asked to insert 2g (one applicator full) of HPTN 035 Placebo Gel into their vagina one hour prior to vaginal sexual intercourse for a period of 4 weeks. During the screening process, informed consent was obtained after providing explanation about the study procedures and forms. Pre-test and post-test counseling was provided for all women who consented to be tested for HIV. Demographic information forms, sexual behavior forms were filled in for women who were eligible and consented to participate.

After screening, participants reported to MDP clinics for 4 follow-up visits: enrollment, week 2, week 3, and week 4. Sexual behaviour data was collected using case record forms, coital diaries and in-depth interviews. Coital diaries were issued at enrollment, and participants were instructed to return completed diaries at the week 2 clinic visit. Fresh coital diaries were provided at week 2, and participants returned these completed diaries at the week 4 visit, during which time the CRF was also administered. Within two weeks

after the final clinic visit, participants were interviewed regarding their sexual behaviour and data collection method acceptability. The interview also included probing of inconsistencies in sexual behavior reporting.

3.4 Data collection techniques

3.4.1 Case Record forms

Demographic data and sexual behaviour data were collected from all 51 enrolled participants using the CRF completed by the counselors. The demographic CRF was completed at the screening visit, and the sexual behaviour forms were completed at enrolment and at the final clinical visit.

3.4.2 Coital diaries

All participants were asked to keep coital diaries whilst they were using the gel. In these diaries, participants recorded details of their sexual behaviour, gel and condom use. The diaries were completed and reviewed with participants on a weekly basis between enrolment and final follow-up visit.

3.4.3 In-depth interviews

All participants were interviewed by the social science coordinator or research assistants within two weeks of their final clinic follow-up visit. The interviews were semi-structured, combining an interview guide with spontaneous probes and free discussion. At the end of the interviews the diary entries were discussed and any discrepancies with the interview examined. All interviews were recorded, transcribed and translated.

3.4.4. Validity and Reliability

One way of validating the self-reported sexual behaviour data is using the biological marker (Catania, Gibson, et al 1990). This is when the validity of self-reported sexual behaviour can be corroborated through the biological marker; which is unachievable and cumbersome. Since a solid validity index of self-reported sexual behaviour is not available; the goal of minimizing measurement error became more important in this

study. This included ensuring that participants are asked to report sexual behavior data of the same time period across all methods. For this analysis, triangulation was also done to achieve some degree of validity and reliability of data.

3.5 Quality Control and Quality Assurance

Clinic counsellors reviewed coital diaries with participants at the final clinic visit. When a participant admitted to have made a mistake; the counsellor used a red pen to correct that mistake, and completed documentation of the change. If necessary, the sexual behaviour CRF was also corrected by the counsellor. The clinic manager quality controlled both the coital diaries and final visit CRF's before they were sent to the Africa Centre. At the Africa Centre the forms were captured by the Data centre team, and copies were filed in the Social Science IDI guide to be used during CD-CRF comparison prior to the in-depth interview.

Audio recordings of in-depth interviews were downloaded to the Social Science computer, which was password-protected. Transcriptions and translations were done by the research assistants and the social science coordinator; quality control of 10% of those transcripts was done by the social science coordinator. Coding of transcripts was done and quality controlled by the microbicide project leader and the social science coordinator.

3.6 Data management procedures

CRF's were printed in duplicate and in triplicate. The study staff authorised by the Principal investigator entered information directly onto the CRF's, signed and dated the form on completion, and separated the copies. The top copy of the form was sent to the data entry team, for capturing into the EpiInfo database. Double entry was done as an extra validation control to ensure quality. The bottom copy was kept in a Clinical Folder individual to each participant in the clinic. Clinical Folders were stored in the location most likely to guarantee security, confidentiality and ability to retrieve individual records.

Changes to the bottom copy of the CRF could only be made by the study personnel that collected data directly from the participants (counsellors, clinical personnel and interviewers), and all changes were signed and dated. Alterations made after separation of the two copies were photocopied and sent to the data management team. If the change was in response to a query, then the change to the bottom copy of the CRF was made, signed and dated and the Query Form completed describing the change. The Query Form was also in duplicate and the bottom copy was filed in the Clinical Folder, and the top one sent to the data management team. The CD's were entered into the CD data base.

In order to maintain participant confidentiality, all files, CRF's and voice text interviews were identified using participant study numbers. In-depth interviews were transcribed, translated and entered into a separate database to the CRF data for analysis using an appropriate qualitative statistical software package.

3.7 Data Analysis

3.7.1 Statistical packages

Both quantitative and qualitative data analysis techniques were used in this study. Quantitative analysis was conducted using STATA v8. NVivo v2.0 was used for coding and analysis of qualitative data.

3.7.2 Data Analysis

Analysis of associations between coital diary data, in-depth interview data and data from case record forms assisted in identifying relationships between adherence and barriers to use with socio-demographic factors. The in-depth interview (IDI) was used as the gold standard for collecting sexual behavior data, and was compared to coital diary and CRF data for differences in reporting.

Descriptive statistics were computed for the demographic characteristics of the sample. Proportions of gel use and condom use per sex act were calculated using data on number

of sex acts, gel and condom use for each woman. These proportions were stratified by time frame of sexual behavior reporting (sex in the last week vs. sex in the last 4 weeks). Qualitative data analysis was conducted using NVivo. Reasons for variability in self-reported sexual behavior across methods were explored and common themes identified across subjects.

CHAPTER 4

RESEARCH FINDINGS

4.1 Introduction

This section details the results of the above analyses and provides preliminary interpretations of these results, which will be further discussed in Chapter 5.

4.2 Results

4.2.1 Quantitative Results

Descriptive statistics were calculated for the 51 women enrolled in the microbicides pilot study (see Table 1).

Table 1: Descriptive statistics: Summary Statistics for women enrolled (n=51)

Variable	*Sub-category*	*N*	*%*	*Mean (SD)*	*Range*
Age		51		31.9 (10.7)	18 - 56
Relationship status					
	Married	14			
	In relationship	37			
Education level					
	None	2			
	Some primary	14			
	Some secondary	34			
	Some tertiary	1			
Employment status					
	Employed full time	5	9.8		
	Employed part time	5	9.8		
	Student/scholar	4	7.8		
	Work seeker	1	2.0		
	Unemployed	35	68.6		
	Other	1	2.0		

Source of cash income		41	80.4		
	Own salary/earnings	8	15.7		
	Partner's salary/earnings	15	29.4		
	Parental contribution	1	2.0		
	Other relative	2	3.9		
	Government grant/child maintenance	23	45.1		
	Child's father pays some money	4	7.8		
	Other	2	3.9		
Housing					
	Council house	2	3.9		
	Rented house	1	2.0		
	Room inside/outside house	48	94.1		
Religion					
	Christian (unspecified)	8	15.7		
	Christian (catholic)	3	5.9		
	Born again Christian	7	13.7		
	Zionist	24	47.1		
	Shembe	6	11.8		
	Other	3	5.6		

Of the 51 enrolled women, 37 (73%) are not legally married and only 14 (27%) are in marriage relationships. Most women are literate as 34 (67%) have some secondary education. A large number of women are unemployed 35 (68, 6%).

In the analysis, 50 of 51 enrolled women were included (1 woman dropped out prior to study completion). The following tables provide information on proportions of condom and gel use among study participants. Table 2 provides information on the combined sample (n=50), Table 3 describes women who had sex in the last week (n=32), and Table 4 describes women who had sex in the last 4 weeks (n=18).

Table 2: Proportion of condom and gel use per sex acts reported in each of the 3 data collection methods (n=50).

Method of data collection	Total number of sex acts reported	Percentage of acts with condoms	Percentage of acts with gel
CRF	226	45%	85%
CD	245	45%	82%
IDI	304	39%	82%

Table 2 shows that across the 3 data collection methods, there is only 6% variability in reports of the proportional use of condoms, and 3% variability in reports of the proportional use of gel.

Of the 50 women who completed the study, 82% gave discrepant reports across 1 of the 3 data collection methods in relation to either number of sex acts, number of partners, and type of sex, condom use or gel use.

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Table 3: Proportion of condom and gel use per sex acts reported in each of the 3 data collection methods for women who had sex in the last week (n=32)

Method of data collection	Mean (SD) proportion of sex acts with condoms	Mean (SD) proportion of sex acts with gel
CRF	0.50 (0.49)	0.82 (0.35)
CD	0.44 (0.48)	0.63 (0.47)
IDI	0.52 (0.49)	0.84 (0.34)

For women who had sex in the last week, there was highest reporting of gel use in the IDI and in the CRF, as opposed to low reporting of gel use in the CD. This might have been due to the difficulties encountered by women when recording in the CD as reported during the IDI. The reports on sex with a condom are more or less similar across all three methods and low.

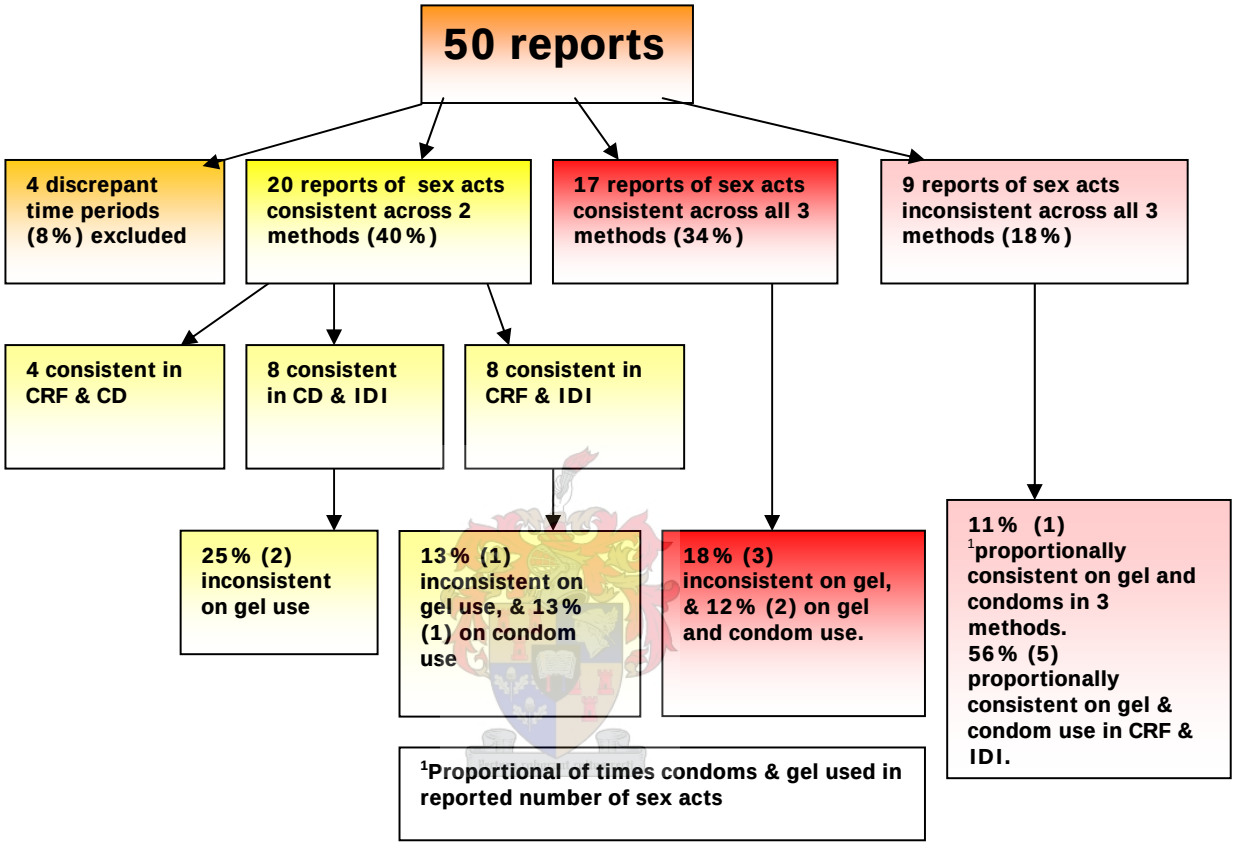
Table 4: Proportion of condom and gel use per sex acts reported in each of the 3 data collection methods for women who had sex in the last 4 weeks (n=18).

Method of data collection	Mean (SD) proportion of sex acts with condoms	Mean (SD) proportion of sex acts with gel
CRF	0.26 (0.44)	0.81 (0.33)
CD	0.28 (0.42)	0.85 (0.25)
IDI	0.25 (0.42)	0.75 (0.33)

For women who had sex in the last 4 weeks, the reporting of sex acts with gel is relatively high across all methods but a bit lower in IDI. It is highest in CD. This is the opposite from what was found among women having sex in the last week. This finding might be due to recall problems during the IDI, since women were being asked to remember their sex acts for the past 4 weeks rather than just 1 week. This suggests that the time period being asked about may influence the reporting of sexual behaviour data, as well as which data collection instrument will be most accurate.

When comparing groups of those that had sex in the last week and those that had sex in the last four weeks, it is found that there is much lower condom use in the last 4 weeks. The proportion of gel use is similar in both groups.

Figure 1: Variability in the reports from 50 women on the number of sex acts, condom use and gel use over 1 (62%) or 4 (30%) weeks (8% excluded):



Of the 51 enrolled women, 33 (65%) had sex in the last week. 18 (54%) of these women reported different numbers of sex acts in different data collection methods (see Figure 1). Where there was a variance, 72% of women reported a higher number of sex acts in the interviews. Of the 18 discrepant reports, we looked at whether the percentage of condom and gel use per number of sex acts differed across the 3 methods, and this occurred in 4 (22%) cases. Out of the 15 cases where the number of sex acts corresponded, 2 (13%) reports showed variance in condom use and another 2 (13%) in gel use.

Out of 46 reports of number of sex acts that were comparable within a defined time frame:

- 37% (17/46) were consistent across all 3 methods.
- 72% (33/46) of IDI's were consistent with at least 1 other method.
- 63% (29/46) of CRF's were consistent with at least 1 other method.
- 63% (29/46) of CDs were consistent with at least 1 other method.

Only 2 women reported more than 1 partner during the study. Both of these reports were discrepant across the data collecting methods. One was reported to be an error in CD completion (ticked wrong box); the other was only reported in the IDI. One women reported anal sex in the CD and IDI but not the questionnaire. However, due to the structure of the CRF and CD, if a woman reported no sex acts in the past week, the questions about number of partners and type of sex were omitted by default. Therefore, variation across methods in these 2 categories was largely due to blank entries in CRF's and CDs, compared to IDI's. The under-reporting of anal sex and number of partners was reported to be due to social desirability bias (not wanting to tell clinic staff).

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4.2.2 Qualitative Results:

4.2.2.1 Reasons for variability as quoted from the In-depth interviews:

- "I can say it's because I didn't tick immediately after having sex and thought I had sex because I didn't tick on time and told myself I had sex on a certain time. I then ticked after, I didn't remember that I did not use it because I was having my periods". *(27 year old women who reported more sex acts & gel use in CD than CRF and IDI)*

- "There is somewhere I got mixed up I marked this side and not the other side……I used to fill it some other time you see when I went to see this person then come back then fill it, I did not bring it with me". *(A 23 year old who reported sex in the last week in IDI, but not in the CD or CRF)*

- "Maybe I have mixed it up. Maybe it's me who mixes up it's only the 9th I remember clearly".

- "I never used it but I made a mistake by ticking by the time I was counting gels used and found that there were 19. It means I had sex and forgot to tick". (Women who had reported less sex acts on CD).

- "It means the 9th and 10th was supposed to be on this page, I was supposed to open here I was confused I saw Saturday then marked it as well as the Sunday. I used to fill it some other time you see when I went to see this person then come back then fill it, I did not bring it with me"

4.2.2.2 Other reasons for variability from the triangulation

- In CD sex reported in the last 4 weeks but in the CRF and IDI sex is reported in the last week- the participant gave the reason that the first two weeks worth of CD was not taken from her by the study staff so she mistakenly continued to mark the sex acts on the 3rd week space instead of the 5th week space.
- In CRF participant reported gel use with a sex act which in the IDI is reported to have been without gel use- the participant gave the reason that she was menstruating and is sure that she did not use gel, thus might have forgotten to explain during CRF interview.
- Reported 10 gel use in CRF and CD but 4 in IDI- participant has inserted gels but did not continue to have sex for the 6 times thus reported 10 gel use in CRF and CD so that the number of sex acts number of used applicators would tally.
- Inconsistency about gel, condom and no of sex acts- forgotten to tick 2 sex acts, where she has used both condom & gel.

CHAPTER 5

Conclusions and Recommendations

There was considerable variability in reporting the number of sex acts across the 3 data collection methods. The variability in reporting sex acts appears to be predominantly due to recall bias, and variability in reporting of condom and gel use appears to be due to social desirability bias as confirmed by qualitative interviews. The majority of discrepancies were reported by the women to be due to misunderstandings or recall bias also obtained from qualitative interviews.

A higher number of sex acts are reported in IDI's than in other methods, and this is probably due to the level of probing involved in IDI's. However, IDI's require extensive training and time of staff. In a large scale clinical trial, CRF's would be the most practical way of collecting sexual behaviour data on a regular basis. The results from this study suggest that CRF's are similar to CDs and IDI's in collecting proportional use of condoms and gel per sex acts reported. When assessed against IDI's, it appears that CRF's may under-estimate the number of at risk sex acts (i.e. sex without a condom). However, in the absence of sufficient resources to conduct IDI's with all participants, the use of CRF's in larger clinical trials should be adequate to collect sexual behaviour data.

There are obvious advantages of using multiple sexual behaviour data collection methods in terms of being able to quantify the level of variation across different methods, and thereby inform the interpretation of sexual behaviour data. The strength of this analysis is that it combined both the quantitative and qualitative models of research which was useful in eliciting the reasons for variability. Also the fact that data reported on different methods was of the same time frame (either sex reported on last week or on last four weeks) was perfect to ensure reliability of data. Strength of this analysis is that there was chance to validate the reported sexual behaviour data during the triangulation done within

the IDI and the final record of sex acts, gel and condom use in the IDI was the triangulated one. The weakness of this analysis is that the sample is small and results might not be generalisable to other populations in which studies on sexual behaviour are conducted.

Further analysis of the in-depth interviews is necessary to assess the level of social desirability bias. Using multiple methods of sexual behaviour data collection methods adds value in terms of being able to report on the level of variance thereby improving the confidence with which the data can be interpreted.

In summary, this study shows that sexual behaviour data varies according to method of data collection, but this variability is minor and would not discourage future studies from using CRF's rather than IDI's. The results of this study are useful both for the current microbicides clinical trial at the Africa Centre site, as well as other microbicides clinical trials that rely on accurate and efficient collection of sexual behavior data.

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Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐
	Trial number ☐☐☐☐☐

Interviewer: read the questions to the volunteers verbatim and allocate the correct answer from the selection, unless it is indicated that you read out each answer to the volunteer as well. Boxed type is instructions to the interviewer. Type in italics is to be read to the volunteer.

Please try to answer these questions accurately as the answers to them are very important to the outcome of the study. Remember that the information you give us is confidential and will only be used for the purposes of this study.

Section 1: Gel accountability

1 Interviewer, write the number of applicators dispensed at the last visit according to the last CRF ☐☐☐

2 Interviewer, write the number of used applicators returned today ☐☐☐

3 Interviewer, write the number of unused applicators returned today ☐☐☐

4 How many applicators have you used since your last visit? ☐☐☐

Interviewer: check the number of applicators returned (questions 2 & 3) corresponds with the number dispensed (question 1). Specify below in question 5 if there is any discrepancy. If no discrepancy, go to section 2.

5 What happened to the missing applicators?

Left them behind ☐ Lost them ☐

Gave them to someone else ☐ Threw them away ☐

Other ☐ Specify_____

Section 2: Family planning

6 Are you currently using any method of family planning? Yes ☐ → Q. 6a

No ☐ → Q. 6b

6a If yes, which of the following methods are you using?

Natural/rhythm ☐ → Q. 2

Pills ☐ Foam/jelly/spermicide [exclude if using spermicides regularly ☐ → Q. 2

Diaphragm ☐ Injectable Nur-Isterate ☐ → Q. 2

Injectable Depo-Provera ☐ Injectable other ☐ → Q. 2

IUCD ☐ Norplant implant ☐ → Q. 2

Condom (male or female) ☐ Traditional vaginal ☐ → Q. 2

Traditional oral ☐ Traditional other ☐ → Q. 2

Other (specify) ☐ _____

_____

6b If no, why are you not using any method of family planning? Breastfeeding ☐

Signature	Print name	Date

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Wanting to become pregnant ☐ Not sexually active ☐

Menopause ☐ Sterilised (participant or partner) ☐

Other ☐ Specify_____

7 How many days ago was the first day of your last menstrual period? [List number, 99 if more than 3 months or 00 if menstruating now] ☐☐

7a Was this period when you expected it to be? Yes ☐

Refer for clinical assessment No ☐

Section 3: Sexual activity and condom use

Interviewer: please spend some time ensuring that the volunteer understands what is termed by a sex act: one sex act is "penetrative vaginal sex that may or may not end with ejaculation".

"I am now going to ask you about your sexual activity, gel and condom use. Please answer accurately as the responses are very important to the study results."

8 How many days ago did you last have sex?

1 (includes today) ☐ 2 ☐ → Q. 9

3 ☐ 4 ☐ → Q. 9

5 ☐ 6 ☐ → Q. 9

7 ☐ → Q. 9

1-4 weeks ☐ → Q. 15

More than 4 weeks ☐ → Q. 22

9 How many times have you had sex in the last week? [list number of times or 77 if unsure] ☐☐

10 How many different people have you had sex with in the last week? [list number or 77 if unsure] ☐☐

Ensure that the volunteer understands what we mean by each category of partner. 1*) Long-term stable relationships* include some/most of the following characteristics: official marriage, traditional marriage, bride price paid, man known to and accepted by woman's family, have children together, live together, long-term relationship, man provides regular financial/material support, may be cohabiting or non-cohabiting. 2) *One-off sexual encounter* includes one of the following characteristics: occasional sex at party or while away from home, very few sex acts with no commitments involved, sex in direct exchange for money or other payment. 3) other types of partner are those who are not part of a long-term stable relationship, but someone the woman has seen more than once, any other kind of partner who doesn't fit into the first 2 categories.

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: □□/□□/□□□□ DD/MM/YYYY	
Screening number: □□□□□□□	Initials: □□□	Trial number □□□□□

10a How many of these partners were:

Long-term stable relationships □□

One off sexual encounters □□

Other types of partner □□

Interviewer: check that the total of the answers given in question 10a is the same as the answer given in question 10 and rectify if necessary.

Signature	Print name	Date

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Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY	
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number ☐☐☐☐☐

Interviewer: only fill this table in with participants who HAVE had sex in the last 1 week.

"Now I am going to ask you some more detailed questions about your condom and gel use each time you had sex in the last week."

Interviewer: each question (row) refers to a particular sex act. Go through all columns for the individual sex act before moving on to the next row. Write the number corresponding to the answer code for each column in the box in each cell. Remind the participant about the definition of a 'sex act' and allow enough time for the participant to carefully consider each answer.

11.	**Partner**	**Condom**	**Gel**	**Gel timing**	**Vaginal Cleaning**	**Washing timing**	**Partner informed**
Sex acts in the last week	What **type** of partner was this act with?	Did you use a condom during this sex act?	Did you use gel before this sex act?	If you used the gel how long before sex did you insert it?	Did you clean inside your vagina after sex? **(This includes using a dry cloth)**	If you cleaned, how long after sex was this?	If you used the gel, did you tell your partner about it?
Codes	1=long-term stable relationship 2=one off sexual encounter, 3=other type of partner 8=don't remember	1=yes 2=no 8=don't remember	1=yes 2=no 8=don't remember	1=less than 1 hour 2= 1 to 3 hours 3= more than 3 hours 8=don't remember 9=didn't use it	1=yes 2=no 8=don't remember	1=less than 1 hour 2= 1 to 2 hours 3= more than 2 hours 8=don't remember 9=didn't clean	1=yes 2=no 8=don't remember 9=didn't use it
1 last sex act	☐	☐	☐	☐	☐	☐	☐
2 sex act before that	☐	☐	☐	☐	☐	☐	☐
3 sex act before that	☐	☐	☐	☐	☐	☐	☐
4 etc.	☐	☐	☐	☐	☐	☐	☐
5	☐	☐	☐	☐	☐	☐	☐
6	☐	☐	☐	☐	☐	☐	☐
7	☐	☐	☐	☐	☐	☐	☐
8	☐	☐	☐	☐	☐	☐	☐
9	☐	☐	☐	☐	☐	☐	☐
10	☐	☐	☐	☐	☐	☐	☐

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY	
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number ☐☐☐☐☐

Interviewer: read each of the responses to questions 12 to 14 to the participant so she can choose the one that most accurately reflects her answer

12 How confident are you that the responses you gave to the detailed questions about sex, condom and gel use in the last week are accurate?

Very confident they are accurate ☐

Quite confident but I may have mistaken some details ☐

Not very confident about the accuracy of my answers ☐

Not at all confident about the accuracy of my answers ☐

13 How often was a condom used when you had sex in the last 4 weeks?

Always ☐ Most of the time ☐

Sometimes ☐ Never ☐

14 How often was the gel used before you had sex in the last week?

Always ☐ → Q. 20

Most of the time ☐ Sometimes ☐ → Q. 19

Never ☐ → Q. 19

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY	
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number ☐☐☐☐☐

Interviewer: only fill this table in with participants who have NOT have sex in the last 1 week but who HAVE had sex in the last 4 weeks.

"Now I am going to ask you some more detailed questions about each sex act in the last 4 weeks. Please answer the questions for each time you had sex."

Interviewer: each question (row) refers to a particular sex act. Go through all columns for the individual sex act before moving on to the next row. Write the number corresponding to the answer code for each column in the box in each cell. Remind the participant about the definition of a 'sex act' and allow enough time for the participant to carefully consider each answer.

15.	**Partner**	**Condom**	**Gel**	**Gel timing**	**Vaginal Cleaning**	**Washing timing**	**Partner informed**
Sex acts in the last week	What **type** of partner was this act with?	Did you use a condom during this sex act?	Did you use gel before this sex act?	If you used the gel, how long before sex did you insert it?	Did you clean inside your vagina after sex? **(This includes using a dry cloth)**	If you washed, how long after sex was this?	If you used the gel, did you tell your partner about it?
Codes	1=long-term stable relationship 2=one off sexual encounter, 3=other type of partner 8=don't remember	1=yes 2=no 8=don't remember	1=yes 2=no 8=don't remember	1=less than 1 hour 2= 1 to 3 hours 3= more than 3 hours 8=don't remember 9=didn't use it	1=yes 2=no 8=don't remember	1=less than 1 hour 2= 1 to 2 hours 3= more than 2 hours 8=don't remember 9=didn't clean	1=yes 2=no 8=don't remember 9=didn't use it
1 last sex act	☐	☐	☐	☐	☐	☐	☐
2 sex act before that	☐	☐	☐	☐	☐	☐	☐
3 sex act before that	☐	☐	☐	☐	☐	☐	☐
4 etc.	☐	☐	☐	☐	☐	☐	☐
5	☐	☐	☐	☐	☐	☐	☐
6	☐	☐	☐	☐	☐	☐	☐
7	☐	☐	☐	☐	☐	☐	☐
8	☐	☐	☐	☐	☐	☐	☐
9	☐	☐	☐	☐	☐	☐	☐
10	☐	☐	☐	☐	☐	☐	☐

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY	
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number ☐☐☐☐☐

Interviewer: read each of the responses to questions 16 to 19 to the participant so she can choose the one that most accurately reflects her answer

16 How confident are you that the responses you gave to the detailed questions about sex, condom and gel use in the last 4 weeks are accurate?

- Very certain they are accurate ☐
- Quite certain but I may have mistaken some details ☐
- Not very certain about the accuracy of my answers ☐
- Not at all certain about the accuracy of my answers ☐

17 How often was a condom used when you had sex in the last 4 weeks?

- Always ☐
- Most of the time ☐
- Sometimes ☐
- Never ☐

18 How often was the gel used before you had sex in the last 4 weeks?

- Always ☐ → Q. 20
- Most of the time ☐
- Sometimes ☐
- Never ☐

19 If you didn't use the gel every time you had sex, why not? (tick each that applies)

- Found it physically difficult to apply the gel ☐
- Partner opposition ☐
- Didn't have the gel with me ☐
- Ran out of gel ☐
- Didn't like the gel ☐
- Didn't like the applicator ☐
- No opportunity to insert the gel ☐
- Other ☐ Specify:_____ _____

20 In the last 4 weeks, did you ever insert the gel and then not proceed to having sex?

- Yes ☐
- No ☐ → Q. 21

20a How many times did this happen? List number of times or 77 if not sure ☐☐

21 In the last 4 weeks have you had sex whilst you were menstruating?

- Yes ☐
- No ☐ → Q. 22

21a If yes, did you use the gel at this (these) times?

- Always ☐
- Most of the time ☐
- Sometimes ☐
- Never ☐

Section 4: Other products and practices

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐
	Trial number ☐☐☐☐☐

"Some women insert products into their vaginas for a variety of reasons, such as cleaning inside the vagina, or drying or lubricating the vagina before sex. The next questions are about this".

22	In the last week have you inserted anything other than the study gel (excluding water/fingers/tampon) into your vagina?			Yes ☐ No ☐	→ Q. 23
22a	Why did you insert this other thing?	To clean the vagina ☐ To dry the vagina ☐ Other ☐		To lubricate the vagina ☐ Specify_____ _____ _____	
22b	If yes, how many times did you do this?	More than once per day ☐ Less than once per day but more than once in the week ☐		Once per day ☐ Once in the week ☐ Don't remember ☐	
22c	What time of day did you normally do this?	Morning ☐ Evening ☐		Afternoon ☐	
22d	When in relation to sex did you normally do this?	After sex ☐		Before sex ☐ Some other time ☐	
22e	What did you insert?	MULTIPLE ANSWERS Disinfectant ☐ Vaseline ☐ Herbs ☐ Other ☐		Creams ☐ Dry cloth ☐ Wet cloth ☐ Lemon ☐ Specify:	

Interviewer: spend some time making sure the participant understands what anal sex is: "penetrative anal sex that may or may not end with ejaculation".

"Some women have anal sex. The next question refers to this practice".

23	Have you had anal sex in the last 4 weeks?			Yes ☐ No ☐	→ Q. 24
23a	Did you use a condom?	Always ☐ Sometimes ☐		Most of the time ☐ Never ☐	

Section 5: Acceptability

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐
	Trial number ☐☐☐☐☐

"I now want to ask you some questions about how easy the gel is to use and if you had any problems using it."

Interviewer: explain that question 24 is about ease of inserting the gel into the vagina and question 25 is about things in the immediate environment that facilitate or hinder gel use such as having children/partner around, lighting, access to water etc.

24	Was the insertion of the gel easy or difficult?	Very easy	☐	Easy	☐	→ Q. 25
		Difficult	☐	Very difficult	☐	
24a	If difficult/very difficult, why? _____					
25	Was it convenient or inconvenient to use the gel?			Convenient	☐	→ Q. 26
				Inconvenient	☐	
25a	If inconvenient, why? _____					
26	Did you feel the gel during sexual intercourse?			Yes	☐	
				No	☐	→ Q. 27
26a	If yes, what did you feel? _____					
26b	Did you like this feeling?			Yes	☐	
				No	☐	
				Neither	☐	
27	Did using the gel interfere with sex in any way?			Yes	☐	
				No	☐	→ Q. 28
27a	If yes, how did it interfere? _____					
28	Did the gel affect your enjoyment of sex?			Yes	☐	
				No	☐	→ Q. 29
28a	If yes, how?	More enjoyable	☐	Less enjoyable	☐	
29	Have you noticed any change in vaginal discharge since using the gel?			Yes	☐	
				No	☐	

Signature	Print name	Date

Site name: Africa Centre for Health and Population Studies	Date of visit: ☐☐/☐☐/☐☐☐☐ DD/MM/YYYY
Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐
	Trial number ☐☐☐☐☐

30 Have you noticed any change in vaginal irritation or itching since using the gel? Yes ☐ No ☐ → Q. 31

30a If yes, how? More irritation ☐ More itching ☐ Less irritation ☐ Less itching ☐

31 Did you have any other problems using the gel? Yes ☐ No ☐ → Q. 32

31a If yes, what were they?

_____

_____

32 What do you like most about the gel?

_____

33 What do you like least about the gel?

_____

34 Did you tell any of your partners you were using the gel? Yes ☐ No ☐ → Q. 35

34a If you told any of them, why?

_____

35 Did any of those you did not tell find out? Yes ☐ No ☐ → Q. 37

35a If yes, what was their response?

_____

36 How did your partner(s) respond to the gel? (All) liked it ☐ Some liked it and some didn't like it ☐ (All) didn't like it ☐ Partner(s) didn't notice/mention the gel ☐

37 Would you recommend the gel to others? Yes ☐ → Q. 37a Don't know ☐ No ☐ → Q. 37b

37a If yes, why?

_____

37b If no, why not?

_____

38 Would you be willing to use a gel before sex for a longer period of about a year?

Signature	Print name	Date

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Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐
	Trial number ☐☐☐☐☐

Yes ☐

No ☐

39 Have you had any difficulty answering these questions? Yes ☐

No ☐ → Q. 40

39a If yes, which ones? Gel accountability ☐ Family planning ☐

Sexual activity and condom use ☐ Acceptability ☐

Other products & practices ☐

39b If yes, in what way?

_____

_____

40 Interviewer, please tick whether you think the participant has had some difficulty answering any of these questions.

Yes ☐

No ☐

Section 6: Pregnancy test and clinical symptoms

41 Is pregnancy test indicated? Yes ☐ → Q. 41b

No ☐ → Q. 41a

41a Why not? Participant on hormonal contraception ☐

Participant has IUCD fitted ☐ Participant sterilised ☐

41b Has urine sample been collected? Yes ☐ → Q. 42

No ☐ → Q. 41c

41c Why not? _____

42 Have you experienced any bleeding or spotting that was not your period in the last week? Refer for clinical assessment Yes ☐

No ☐

43 Have you experienced any genital sores or ulcers in the last week? Refer for clinical assessment Yes ☐

No ☐

44 Have you experienced any genital discomfort in the last week? Refer for clinical assessment Yes ☐

No ☐

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Screening number: ☐☐☐☐☐☐☐	Initials: ☐☐☐	Trial number ☐☐☐☐☐

45	Have you had any other symptoms in the last 4 weeks that you thought were serious enough to make you want to see a doctor or nurse?	Refer for clinical assessment	Yes ☐ No ☐	

Section 7: Contacts

46	Do you give your consent for a member of the study team to contact your partner to ask him some questions about the gel?		Yes ☐ No ☐	→ Q. 47
46a	Did you tell this partner about your participation in the study?		Yes ☐ No ☐	
47	Do you give your consent to be contacted at a later date about future microbicide trials?		Yes ☐ No ☐	

Interviewer code ☐☐☐

Comments

_____
_____
_____
_____
_____
_____

MDP 301 PILOT 01 – CRF-CD COMPARISON TABLE – CFRCD 27-08-04

Site name: Africa Centre for Health and Population Studies	Trial number: □□□□□□□	Initials: □□□	Date of visit: □□/□□/□□□□ DD /MM / YYYY

CRF	QUESTION	CRF Answer	CD Question	CD answer
2.	No. of Applicators used		No. of times gel used in 4 weeks	
8.	Had Sex in last week or only last 4 weeks or more than 4 weeks ago		Sex reported in last week or last 4 weeks or not in last 4 weeks	
9./15	No. of times had sex in last week/4weeks		No. of times had sex in last week/4 weeks	
10.	No. of partners in last week		Different types of partners reported	

11/15. Acts	Partners	Condom	Gel	Gel timing	Vaginal Cleaning	Washing timing	Partner informed		
i.									
ii.									
iii.									

13	How often condoms used		No. of condoms	
19	Reason no gel			

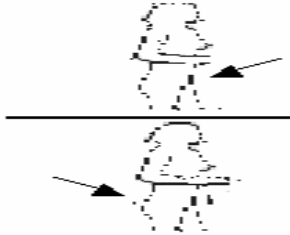
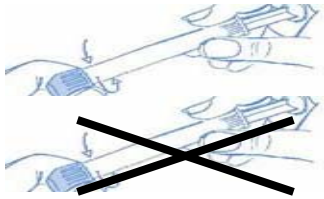
21	Sex during menstruation last month (21a. gel)			
22	Insert anything in vagina last month (22e. what)			
23	Anal sex last month (24. condom)		Anal Sex	

24	Easy or difficult			
25	Convenient/inconvenient			
26	Feel the gel			
27	Interfere			
28	Affect enjoyment (28a. How)			
29	Discharge			

Signature:	Print name:	Date:

MDP 301 PILOT 01 – COITAL DIARY – CD 27-08-04

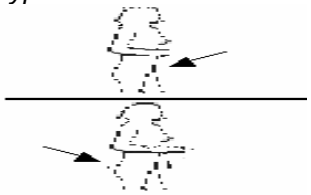
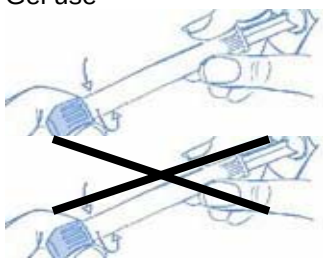
Site name: Africa Centre for Health and Population Studies	Date Issued: □□/□□/□□□□ DD/MM/YYYY	Date Returned: □□/□□/□□□□ DD/MM/YYYY
Trial number: □□□□□□□	Initials: □□□	

WEEK ONE	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Type of a partner							
Type of sex 							
Condom use							
Gel use 							

Signature	Print name	Date

MDP 301 PILOT 01 – COITAL DIARY – CD 27-08-04

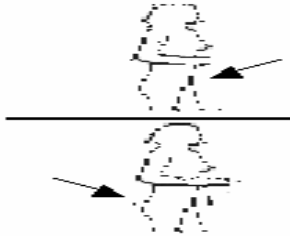
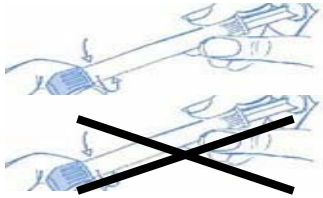
Site name: Africa Centre for Health and Population Studies	Date Issued: □□/□□/□□□□ DD/MM/YYYY	Date Returned: □□/□□/□□□□ DD/MM/YYYY
Trial number: □□□□□□□	Initials: □□□	

WEEK TWO	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Type of a partner							
Type of sex 							
Condom use							
Gel use 							
WEEK THREE	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**	**Sunday**

Signature	Print name	Date

MDP 301 PILOT 01 – COITAL DIARY – CD 27-08-04

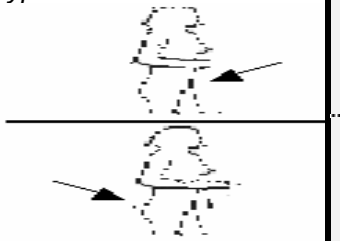
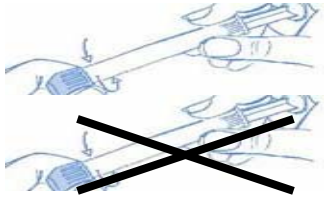
Site name: Africa Centre for Health and Population Studies	Date Issued: □□/□□/□□□□ DD/MM/YYYY	Date Returned: □□/□□/□□□□ DD/MM/YYYY
Trial number: □□□□□□□	Initials: □□□	

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Type of a partner							
Type of sex 							
Condom use							
Gel use 							
WEEK FOUR							

Signature	Print name	Date

MDP 301 PILOT 01 – COITAL DIARY – CD 27-08-04

Site name: Africa Centre for Health and Population Studies	Date Issued: □□/□□/□□□□ DD/MM/YYYY	Date Returned: □□/□□/□□□□ DD/MM/YYYY
Trial number: □□□□□□□	Initials: □□□	

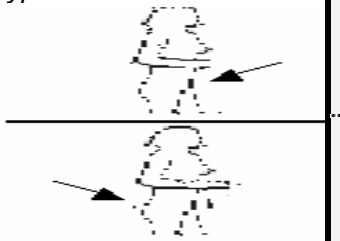
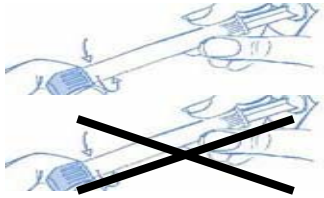
Type of a partner							
Type of sex 							
Condom use							
Gel use 							

WEEK FIVE	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

Signature	Print name	Date

MDP 301 PILOT 01 – COITAL DIARY – CD 27-08-04

Site name: Africa Centre for Health and Population Studies	Date Issued: □□/□□/□□□□ DD/MM/YYYY	Date Returned: □□/□□/□□□□ DD/MM/YYYY
Trial number: □□□□□□□	Initials: □□□	

Type of a partner								
Type of sex 								
Condom use								
Gel use 								

Signature	Print name	Date