

UNIVERSITY OF CAPE TOWN

Predictors of sexual risk behaviour among adolescents from low socioeconomic settings in South Africa

A mini-dissertation submitted to the Faculty of Health Sciences, University of Cape Town, in
partial fulfilment of the requirements for the degree of Master of Public Health

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PREAMBLE

1.0 DECLARATION

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2.0 ACKNOWLEDGEMENTS

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3.0 THESIS ABSTRACT

Predictors of sexual risk behaviour among adolescents from low socioeconomic settings in South Africa

The HIV epidemic continues to be a public health concern with evidence indicating that in South Africa, the epidemic is being driven largely by new infections in adolescents. Behavioural change is key to successful prevention strategies. This study sets out to determine the prevalence and predictors of sexual risk behaviours among adolescents aged 12–18 from low socioeconomic settings in South Africa with the aim of informing future prevention interventions.

Part A is the study protocol which states the research question and hypothesis and outlines the research methodology, analysis plan and ethical considerations. Part B forms the literature review which provides a context of the dissertation. The objectives of the literature review included an assessment of the prevalence of, and predictors of sexual risk behaviour among South African youth and draws from other studies in low socioeconomic settings. And finally Part C presents the results and examines the key findings as well as a discussion on implications and recommendations for prevention strategies.

The results showed that there is high prevalence of sexual risk behaviours, with males exhibiting more sexual risk behaviours than females. Factors found to be significant predictors of sexual risk behaviour were age, gender, condom use, drug and substance use, area of residence and whether adolescents knew their partners' status at the time of intercourse. Recommendations for prevention strategies included that prevention messaging starts as early as 12 years of age, before the age of sexual debut, that messaging must be gender specific and that local sociocultural contexts be taken into consideration in the design of interventions.

4.0 LIST OF ACRONYMS

AIDS	Acquired Immunodeficiency Disease Syndrome
CAPRISA	Centre for AIDS Programme of Research in South Africa
CDC	Centres for Disease Control and Prevention
DTHF	Desmond Tutu HIV Foundation
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HSRC	Human Sciences Research Council
MeCRU	Medunsa Clinical Research Unit
PHRU	Perinatal HIV Research Unit
STD	Sexually Transmitted Disease
STI	Sexually transmitted Infections
UNAIDS	United Nations Programmed on HIV and AIDS.
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization

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PART A: PROTOCOL

1.0 BACKGROUND OF PARENT PROTOCOL

The sub-study on which this mini-dissertation is based is nested within a larger study whose overall aim was to prepare seven¹ clinical research sites in South Africa to conduct HIV vaccine trials with adolescents. The parent study, entitled South African Studies for HIV in Adolescents (SASHA), was conducted at seven sites in five different provinces of South Africa. SASHA was approved by all Human Research Ethics Committees affiliated with the seven sites. The parent protocol was written in 2008 and the study was conducted between March 2009 and December 2010.

The primary objective of the parent study was to assess recruitment and retention of adolescents in a vaccine trial for sexually transmitted diseases, and identify parental, adolescent and study characteristics associated with recruitment, vaccine uptake and retention. This was done by emulating an HIV vaccine trial using the human papilloma virus (HPV) vaccine as a proxy for an HIV vaccine.

The study design was an observational longitudinal cohort that followed up adolescents aged 12 to 18 over a nine-month period. Visits consisted of a screening visit, an enrolment visit and follow-up visits at month 2, month 6 and month 9. The three-course HPV quadrivalent vaccine was administered at enrolment, month 2 and month 6 as per licensure. At all study visits, a set of socio-behavioural questionnaires were administered to address primary and secondary objectives.

The sub-study's main objective is to assess the prevalence of sexual risk behaviour and to investigate the predictors of sexual risk behaviour in sexually active adolescents. The study population for the sub-study is therefore sexually active adolescents from the parent study. Descriptive statistics will include all participants screened and enrolled for the parent protocol in order to provide context of the population from which the sub-study draws.

¹ Due to delays in obtaining regulatory approvals, only five of the seven sites screened and enrolled participants.

Throughout this paper, the study on which this dissertation is based will be referred to as the ‘sub-study’ and the main SASHA study will be referred to as the ‘parent protocol’

2.0 STUDY BACKGROUND

The HIV epidemic continues to be a public health concern as the number of people living with HIV continues to grow. The highest prevalence rates are among young people. Furthermore, there is a great deal of research indicating that the HIV epidemic in South Africa is being driven largely by new infections in adolescents. Numerous prevention efforts that focus on abstinence and safer sexual practices have not been successful in reducing HIV in adolescents. This is evidenced by numerous studies conducted in South Africa that show that prevalence rates remain a concern (HSRC, 2002; RHRU, 2003). Behavioural change among adolescents is key to such prevention strategies. It is therefore critical to study adolescent behaviours in order to determine some of the predictors of sexual risk behaviours. Gaining a better understanding of predictors of sexual risk behaviours will, in turn, inform effective prevention strategies.

For the purpose of this paper, the author is using the World Health Organization (WHO) term, which defines ‘adolescent’ as any individual between the ages of 10 and 19 (WHO 2014), and the UNESCO definition of ‘youth’, namely any individual between the ages of 15 and 24 (UNESCO 2014).

3.0 LITERATURE REVIEW

According to UNAIDS, approximately 2.1 million adolescents aged 15–19 years were living with HIV in 2012 and approximately 300 000 new infections occurred in this age group. Two-thirds of the new infections were among females. Sub-Saharan Africa contains almost two-thirds of all young people living with HIV/AIDS. While the 2012 data showed a 35% decline in new infections among children under the age of 15 compared to 2009, reducing the rate of new transmissions remains a priority (UNICEF, 2013).

Given this concerning evidence that would indicate that the HIV epidemic in sub-Saharan Africa is being driven largely by new infections in adolescents, particularly young women, there has been a growing body of research aimed at understanding adolescent sexual risk behaviour.

Research thus far has shown that high-risk sexual behaviour among adolescents can lead to serious long-term health consequences such as sexually transmitted diseases (STDs), HIV/AIDS and unintended pregnancy. A report by the Centres for Disease Control and Prevention (CDC, 2004) showed that approximately 870 000 pregnancies occur each year among women aged 15–19, and about 3 million cases of STDs are reported annually among 10- to 19-year-olds (CDC, 2004).

Research conducted in South Africa shows that adolescents commence sexual activity at a young age (Stockl et al, 2013; Eaton 2003). Previous research conducted among urban black youth in South Africa by Wood et al. 1997, aged 16 to 20 years, showed that 40% of the females and 60% of the males reported having had more than one sexual partner in the previous six months, and condom use was reported to be very low (Wood et al., 1997). In another study conducted in a rural area in the south-eastern part of South Africa in which the population mean age was 15 for females and 16 for males, 76% of the females and 91% of the males reported being sexually active. Males reported having sexual debut earlier at 13.4 years compared to females at 14.9 years. Furthermore, males had a history of more partners and nearly twice as many sexually transmitted infections than females (Kelly and Ntlabati, 2002). A systematic review by Eaton et al., 2003, showed that South African teenagers are at risk for HIV infection through unprotected sex. Findings of the review showed that at least 50% of youth in South Africa are sexually active by age 16, and that as much as 50% to 60% reported not using condoms. Primary research conducted among Cape Town secondary school students show age of sexual debut to be 13, and an annual incidence among this population of 15%. The study established that by age of 17, 60% of students have had their sexual debut (Pettifor et al., 2005).

And finally, a study by Flisher et al. in 2003 amongst 2 748 Grade 8 students in Cape Town, 58.4% female and 49.5% male showed that 23.2% (CI 18.0–28.3) of the males and 10.8% (CI 7.4–14.1) of females in Grade 8 had already had intercourse.

4.0 RATIONALE FOR STUDY

The above research evidence shows significant prevalence of sexual risk behaviours, such as, early age of sexual debut, unprotected sex and having multiple partners that place adolescents at risk of acquiring HIV infection. It is therefore critical to identify what some of the predictors of these behaviours might be. One can hypothesise that personal and socio-demographic variables, as well as other factors that are a natural reflection of adolescents' physical and social development may have an impact on adolescents' sexual risk behaviour. Understanding these factors in order to manage them carefully is therefore critical in order to reduce the kinds of risk adolescents face in terms of sexual behaviour. This paper assesses the prevalence of sexual risk behaviours in several different settings in South Africa and explores factors that may predict sexual risk behaviours. Knowledge gained from the findings will contribute to HIV prevention strategies for the different settings in South Africa.

5.0 OBJECTIVES

The study objectives were to assess the prevalence of sexual risk behaviour in sexually active adolescents and to investigate the predictors of sexual risk behaviours in this population. Outcome variables measured to determine risky behaviour were sexual activity under the age of 16, age of sexual debut (age of first sexual intercourse), condom use and multiple partners.

6.0 HYPOTHESIS

We hypothesized that the factors that would predict sexual risk behaviour are; being male, being a school dropout, residing in informal communities, having used drug and substance, not knowing partner's status and having intercourse with someone known to be HIV-positive. Study outcome variables were age of sexual debut, sexual activity under the age of 16, condom use and multiple partners.

7.0 METHODOLOGY

Study design

The study design is a nested cross-sectional descriptive study with data derived from a multicentre longitudinal cohort study whose objective was to prepare South African sites for adolescent HIV vaccine trials. For the parent study, baseline data were obtained at the screening and enrolment visit. The two visits were no more than 30 days apart. For the purpose of this study, the screening and enrolment visits were combined and considered as one time point.

Settings

The DTHF site is located in the Nyanga district, Cape Town, which is a predominantly Xhosa community of over 400 000 people in an area of 16 square kilometres. The community is serviced by basic amenities, but a large portion of the community is housed in informal aggregated shacks or basic government-supplied two-room houses. There is a high unemployment rate with poor socioeconomic status.

The PHRU site is situated in Soweto, an urban African township 15 kilometres to the south-west of Johannesburg. The population is reported to be between 2.5–3 million in an area of 63 square kilometres. Fifty-eight per cent of the population live in brick houses, 28% of residents reside in backyard shacks and 14% live in informal settlements. More than 10% of adults in this community have no formal education and a quarter have a maximum of seven years of education.

The KOSH site is situated in the city of Rustenburg, which is located in the Bonjanala Platinum District. Rustenburg is predominantly an urban area within the district, facilitating access to large populations within and beyond Rustenburg. It is home to a large, diverse and growing influx of residents attracted to the area for work in the mining industry.

The MEDUNSA site is situated at the Medunsa Clinical Research Unit, (MeCRU), in Pretoria. The community consists of four large residential areas (townships) that serve as the study

catchment area, with an estimated population of 1.2 million. It is made up of both formal and informal settlements.

The CAPRISA site is situated at the eThekweni Clinical Research site which is located adjacent to the Prince Cyril Zulu Communicable Disease Centre (CDC) in Durban. It is a designated primary health care clinic for the diagnosis and treatment of STI's and tuberculosis. Annually, about 40 000 cases of STI's are treated at this clinic.

Study population and eligibility criteria

The study population was made up of adolescents aged 12–18 who resided in rural, urban formal and urban informal settings in five sites in South Africa. The eligibility criteria for entry into the parent study were adolescents between the ages of 12 and 18. Adolescents over the age of 16 had to be sexually active to be included in the study. Those under the legal age of consent (i.e. 12–15-year-olds) were not required to be sexually active. Descriptive data included characteristics of all adolescents screened for the sub-study i.e. all adolescents screened for the parent study. Bivariate and multivariate analysis included only sexually active adolescents who had been screened and enrolled into the sub-study. These included all adolescents over the age of 16 and those under the age of 16 who had reported being sexually active. Adolescents under the age of 16 who were not sexually active were excluded from the analysis. Sexual activity was made a requirement for those over 16 years of age in order to ensure that our sample had a proportion of sexually active adolescents that would allow us to accurately assess certain aspects of sexual risk behaviour. Adolescents had to be willing and able to assent to take part in the study; a parent or legal guardian had to be willing to provide written consent.

Sampling method

Secondary data from the parent protocol as described under study design was used. The parent protocol was a multicentre longitudinal cohort study that was aimed at preparing for adolescent HIV vaccine trials in South Africa.

Study procedures

Recruitment

Adolescents were recruited through community outreach. This included targeting schools, youth groups, sports clubs, taxi ranks and other points of convergence in the community. In addition, the friendly voluntary testing centres were targeted. Following information given by community recruiters, all adolescents who showed interest in taking part in the study were invited to the study sites for informed consent, screening and enrolment into the study. To maintain confidentiality around sexual activity, detailed information regarding sexual activity and eligibility was only discussed with the study participants on a one to one by study counsellors.

Screening

Interested adolescents were asked to bring a parent or legal guardian to the clinic for informed consent and for screening and enrolment into the study. Information regarding the study objectives, protocols and procedures was discussed with the parents and adolescents to address any concerns raised before signing of the informed consent document. Part of the informed consent process was to clarify those aspects of the research for which adolescents were to enjoy privacy, as outlined under the ethical considerations. Provision was made for participants who could not read the form to have it read to them in their home language by an independent witness. All participants were given copies of the informed consent document to take home; another copy was kept in the site file. At the screening visit, adolescents were asked to complete questionnaires that captured demographic information and information about their current sexual activity. At the study visits, an interviewer fluent in the participants' language or English (at the preference of the participant) who had received training for this purpose administered the questionnaires.

Enrolment

The second visit was scheduled to take place within 45 days of screening. An interviewer fluent in the participants' language administered questionnaires to the participants. Information collected included demographic information, sexual activity and sexual risk behaviour, correlates of sexual risk and protective behaviours (condom use, delaying sexual debut, number of partners, partner status). The tools were not all validated. Pilot testing was however conducted at the Cape Town site. Results of the pilot testing led to refining of tools.

Tools and instruments in this sub-study were used only in adolescents who were sexually active. The questionnaires were designed with appropriate skip patterns to ensure that sexually active adolescents were taken through the relevant questionnaires.

Sample size

The total sample size for the seven sites was aimed at 1 400 adolescents. This sample size for this study was based on the parent study. This sample size was based on the calculation of precision in the proportion of adolescents completing the six-month vaccination schedule (for the parent study). It was estimated that a successful vaccination programme must demonstrate greater than 90% completion of the entire six-month vaccination schedule. To estimate this proportion with a margin of error of 2%, a sample size of 1 400 individuals was needed in order to have 1 260 complete the six months (95% exact CI: 88%–92%).

Statistical methods

A customized, online data-management system with an automatic daily back up was built. Data were downloaded on a regular basis to Microsoft Excel, at the central data management unit at the Desmond Tutu HIV Centre in Cape Town.

Data were analysed using the statistical programme STATA (Stata Corporation, College Station, Texas, USA). Simple descriptive statistics, including frequency distributions, were used to assist in data cleaning and summarisation. A bivariate analysis was performed to explore factors potentially associated with sexual risk behaviours. Pearson's chi-squared test

and Fisher's exact test were used to examine overall bivariate associations between the outcome variables and the predictors. Logistic regression was then conducted for multivariate analysis. The bivariate and multivariate for this sub-study only included sexually active adolescents i.e. all adolescents above the age of 16 and those under 16 who reported being sexually active.

8.0 ETHICAL CONSIDERATIONS

This study was approved by the University of Cape Town Human Research Ethics Committee prior to implementation.

Given that the age of participation is 12–18 years and that the age of lawful consent to sex in South Africa is 16 years, special ethico-legal considerations had to be taken into account. In consultation with ethico-legal specialists and all five all the Ethics Committee Chairpersons who were responsible for approving the study at each site for the parent study, certain recommendations were developed (appendix 10). These recommendations outlined sections of the law relating to participation in research, age of consent for sex and consent for treatment and how these were to be applied in relation to the study. These were to guide sites to ensure the study was being implemented in a manner that was ethico-legally compliant.

Community Advisory Board (CABS) Consultation

As part of the capacity building component of the parent study, all sites were supported by the coordinating centre in developing an adolescent community advisory board. The CABS were consulted prior to implementation and their feedback was taken into consideration in refinement of the protocol and study documents as well as study implementation.

Informed consent

Given that all participants were to be under the age of consent for study participation (18 years) at enrolment, informed consent and informed assent were obtained from parents/legal guardians and the adolescent participants prior to participation. Participation was voluntary and

participants were free to withdraw from the study at any stage without any disadvantage to them.

Privacy and confidentiality

As adolescents over the age of 16 were required to be sexually active to participate, parents were made aware of this information. Parents were also made aware of what information would remain private for the adolescents and what information they would have access to. However, it was recognised that disclosure of information regarding sexual activity could have been problematic for adolescents and/or parents, and for this reason mediation and facilitation of adolescent disclosure of sexual activity were provided where required.

Risks and benefits

The benefits of study participation were that adolescents would have access to support through the counselling services provided by the study team and additional support would be facilitated where necessary. Adolescents would also have physical examinations and be tested for STIs regularly, and medical treatment would be provided as necessary. Regular risk reduction counselling was also likely to result in altered risk behaviour. It could however be argued that sexual health services are available to adolescents in Primary Health Care facilities and therefore should not be considered to be benefits of study participation. On the other hand, there is evidence that in some communities, adolescents do not access sexual and reproductive services due to the negative experiences of using such services (Dickson-Tetteh 2001, Mfono 1998 & Wood and Jewkes 2006). The study created an adolescent friendly environment which we believe would have removed the barrier to access services, thus enabling more adolescents than usual to utilise services.

As well as counselling provided by study counsellors, provisions were made to ensure that adolescents who were diagnosed with STIs, pregnant or had emotional complications would be assisted to disclose this information to a trusted adult of their choice for on-going support.

Where social harms were detected, adolescents were assisted and supported in communicating with parents about sexual activity, and where necessary, about test results.

The study team were aware of the possibility of adolescents increasing their sexual risk behaviour as a result of participation in the study and their heightened awareness of matters concerning sexual activity. For this reason, sexual risk was carefully monitored and risk-reduction counselling provided.

Reimbursement

Participants were reimbursed for their time and inconvenience. The reimbursements were between R50 and R150 per scheduled visit, depending on length of visit and inconvenience.

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PART B: LITERATURE REVIEW

1.0 BACKGROUND

The HIV epidemic continues to be a public-health concern as the number of people living with HIV continues to grow, with the highest prevalence being among young people (age 15–24). In 2011 the total global figure for people living with HIV was 34.0 million and 69% of these were said to be in sub-Saharan Africa (WHO, 2011). More recently, according to the 2013 ‘Taking Stock Report by UNICEF, approximately 2.1 million adolescents aged 15 – 19 years were living with HIV in 2012 and approximately 300 000 approximately new infections occurred in this age group. Two-thirds of the new infections were among females. Sub-Saharan Africa contains almost two-thirds of all young people living with HIV/AIDS (UNICEF, 2013).

South Africa is said to bear the heaviest burden of HIV and accounts for as much as 17% of the global burden. It is, however, important to note that the number of people (adults and children) acquiring HIV infection has started to decline over the last decade. In 2011 the number of people acquiring new infections was 2.5 million and this is reported to be 20% lower than the number of new infections in 2001. This decline is said to be particularly marked in sub-Saharan Africa (WHO, 2011). Despite this decline, the number of new infections, particularly among young people, remains a concern.

Table 1: Estimated breakdown of HIV prevalence in 15- to 24-year-olds by gender for the sub-Saharan region

Country	HIV prevalence (%) among young people (15–24 years old)		% of young people (15–24 years old) with comprehensive knowledge of HIV	
	Male	Female	Male	Female
Angola	0.6	1.6	32	25
Botswana	5.2	11.8	-	-
Burundi	1.0	2.1	1	30
Comoros	<0.1	<0.1	-	-
Eritrea	0.2	0.4	-	-
Ethiopia	-	-	33	20
Kenya	1.8	4.1	55	48
Lesotho	5.4	14.2	29	39
Madagascar	0.1	0.1	26	23
Malawi	3.1	0.1	42	42
Mozambique	3.1	8.6	34	36
Namibia	2.3	5.8	62	65
Rwanda	1.3	1.9	54	51
Somalia	0.4	0.6	-	4
South Africa	4.5	13.6	-	-
South Sudan	-	-	-	-
Swaziland	6.5	15.6	54	58
Uganda	2.3	4.8	38	32
Tanzania (United)	1.7	3.9	43	48
Zambia	4.2	8.9	41	38
Zimbabwe	3.3	6.9	-	53

Source: *State of the World's Children*, UNICEF, 2012

In South Africa, data concerning HIV prevalence is mainly derived from the South African national household survey of HIV/AIDS prevalence and the Department of Health antenatal

surveys. According to the 2012 the South African National HIV, Behaviour and Health Survey 2012, conducted by the Human Sciences Research Council (HSRC), the proportion of people living with HIV in South Africa had increased from 10.6% in 2008 to 12.3% in 2012 (HSRC, 2012). Data from the HSRC household surveys shows regional variations across the provinces. KwaZulu-Natal is said to have the highest prevalence among young people, with this province accounting for about a third of infections in South African youth. Gauteng is the second highest with approximately 17.3% and the Eastern Cape has the third highest rates of youth infections at 12.1% (Dorrington et al., 2006). Information on risk factors associated with HIV acquisition that lead to these regional variations is key to informing targeted interventions to curb the pandemic.

2.0 OBJECTIVES OF LITERATURE REVIEW

The literature review provides a context for this dissertation, entitled ‘Predictors of sexual risk among adolescents in South Africa: A study to determine the prevalence and predictors of sexual risk behaviours among adolescents from low socioeconomic settings in South Africa with the aim of informing future interventions to reduce sexual risk behaviour’. The objectives of the literature review include an assessment of the prevalence of HIV and sexual risk behaviour among South African youth. The review also examines some of the predictors among youth associated with sexual risk behaviour. While the dissertation focuses on South African youth, the review also draws from literature from other sub-Saharan studies. Our study hypothesised that socio-demographic factors, alcohol and substance use, level of education, not knowing partners’ status and having sexual intercourse with someone who is HIV-positive. The literature review examines these factors, and draws from local and global studies.

The literature review included articles published between 1995 and 2014. Summary of papers reviewed is attached in appendix 1.

Quantitative and qualitative studies of various study designs were included in the literature search. Online literature searches in PubMed, BioMed Central and MEDLINE were utilised. The search included all the proposed outcome variables: sexual activity, condom use, age of sexual debut and multiple partners, with the words 'adolescent' and 'youth'. Even though the study is cross-sectional, all study designs were included in the review. Given the large number of articles yielded by the search, studies were then narrowed down to mainly those conducted in South Africa and similar settings in sub-Saharan Africa.

For the purpose of this paper, adolescents are described as young people between the ages of 12 and 18 years of age. The literature review however included studies conducted on young people/youth in the age range 12 to 24 years old.

A limitation of many of the studies reviewed was that they were based on self-reported data. Results need to be interpreted with caution especially given the sensitivity of the subject of sexual behaviour in this population and particularly this age group. Results may be subject to various biases such as a) social desirability, particularly where interviewer administered b) recall bias which may result in inconsistent and inaccurate reporting and c) measurement bias.

3.0 HIV AMONG SOUTH AFRICAN YOUTH

There have been at least two large, nationwide cross-sectional studies of HIV prevalence and risk in children and young adults in South Africa. Firstly, in a survey conducted by the HSRC in 2002 among youth aged 15–24, it was found that the prevalence rates among females were double those of males, with 6% for males and 12% for females (Shisana O, Simbayi L, 2002).

In another study conducted by the Reproductive Health Research Unit 11 904 young people were tested and interviewed in 2003. Overall, HIV prevalence amongst 15- to 24-year-olds was 10.2% (95% CI 9.3–11.3). In this age group, the prevalence in males was 4.8% (95% CI 3.9–5.9) and in females 15.5% (95% CI 13.7–17.6). Amongst the 15- to 19-year-old age group, the prevalence in males was 2.5% (1.8–3.4) and in females 7.3% (5.9–9.0) (Pettifor et al., 2005)

While the three South African National Household Surveys conducted by the HSRC since 2005 have shown a decline in prevalence among youth aged 15–24 years, 10.3% in 2005 to 8.7% in 2008 and 7.3% in 2012, data from the 2011 National Antenatal Sentinel HIV & Syphilis Prevalence Survey in South Africa showed an increase in HIV prevalence in the 15–19 years age group from 13.7% in 2009 to 14.0% in 2010. There was however a slight decrease to 12.7% in the 2011 survey (Department of Health, 2011).

4.0 SEXUAL ACTIVITY IN ADOLESCENTS

Given these concerning high rates of HIV prevalence in young people, the risk of HIV among adolescents is an important topic to understand, as this is a particularly vulnerable time for this age group. They are at a peak of their development biologically and cognitively. Developmentally, this is the period when adolescents become more aware of their sexuality and may want to explore sexual experiences. Adolescents are said to have increased interest in the opposite sex, concerns regarding physical and sexual attractiveness, they frequently change relationships and indulge in experimentation with sex (Weatherburn and Project SIGMA in MacPhail, 1998). In addition to revealing these biological and developmental factors, research has also shown that adolescence is a period when young people tend to experiment with drugs and alcohol. All these developmental and social experiences may place adolescents at risk of unsafe sexual behaviours, such as engaging in early initiation of sexual intercourse, unprotected intercourse and multiple sexual partners. Understanding sexual risk in this age group is therefore particularly important.

5.0 SEXUAL RISK BEHAVIOUR IN ADOLESCENTS

The aim of this paper is to identify factors that are associated with risky behaviours in South African adolescents from low socioeconomic communities. Eaton et al. (2003) divide such factors into those that are personal (e.g. beliefs and knowledge), proximal (e.g. negotiating condom use, peer influence) and distal cultural and structural (e.g. urban vs rural). They argue that distal and proximal factors play a significant role in influencing sexual risk behaviour in

South African adolescents (Eaton et al., 2003). This study will mainly focus on exploring some of the proximal and distal factors associated with sexual risk behaviour among adolescents.

For the purpose of this study, sexual risk behaviour was described as sexual activity below the age of consent in South Africa i.e. 16 years old, early age of sexual debut, having ever had unprotected sex and having had multiple partners.

Age of sexual debut

The age of sexual debut marks the beginning of possible exposure and risk to HIV infection for the adolescent. A systematic review by Stokhl et al, (2012) showed that there was a significant association between early sexual debut and HIV. Early sexual debut is therefore a major concern, particularly in high-prevalence areas like South Africa.

In a study by Mathews et al. (2009), which looked at age of sexual debut in high-school learners, initiation of sexual activity was found to be as early as 13 years with 13% among females and 31% among males of this age having already initiated sex. In another study conducted in a rural area in the south-eastern part of South Africa, where the mean ages of females and males were 15 and 16 years, respectively, 76% of females and 91% of males were sexually active. Males were found to initiate sexual activity earlier than females (13.4 years versus 14.9 years), and had a history of more partners and nearly twice as many sexually transmitted infections than females (Kelly and Ntlabati, 2002).

Findings from a study in the Northern Cape, among 900 adolescents aged 16 to 20 which conducted interviews and focus group discussions in nine schools, showed an early sexual debut occurring by the age of 15 as well as a high incidence of multiple partners (Pettifor et al., 2004). In another study, conducted by Flisher et al. (2003), which included 2 740 students, 58.4% females and 49.5% males in Grade 8, a significant number of the males, 23.2% (CI 18.0–28.3) in Grade 8 had had sexual intercourse and by Grade 11 as high as 57.8% (CI 51.0–64.6) had had first intercourse. For females, the percentages were 10.8% (CI 7.4–14.1) and 42.8% (CI 37.3–47.8) respectively. These proportions were much higher compared to study

conducted in 1999 (Flisher et al., 2003). This is a clear indicator that more and more adolescents are initiating sex earlier.

The above studies show that adolescents are becoming sexually active at a significantly early age ranging between 12 and 15 years. This means that an even greater number of adolescents are becoming exposed to these sexual risk behaviours and have a prolonged exposure to the risk of acquiring HIV infection. Understanding factors associated with age of sexual debut is particularly important given these findings and that early sexual initiation is a potential risk factor for HIV acquisition.

Condom use

Results from clinical and epidemiological studies show that condom use is so far regarded as the best method to prevent HIV infection. Failure to use condoms can therefore be regarded as the most common indicator of risk in adolescents. A systematic review conducted by Weller and Davis (2002) showed that consistent male condom use resulted in an approximately 80% reduction in HIV transmission. Worryingly, and despite decades of HIV education and prevention, numerous research studies have shown that correct and consistent condom use remains very low in sub-Saharan Africa. This section will look at this evidence, and examine the prevalence of correct and consistent condom use in adolescents globally and specifically in South Africa.

A review of unsafe sexual behaviour among South African youth by Eaton et al. (2003) demonstrated that South African teenagers are at risk for HIV infection through unprotected sex. The review established that at least 50% of young people in South Africa are sexually active by age 16, and that 50 to 60% report not using condoms (Eaton et al., 2003). A more recent survey by the HSRC in 2012 showed a decline in condom use in all age groups.

Other studies looking at condom use examined gender differences. A South African survey among youth in 2002 showed that only 29% of sexually active women surveyed used condoms consistently with the most recent partner (Pettifor et al., 2004). Another cross-sectional study

looking at condom use and masculinity by Shai et al. (2012), found that 48% of men aged 15–26 in rural areas of the Eastern Cape had never used condoms.

These findings demonstrate that condom use is a particularly problematic issue among South African adolescents. Shai's study alluded to the fact that the poor condom use among African youth may be attributed to the conservative gender norms of African societies. Encouraging condom use is often seen as encouraging adolescents to engage in sexual activity (World Bank, 1992). As well as determining other factors associated with poor condom use, it is therefore critical that prevention programmes take cognisance of the prevailing beliefs and cultural norms of the different South African communities that contribute to inconsistent condom among youths.

Multiple partners

Having multiple partners is reported to be one of the main factors behind that rapid spread of the HIV epidemic and this is particularly problematic in a region with high HIV prevalence such as southern Africa. Mathematical modelling based on transmission per partnership has demonstrated that in southern Africa, the rate of transmission where multiple partnerships occurs is much faster than would be predicted in the absence of multiple partners (Watts and May 1992, in Mah and Halperin, 2010).

In South Africa, a study conducted in an urban area among black youths aged 16 to 20 years, 40% of young women and 60% of young men had had more than one sexual partner in the preceding six months. In the same study, level of condom use was shown to be low (Wood et al., 1997).

Even more concerning are the results of research conducted by Kalichman (2000) in Botswana showed concerning evidence that multiple partners are associated with other risky behaviours. For example, those with multiple partners used condoms less than those with one partner; there was evidence of greater alcohol use; and those with multiple partners were more likely not to disclose their status to partners compared to those who did not have multiple partners.

Given the low and inconsistent condom use highlighted above, the issue of multiple sexual partners therefore becomes important in the context of understanding sexual risk behaviour and the design of prevention studies for young people.

6.0 PREDICTORS OF SEXUAL RISK BEHAVIOUR

Our study hypothesised that age, being male, being a school dropout, residing in informal communities, drug and substance use, having sex with someone known to be HIV positive and adolescents not knowing their sexual partners' HIV status, would be predictors of sexual risk behaviours. The following section will examine what current literature has shown regarding these predictors.

In a survey conducted by Amoateng et al. (2014), in the North West Province of South Africa among grade 9 and 11 students looking at individual and contextual factors that affects sexual risk behaviour, results showed that gender, grade, school attachment, the use of alcohol and substance like tobacco and marijuana to be predictors of sexual risk behaviours. A longitudinal study among 2 063 high-school students in Cape Town, Mathews et al. (2004), found that there was a relationship between socioeconomic status and intention to have an early sexual debut with youth from lower socioeconomic backgrounds initiating sex as early as 15 years of age or younger. The same study also showed gender to be a significant predictor, with more males initiating sex earlier than females. However, contrary to Mathews findings, Jaspán (2011), points out that there are gender imbalances in rates of infection, with higher rates in females, and that some of this can be attributed to low self-efficacy and non-consensual sex in women.

Studies have shown current school attendance to be a protective factor against risky behaviour, specifically when it comes to age of sexual debut (Karin et al., 2003 and Magnan et al., 2002). In a study investigating the factors associated with increased risk among South African youth, Hargreaves et al. (2002) found that attending school was associated with a lower risk of HIV infection. In another study examining protective factors among young South African females, Petiffor et al. (2008) found that females who completed secondary-school education were less

likely to become HIV infected compared to those who did not. Lastly, a study by MacGrath et al. (2009) on South African rural youth, showed that school attendance was significantly associated with later age of sexual debut and that rural residence, as opposed to urban, and alcohol use were all associated with early sexual initiation.

Another factor that goes hand in hand with education is HIV knowledge. HIV knowledge in general is said to play a role in the risk of acquiring HIV faced by young people. What is worrying is that despite education interventions that have been implemented over the years, levels of HIV knowledge are still very low among South African adolescents. Results of the South African National HIV Prevalence, Incidence, Behaviour and Communication Survey, 2008, conducted by the HSRC showed that among South African adolescents, 18.7% do not accept the fact that HIV can be transmitted through unprotected sex; 18.1% disagree that HIV can be prevented by using condoms (or are unsure); and, lastly, 32.8% do not accept that HIV can be reduced by having fewer sexual partners.

Other studies looking at predictors of sexual risk behaviour have shown that alcohol use positively predicts multiple sexual partners in 16 to 21-year-olds (Wells et al., 2004 in Dogan et al., 2010). Pharmacological evidence shows that, alcohol affects cognition and behaviour, and that it has been hypothesised that alcohol reduces inhibitions thus leading to behaviours such as sexually risky behaviour (Dogan et al., 2010). Theoretical and empirical evidence also points to the same fact. A study by Tapert et al. (2001) showed that young people who had been treated for substance abuse were likely to engage in high-risk sexual behaviour such as reporting having multiple partners and less consistent condom use. Females in this study reported no stable relationships as well as high pregnancy rates. They also reported that risky sexual behaviour continued beyond adolescence into adult for the young people who had a history of substance abuse.

Knowing one's sexual partner's HIV status is key to HIV prevention and yet there is a general concern regarding disclosure of HIV status among sexual partners. A study among adolescent

females in Nairobi looking at disclosure among partnerships showed that knowing one's partner had a protective effect. The study found that females who did not know their sexual partners' status were 14 times more likely to become HIV-positive than those who did not (Rositch et al., 2012).

Disclosure generally remains a concern even among adults due to issues relating to stigma. It may be more of an issue in adolescence, as sex may often be unplanned with no discussions about each other status prior to the act.

It is worth acknowledging that, a limitation of many of the studies reviewed was that they were based on self-reported data. Results need to be interpreted with caution especially given the sensitivity of the subject of sexual behaviour in this population and particularly this age group. Results may be subject to various biases such as a) social desirability, particularly where interviewer administered b) recall bias which may result in inconsistent and inaccurate reporting and c) measurement bias.

7.0 JUSTIFICATION

In light of the evidence presented above, prevalence of sexual risk behaviours in adolescents remains a concern. Several factors that contribute to these sexual risk behaviours and heightened risk of HIV among young people have been identified. Over the last decade, many resources and efforts have gone into HIV prevention and, in particular, among adolescents. However, as evident from the review of literature above, rates of transmission in this age group remain a concern. This is a clear sign that some of the interventions may not be as effective as intended.

In South Africa, various isolated prevention interventions have been implemented. Most of these have been mass public prevention messaging, often resulting in change only in certain population groups. In addition, a lot of the prevention work in South Africa has been informed by studies such as those discussed above, which are largely based on studies conducted in single communities or geographic locations. This may limit the generalisability of findings

from these studies and may therefore not offer enough basis for the design of behaviour change interventions for wider South African settings. This highlights a gap in terms of evidence to inform prevention strategies that will address the different low socioeconomic settings in South Africa. Further research is therefore needed to provide a better understanding of the contextual influences of South African communities at which the interventions are aimed at. This present research will provide data from five different settings in South Africa with different types of communities, socio-culturally. It is hoped that the contextual insight will provide robust evidence to inform interventions with a greater likelihood of success.

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PART C: MANUSCRIPT

MANUSCRIPT COVER PAGE²

**Predictors of sexual risk behaviour among adolescents from low socioeconomic settings
in South Africa**

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Predictors of sexual risk behaviour among adolescents from low socioeconomic settings in South Africa

INTRODUCTION

Evidence indicates that South Africa's HIV epidemic is driven largely by new adolescent infections. This study aims to determine the prevalence and predictors of sexual risk behaviours among adolescents aged 12-18 from low socioeconomic settings in South Africa with the aim of informing future prevention interventions.

METHODOLOGY

This study is a cross-sectional descriptive study to assess sexual risk behaviour by measuring the following outcome variables: sexual activity under the age of 16, age of sexual debut, condom use and whether the adolescents in the study had multiple partners. Adolescents over the age of 16 were required to be sexually active for inclusion into the study. Questionnaires were interviewer administered to collect information on sexual risk behaviours and predictors.

RESULTS

Total sample size was n=843, of which (60%) were females and (40%) were males. Nine per cent of those under 16 years reported being sexually active; median age of sexual debut was 15 years (range 14–16); 35% reported not always using a condom; and 48% reported having multiple partners. When adjusted for gender, those who reported drug and substance use were less likely to delay sexual debut until 14–16 years compared to those who did not. (OR: 0.15; 95%CI: 0.05–0.50; p=0.002). Females were less likely to report having multiple partners compared to males (OR: 0.31; 95%CI: 0.15–0.61; p=0.001). Adolescents from urban informal areas were less likely to have multiple partners compared to those from urban formal areas (OR: 0.43; 95%CI: 0.22–0.88; p= 0.020), and those who reported drug and substance use

during sex were more at risk compared to those who did not (OR: 3.34; 95%CI: 1.27–9.27; $p=0.015$). Age was a significant predictor for all outcomes: sexual debut age (OR: 2.27; 95%CI 1.71–3.00; $p<0.001$), condom use (OR: 1.37; 95%CI: 1.05–1.78; $p=0.02$) and multiple partners (OR: 1.49; 95% CI: 0.06–2.09; $p=0.022$).

DISCUSSION

Our study showed high prevalence of sexual risk behaviours, with males exhibiting more sexual risk behaviours than females. Prevention messaging must start as early as 12 years of age (before sexual debut) and must include promotion of safer sex and a reduction of sexual risk behaviours such as multiple partners, inconsistent condom use and drug and substance use. When designing prevention interventions, gender specific messaging should be incorporated and local sociocultural contexts taken into consideration.

Keywords: HIV, sexual risk behaviour, adolescents, sexual activity, condom use, age of sexual debut, multiple partners

1.0 BACKGROUND

The HIV epidemic continues to be a public health concern as the number of people living with HIV continues to grow. According to UNICEF, approximately 2.1 million adolescents aged 15–19 years were living with HIV in 2012 and approximately 300 000 new infections occurred in this age group. Two-thirds of the new infections were among females. Sub-Saharan Africa contains almost two-thirds of all young people living with HIV/AIDS. While the 2012 data showed a 35% decline in new infections among children under the age of 15 compared to 2009, reducing the rate of new transmissions remains a priority (UNICEF, 2013).

At an international level, advocates for HIV prevention are calling for combination prevention strategies that must start early and that must be delivered in age appropriate ways. They emphasize the need for governments to know their epidemic in terms of risks and trends in order to frame prevention strategies appropriately (UNICEF, UNAIDS, UNESCO, UNFPA, ILO, WHO and The World Bank 2011).

UNICEF calls for comprehensive prevention strategies in order to avert 2 million new infections in adolescents by 2020 (UNICEF, 2013). Furthermore, in a 2005 regional meeting about adolescents exposed to high risk of HIV, UNICEF called for improved efforts to prevent new infections among young people (UNICEF, 2005). Research commissioned by UNICEF that examines the cost-effectiveness of intervention programmes showed that increasing prevention programmes could more than halve the number of HIV infections by 2015 and, in the process, save billions of dollars globally in treatment costs (Homans, 2008).

In South Africa, the incidence of HIV is being driven largely by new infections in adolescents. Prevalence data from studies conducted in South Africa show that prevalence rates remain a concern (HSRC, 2002; RHRU, 2003). Three South African National Household Surveys conducted by the HSRC since 2005 showed prevalence among youth aged 15–24 years of 10.3% in 2005 to 8.7% in 2008 and 7.3% in 2012. While this data shows a decline in prevalence rates,

these figures remain a concern given the many resources and efforts that have gone into HIV prevention and, in particular, among adolescents over the last decade.

One of the recommendations of the South African National Strategic Plan on HIV, STIs and TB 2012-2016 was to ensure tailored prevention interventions for the youth to facilitate delay of sexual debut as well as sustain protective behaviours. (South African National AIDS Council, 2011). Focusing on prevention in this age group is therefore regarded as one of the most effective approaches in the fight against the epidemic and has become a key priority for the South African Government.

To date, most research informing intervention design has been conducted in the Western world, where cultural and sexual practices are very different from those in Africa. Given the theory that human behaviour is shaped by the social context in which it occurs (Smith, 2008 in Uchudi et al., 2010), it is imperative to conduct similar studies across diverse settings in order to have a contextual understanding of different human behaviours of South African adolescents. This is particularly important for South Africa, where people's attitudes towards sexual conduct, and the meanings and perceptions that characterise contemporary sexual relations are determined by cultural and/or religious values. Where research to inform prevention interventions has been conducted in South Africa, studies have been mainly conducted in single communities or geographic locations. This may have the effect of limiting the generalisability of findings from these studies and hinder the development of definitive behaviour change interventions for wider South African settings.

Another important reason for conducting this kind of research is that, as highlighted by Kirby (2003), the influence of norms is enhanced when adolescents feel connected to the source of the normative information. Emphasis is placed on the importance of clarity of norms espoused by family, friends, communities and institutions within those communities (e.g. schools and churches). This is echoed by one of South Africa's leading researchers in HIV-prevention work, MacPhail (1998), points out that 'the unique social norms and values affecting adolescents in

South Africa require localised research, which, ‘although informed by work in the developed world, cannot be fully explained by it.’

Given that HIV incidence rates in South African adolescents remain a concern, and given the importance of the role played by cultural and contextual issues in terms of shaping behaviours, it is crucial to conduct studies to understand sexual risk behaviour and predictors of these behaviours within South African settings in order to inform the design of effective, locally relevant interventions.

2.0 METHODOLOGY

Hypothesis

This paper firstly seeks to assess the prevalence of sexual risk behaviours in adolescents from low socioeconomic settings in South Africa. The paper then hypothesises that; being male, being a school dropout, residing in informal communities, having used drug and substance, not knowing partner’s status and having intercourse with someone known to be HIV-positive would predict sexual risk behaviour in adolescents.

Objectives

The objectives of this paper are to assess the prevalence of sexual risk behaviour in sexually active adolescents between the ages of 12 and 18 and to investigate the predictors for sexual risk behaviour in this age group. Sexual risk behaviour will be assessed by measuring the following outcome variables: sexual activity under the age of 16, age of sexual debut, condom use and whether the adolescents in the study had multiple partners.

Methods

The study is a cross-sectional sub-study based on secondary data from another study. The parent study was a multicentre longitudinal cohort study with self-selecting intervention and control groups. The parent study was aimed at preparing for adolescent HIV vaccine trials_in South Africa. For this cross-sectional sub-study, data from the screening and enrolment visits was

utilised and this was considered as one time point. Outcome variables measured were sexual activity under the age of 16, age of sexual debut, condom use and whether the adolescents in the study had multiple partners. Predictor variables investigated included; gender schooling, area of residence, drug and substance use, knowing partner's status and having intercourse with someone known to be HIV-positive.

Study setting

Adolescents were recruited from rural, urban formal and urban informal settlements in five different provinces in South Africa. Description of each study site is included in appendix 2

Population and inclusion criteria

For the parent study, the population comprised of adolescents aged 12 to 18 who resided in rural, urban formal and urban informal settlements in five different provinces in South Africa. To be eligible for the parent study, participants had to be between the ages of 12 and 18. In order to ensure that we had sexually active adolescents in the parent protocol and to properly assess sexual risk behaviours, adolescents above the age of 16 were required to be sexually active as a criterion for study entry. Adolescents below this age were not required to be sexually active.

This cross-sectional sub-study investigated sexual risk behaviours only in adolescents who were sexually active. The analysis for the sub-study was therefore all sexually active adolescents from the parent study. This included all adolescents over the age of 16 (n=134) and adolescents under the age of 16 who reported being sexually active (n=65). This means that adolescents under the age of 16 who reported not being sexually active were excluded from the analysis (n=630). Descriptive data included characteristics of all adolescents screened for the sub-study i.e. all adolescents screened for the parent study. Bivariate and multivariate analysis included only sexually active adolescents who had been screened and enrolled into the sub-study.

Study procedures

Participants were required to attend two study visits – the first for screening and informed consent, and the second for enrolment. The two visits were no more than 30 days apart. For the purpose of this paper as a cross-sectional study, the screening and enrolment visits were combined and considered as one time point. Parents or guardians were invited to attend the screening visit to sign informed consent documents. Information regarding the study objectives and procedure was discussed with the parents/guardians and adolescents before signing the informed consent document. At both visits, adolescents were asked to complete questionnaires some of which were not validated for use in South African. While some of the tools were not validated, rigorous pilot testing had been conducted and the tools had been revised based on feedback from the pilot. Questionnaires were administered by trained interviewers fluent in the participants' home languages. Information collected in the questionnaires included demographic measures, sexual risk behaviour and correlates of sexual risk behaviour.

Measurements

Outcome and predictor variables were measured by assessing the information listed in Table 1.⁴

⁴ Tools and instruments for the sub-study were used only in adolescents who were sexually active.

Table1: Predictor and outcome variables

Outcome variables		
Objective	Data required	Questions asked
To assess the prevalence of sexual risk behaviour in all sexually active adolescents	Sexual activity under the age of 16	For adolescents under 16, Have you ever had sexual intercourse? ☐ yes ☐ no
	Age of sexual debut	How old were you when you first had sex?
	Multiple partners	Approximately, how many sexual partners have you had?
	Condom use	When you think of all the times you have had sex, how often did you and/or your partner use a condom? ☐ always ☐ usually ☐ about half the time ☐ rarely ☐ never
Predictor variables		
Objective	Data required	Questions asked
To investigate the predictors of sexual risk behaviours in all sexually active adolescents	Age	Date of birth
	Gender	Sex ☐ male ☐ female
	Area of residence ⁵	Where do you live? ☐ Urban formal ☐ Urban informal ☐ Rural ☐ Other
	Education	Are you currently enrolled in school? ☐ yes ☐ no
	Alcohol and substance use	Have you ever had sex while drunk or under the influence of drugs? ☐ yes ☐ no
	Sex with someone of unknown status	Have you ever had sex with someone whose HIV status you did not? ☐ yes ☐ no
	Sex with someone HIV-positive	Have you ever had sex with someone who you knew to be HIV- positive? ☐ yes ☐ no

⁵ Urban formal: formal housing in Cities, towns, townships, suburbs, etc., are typical urban settlements.

Urban informal: unplanned settlement on land which has not been surveyed or proclaimed as residential, consisting mainly of informal dwellings

Rural: any area that is not classified urban. Rural areas are subdivided into tribal areas and commercial farms (Statistics South Africa 2001)

Data management and data analysis

All data was entered into a password protected Microsoft Access database at the study clinics for each site on desktop computers with log-in and screen saver password.

The Access database was programmed to include range and valid response code checks to reduce invalid entries for any given measure. The Access database was also programmed to include skip patterns to facilitate the speed and accuracy of the data entry process.

While the sample size for the parent protocol was large the analysis was restricted to 199 adolescents who were eligible for the sub-study i.e. those who had reported being sexually active. The maximum expected response rate was therefore 199. The response rate varied between 187 and 199. Given the missing values were less than 5% for each variable, the missing values were dropped from the analysis.

Data were analysed using the statistical programme STATA (Stata Corporation, College Station, Texas, USA). Simple descriptive statistics, including frequency distributions, were used to assist in data cleaning and summarisation. We explored potential factors associated with sexual risk behaviours. For the purposes of this analysis, a binary variable was generated for reporting condom use. 'Always' using condoms was coded as 'always' and those reporting 'usually', 'half the time', 'rarely' and 'never' using condoms were coded as 'never'. For multiple partners, serial monogamy was used to define multiple partnership, two or more lifetime partners was coded as 'yes' and only 1 partner 'no'. The reason why more than one partner was considered as multiple partners was that, in such a high prevalence society having had more than one partner could be considered risk especially in this age group where condom use has been shown to be poor. Age of sexual debut was defined as the age at which the participant had first sexual intercourse. Sexual intercourse included vaginal sex, anal sex, forced sex and consensual sex. Pearson's chi-squared test and Fisher's exact test were used to examine overall bivariate associations between the outcome and predictor variables. Logistic regression was then

conducted for each outcome with single predictor variables. Each of the models was adjusted for gender and age. Throughout the analysis, all statistical tests were 2-sided at $\alpha=0.05$.

3.0 ETHICAL CONSIDERATIONS

This study was approved by the University of Cape Town Human Research Ethics Committee prior to implementation. Informed consent and informed assent were obtained from parents/legal guardians and adolescents, respectively, prior to participation. Sexual risk was carefully monitored and risk-reduction counselling provided. In order to minimise the possible impact of risk compensation, counselling emphasised high levels of personal risk. As it was important that a high-risk population was targeted, it was a prerequisite of participation in the study that adolescents over 16 years were sexually active. This necessitated making parents aware of this information. However, it was simultaneously recognised that disclosing information regarding sexual activity may be problematic for adolescents and/or parents. To counter this, mediation and facilitation of adolescent disclosure were implemented where necessary. The circumstances in which adolescent information would be kept private were spelt out in the consent form and process to enable parents and children to have a good understanding of the privacy norm.

4.0 RESULTS

Descriptive data

Descriptive data to identify characteristics of participants who were in the parent study and screened for the sub-study are shown in Table 2. A total of 843 adolescents⁶ were enrolled, 60% were male and 40% were female. Age distribution was: 43% were aged 12–13; 41% were aged 14–15; and 16% were aged 16–18. Five participants (1%) were not in school. Thirty three per cent resided in formal urban areas, 56% in urban informal areas and 11% in rural settings. Prevalence of sexual risk behaviour for adolescents who reported being sexually active (n=191) was as follows, median age of sexual debut was 15 years (IQR 14–16); 65% reported always using a condom; 5% said they usually used the condom; 10% used condoms half the time; 4%

⁶ The planned sample size of 1 400 was not achieved due to logistical and time constraints.

used condoms rarely; and 17% had never used a condom; 10% reported using drugs and alcohol during sex; 1% reported having had sex with someone known to be HIV-positive; and 58% had had sex with someone whose HIV status they did not know. Of those under the age of 16 (n=695), only 9% reported being sexually active. While median number of sexual partners was only one, 26 % reported having had sex with two or more partners.

Table 3 shows basic demographic information and risk factors of participants who were in the parent study and were screened for the sub-study stratified by gender. The median age of sexual debut was the same in both genders (age 15). The median range for males and females was 14–15 and 14–16 (p=0.005) respectively. Thirty nine per cent of males compared to 16% of females reported having multiple sexual partners (p; 0.001). Seventy-three per cent of males reported having sex with someone whose HIV status they did not know, compared to 47% of the females (p; 0.001).

Table 2: Descriptive statistics for adolescents aged 12-18 years from five settings in South Africa

Variables	N	%
<i>Total sample size</i>	843	
<i>Age (n=838)</i>		
12–13 years old	364	43
14–15 years old	340	41
16–18 years old	134	16
<i>Education (n=838)</i>	Variable	
Out of school	5	1
In school	833	99
<i>Residence (n=834)</i>		
Urban formal	273	33
Urban informal	471	56
Rural	90	11
<i>Sexually active (if age<16 yrs old) (n=695)</i>		
Yes	65	9
No	630	91
<i>Median age of sexual debut (IQR) (if sexually active) (n=191)</i>	15	(14–16)
<i>Multiple partners (if sexually active) (n=185)</i>		
Yes	48	25
No	137	72
<i>Condom use during sex (if sexually active) (n=192)</i>		
Always	124	65
Usually	10	5
Half the time	19	10
Rarely	7	4
Never	32	17
<i>Drug or alcohol use during sex (if sexually active) (n=189)</i>		
Yes	19	10
No	170	90
<i>Sex with HIV-positive individual (n=187)</i>		
Yes	1	1
No	186	99
<i>Sex with someone of unknown HIV status (n=190)</i>		
Yes	111	58
No	79	42

Table 3: Basic demographic information and sexual risk factors stratified by gender for adolescents aged 12-18 years from five settings in South Africa

	Female		Male		Total	P-value
	n	%	N	%	n	
<i>Total (N)</i>	510	60	333	40	843	
Site						
<i>DTHF</i>	109	21	78	23	187	
<i>PHRU</i>	130	26	72	21	202	
<i>KOSH</i>	51	10	32	10	83	
<i>CAPRISA</i>	134	26	67	20	201	
<i>MEDUNSA</i>	86	17	86	26	172	
Age (n=838)						0.270[†]
12–13 years old	232	46	132	40	364	
14–15 years old	198	39	142	43	340	
16–18 years old	78	15	56	17	134	
Education(n=838)						0.390[†]
In school	505	100	328	99	5	
Out of school	2	0	3	1	833	
Residence (n=834)						0.150[†]
Urban formal	152	30	121	37	273	
Urban informal	296	59	175	53	471	
Rural	56	11	34	10	90	
Sexually active (if age<16 yrs old)(n=695)						0.490[†]
Yes	37	9	28	10	65	
No	386	91	244	90	630	
Median age of sexual debut (IQR) (if sexually active) (n=191)						0.005[‡]
Age (years)	15	14–16	15	14–15	15 (14–16)	
Multiple partners (if sexually active) (n=185)						0.001[†]
Yes	17	16	31	39	48	
No	88	84	49	61	137	
Condom use during sex (if sexually active) (n=192)						0.060[†]
Always	74	67	50	61	124	
Usually	5	5	5	6	10	
Half the time	15	14	4	5	19	
Rarely	2	2	5	6	7	
Never	14	13	18	22	32	
Drug or alcohol use during sex (if sexually active) (n=189)						0.640[†]
Yes	10	9	9	11	19	
No	99	91	71	89	170	
Sex with HIV-positive individual (n=187)						1.000[†]
Yes	1	1	0	0	1	
No	104	99	82	100	186	
Sex with someone of unknown HIV status (n=190)						<0.001[†]
Yes	51	47	60	73	111	
No	57	53	22	27	79	

[†]Chi-squared test; [‡]Fisher's exact test; [‡]Wilcoxon rank-sum test

Bivariate analysis

Tables 4 and 5 show the results of the bivariate analysis for adolescents included in the sub-study i.e. only adolescents who were sexually active. Among those who were under the age of 16, 2% of the age group 12–13 and 17% of those in the age group 14–15 reported being sexually active ($p=<0.001$). Of the adolescents who had their sexual debut between the ages of 12 and 13 years; 67% were from urban formal areas; 25% were from urban informal areas; and 8% were from rural areas and for those who had their sexual debut between the ages of 14 to 16 years the

percentages were 30%, 61% and 9% respectively ($p=0.030$). Of those who reported having multiple sexual partners, 35% were female and 65% were male ($p=0.001$). Forty-nine per cent were from urban formal areas; 45% from urban informal; and 6% from rural areas. Twenty per cent reported using drugs and alcohol during sex ($p=0.020$). When we examined sexual risk behaviours by site, the Caprisa site had the least Usage of condoms ($p=0.027$). There were no other statistically significant differences in sexual risk behaviour between the five sites.

Table 4: Bivariate analysis sexual activity < 16 years age and age of sexual debut (12–18 years) for adolescents aged 12–18 years from five settings in South Africa

	Sexually active (<16 year olds)				Total	p-value
	Yes n	%	No n	%		
<i>Total (N)</i>	65	9	630	91	695	
Age						<0.001[†]
12–13 years old	7	2	350	98	357	
14–15 years old	58	17	280	83	338	
16–18 years old						
Gender						0.490[†]
Female	37	9	386	91	423	
Male	28	10	244	90	272	
Education						0.820[†]
In school	65	9	627	91	692	
Out of school	0	0	2	100	1	
Residence						0.350[†]
Urban formal	26	12	200	88	226	
Urban informal	34	9	355	91	389	
Rural	5	7	71	93	76	
Drug or alcohol use during sex						NA
Yes	4	6	NA	NA	NA	
No	60	94	NA	NA	NA	
Sex with HIV-positive individual						NA
Yes	0	0	NA	NA	NA	
No	62	100	NA	NA	NA	
Sex with partner of unknown status						NA
Yes	37	59	NA	NA	NA	
No	26	41	NA	NA	NA	
	Age of sexual debut (12–18-year-olds)				Total n	p-value
	12–13 yrs old n	%	14–16 yrs old n	%		
<i>Total (N)</i>	12	7	155	93	167	
Age						<0.001[†]
12–13 years old	3	25	0	0	3	
14–15 years old	5	42	46	30	51	
16–18 years old	4	33	109	70	113	
Gender						0.530[†]
Female	6	50	92	59	98	
Male	6	50	63	41	69	
Education						1.000[†]
In school	12	100	152	98	164	
Out of school	0	0	3	2	3	
Residence						0.030[†]
Urban formal	8	67	46	30	54	
Urban informal	3	25	94	61	97	
Rural	1	8	14	9	15	
Drug or alcohol use during sex						0.130[†]
Yes	3	25	15	10	18	
No	9	75	139	90	148	
Sex with HIV-positive individual						1.000[†]
Yes	0	0	1	1	1	
No	11	100	152	99	163	
Sex with partner of unknown status						0.760[†]
Yes	7	64	84	55	91	
No	4	36	70	45	74	

†Chi-squared test; ‡Fisher's exact test

Table 5: Bivariate analysis condom use and multiple partners for adolescents aged 12-18 years from five settings in South Africa

Condom use (12–18-year-olds)						p-value
	Always		Not always		Total	
	n	%	n	%	n	
<i>Total (N)</i>	124	65	68	35	192	
Age						0.090[†]
12–13 years old	2	2	4	6	6	
14–15 years old	34	27	24	36	58	
16–18 years old	88	71	39	58	127	
Gender						0.400[†]
Female	74	60	36	53	110	
Male	50	40	32	47	82	
Education						0.290[†]
In school	123	99	66	97	189	
Out of school	1	1	2	3	3	
Residence						0.900[†]
Urban formal	43	35	21	31	64	
Urban informal	69	56	39	58	108	
Rural	12	10	7	10	19	
Drug or alcohol use during sex						0.250[†]
Yes	10	8	9	13	19	
No	112	92	58	87	170	
Sex with HIV-positive individual						0.350[†]
Yes	0	0	1	2	1	
No	121	100	65	98	187	
Sex with partner of unknown status						0.790[†]
Yes	71	58	40	60	111	
No	52	42	27	40	79	
Multiple partners (12–18-year-olds)						P-value
	Yes		No		Total	
	n	%	n	%	n	
<i>Total (N)</i>	48	26	137	74	185	
Age						0.250[†]
12–13 years old	0	0	5	4	5	
14–15 years old	11	23	43	32	54	
16–18 years old	37	77	88	65	125	
Gender						0.001[†]
Female	17	35	88	64	105	
Male	31	65	49	36	80	
Education						0.170[†]
In school	46	96	136	99	182	
Out of school	2	4	1	1	3	
Residence						0.040[†]
Urban formal	23	49	39	28	62	
Urban informal	21	45	82	60	103	
Rural	3	6	16	12	19	
Drug or alcohol use during sex						0.020[†]
Yes	9	20	9	7	18	
No	37	80	127	93	164	
Sex with HIV-positive individual						NA
Yes	0	0	0	0	0	
No	47	100	134	100	181	
Sex with partner of unknown status						0.170[†]
Yes	31	66	74	54	105	
No	16	34	62	46	78	

†Chi-squared test; ‡Fisher's exact test

Multivariate analysis

Logistic regression modelling was performed using Stata to assess the association between each outcome and predictor variable (see Table 6). Models were fitted with one covariate at a time and analysed the likelihood ratio test for the significance of the coefficient.

In the subsample of 12–16-year-olds, age was the only variable found to be a significant predictor for age of sexual debut, even when adjusted for gender. For every one year increase in age, the odds of becoming sexually active before the age of 16 increased; OR 2.27 ($p < 0.001$; 95%CI: 1.71–3.00; $p < 0.001$). Area of residence, gender, drug and substance use, and whether the participants had had intercourse with a partner of unknown HIV status were not found to be significant.

In the models examining condom use, age was found to be a significant predictor of this outcome. For every one year increase in age, the odds of using condoms for those who were sexually active increased by nearly 1.37 times (95%CI: 1.05–1.78 $p = 0.02$). No other variables were found to be significant predictors of condom use.

Similar to the other outcome variables, age was found to be a significant predictor for multiple partners. With every one-year increase in age, the odds of having multiple partners increased by 49% (OR: 1.49; 95%CI: 0.06–2.09; $p = 0.022$). Gender was also significant, with females being 70% less likely than males to have multiple partners (OR: 0.31; 95%CI 0.15–0.61; $p = 0.001$). The risk of having multiple partners for those who resided in urban informal areas was found to be about 60% less than that of those who resided in urban formal areas (OR: 0.43; 95%CI: 0.22–0.88; $p = 0.020$). The odds of having multiple partners remained approximately the same when adjusted for gender and age. There was no increased risk in those who live in rural areas compared to those who lived in urban formal areas. There was a strong association between drug and substance abuse during intercourse and having multiple partners. The relative risk of having multiple partners among those who reported drug and substance use during sex is 3.43-fold compared to those who did not report using substances (95%CI; 1.27–9.27; $p = 0.015$). The

risk was found not to be significant when adjusted for age and gender. There was no association between having multiple partners and knowing one's partners' HIV status.

Drug and substance use alone was not found to be a significant predictor for age of sexual debut, but when adjusted for age and gender, it was found to be significant. The odds of delaying sexual debut until 14–16 years was decreased in those who reported drug and substance use compared to those who did not report using substances (OR: 0.15; 95%CI: 0.05–0.50; $p=0.002$). None of the other variables were significant predictors of age of sexual debut.

Table 6: Multivariate analysis for adolescents aged 12-18 years from five settings in South Africa

Variable	Crude association			Adjusted for gender and age		
	OR	P value	CI	OR	P value	CI
Sexual activity (12–15-year-olds)						
Age	2.26	0.000	(1.71–3.00)	2.26	0.000	(1.70–3.00)
<u>Gender</u>						
Female	0.80	0.405	(0.48–1.34)	0.84	0.520	(0.49–1.43)
Male(reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Residence</u>						
Urban informal	0.71	0.214	(0.42–1.23)	0.79	0.396	(0.45– 1.37)
Rural	0.52	0.202	(0.19–1.4)	0.59	0.308	(0.21–1.64)
Urban formal (reference)	1.0	1.0	1.0	1.0	1.0	1.0
Age of sexual debut (12–13)						
<u>Gender</u>						
Female	1.60	0.124	(0.88–2.92)	1.82	0.093	(0.91–3.66)
Male (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Residence</u>						
Urban informal	1.63	0.135	(0.86–3.11)	1.64	0.218	(0.75– 3.59)
Rural	2.81	0.094	(0.84–9.44)	2.63	0.185	(0.63–11.03)
Urban formal (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Drug and substance abuse</u>						
Yes	0.43	0.087	(0.16–1.13)	0.15	0.002	(0.05–0.50)
No (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Sex with partner of unknown status</u>						
Yes	0.54	0.057	(0.29–1.02)	0.61	0.207	(0.29–1.31)
No (reference)	1.0	1.0	1.0	1.0	1.0	1.0
Condom use						
Age	1.37	0.02	(1.05–1.78)	1.37	0.02	(1.05–1.78)
<u>Gender</u>						
Female	0.76	0.37	(0.42–1.38)	0.78	0.43	(0.42–1.43)
Male (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Residence</u>						
Urban informal	0.86	0.66	(0.45–1.66)	0.77	0.45	(0.39–1.52)
Rural	0.84	0.74	(0.29–2.44)	0.70	0.53	(0.23–2.12)
Urban formal (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Drug and substance abuse</u>						
Yes	0.58	0.26	(0.22–1.49)	0.49	0.15	(0.18–1.30)
No (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Sex with partner of unknown status</u>						
Yes	0.92	0.79	(0.50–1.69)	1.05	0.89	(0.55–1.98)
No(reference)	1.0	1.0	1.0	1.0	1.0	1.0
Multiple partners						
Age	1.49	0.022	(0.06–2.09)	1.53	0.016	(1.08–2.17)
<u>Gender</u>						
Female	0.31	0.001	(0.15–0.61)	0.28	0.000	(0.14–0.57)
Male (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Residence</u>						
Urban informal	0.43	0.020	(0.22–0.88)	0.46	0.041	(0.22–0.97)
Rural	0.32	0.093	(0.84–1.21)	0.34	0.125	(0.08–1.35)
Urban formal (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Drug and substance abuse during sex</u>						
Yes	3.43	0.015	(1.27–9.27)	2.71	0.063	(0.95–7.74)
No (reference)	1.0	1.0	1.0	1.0	1.0	1.0
<u>Sex with partner of unknown status</u>						
Yes	1.62	0.170	(0.81–3.24)	1.28	0.517	(0.60–2.72)
No (reference)	1.0	1.0	1.0	1.0	1.0	1.0

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⁷ Additional data tables are included in appendix 3

5.0 DISCUSSION

This study presents valuable insights into the prevalence and predictors of sexual risk-taking in adolescents across South Africa. Our findings showed evidence of prevalence of sexual risk behaviours with 48% reporting having multiple partners, 9% of those under 16 years reported being sexually active; and although an improvement from previous studies, 35% reported not always using a condom. Males exhibited more sexual risk behaviours than females. Factors that were found to be associated with the sexual risk behaviours were age, gender, condom use, drug and substance use and area of residence. The association of age with most outcomes however needs to be treated with caution. The spurious association may be due to the fact that some of the variables are “ever” of lifetime experience variables.

The most prevalent risk behaviour was having multiple partners, and this propensity was more prevalent in males than in females. Contrary to our hypothesis, knowing partners’ status at the time of intercourse was not found to be a predictor. Some of our findings echoed findings of work done in similar populations while others revealed contradictory results. These are discussed below.

Sexual Activity under the age of 16

Of the 704 adolescents below the age of 16, 9% of females and 10% of males reported being sexually active. What this means for HIV prevention in adolescents is that healthcare professionals and legal authorities need to take cognisance of the fact that there is a significant number of adolescents becoming sexually active under the lawful age of consent for sex. With the current law, Health Care Professionals have a legal obligation to report to the police sexual activity under the age of 16. This lands the question as to whether the legal framework which is designed to protect children may have the unintended effect of driving risk by not acknowledging that there is underage sex. Prevention strategists and legal authorities must

therefore work together to review and inform policy to facilitate prevention work in this age group.

From the descriptive analysis, we can see that the age of sexual debut is 14-16 with about 13% of the adolescents having first intercourse below the age of 14. While it is important to advocate for adolescents to delay sexual debut, the early sexual activity necessitates the need to engage with adolescents earlier. Engaging with adolescents earlier is particularly important as the pubertal development is said to be occurring earlier than before (Dunger, 2006 in Dorn and Biro, 200 Papadimitriou 2008) and research has shown that early maturing adolescents may actively seek out opportunities to engage in sexual activity (Negriff, 2011). This means that prevention programmes need to be age-specific. They need to target adolescents at a much younger age while their propensity for risk is still low in order to influence behaviour earlier with messaging becoming more aggressive with age.

Age of sexual debut

Our findings showed that for our population, the median age of sexual debut of 15 years (range 14–16) was consistent with the findings of Kelly and Ntlabati (2002). While acknowledging that this was more than 10 years ago, the study was conducted in a similar age group and found mean ages of females and males to be 15 and 16 years, respectively, with males initiating sexual activity earlier than females (13.4 years versus 14.9 years). The median age of sexual debut was slightly lower for males than for females. The early age of sexual debut is of concern in HIV prevention, as sexual debut marks the onset of exposure to infection. This means that a much bigger proportion of the adolescent population are exposing themselves to the risk of acquiring HIV infection at a very early age.

Again this points to the need for prevention early in adolescence. Prevention strategies must therefore incorporate sex education at an even earlier age before adolescents start engaging in sex. Some advocates recommend that sex education should start as early as 12 to 13 (Manzini, 2009). Given this notion, and the fact that the results above showed mean age of sexual debut to

be 15 years, sex before the age of 14 was considered to be 14 years of age for the purposes of this paper.

The bivariate analysis showed significant differences in proportions from the different areas of residence in terms of age of sexual debut, with more adolescents from formal urban areas (67%) having their first intercourse as early sexual debut at age 12–13 years, compared to 25% from urban informal and 8% from rural. Given the findings of Shisana et al. (2005), which found a higher prevalence of HIV in informal settlements compared to formal settlements and that of Ambert et al. (2007), which found that people living in slums and informal settlements were most at risk of infection, we would have expected a higher prevalence of risk behaviours in the informal settlements than we found. This is also contradictory to findings from studies that have shown that adolescents from poor resource settings are more likely to engage in risky behaviours (Ngom et al., 2003; Zulu et al., 2002; Zulu et al., 2007). We speculate that the reason for the contradictory results may be that the proportion of adolescents from informal settlements may have been too small to yield significant results.

Our results also showed that when adjusted for gender, drug and substance use was a significant predictor for early age of sexual debut i.e. before the age of 14. Those who used drugs and substances were slightly more likely to delay sexual intercourse to the age 14 to 16. This phenomenon may be explained by the fact that, perhaps, adolescents who go down the route of experimenting with alcohol and substances do not engage in sexual risk activities. These results should however be treated with caution. They are counterintuitive and contradictory to the results of a systematic review by Baldwin et al., 2013 and research by Pluddemann et al., 2012, which suggest that there is an association between drug use and early sexual debut. Furthermore, the proportion of drug and substance users in our sample may have been insufficient to detect meaningful associations. Further studies are also required to understand the confounding effect of gender and age in order to frame prevention messaging appropriately.

Multiple sexual partners

In communities with a high prevalence of HIV, each contact with a new partner increases the likelihood of becoming HIV-infected. It is therefore critical that predictors for multiple partnerships are understood in order to inform interventions to reduce multiple partners. Forty eight per cent of our population reported having had multiple partners with more males reporting having had multiple sexual partners compared to females. This supports findings from a South African national survey in 2005, which showed that the mean number of lifetime sexual partners for males was significantly higher (7.2) than females (4.7) (Pettifor et al., 2005). Prevention interventions to reduce multiple partnerships need to start with basic education around transmission of HIV and how sexual networks increase risk. Messaging must also emphasise personal risk and promote condom use.

There was a strong association between drug and substance use during intercourse, and having multiple partners, pointing to an increased relative likelihood of having multiple partners among those who reported drug and substance use during sex. This finding is in line with the notion that alcohol may cause people to engage in risky behaviours that they would not normally engage with when not under the influence of alcohol (Kalina et al., 2009). After adjusting for age and gender, drug and substance abuse was no longer a significant predictor of multiple partners. Further longitudinal studies are required in order to understand the confounding effect of age and gender.

We also found an association between area of residence and multiple partners. Adolescents from urban informal areas were 60% less likely to have multiple partners compared to those who resided in urban formal areas. Living in rural areas was not a significant predictor. Again, these findings are not consistent with the findings of Shisana et al. (2005), Zulu et al. (2002) and Zulu et al. (2007). Our findings therefore need to be treated with caution, especially given findings from a study by Beguy et al. (2009) conducted in Nigeria, which showed that adolescents from slums were more likely to give inconsistent information on sexual risk behaviour.

Adolescence is a phase where by nature of it, serial monogamy can be considered a norm with adolescents trying different partners. Prevention messaging should therefore emphasise consistent condom use. Biomedical prevention should also be considered as an intervention to avert risk during this normal developmental phase.

Condom use

Prevalence of condom use was relatively high with 61% of males and 67 % of females reporting always having used condoms, in comparison to previous studies, which reported 50–60% of young people never having used condoms (Eaton et al., 2003). Data from the South African National HIV Prevalence, Incidence, Behaviour and Communication surveys showed condom use at last intercourse in 15-24 year olds to have increased between 2002 and 2008, (Shisana, 2008) but then decreased in 2012 (Shisana, 2012). The increase in condom use might be explained by extensive mass campaigns that have mainly focused on promoting condom use. When we investigated the predictors for condom use, we found very little association with the hypothesised predictors. Age was the only variable found to be a significant predictor, showing that condom use increased with age. The differences between genders for condom use were insignificant. These findings are in contradiction with the findings of Pettifor et al. (2009), which showed that males reported greater condom use compared to females. Another study, by Exavery et al. (2011), conducted in Tanzania, showed that male adolescents were twice as likely to report condom use as females. We also expected drug and substance use, and knowing the partners' status to be significant predictors, as evidenced by current literature (Wells et al., 2004; Doogan et al., 2010; Rositch et al., 2012). We suspect that the lack of significant associations may be due to the fact that sexual risk behaviour may be difficult to accurately measure, particularly in adolescence.

Limitations

The study exhibited certain strengths and limitations. The strength of our study was that the study population was made up of adolescents from diverse communities from low

socioeconomic settings in South African population where HIV prevalence has been shown to be high.

In terms of the study's limitations, firstly, the sample size may not have been large enough, resulting in too small proportions to detect significance in some of the variables. As has been highlighted by many behavioural scientists, self-reported data on sexual risk behaviour is subject to underreporting, particularly with adolescents (Beguy, 2009). We cannot rule out the fact that there may have been underreporting of certain aspects of sexual risk. This could have been as a result of recall bias, whereby adolescents were asked to report on events that occurred too far in the past to be able to accurately recall.

Social desirability is another factor that may have led to underreporting. Some of the participants' communities are closely knit by nature, and participants and the study team may have known each other outside the study. Participants may not have felt totally assured that confidentiality would be maintained. This may also have been compounded by some of the societal beliefs in some of the communities regarding sex before marriage, which is often not seen as acceptable behaviour. Adolescents might therefore have misreported for fear of being judged by the study team. Underreporting may have contributed to the lower than hypothesised associations between outcomes and predictors. On the other hand, because those 16 and older were required to be sexually active to participate, misreporting might not have been an issue as these adolescents would have already disclosed to parents and other adults. There has been a move to utilise hand held computer devices to collect sensitive information, however, research by Jaspan et al., 2007, showed that paper questionnaires were not inferior to the hand held devices. The best method to validate such data would therefore be to include biological measures.

In addition, due to the cross-sectional nature of the study, it is difficult to establish temporality of some of the associations. For example, behavioural theorists argue that, during adolescence, other external factors can cause a syndemic effect of risk behaviours. This means that, for

instance, alcohol and substance use could occur at the same time as sexual debut, but in any order. This makes it difficult to determine whether some of the behaviours are real predictors or whether they are a set of behaviours that happen to coexist at the same time (Jessor, 1987 in Palen et al., 2009). This may suggest that our findings of an association between some of the variables may be spurious.

Lastly, the very specific inclusion and exclusion criteria of our study places limitations on the generalizability of the findings. The results are only generalizable to adolescents between the ages of 12-18 who are sexually active by the age of 16.

6.0 CONCLUSION

Our study has shown that the prevalence of sexual risk behaviour remains at worryingly high levels. We found age, gender, condom use, drug and substance use, area of residence to be significant predictors of these behaviours.

These findings provide insights into the critical areas to be considered when planning prevention interventions. Given the strong association between age and all the outcome variables, combined with the continually decreasing age of sexual debut, efforts to reduce sexual behaviours must start before the age of sexual debut and before patterns of sexual risk behaviour become entrenched in adolescents. Although the age of lawful consent to sex in South Africa is 16 years, our evidence shows that adolescents are sexually active at a significantly earlier age. It is therefore imperative that prevention strategies acknowledge this and engage with adolescents before the age of 16. This requires engaging with communities to manage sociocultural sensitivities as well as engaging with policy makers to negotiate laws regarding underage sexual activity. These interventions may be better received if delivered through the establishment of safe community based adolescent friendly recreational facilities which are likely to be popular with younger age groups.

The gender differences point to the need for ensuring that interventions messaging be gender specific. The differences in sexual risk resulting from areas of residence calls for the need to

further understand the sociocultural contexts of the different South African communities. Whether adolescents were still in school or out of school was explored. However this variable was not examined any further as descriptive statistics showed that only three adolescents were out of school. We recognise the importance of social context in determining the risk facing adolescents and acknowledge that this study did not adequately examine these. We therefore highly recommend further studies to understand the role that social context plays in order to develop locally relevant and culturally sensitive strategies.

Careful planning that takes these predictors into account may contribute to effective interventions. In addition, larger longitudinal studies with biological endpoints and improved methods of validating self-reported data to minimise underreporting or information bias are recommended in order to yield more accurate results that can better inform more effective interventions.

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PART D: APPENDICES

Appendix 1: Summary of studies

<u>Study</u>	<u>Setting</u>	<u>Design</u>	<u>Population</u>	<u>Sample size</u>	<u>Outcome</u>	<u>Comment</u>
<u>Amoateng et al., 2014</u>	<u>North West Province of South Africa</u>	<u>Cross sectional Survey</u>	Grade 9-11 pupils age 12-21	1065	47% of adolescent males reported ever having had sex compared to only 23% of females. The odds of those who had ever smoked cigarettes having ever had sex were more than 3 times higher than those who had never smoked a cigarette and the odds of those who had ever drunk alcohol were 2.64 times higher than those who had never drunk.	Being male, not being attached to a school and smoking cigarettes and using alcohol were found to be predictors of sexual risk behaviour.
Department of Health, 2011	2012 National Antenatal Sentinel HIV & Syphilis Prevalence Survey in South Africa	Prevalence Survey	Females age 15 -19.		Increase in HIV prevalence among young Prevalence was 12.7 percent in 2011 compared to 14% in 2010	HIV prevalence in young people on the increase
<u>Doyle et al., 2012</u>	<u>Sub-Saharan Africa</u>	DHS/AIS data	Adolescents aged 15-19	24 countries	Up to 25% of 15- to 19-year-olds reported sex before age 15 Early sexual debut was more common among the least educated and/or rural females. Males	Early sexual debut, poor condom use and multiple partnerships are risk factors for HIV infection in adolescents.

					reported having multiple sexual partner than females. Males and females from urban areas and females with higher education were more likely to report having multiple partners. Both males and females from urban areas, with higher education were also more likely to report more condom use. Many youths at risk of HIV infection due to multiple partnerships and insufficient condom.	
<u>Eaton, 2003</u>	<u>South African Studies</u>	<u>Systematic review</u>	Studies done between 1990 and 2000 addressing sexual behaviour of youth aged between 14-35		50% sexually active by the age of 16. Between 50% and 60% of sexually active youth report never using condoms.	First sex intercourse occurring before the age of 16 Poor condom use a problem among youth.
<u>Flisher et al., 2003</u>	<u>Cape Town</u>	<u>Cross-sectional survey</u>	grade 8 and 11 students at 39 Cape Town schools	2,740	By the age of 14 years, 23.4% of males and 5.5% of females had had sexual intercourse.	Age of sexual debut as early as 14 years and below with more males having early sexual debut than males
<u>Hargreaves et al., 2002</u>	<u>Rural South Africa</u>	<u>Random population survey</u>	males and females aged 14-25	1919	Those attending school were less likely to have unprotected intercourse and males attending school were less likely to be HIV positive	Attending school associated with less risky behaviours.

					compared to those not attending school.	
<u>HSRC, 2012</u>	<u>National</u>	<u>National Household surveys</u>	National	29 000	Less than 68% of young men aged 15 to 24 used condoms at last sex in comparison to 85% in 2008.	Decline in condom use compared to the 2008 National Household Survey
<u>Kalichman et al., 2000</u>	<u>Gaborone</u>	<u>Cross-sectional survey</u>	HIV positive men and HIV positive women	500	Multiple partners were associated not having disclosed HIV to sex partners and less consistent use of condoms	Multiple partners are associated with other risky behaviours
<u>MacGrath, 2009</u>	<u>Kwa Zulu Natal</u>	<u>Longitudinal data from four rounds (2003–7) of a prospective population-based HIV and sexual behaviour survey</u>	Males and females age 12-25	8753	Factors associated with earlier age of sexual debut were periurban residence (vs rural), use of alcohol and knowing someone with HIV. School attendance had a protective effect.	Area of residence and alcohol use are associated with sexual risk behaviour and school attendance had a protective effect.
<u>Pettifor et al., 2004</u>	<u>Northern Cape</u>	<u>Interviews and Focus discussion groups</u>	Adolescents aged 16 to 20	<u>900</u>	Early sexual debut occurring by the age of 15 as well as a high incidence of multiple partners	Evidence of sexual debut before the age of 16
<u>Pettifor, 2008</u>	<u>South Africa</u>	<u>National Household survey</u>	Females Age 15-24	11904	Females who had not completed high school were more likely to be infected with HIV compared with those that had completed high school (AOR 3.75; 95% CI 1.34–10.46).	Attending school has a protective effect against sexual risky behaviours
<u>Shai et al.,</u>	<u>Rural</u>	<u>Cross-sectional</u>	Men aged 15-	1219	48% of men aged 15–26 in	Poor condom use among males

<u>2012</u>	<u>Eastern Cape</u>	<u>survey</u>	26		rural areas of the Eastern Cape had never used condoms.	
<u>Shisana et al.,</u>	<u>South Africa</u>	<u>Household Survey</u>	18-24	<u>13518</u>	Prevalence rates 6% for males and 12% for females	Prevalence rates among females were double those of males
<u>Stockl et al., 2013</u>	<u>Sub-Saharan Africa</u>	<u>Systematic review</u>	Quantitative studies from sub-Saharan Africa with biologically confirmed HIV infection measures	25 studies	Half of the studies found a significant association between early sexual debut in women and HIV infection	Early sexual debut a major concern. Given these findings understanding factors associated with early of sexual debut in South African Adolescents to reduce the effect of early sexual debut as a risk factor for HIV acquisition.
<u>Tapert, 2001</u>		Prospective study with participants recruited from a longitudinal study of alcohol- and drug-abuse in youth	Females 15-22	103	Youth with a history of substance abuse reported earlier age of onset to sexual activity, more sexual partners, less consistent use of condoms, more sexually transmitted diseases.	Young people who had been treated for substance abuse were likely to engage in high-risk sexual behaviour affect women
<u>Wood et al., 1997</u>					40% of the females and 60% of the males reported having had more than one sexual partner in the previous six months, and condom use was reported to be very low	

Appendix 2: Additional information regarding the study settings

The DTHF site is located in the Nyanga district, Cape Town, which is a predominantly Xhosa community of over 400 000 people in an area of 16 square kilometres. The community is serviced by basic amenities, but a large portion of the community is housed in informal aggregated shacks or basic government-supplied two-room houses. There is a high unemployment rate with poor socioeconomic status.

The PHRU site is situated in Soweto, an urban African township 15 kilometres to the south-west of Johannesburg. The population is reported to be between 2.5–3 million in an area of 63 square kilometres. Fifty-eight per cent of the population live in brick houses, 28% of residents reside in backyard shacks and 14% live in informal settlements. More than 10% of adults in this community have no formal education and a quarter have a maximum of seven years of education.

The KOSH site is situated in the city of Rustenburg, which is located in the Bonjanala Platinum District. Rustenburg is predominantly an urban area within the district, facilitating access to large populations within and beyond Rustenburg. It is home to a large, diverse and growing influx of residents attracted to the area for work in the mining industry.

The MEDUNSA site is situated at the Medunsa Clinical Research Unit, (MeCRU), in Pretoria. The community consists of four large residential areas (townships) that serve as the study catchment area, with an estimated population of 1.2 million. It is made up of both formal and informal settlements.

The CAPRISA site is situated at the eThekweni Clinical Research site is located adjacent to the Prince Cyril Zulu Communicable Disease Centre (CDC) in Durban. It is a designated primary health care clinic for the diagnosis and treatment of STI's and tuberculosis. Annually, about 40 000 cases of STI's are treated at this clinic.

Appendix 3: Supplementary data tables

Table 1: Frequency distribution of age of sexual debut by gender among sexually active adolescents aged 12-18 years from five settings in South Africa

Age of first sexual intercourse	female	male	Total
<=13 years	10 (9.1)	16 (19.8)	26 (13.6)
14 years	23 (20.9)	17 (21)	40 (20.9)
15 years	28 (25.5)	28 (34.6)	56 (29.3)
16 years	41 (37.3)	18 (22.2)	59 (30.9)
17 years	8 (7.3)	2 (2.5)	10 (5.2)
Total	110 (100)	81 (100)	191 (100)
Pr = 0.030 Significant differences between the gender P = 0.030			

Table 2: Frequency distribution of multiple partners among sexually active adolescents aged 12-18 years from five settings in South Africa

Number of sexual partners	female	male	Total
1 Partner	88 (83.8)	49 (61.3)	137 (74.1)
2 Partners	13 (12.4)	9 (11.3)	22 (11.9)
3 Partner	4 (3.8)	11 (13.8)	15 (8.1)
4 or more partners	0 (0)	11 (13.8)	11 (6)
Total	105 (100)	80 (100)	185 (100)
Significant difference between genders p = 0.01			

Table 3: Sexual risk behaviour among sexually active adolescents aged 12-18 years by site

Age of sexual Debut	DT	PHRU	KOSH	Caprisa	Medunsa	Total
12-13	2 (4.1)	7 (14.9)	3 (17.7)	10 (21.3)	4 (12.9)	26 (13.6)
14-15	31 (63.3)	21 (44.7)	9 (52.9)	20 (42.6)	15 (48.4)	96 (50.3)
16-17	16 (32.7)	19 (40.4)	5 (29.4)	17 (36.2)	12 (38.7)	69 (36.1)
Total	49 (100)	47 (100)	17 (100)	47 (100)	31 (100)	191 (100)
No statistical significant association between Age at sexual debut and site Pearson chi2(8) = 8.7842 p = 0.361						
Condom Use						
	DT	PHRU	KOSH	Caprisa	Medunsa	Total
No	3 (6.1)	9 (19.2)	1 (5.9)	14 (29.2)	5 (16.1)	32 (16.7)
Yes	46 (93.9)	38 (80.9)	16 (94.1)	34 (70.8)	26 (83.9)	160 (83.3)
Total	49 (100)	47 (100)	17 (100)	48 (100)	31 (100)	192 (100)
Significant, CAPRISA has the least usage of condoms Pearson chi2(4) = 10.9609 p = 0.027						
Multiple partners						
	DT	PHRU	KOSH	Caprisa	Medunsa	Total
No	32 (65.3)	36 (80)	14 (82.4)	31 (70.5)	24 (80)	137 (74.1)
Yes	17 (34.7)	9 (20)	3 (17.7)	13 (29.6)	6 (20)	48 (26)
Total	49 (100)	45 (100)	17 (100)	44 (100)	30 (100)	185 (100)
Pearson chi2(4) = 4.2377 Pr = 0.375 No statistical significant association between having multiple partners and site						

Mean	Standard Deviation	Median	Q1	Q3	IQR
1.5	1.1	1	1	5	1

Appendix 4: Post hoc power calculations

We performed a post hoc power analysis on one of our outcome variables, multiple partners, to examine the ability of the study sample size to detect statistically significant differences in the observed data.

In many of these instances, the relatively low power demonstrated by this post hoc analysis may lead us to conclude that type II error may explain several of the non-significant findings documented in this analysis. In turn, it is possible that with increased sample size, we may have found these predictors to be significant, and limited statistical power is an important limitation of this thesis as noted in the discussion section.

Multiple partners (12–18-year-olds)							
	Yes		No		Total	P-value	Power
	N	%	N	%	N		%
<i>Total (N)</i>	48	26	137	74	185		
<i>Gender</i>						0.001 [†]	92
Female	17	35	88	64	105		
Male	31	65	49	36	80		
<i>Education</i>						0.170 [‡]	18
In school	46	96	136	99	182		
Out of school	2	4	1	1	3		
<i>Residence</i>						0.040 [‡]	
Urban formal	23	49	39	28	62		
Urban informal	21	45	82	60	103		60
Rural	3	6	16	12	19		27
<i>Drug or alcohol use during sex</i>						0.020 [‡]	57
Yes	9	20	9	7	18		
No	37	80	127	93	164		
<i>Sex with partner of unknown status</i>						0.170 [‡]	23
Yes	31	66	74	54	105		
No	16	34	62	46	78		
†Chi-squared test; ‡Fisher's exact test							

Appendix 5: Ethics approval letter



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E52-24 Old Main Building
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Observatory 7925
Telephone [021] 406 6492 • Facsimile [021] 406 6411
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23 January 2014

HREC/REF: 052/2014

A/Prof L Myer
School of Public Health & Family Medicine
Falmouth Building

Dear A/Prof Myer

Project Title: PREDICTORS OF SEXUAL RISK AMONG ADOLESCENTS IN SOUTH AFRICA; A STUDY TO DETERMINE THE PREVALENCE AND PREDICTORS OF SEXUAL RISK BEHAVIOURS AMONG ADOLESCENTS FROM LOW SOCIOECONOMIC SETTINGS IN SOUTH AFRICA WITH THE AIM OF INFORMING FUTURE INTERVENTIONS TO REDUCE SEXUAL RISK BEHAVIOUR.

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above mentioned study.

Approval is granted for one year until the 30 January 2015.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

We acknowledge that the student Agnes Ronan is also involved in this study.

Please note that the on-going ethical conduct of the study remains the responsibility of the principal investigator

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Hrec/ref:052/2014

Appendix 6: Informed consent form

Parent Information Sheet and Consent Form

Preparing for adolescent HIV vaccine trials in South Africa: A multi-centre study to evaluate acceptability of the HPV vaccine in adolescents

Thank you for your interest in this study

The Desmond Tutu HIV Centre of the University of Cape Town is conducting a research study.

Your child is being invited to take part in it with your permission.

We will require you to read this form or have it read to you. Please take your time in deciding if you wish your child to join this study. Talk to people you trust such as your friends, family, or doctor if it helps you decide. We will test your understanding of the information in this form to make sure we have explained everything clearly. If you decide to let your child join the study, we will ask you to sign this form. You will get a copy to keep.

In research studies, researchers are trying to find answers to a question or questions. In this study, we are seeking to find out the following:

- If parents/guardians and young people will agree to take part in a vaccine study for a disease that is passed on through sex, and if young people will stay in the study until it is finished
- Young people's thoughts and feelings about sexual behaviour, vaccines, circumcision, HIV and taking part in this study

The study is paid for by the European and Developing Countries Clinical Trials Partnership. The researcher in charge of the study at this clinic is Dr Linda-Gail Bekker.

About 200 people will take part in the study at Emavundleni Vaccine Centre, Crossroads. A further 1200 young people will take part from other places around South Africa.

This is an information sheet and statement of consent form. Please read this information sheet carefully and feel free to ask questions about anything you do not understand or want to know

more about. The clinic staff will talk with you about the information in this sheet. We also encourage you to ask questions about this study at any time in the future.

You may want to talk to others (such as family, friends or your doctor) before you decide whether you want your child to join the study.

If you decide that you are happy for your child to join the study, we will ask you to sign the statement of consent at the end of this information sheet. Signing the statement means that you have read the form (or had it explained to you), understand it and that you are giving permission for your child to join the study. You will get a copy to keep. Your child will not be able to take part if you do not sign the statement of consent. Your child can decide not to take part even if you give them consent to do so.

What is HPV?

The human papilloma viruses (HPVs) are a group of more than 100 different types of virus. They are given numbers to help us label them.

HPVs can be passed on through close contact, including sex. Some of the HPV viruses can cause genital warts (warts/growths in the genital area) in men and women - those numbered HPV 6 and HPV 11. These two are sometimes called low risk because they are not linked with cervical cancer.

However, some types of HPV can increase the risk for women of getting cervical cancer (cancer of the mouth of the womb). In particular, virus numbers 16, 18, 30 and 33 are called high risk because just about all cervical cancers are positive for these HP viruses.

What is a vaccine?

When an infection or disease gets into a person, the person's immune system responds to this infection or disease by making antibodies to fight off the infection. We call the immune system the army of the body as it fights off infections, and the antibodies (soldiers and weapons) the immune system makes, helps us fight off disease or illness. Sometimes a disease comes along

that is so strong the body does not have time to make weapons that fight it off before it makes us sick.

Vaccines act by mimicking a disease or infection, and are usually given to a person before they have been exposed to an illness or disease. Vaccines trick the body into making antibodies against a disease even when that disease is not in the body. Then if that disease gets into the body, the body already has made a lot of antibodies (soldiers and weapons) against it and has a better chance of fighting it off.

What is the HPV vaccine?

Vaccines are now available to prevent infection with certain types of HPV (types 16, 18, 6 and 11 mentioned above). As HPV can make cervical cancer more likely, this vaccine will help to stop women from getting this type of cancer.

The vaccine is called Gardasil and it has been registered in South Africa, which means that it has been tested before on people and has been found to be safe and to work well, and so far, we know it protects against HPV types 16, 18, 6 and 11 for at least 48 months. It is now available for people to use.

What does this have to do with an HIV vaccine trial?

When human immunodeficiency virus (HIV) gets into the body it attacks the soldiers that our body makes to fight off disease.

One of the ways in which HIV can be passed on is through sex.

Vaccines that may be able to protect people from getting HIV are still in the developmental stages and it is not known how long it will take to develop an effective vaccine. They may be ready to test on people at some time in the future. When they are, we will want to test them on people your child's age, so that if they work, we can give them to people your child's age.

In the meantime, we want to see what it would be like to get people between the age of 12-17 years to take part in a study that lasts a while and talks about sex. In this way, we can see what might make it difficult to do this, so that if an HIV vaccine is ready to test on young people, we will know how to do that well.

Why is my child being asked to help?

We are asking young people to help with this research if:

- They are between the ages of 12 and 17
- They are sexually active if 16 or 17 years old
- They are willing to be tested for HIV and receive counseling
- They are willing to give assent for taking part in the study
- They have not received any HPV immunisations before
- They are not pregnant or breastfeeding at the start of the study
- You are willing to give consent for your child's participation in the study

Does my child have to take part in this research?

No, you can decide for your child not to be in the study.

You can make the decision about your child being in the study, by using this information and talking to our research staff.

How does my child join the study?

After you have read this information sheet, clinic staff will answer any questions you and your child may have about the study. When you are both satisfied that all your questions have been answered and if you decide to let your child join the study, you will then be asked to sign the statement of consent at the end of this information sheet, and your child will sign a statement of assent for them to take part.

You will then be asked to complete a short questionnaire to see how much of the informed consent information you understood. We will explain to you anything that you do not

understand. However if clinic staff feel that you or your child are getting too many or important questions wrong your child may be unable to go ahead with the study. This is for your benefit - to ensure that those who assent to participate really understand what they are agreeing to.

If your child does decide to assent with your permission, they will be agreeing to allow the researchers to link the information from the questionnaires that they completed at the VDG, with their personal details, through their date of birth. This information will still remain private.

After signing the assent form, your child will be asked to take part in screening procedures.

It is important that you know the following:

- You and/or your child can refuse to participate in the study
- Your child can refuse to answer any questions he/she is uncomfortable with
- Your child has a right to withdraw his/her participation in the study any time.

Screening procedures will involve the following for your child:

- A physical exam, to check his/her health
- Your child will be asked questions about his/her health
- He/she will also be asked questions about his/her HIV risk
- We will ask him/her to fill in questionnaires about his/her attitudes towards HPV, the HPV vaccine, HIV and HIV vaccine trials
- We will take blood for an HIV test
- We will also take blood to test your child for syphilis
- If your child is female we will perform a pregnancy test

Clinic staff will talk to your child and explain more about these tests before they are performed.

We are going to test all participants for syphilis because it is a sexually transmitted disease that can lead to serious health problems and increase a person's risk for getting HIV, if it is not treated. It can however be treated with antibiotics. If your child's blood tests show that he/she has syphilis, we will refer them for treatment. If your child is 14 or older they can consent to this

treatment on their own, but if they are 12 or 13, your or another care-giver will have to consent in order for them to receive treatment. We are going to test all females for pregnancy because the HPV vaccine is not recommended for people who are pregnant or plan to be pregnant during the vaccination period. If your child is sexually active, she will be asked to use effective birth control throughout the study which we will provide. Your child can receive information about contraception and access to contraceptives without your consent, and we will try to help them practice safer sex.

The screening results may show that your child can't join the study. The clinic staff will explain these results to your child and refer them for appropriate care if needed.

If the screening results show that your child can join the study, your child will be asked to visit the clinic at least 4 times for enrolment at month 0, then for follow up at month 2 month 6 and month 9. The length of visits will vary from an hour to three hours depending on how many tests we do and how many questions we ask them at the particular test.

Before your child has joined the study, you and your child will need to decide whether he/she would like to get vaccinated for HPV. YOUR CHILD DOES NOT HAVE TO GET VACCINATED FOR HPV TO JOIN THE STUDY. If your child is 14 or older you have consented for them to receive the vaccine, and they decide they should receive this vaccine, they can receive this vaccine in your absence. If they are 12 or 13, you will be reminded that you have provided consent for them to receive the vaccine in your absence. If you decide that your child should not get the vaccine, your child can still take part in the study. If you decide you do not want your child to get vaccinated, we will ask you to fill out a questionnaire about your reasons for not wanting your child to get the vaccine. Your child will continue to be part of the study but not be vaccinated. Your child will have the same number and type of visits as those young people who did decide to get vaccinated. Your child will still have access to contraception if they want it. If they decide they do not want to get vaccinated for HPV during the study and then change their mind, they can get vaccinated after the study.

Even if you decide you want your child to get vaccinated, your child will not be able to get vaccinated if:

- He/she has any serious illness requiring treatment with systemic medications, apart from treatment for asthma
- He/she has a medical condition that may cause problems with injections, such as a bleeding disorder
- He/she has had previous allergic reaction to vaccines or to parts of vaccines (yeast, thimerosal or aluminum)
- He/she is on treatment that affects the immune system.
- If pregnant or breastfeeding (for girls)
- He/she has previously been vaccinated for HPV
- Your child decides they do not want to be vaccinated

At enrolment the following will take place:

- He/she will receive pre-test counseling for an HIV test.
- An HIV test will be performed using a drop of blood from his/her finger.
- He/she will be given HIV test results and post-test counseling on the same day.
- He/she will be asked questions about their sexual behaviour and HIV, their attitudes towards consent and confidentiality for adolescents during research studies and how they feel about themselves
- A urine pregnancy test will be performed for females– if your child is found to be pregnant she child will not be vaccinated.
- If you and your child decided they want to be vaccinated, your child will be assigned by chance to receive the injection in the left arm or right arm. This is like making a decision by drawing names out of a hat. We will be doing this in order to train staff and give them practice on how to do this properly. This may be important in future vaccine trials where people receive different medication. Whichever arm they are assigned, is the one they will get injected in for all three injections.

- He/she will be vaccinated (unless he/she has opted not to be vaccinated)
- If vaccinated your child will be asked to remain in the clinic for at least 15 minutes after the vaccination so that the study nurse can look for side effects and allergic reactions.
- Your child will be invited to take part in various activities to help them stay in the study

At month 2, month 6 and month 9 visits the following will take place:

We will ask your child questions about whether or not he/she has been sick since that first exam.

He/she will receive pre-test counseling for an HIV test.

An HIV test will be performed using a drop of blood from his/her finger.

HIV test result and post-test counseling will be given on the same day.

Your child will be asked questions about their attitudes toward circumcision, HIV testing, birth control, privacy and independence for young people, some more questions about their sexual behaviour, their communication with you, whether anything good or bad has happened to them because of taking part in the study, and how they feel about studies

If female, urine pregnancy test will also be done – if your child is found to be pregnant she child will not be vaccinated. She can however remain in the study and complete the vaccine schedule after childbirth if she chooses to

If sexually active, females will be asked about their method of birth control.

At month 2 and 6, he/she will be vaccinated (unless opted not to be vaccinated)

If vaccinated he/she will be asked to remain in the clinic for at least 15 minutes after vaccination so that the study nurse can look for side effects and allergic reactions.

Your child will be asked to either contact or come to the clinic if they have any problems in the first seventy two hours (1 to 3 days) after the injection.

Your child will be asked to call the clinic if they are worried about symptoms they are having, or if any symptoms seem severe.

At month 2, if male, we will assess whether your child is circumcised or not. If they are 12 or 13, you will have to consent for this assessment, but if they are 14 or over, they can consent on their own.

If your child chooses to be vaccinated it is very important that they complete the course by receiving all three vaccinations. This is because the vaccine will not work properly to protect you against certain types of HPV unless you have received all three vaccinations.

At any time during the study, if your child reveals that they may have been at recent risk of exposure to HIV, they will be offered treatment that will help to prevent them from contracting HIV. This treatment is only useful if it is given very soon after risk of exposure to HIV. It is called post-exposure prophylaxis (PEP). If your child is over 14 they can consent to get PEP on their own, but if they are 12 or 13 you will have to give consent.

At the visit at month 9, some participants may be asked to take part in an interview with one of the researchers. This will be about their ideas about risk behaviour and sexual risk behaviour generally. The researcher will also ask them about their own behaviour.

If your child is asked to take part in this interview, it will be up to them to decide whether they want to take part. They can make the decision at that time.

When signing this consent form you will also give us permission to use the information your child provided to us during the VDG session.

What if my child decides to quit the study early?

If your child decides to leave the study before he/she has received all three injections or at any other time before the study is over, we will ask him/her to come back to the study clinic for an HIV test and will ask questions about his/her health since the last visit. We will also ask him/her

to fill in a short questionnaire about his/her reasons for leaving the study and whether anything good or bad has happened to him/her because of being in the study.

What are the risks of being in the study?

Although the HPV vaccine has been tested in young people your child's age and approved by scientists, some people do report side effects. The most commonly reported side effects included:

- Pain, swelling, itching, and redness at the injection site.
- Fever.
- Nausea.
- Dizziness.
- Vomiting

The blood tests may hurt a little. Your child might feel a little pain, or have some bleeding, or a bruise where the needle enters the skin to draw the blood from their arm.

More serious side effects don't happen very often. They can include allergic reactions such as skin rash, hives, itching, difficulty breathing, hoarseness or wheezing, a fast heartbeat and shock. If your child has had bad reactions to any vaccine in the past, it is important that they tell the study nurse about them. Your child will be asked to call the study doctor or nurse immediately if he/she has any of these more serious side effects. There may be other risks that we don't know about yet.

Vaccines with HPV have very few other risks. It is however possible that those receiving vaccines may increase their sexual risk behaviour because they think that they are protected against sexually transmitted infections. This is not true. The HPV vaccine only protects against certain types of HPV and does not protect against other sexually transmitted infections. However your child will receive risk reduction counseling every time he/she comes to the clinic, to help them with ways of changing any behaviour that might put them at risk for other sexually transmitted infections.

Some participants in other HIV vaccine studies have reported experiencing personal problems because of their participation. Friends and family members, or sexual partners may react by:

becoming angry that your child has joined the study without consulting them

worrying that the test vaccine would be harmful

assuming that your child is infected with HIV

assuming that your child is doing things to put themselves at risk, like using drugs or taking risks with sex, and because of this, they may treat you or your child unfairly

If you or your child have any of these or other bad experiences while taking part in the study, we would like you or them to tell the study nurse about them. We don't want being in the study to make things difficult for you or your child and we would like to try to help you if this happens.

What kind of good things could come from this study?

These vaccines have worked in most children and adults to protect them from certain types of HPV and they are generally recommended for people your child's age.

Taking part in this study may protect your child from becoming infected with HPV, but your child can receive this vaccine without participating in the study if you pay for it. Therefore free vaccination is a benefit from this study.

The counseling that your child gets as part of the study may help him/her avoid getting HIV infection. The tests and exams by a doctor that your child gets while in this study might detect health problems that your child may have already but doesn't yet know about. We will not provide treatment for health problems that are not related to being in the study, but will refer your child to get treatment if needed.

What will my child be told about the study?

If we learn anything during the study that might make your child change his/her mind about staying in the study, we will let you and your child know as soon as possible.

At the end of the study, we will tell you and your child when the study results will be ready and how to learn about them.

Could my child be asked to leave the study before it ends even if he/she does not want to leave?

Your child could be asked to leave the study for the following reasons:

- The study doctor decides that staying in the study would be harmful to your child
- Your child has a health problem and need treatment that would not be allowed on this study;
- Your child cannot keep study appointments.
- Your child has a bad side effect from the study vaccine;
- If the study has to be stopped for any reason.

What happens if my child has to stop the study before it ends?

Depending upon the reason why he/she has to stop taking part in the study before it ends, he/she may or may not receive the rest of the vaccinations.

If your child becomes pregnant during the trial, we will stop study injections. This is because the vaccine has not been tested in enough pregnant females to know for sure whether it is safe to use during pregnancy. We will ask your child to stay in the trial so that we can monitor her safety. If it does not cause problems, we will want to continue to take blood from her to do the laboratory tests we describe in this consent form. If your child leaves the trial or the trial ends before she delivers the baby, we will ask to contact her to know the outcome of the pregnancy. Your daughter will be able to complete the vaccine schedule after childbirth if she wishes to. If your daughter falls pregnant during the study and would like to have a termination, we will refer her for this. Although we will encourage her to tell you this, we will not tell you without her permission.

Can my child get medical treatment or the HPV vaccine if he/she does not want to be in the study?

Your child can get the same vaccines for HPV from his/her doctor. If your child decides not to be in the study or start the study and changes his/her mind and wants to quit, this will not change his/her regular medical care and he/she may join other future studies.

Will being in this study cost my child any money?

Your child will not have to pay for any of the study visits, physical examinations or tests that are done for the study or for the vaccines.

If your child needs any medical care or treatment outside the study, he/she will have to go to the regular clinic or private doctor.

Will my child be paid for taking part in this study?

Your child will not be compensated for each study visit but will receive telephone or airtime vouchers between R50 and R150 per scheduled visit, depending on time and inconvenience. If your child requires transport money, we will give them up to R20 in cash and the rest in vouchers. We will not be able to give your child vouchers or transport money for visits that are not part of the regular visit schedule.

Will my child be entitled to privacy?

There are many different aspects to his study and although we will generally keep information about your involvement in the study private there are some exceptions.

Firstly, your child will be entitled to privacy for what they tell us about their attitudes towards circumcision; their knowledge of and attitudes towards HPV and HIV; how they feel about themselves; their feelings about HIV testing, birth control, and privacy and independence for young people; whether anything good or bad has happened to them because of taking part in the study and how they feel about studies.

Secondly, information that the trial site staff get through medical examinations and tests will be private in most situations. This means that trial site staff will NOT tell you:

If your child is engaged in sexual behaviour even if they are under 16, although they will get help like counseling and support to help them practice safer sex

If your child gets contraceptives or contraceptive information while on the study

The results of tests and treatment that your child has consented to themselves without your help

If your child is 12 or 13 and can't consent to medical treatment of their own (for example for STI treatment, HPV vaccination, PEP, circumcision assessment) they will need you or a caregiver to consent to their treatment and this means that they will not have privacy about this information.

However in certain cases because your child is under the age of 18 and we need to ensure that they are protected from harm we will help them to tell a trusted adult about a difficult decision or hardship that they have had to face. We will also help and support them when they tell others about these difficult situations. This is why we need them to tell a trusted adult (not necessarily you):

If they have a termination of pregnancy, or become pregnant. They will also be referred for counseling and support in this situation.

The results of their HIV test if they are positive and they will be referred for counseling and support in this situation

If they are below the age of legal sex yet they have an STI.

Also, the law places some special obligations on people working with children. This makes sure that if children are in need of care or they are in danger then this must be reported so that these children can be helped. Because of these obligations the things they tell us about their sexual behaviour will be private unless we find that they are in a situation where they are being hurt or

taken advantage of by someone, for example they have been raped by a neighbour. In this case we will tell the appropriate authorities so that they can help them to get out of that situation. We will let them know if we are going to do that.

So, trial staff WILL tell the authorities but NOT you:

If your child tells them that they are being abused or neglected

If your child tells them they have been the victim of a sexual offense, like rape

If your child tells them they are in a sexually exploitative relationship, in other words, even if they have agreed to sex, the person is using them in an unfair way.

In the above cases your child will be provided with appropriate support and the trial site will help your child tell their family so that you can help deal with this situation.

But, trial staff WILL NOT tell the authorities, NOR will they tell you:

If your child informs them that they are abusing substances

If your child is truant from school (not going to school), unless they are under the age of 15, as all children must go to school until the end of the year in which they turn 15. (Please note your child will never be asked to attend the clinic during school hours)

In the above cases, they will be referred for appropriate support and help

Who will know about my child being in this study and about the information you get about him/her during the study?

Your child's research records, including lab tests, will be kept confidential unless the law says some information must be shared.

The information we get from your child, including lab tests, will be stored under a code number, not under your child's name.

Your child's personal information will not be released to you, caregivers, or anyone else without his/her written permission.

If the results of this research are published or presented, only group information will be given, not names of people in the study.

However, a few staff will look at study records and may see your child's name. These are researchers and health experts who are watching the study to see that it is being run correctly and that the people in the study are being kept as safe as possible.

There are some times where we may not be able to protect your child's privacy. If we find that they are in a situation where they are being hurt by someone, we may need to tell people who can help them get out of that situation. We will let them know if we are going to do that.

Organisations that may inspect and/or copy your child's research records for quality assurance and data analysis include groups such as the Research Ethics Committee, Data Safety Monitoring Committee and the sponsors (where appropriate).

What happens if being in the study hurts your child?

If your child is hurt as a result of being in this study, the study clinic will give him/her any treatment needed right away or refer them for more treatment if necessary. The treatment will not cost you or child anything. Our clinic staff will then tell your child where he/she can get more treatment, if needed. No payment will be made to your child either by the research clinic or the agency that is sponsoring this research. Your child will be responsible for any treatment for things not related to the vaccine.

Who can I call for information about this study?

If you or your child have questions about the study or have an injury or problem that you think was caused by the study, you can call Dr Linda-Gail Bekker at 021 650 6966.

Who can my child call for information about his/her rights as someone who is helping with research?

There is a group of doctors and researchers whose job is to help see that research is done carefully and that people in the research are treated fairly and made as safe as possible. If you or your child has any questions about these things, you can call Professor Blockman at 021 406 6492.

STATEMENT OF CONSENT:

Information about this study has been given to you and you have had a chance to ask any questions you have had about the study. We have told you that it is your decision about whether or not you give permission for your child to be in the study. Your child can be in the research only if you give permission, and you can decide for your child not to be in the research, or change your mind about your child's participation without changing their care at this clinic, or changing the way people who work for the clinic treat your child. If, at this time, you voluntarily agree for your child to take part in this study, please sign your name below.

HPV VACCINATION: (Please tick box as appropriate)

I consent for my child to receive the HPV vaccine in my absence. I know that my child can still make the decision not to receive the HPV vaccine

☐

I do not consent for my child to receive the HPV vaccine in my absence. I know that my child cannot receive this vaccine without my consent.

☐

TREATMENT CONSENT: (Agreement with ALL statements is needed for consent)

I consent for my child to receive contraception in my absence

☐

I consent for my child to receive treatment for syphilis in my absence

☐

I consent for my child to receive post-exposure prophylaxis in my absence

☐

SIGNATURES

Volunteer's Name (print)

Parent/ Guardian's Name (print) Parent/ Guardian's Signature Date

Study Staff Member Study Staff Member's Signature Date

Conducting IC Discussion (print)

Witness' Name (print) Witness' Signature Date

NOTE: This form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the parent. A copy should be placed in the participant's medical record, if applicable.

Appendix 7: Adolescent information sheet and assent form

Preparing for adolescent HIV vaccine trials in South Africa: A multi-centre study to evaluate acceptability of the HPV vaccine in adolescents

Thank you for your interest in this study.

The Desmond Tutu HIV Centre of the University of Cape Town is conducting a research study.

You are being invited to take part in it.

We will require you to read this form or have it read to you. Please take your time in deciding if you wish to join this study. Talk to people you trust such as your friends, family, or doctor if it helps you decide. We will test your understanding of the information in this form to make sure we have explained everything clearly. If you decide to join the study, we will ask you to sign this form. You will get a copy to keep.

In research studies, researchers are trying to find answers to a question or questions. In this study, we are seeking to find out the following:

If parents/guardians and young people will agree to take part in a vaccine study for a disease that is passed on through sex, and if young people will stay in the study until it is finished

Young people's thoughts and feelings about sexual behaviour, vaccines, circumcision, HIV, and taking part in this study

The study is being paid for by the European and Developing Countries Clinical Trials Partnership. The researcher in charge of the study at this clinic is Dr Linda-Gail Bekker.

About 200 young people will take part in the study at Emavundleni Vaccine Centre, Crossroads. A further 1200 young people will take part from other places around South Africa.

This is an information sheet and statement of assent form. Please read this information sheet carefully and feel free to ask questions about anything you do not understand or want to know

more about. The clinic staff will talk with you about the information on this sheet. We also encourage you to ask questions about this study at any time in the future.

You may want to talk to others (such as family, friends or your doctor) before you decide whether to join the study.

If you decide to join the study, we will ask you to sign the statement of assent at the back of this information sheet. Signing the statement means that you have read the information sheet (or had it read to you), understand it and agree to join the study. You will get a copy to keep. One of your parents or your guardian will also be asked to sign a statement of consent giving permission for you to take part in the study. You will not be able to take part if your parent or legal guardian does not sign the statement of consent. You can decide not to take part even if your parent or legal guardian gives consent for you to do so.

What is HPV?

The human papilloma viruses (HPVs) are a group of more than 100 different types of virus. They are given numbers to help us name them.

HPVs can be passed on through close contact, including sex. Some of the HPV viruses can cause genital warts (warts/growths in the genital area) in men and women - those numbered HPV 6 and HPV 11. These two are sometimes called low risk HPV viruses because they are not linked with cervical cancer.

However, some types of HPV can increase the risk for women of getting cervical cancer (cancer of the mouth of the womb). In particular, virus numbers 16, 18, 30 and 33 are called high risk because just about all cervical cancers are positive for these HP viruses.

What is a vaccine?

When an infection or disease gets into a person, the person's immune system responds to this infection or disease by making antibodies to fight off the infection. We call the immune system the army of the body as it fights off infections, and the antibodies (soldiers and weapons) the

immune system makes, helps us fight off disease or illness. Sometimes a disease comes along that is so strong the body does not have time to make weapons that fight it off before it makes us sick.

Vaccines act by mimicking a disease or infection, and are usually given to a person before they have been exposed to an illness or disease. Vaccines trick the body into making antibodies against a disease even when that disease is not in the body. Then if that disease gets into the body, the body already has made a lot of antibodies (soldiers and weapons) against it and has a better chance of fighting it off.

What is the HPV vaccine?

Vaccines are now available to prevent infection with certain types of HPV (types 16, 18, 30 and 33 mentioned above). As HPV can make cervical cancer more likely, this vaccine will help to stop women from getting this type of cancer.

The vaccine is called Gardasil and it has been registered in South Africa, which means that it has been tested before on people and has been found to be safe and to work well. It is now available for people to use. The vaccine has been shown to work well in trials, and so far, we know it protects against HPV types 16, 18, 30 and 33 for at least 48 months.

What does this have to do with an HIV vaccine trial?

When human immunodeficiency virus (HIV) gets into the body, it attacks the soldiers that our body makes to fight off disease.

One of the ways in which HIV can be passed on is through sex.

Vaccines that may be able to protect people from getting HIV are still in the developmental stages and it is not known how long it will take to develop an effective vaccine. They may be ready to test on people at some time in the future. When they are, we will want to test them on people your age, so that if they work, we can give them to people your age.

In the meantime, we want to see what it would be like to get people your age to take part in a study that lasts a while and talks about sex. In this way, we can see what might make it difficult to do this, so that if an HIV vaccine is ready to test on people, we will know how to do that well.

Why am I being asked to help?

We are asking young people to help with this research if:

- They are between the ages of 12 and 17.
- They are willing to be tested for HIV and receive counseling
- They are willing to give assent for taking part in the study
- Their parent or guardian is willing to give consent for their participation in the study
- They have not received any HPV immunisations before
- They are not pregnant or breastfeeding at the start of the study

Do I have to be in the research study?

No, you can decide not to be in the study.

You can make the decision about being in the study, by using this information and talking to our research staff.

How do I join the study?

After you have read this information sheet, clinic staff will answer any questions you and your parent/ guardian may have about the study. When you are both satisfied that all your questions have been answered and if you decide to join the study, you will then be asked to sign the statement of assent at the end of this information sheet, and your parent or guardian will sign a statement of consent for you to take part.

You will then be asked to complete a short questionnaire to see how much of the information sheet you understood. We will explain to you anything that you do not understand. However, if clinic staff feel that you are getting too many or important questions wrong you may be unable

to go ahead with the study. This is for your benefit - to ensure that those who assent to participate really understand what they are agreeing to.

If you do decide to assent, you will be agreeing to allow the researchers to link the information from the questionnaires that you completed at the Vaccine Discussion Group, with your personal details, through your date of birth. This information will still remain private.

After signing the assent form, you will be asked to take part in screening procedures.

It is important that you know the following:

- You can refuse to participate in the study
- You can refuse to answer any questions you are uncomfortable with
- You have a right to withdraw your participation in the study at any time

At screening:

- We will give you a physical exam to check your health
- We will ask you questions about your health
- We will ask you questions about your HIV risk
- We will ask you to fill in questionnaires about your attitudes towards HPV, the HPV vaccine, HIV and HIV vaccine trials
- We will take blood for an HIV test
- We will also take blood to test you for syphilis
- If you are female, we will perform a pregnancy test

Clinic staff will talk to you and explain more about these tests before they are performed. We are going to test all participants for syphilis because it is a sexually transmitted disease that can lead to serious health problems and increase a person's risk for getting HIV, if it is not treated. It can however be treated with antibiotics. If your blood tests show that you have syphilis, we will refer you for treatment. If you are 14 or older, you can consent to this treatment on your own, but if you are 12 or 13, your parent, guardian or a care-giver will have to consent for you and

accompany you in order for you to receive treatment. We are going to test all females for pregnancy because the HPV vaccine is not recommended for people who are pregnant or plan to be pregnant during the vaccination period. If you are sexually active, you will be asked to use effective birth control throughout the study, which we will provide. You can receive information about contraception and access to contraceptives without your parent or guardians consent, and we will try to help you to practice safer sex.

The screening results may show that you can't join the study. The clinic staff will explain these results to you and refer you for appropriate care if needed.

If the screening results show that you can join the study, you will be asked to visit the clinic at least 4 more times: for enrolment, for follow-up 2 months later, then 4 months after that, and then 3 months after that. The length of visits will vary from half an hour to two hours depending on how many tests we do and how many questions we ask you at the particular visit.

After you join the study, you need to decide whether you want to get vaccinated for HPV. You will decide this at your next visit (when you enroll in the study). **YOU DO NOT HAVE TO GET VACCINATED FOR HPV IF YOU JOIN THIS STUDY.** If you are 14 or older and your parent has consented for you to receive the vaccine and you decide that you should get the vaccine, you can get this vaccination in your parent's absence. If you are 12 or 13, your parent, guardian or a caregiver will have to provide consent for you to receive the vaccine. and accompany you to visits where you receive the vaccine. If you decide that you should not get the vaccine, you can still take part in the study. If you decide you do not want to get vaccinated, we will ask you to fill out a questionnaire about your reasons for not wanting to get the vaccine. You will continue to be part of the study but not be vaccinated. You will have the same number and type of visits as those young people who did decide to get vaccinated. You will still have access to contraception if you want it. If you decide you do not want to get vaccinated for HPV during the study and then change your mind, you can get vaccinated after the study.

Even if you decide you want to get vaccinated, you will not be able to get vaccinated if:

- You have any serious illness that needs treatment with certain medications, apart from treatment for asthma
- You have a medical condition that may cause problems with injections, such as a bleeding disorder
- You have had a previous allergic reaction to vaccines or to parts of vaccines (yeast, thimerosal or aluminum)
- You are on treatment that affects your immune system
- You are pregnant or breastfeeding
- You have been vaccinated for HPV before

At enrolment the following will take place:

- You will receive pre-test counseling for an HIV test
- An HIV test will be performed using a drop of blood from your finger
- You will receive your HIV test result and post-test counseling on the same day
- You will be asked questions about your sexual behaviour and HIV, your attitudes towards consent and confidentiality for adolescents in research studies, and how you feel about yourself
- If you are a woman, a urine pregnancy test will also be done– if you are found to be pregnant you will not be vaccinated.
- If you decide to get the vaccination, you will be assigned by chance to receive your injection in your left or right arm. This is like making a decision by drawing names out of a hat. We will be doing this in order to train staff and give them practice on how to do this properly. This may be important in future vaccine trials where people receive different medication. Whichever arm you are assigned is the one you will get injected in for all three injections.
- You will be vaccinated (unless you have opted not to be vaccinated)

If you are vaccinated, you will be asked to remain in the clinic for at least 15 minutes after you have been vaccinated so that the study nurse can look for side effects and allergic reactions

- You will be invited to take part in various activities to help you stay in the study

At month 2, month 6 and month 9 visits the following will take place:

- We will ask you questions about whether or not you have been sick since that first exam
- You will receive pre-test counseling for an HIV test
- An HIV test will be performed using a drop of blood from your finger
- You will receive your HIV test result and post-test counseling on the same day
- You will be asked questions about your attitudes towards circumcision, HIV testing, birth control, privacy and independence for young people, some more questions about your sexual behaviour, your communication with your parent/guardian, whether anything good or bad has happened to you because of taking part in the study, and how you feel about studies
- If you are a woman, a urine pregnancy test will also be done – if you are found to be pregnant you will not be vaccinated. You can however remain in the study and complete the vaccine schedule after childbirth if you choose to.
- If sexually active we will ask you about your method of birth control.
- You will be vaccinated (unless you have opted not be vaccinated)
- If vaccinated you will be asked to remain in the clinic for at least 15 minutes after you have been vaccinated so that the study nurse can look for side effects and allergic reactions.
- At month 2, if you are male, we will assess whether you are circumcised or not. If you are 12 or 13, a parent, guardian or caregiver will have to consent for this, but if you are 14 or over you can do it on your own,

If you choose to be vaccinated, it is very important that you complete the course by receiving all three vaccinations. This is because the vaccine will not work properly to protect you against certain types of HPV unless you have received all three vaccinations.

At any time during the study, if you reveal that you may have been at recent risk of exposure to HIV, you will be offered treatment that will help to prevent you from contracting HIV. This treatment is only useful if it is given very soon after risk of exposure to HIV. It is called post-

exposure prophylaxis (PEP). If you are over 14 you can consent to get PEP on your own, but if you are 12 or 13 your parent, guardian or a caregiver will have to give consent.

At the visit at month 9, some participants may be asked to take part in an interview with one of the researchers. This will be about their ideas about risk behaviour and sexual risk behaviour generally. The researcher will also ask them about their own behaviour.

If you are asked to take part in this interview, it will be up to you to decide whether you want to take part. You can make the decision at that time.

What if I decide to quit the study early?

If you decide to leave the study before you have received all three injections or at any other time before the study is over, we will ask you to come back to the study clinic for an HIV test and will ask you questions about your health since your last visit. We will also ask you to fill in a short questionnaire about your reasons for leaving the study and whether anything good or bad has happened to you because of being in the study.

What are the risks of being in the study?

Although the HPV vaccine has been tested in young people your age and approved by scientists, some people do report side effects. The most commonly reported side effects included:

- Pain, swelling, itching, and redness at the injection site
- Fever
- Nausea
- Dizziness
- Vomiting

The blood tests may hurt a little. You might feel a little pain, or have some bleeding, or a bruise where the needle enters your skin to draw the blood from your arm.

More serious side effects don't happen very often. They can include allergic reactions such as skin rash, hives, itching, difficulty breathing, hoarseness or wheezing, a fast heartbeat and

shock. If you have had bad reactions to any vaccine in the past, it is important that you tell the study nurse about them. Call the study doctor or nurse immediately if you have any of these more serious side effects. There may be other risks that we don't know about yet.

Vaccines with HPV have very few other risks. It is however possible that those getting vaccines may increase their sexual risk behaviour because they think that they are protected against sexually transmitted infections. This is not true. The HPV vaccine only protects against certain types of HPV and does not protect against other sexually transmitted infections. However you will receive risk reduction counseling every time you come to the clinic, to help you with ways of changing any behaviour that might put you at risk for other sexually transmitted infections,.

Some participants in other HIV vaccine studies have reported experiencing personal problems because of their participation. Your friends and family members, or sexual partners may react by:

- Becoming angry that you have joined the study without talking to them about it
- Worrying that the test vaccine would be harmful
- Assuming that you are infected with HIV
- Assuming that you are doing things to put yourself at risk, like using drugs or taking risks with sex, and because of this, they may treat you unfairly

If you do have any of these or other bad experiences while taking part in the study, we would like you to tell the study nurse about them. We don't want being in the study to make things difficult for you and we would like to try to help you if this happens.

What kind of good things could come from this study?

These vaccines have worked in most children and adults to protect them from certain types of HPV and they are generally recommended for people your age.

At the moment, you can only receive this vaccine without taking part in the study if you pay for it. Therefore free vaccination is a benefit from this study.

The counseling that you get as part of the study may help you avoid becoming infected with HIV. This study may help in the search for an HIV vaccine and so may help people at risk for HIV infection in the future. The tests and exams by a doctor that you get while in this study might find health problems that you have already but don't yet know about. We will not provide treatment for health problems that are not related to being in the study, but will refer you to get treatment if you need it.

What will I be told about the study?

If we learn anything during the study that might make you change your mind about staying in it, we will let you know as soon as possible.

At the end of the study, we will tell you when the study results will be ready and how to learn about them.

Could I be asked to leave the study before it ends even if I don't want to leave?

You could be asked to leave the study for the following reasons:

- The study doctor decides that staying in the study would be harmful to you
- You have a health problem and need treatment that would not be allowed on this study;
- You cannot keep study appointments when you are supposed to
- If the study has to be stopped for any reason

What happens if I have to stop taking part in the study before it ends?

Depending upon the reasons why you stopped taking part in the study before it ends, you may or may not receive the rest of your vaccinations.

If you become pregnant during the trial, we will stop your study vaccinations. This is because the vaccine has not been tested in enough pregnant females to know for sure whether it is safe to use during pregnancy. We will ask you to stay in the study so that we can monitor your safety. If it does not cause you problems, we will want to continue to take blood from you to do the laboratory tests we described earlier in this information sheet. If you leave the study or the study

ends before you deliver the baby, we will ask to contact you to know the outcome of the pregnancy. You will be able to complete the vaccine schedule after childbirth if you wish to. If you fall pregnant during the study and would like to have a termination, we will refer you for this. We will not tell your parent/guardian this without your permission.

Can I get medical treatment or the HPV vaccine if I don't want to be in the study?

You can get the same vaccines for HPV from your doctor that you would get in the study. If you decide not to be in the study or start the study and change your mind and want to quit, this will not change your regular medical care and you may join other future studies.

Will being in this study cost me any money?

You will not have to pay for any of the study visits, physical examinations or tests that are done for the study or for the vaccines given to you.

If you need any medical care or treatment outside the study, you will have to go to the regular clinic or private doctor.

Will I be paid for taking part in this study?

You will not be paid cash for each study visit but will receive telephone or airtime vouchers between R50 and R150 per scheduled visit, depending on time and inconvenience. If you require transport money, we will give you up to R20 in cash and the rest in vouchers. We will not be able to give you vouchers or transport money for visits that are not part of the regular visit schedule.

Will I be entitled to privacy?

There are many different aspects to this study and although we will generally keep information about your involvement in the study private there are some exceptions.

Firstly, you will be entitled to privacy for what you tell us about your attitudes towards circumcision; your knowledge of and attitudes towards HPV and HIV; how you feel about yourself; your feelings about HIV testing, birth control, and privacy and independence for

young people; whether anything good or bad has happened to you because of taking part in the study and how you feel about studies.

Secondly, information that the trial site staff get through your medical examinations and tests will be private in most situations. This means that trial site staff will NOT tell your parent or guardian:

If you are engaged in sexual behaviour even if you are under 16, although you will get help like counseling and support to help you practice safer sex

If you get contraceptives or contraceptive information while on the study

The results of tests and treatment that you have consented to yourself without the help of an adult

If you are 12 or 13 and can't consent to medical treatment on your own (for example, for STI treatment, HPV vaccination, PEP, circumcision assessment) you will need your parent / guardian or a caregiver to consent to your treatment and this means that you will not have privacy about this information.

However in certain cases because you are under the age of 18 and we need to ensure that you are protected from harm we will help you to tell a trusted adult about a difficult decision or hardship that you have had to face. We will also help and support you when you tell others about these difficult situations. This is why we need you to tell a trusted adult (not necessarily your parent):

If you have a termination of pregnancy, or become pregnant. You will also be referred for counseling and support in this situation

The results of your HIV test if they are positive and you will be referred for counseling and support

If you are below the age of legal sex yet you have an STI.

Also, the law places some special obligations on people working with children. This makes sure that if children are in need of care or they are in danger then this must be reported so that those children can be helped. Because of these obligations the things you tell us about your sexual behaviour will be private unless we find that you are in a situation where you are being hurt or taken advantage of by someone, for example, you have been raped by a neighbour. In this case we may need to tell the appropriate authorities so that they can help you get out of that situation. We will let you know if we are going to do that.

So, trial staff WILL tell the authorities, but NOT your parents:

- If you tell them that you are being abused or neglected
- If you tell them you have been the victim of a sexual offense, like rape
- If you tell them you are in a sexually exploitative relationship, in other words, even if you have agreed to the sex, the person is using you in an unfair way

In all the above cases you will be provided with appropriate support and trial staff will help you tell your family so that they can help you deal with this situation

But, trial staff WILL NOT tell the authorities, NOR will they tell your parents:

- If you inform them that you are abusing substances
- If you are truant from school (not going to school), unless you are under the age of 15, as all children must go to school until the end of the year in which they turn 15. (Please note you will never be asked to attend the clinic during school hours)

In all the above cases, you will be referred for appropriate support and help

Who will know about my being in this study and about the information you get about me during the study?

Your research records, including blood tests, will be kept private unless the law says some information must be shared

The information we get from you, including your blood tests, will be stored under a code number, not under your name

Your personal information will not be given to your parents, caregivers, or anyone else without your written permission

If the results of this research are published or presented, only group information will be given, not names of people in the study.

However, a few staff will look at study records and may see your name. These are researchers and health experts who are watching the study to see that it is being run correctly and that the people in the study are being kept as safe as possible.

There are some times where we may not be able to protect your privacy. If we find that you are in a situation where you are being hurt by someone, we may need to tell people who can help you get out of that situation. We will let you know if we are going to do that.

Organisations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the Research Ethics Committee, Data Safety Monitoring Committee and the sponsors (where appropriate).

What happens if being in the study hurts me?

If you are hurt as a result of being in this study, the study clinic will give you the treatment you need right away or refer you for more treatment if necessary. The treatment will not cost you anything. Your clinic will then tell you where you can get more treatment, if you need it. No payment will be made to you either by the research clinic or the agency that is sponsoring this research. You will be responsible for any treatment you need for things not related to the vaccine.

Who can I call for information about this study?

If you have questions about the study or have an injury or problem that you think was caused by the study, you can call Dr Linda-Gail Bekker at 650 6966.

Who can I call for information about my rights as someone who is helping with research?

There is a group of doctors and researchers whose job is to help see that research is done carefully and that people in the research are treated fairly and made as safe as possible. If you have any questions about these things, you can call Professor Blockman at 021 406 6492.

STATEMENT OF ASSENT:

Information about this study has been given to you and you have had a chance to ask any questions you have had about the study. We have told you that it is your decision about whether or not to be in the study. You can be in the research study only if you want to, and you can decide not to be in the study, or change your mind about being in the study without changing your care at this clinic, or changing the way people who work for the clinic treat you. If, at this time, you voluntarily agree to take part in this study, please sign your name below.

HPV VACCINATION: (Please tick box as appropriate)

I have decided that I would like to receive the HPV vaccine. I know that I will need parental consent in order to receive it.

☐

I have decided that I would not like to receive the HPV vaccine. I know that I can make this decision even if my parent has consented for me to receive it.

☐

SIGNATURES

Volunteer's Name (print)

Volunteer's Signature

Date

Study Staff Member	Study Staff Member's Signature	Date
Conducting IC Discussion (print)		

Witness' Name (print)	Witness' Signature	Date
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NOTE: This form with the original signatures MUST be retained on file by the principal investigator. A copy must be given to the participant. A copy should be placed in the participant's medical record, if applicable.

Appendix 8: Screening questionnaire (adolescents)

Screening (Adolescents) Version 2.0 November 2008	
Date / /	
PID Number / /	
Reminder: You have a right not to answer questions you feel uncomfortable with	
ASSESSMENT OF UNDERSTANDING (CHECKLIST)	
1. This study is testing if the HPV vaccine is safe and effective	☐ True ☐ False ☐ Don't know
2. Adolescents who join the study will be tested regularly for HIV	☐ True ☐ False ☐ Don't know
3. You may not leave the study at any time, even if you want to do so	☐ True ☐ False ☐ Don't know
4. Adolescents who take part in this study will not need permission from their parent/guardian to do so	☐ True ☐ False ☐ Don't know
5. Being in the study means coming to the clinic just once	☐ True ☐ False ☐ Don't know
6. Adolescents who do not want the HPV vaccine can still join the study	☐ True ☐ False ☐ Don't know
7. If a female adolescent falls pregnant during the study, she can continue to receive the HPV vaccine while pregnant	☐ True ☐ False ☐ Don't know
8. Adolescents will be asked about personal matters, like sex, if they take part in the study	☐ True ☐ False ☐ Don't know
9. There is no need to practice safe sex while taking part in this study	☐ True ☐ False ☐ Don't know

10. It is possible that other people will treat adolescents who take part in the study in a bad way	☐ True ☐ False ☐ Don't know
11. A person can become infected with HPV through getting the HPV vaccine	☐ True ☐ False ☐ Don't know
12. If a female adolescent falls pregnant during the study and wants to have a termination, the researchers will tell her parent/guardian without her permission	☐ True ☐ False ☐ Don't know
13. Those who receive the HPV vaccine may experience side-effects from it	☐ True ☐ False ☐ Don't know
ASSESSMENT OF UNDERSTANDING (OPEN-ENDED)	
14. What kind of choice do adolescents have about leaving the study?	
15. How many times will adolescents have to visit the clinic for the study?	
16. What kinds of questions will adolescents be asked during the study?	
17. How might people treat adolescents who take part on the study?	
ASSESSMENT OF UNDERSTANDING (VIGNETTES)	
18. Thabo has agreed to take part in the study and attends two of the study visits. He still has two study visits left. He decides that he wants to leave the study. He cannot leave the study now	☐ True ☐ False ☐ Don't know
19. Thandi is taking part in the study and has received two injections. The day after her second injection she has a headache and feels feverish. It is possible that this is from the HPV vaccine	☐ True ☐ False ☐ Don't know

20. Thabo has agreed to take part in the study. During the study he may be asked questions about how many people he has had sex with and whether or not he has used condoms	☐ True ☐ False ☐ Don't know
21. Thandi is 16 and is taking part in the study. During the study she finds that she is pregnant. She decides to terminate the pregnancy. The researchers will tell Thandi's mother about the pregnancy and the termination	☐ True ☐ False ☐ Don't know
DEMOGRAPHICS	
22. When were you born?	/ / Day Month Year
23. Are you male or female?	☐ Male ☐ Female
24. What language do you speak most at home?	
25. How would you categorise your population group?	☐ Black African ☐ Coloured ☐ Asian ☐ White ☐ Other:
26. With whom do you live?	☐ Both parents ☐ Mother only ☐ Father only ☐ Legal guardian ☐ Other:
27. Where do you live?	☐ Urban formal ☐ Urban informal ☐ Rural formal ☐ Other:
28. Are you currently enrolled in school?	☐ Yes ☐ No
29. What is the highest grade you have completed?	

RECRUITMENT	
30. How did you first hear about the study? (Choose one).	☐ From my mother ☐ From my father ☐ From my legal guardian ☐ From a friend ☐ From a member of the study team ☐ Other (please describe)
31. If you first heard about the study from a member of the study team, where did this member first meet you?	☐ At my school ☐ At my home ☐ Other: ☐ Not applicable
INTENTION TO CONTINUE	
32. Do you plan to participate in the study? (Choose one).	☐ Definitely ☐ Probably ☐ Probably not ☐ Definitely not
33. Why/ why not?	
34. Which of these things make you <u>want</u> to participate in the study? (Choose all that apply.)	☐ I want to receive free and regular HIV tests ☐ I want to help in the fight against sexually transmitted infections ☐ I think the HPV vaccine will help to protect me against HPV infection ☐ I want to be paid for taking part ☐ I want to learn more about sexually transmitted diseases ☐ I think it would help me to avoid high risk behaviour ☐ I want to help my community ☐ I know someone with a sexually transmitted infection ☐ Social reasons (e.g. to meet people) ☐ Other:

39. If I were infected with HPV, it would badly/ seriously affect my relationships with other people	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
HPV VACCINE ATTITUDES	
Please say how much you agree or disagree with the following statements:	
40. The HPV vaccine works to protect against HPV	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
41. If I had the HPV vaccine, I would be worried about its side-effects	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
42. People would think bad things about me if I got vaccinated against HPV	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
43. I am confident that I can attend all 3 appointments to be vaccinated against HPV	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
HIV ATTITUDES	
Please say how much you agree or disagree with the following statements:	
44. I am at risk of getting HIV	☐ Strongly Agree ☐ Agree ☐ Neither agree or disagree ☐ Disagree ☐ Strongly disagree
45. I am worried about being infected with HIV	☐ Strongly Agree ☐ Agree ☐ Neither agree or disagree ☐ Disagree ☐ Strongly disagree
46. HIV is a minor disease	☐ Strongly Agree ☐ Agree ☐ Neither agree or disagree ☐ Disagree ☐ Strongly disagree

47. If I were infected with HIV, it would badly/ seriously affect my relationships with other people	☐ Strongly Agree ☐ Agree ☐ Neither agree or disagree ☐ Disagree ☐ Strongly disagree
HIV VACCINE TRIAL ATTITUDES	
48. The HIV vaccine tested in HIV vaccine trials will work to protect participants against HIV	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
49. If I took part in an HIV vaccine trial, I would be worried about the vaccine's side-effects	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
50. People would think bad things about me if I took part in an HIV vaccine trial	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree
51. I am confident that I could attend all study visits in an HIV vaccine trial	☐ Strongly Agree ☐ Agree ☐ Disagree ☐ Strongly disagree

Appendix 9: Month 2 questionnaire (adolescents)

Month 2 (Adolescents) Version 2.0 November 2008 Date / / PID Number / / Reminder: You have a right not to answer questions you feel uncomfortable with	
SOCIAL IMPACT	
1. Which of the following people know that you are participating in this study? (Choose all that apply.)	☐ Friends ☐ Partner(s) ☐ Family ☐ Teachers ☐ Other: _____ ☐ None
2. In general, how have you felt about telling people that you are participating in the study? (Choose one).	☐ Proud ☐ Ashamed ☐ Indifferent ☐ Other: _____
3. In general, what did your parents, friends, partner(s), family, teachers or others think about you because of your participation in this study? (Choose one).	☐ Thought better of me ☐ Thought worse of me ☐ Perception of me did not change ☐ Don't know
4. Since your last visit, have you experienced any negative comments or reactions from your parents, friends, partner(s), family, teachers or others about your participation in this study?	☐ Yes (please describe event and say who it relates to) _____ _____ _____ ☐ No
5. If so, what was the level of distress this caused you? (Choose one).	☐ Little/ no distress ☐ Some distress ☐ Extreme distress ☐ Life-altering distress ☐ Not applicable

6. Has this been resolved?	☐ Yes ☐ No ☐ Not applicable
7. Since your last visit, have you had any positive comments or reactions from your parents, friends, partner(s), family, teachers or others about your participation in this study?	☐ Yes (please describe event and say who it relates to) ☐ No
8. Since your last visit, overall what have the comments or reactions been from your parents, friends, partner(s), family, teachers or others about your participation in this study? (Choose one).	☐ Positive ☐ Negative ☐ Balanced
9. Since your last visit, have any of your parents, friends, partner(s), family, teachers or others assumed you were HIV-infected or at high risk of HIV infection because of your participation in this study?	☐ Yes (please describe) ☐ No
10. If so, what was the level of distress this caused you? (Choose one).	☐ Little/ no distress ☐ Some distress ☐ Extreme distress ☐ Life-altering distress ☐ Not applicable
11. Has this been resolved?	☐ Yes ☐ No ☐ Not applicable
12. Since your last visit, have any of your parents, friends, partner(s), family, teachers or others thought you were HIV negative because of your participation in this study?	☐ Yes (please describe) ☐ No
13. Since your last visit, have you experienced any problems at school because of your participation in this study?	☐ Yes (please describe) ☐ No

14. If so, what was the level of distress this caused you? (Choose one).	☐ Little/ no distress ☐ Some distress ☐ Extreme distress ☐ Life-altering distress ☐ Not applicable
15. Has this been resolved?	☐ Yes ☐ No ☐ Not applicable
16. Have you formed any new social connections (such as making a new friend or meeting a new partner) through your participation in the study?	☐ Yes ☐ No
17. Has participating in the study led you to feel connected to or supported by other people (e.g. study counselors, doctors, or other participants)?	☐ Yes ☐ No
18. Since your last visit has anyone asked you to reveal the following test results: (Tick all that apply).	☐ HIV ☐ STI ☐ Pregnancy
19. If you have ticked any of the above in question 18, please describe the event and who this relates to	
20. If you have ticked any of the above in question 18, did you reveal your test results?	☐ Yes ☐ No
21. Since your last visit, have you had any other HIV tests other than those required by this study?	☐ Yes ☐ No
22. If so, why? (Choose all that apply.)	☐ Health insurance ☐ Life insurance ☐ Another research study ☐ VCT ☐ Other: _____ ☐ Not applicable

23. Since your last visit, have you had any other problems because of your participation in this study?	☐ Yes (please describe) _____ _____ _____ ☐ No
24. How has taking part in the study affected your quality of life (the way in which you have enjoyed and been able to manage your life)? (Choose one).	☐ Enhanced my quality of life ☐ Worsened my quality of life ☐ Not affected my quality of life
25. How has taking part in an HIV vaccine study impacted the way you feel about yourself? (Choose one).	☐ Feel better about myself ☐ Feel worse about myself ☐ Feelings about myself have not changed

Appendix 10: Ethicolegal memo



SELECTED ETHICAL-LEGAL NORMS IN CHILD AND ADOLESCENT HIV PREVENTION RESEARCH IN SOUTH AFRICA: CONSENT, CONFIDENTIALITY AND MANDATORY REPORTING [revised]

Suggested citation: Strode, A. & Slack, C. (2012). Selected ethical-legal norms in child and adolescent HIV prevention research: Consent, confidentiality and mandatory reporting [revised]. European and Developing Countries Clinical Trials Partnership (EDCTP): 2011.

Comments to Catherine Slack (slackca@ukzn.ac.za) or Ann Strode (strodea@ukzn.ac.za) at the HIV AIDS Vaccines Ethics Group (HAVEG), University of KwaZulu-Natal (UKZN) South Africa
<http://www.saavi.org.za/haveg.htm>

Updated 28 Feb 2012

INTRODUCTION

The HIV AIDS Vaccines Ethics Group (HAVEG) at the University of KwaZulu-Natal (UKZN) was funded through the European and Developing Countries Clinical Trials Partnership (EDCTP) to develop resources on the ethical-legal framework for researchers and research ethics committees (RECs) working with adolescent HIV prevention trials. This memo was originally designed to assist and guide researchers working on the South African Studies on HIV in Adolescents (SASHA) project. The aim of the SASHA study was to build stakeholder capacity for adolescent prevention trials. It has been revised, updated and adapted to assist other protocol developers and protocol reviewers by identifying key ethical-legal issues in adolescent HIV prevention trials and describing the legal obligations relating thereto. Key legal complexities in HIV prevention research with adolescents include:

- Who consents for trial enrolment? Who consents to the health-related interventions in the trial?
- What components of the trial should adolescents enjoy confidentiality for?
- What disclosures are likely to trigger reporting obligations?
- What should researchers do to intervene to assist adolescents when key problems are picked up?

Based on the current ethical-legal framework, this memo has identified nine key norms which should apply to adolescent HIV prevention trials. These are:

1. A parent or legal guardian (LG) should provide consent for adolescents to take part in prevention trials;
2. Adolescents should consent independently to key trial components, even though their parents/ LGs will provide consent to enrolment in the trial;
3. Adolescents should enjoy confidentiality for key trial components;
4. Adolescents' right to confidentiality can be limited and adolescents could be asked to disclose to otherwise confidential information to a trusted adult in certain instances;
5. Parent s/ LGs and adolescent should understand what information will or will not be made available to parents/ LGs;
6. If adolescents are being abused, neglected or maltreated, this should be reported to authorities and adolescents should be assisted;
7. If adolescents are engaged in sexual offences, this should be reported to the authorities and adolescents should be assisted;
8. There is no legal obligation to report other offenses but adolescents should be assisted; and

9. Parents/ LGs and adolescents should consent to confidentiality limits posed by reporting to authorities.

These are each discussed in more detail below:

1: A parent or legal guardian (LG) must provide consent for adolescents to take part in prevention trials

1. The first norm is that a parent or LG must provide consent for trial enrolment.
2. How was this established? Currently, there is no clear legal standard specifying when children can independently consent to research, however, there are ethical norms. The Department of Health's GCP (2006) guidelines¹ provide that children cannot consent on their own to clinical trials and that consent must be obtained from a parent or a LG. The National Health Research Ethics Council guidelines (2004)² allow that adolescents can only consent unassisted to minimal risk research (where research risks are approximate to those of the child's everyday life). Clinical trials are generally held to present a higher standard of risk than this, therefore, consent from a parent or LG must be secured.
3. Parents or LGs must consent to adolescent enrolment only when they understand the implications for their children and themselves. Some of the norms relating to the manner in which the trial will be run (described in more detail below) may be unacceptable to a parent, for example, the protocol may provide that parents will not necessarily be told that their child is pregnant or that their child elected to have the pregnancy terminated with the assistance of researchers. Therefore, in such situations parents or LGs may refuse to enrol their child in the trial. Adolescents themselves must provide assent to participation. Some norms may be also unacceptable to an adolescent, for example, the obligation to disclose HIV status to a trusted adult if they test positive. Therefore, adolescents may also refuse to enrol in the study.
4. In the future, if Section 71 of the National Health Act³ is implemented, parental/legal guardian consent will be a legal requirement for *all* health research (trial and non-trial). This change in the law will have very few repercussions in the clinical trial environment, where stakeholders are generally used to this requirement. However, repercussions will be felt by social scientists. In addition, should s71 be implemented then children will be required to "consent" rather than assent alongside their parent if they have "sufficient understanding".

2: Adolescents should consent independently to key trial components, even though their parents or LGs will provide consent to trial enrolment

1. The second norm is that even where a parent or LG provides consent for enrolment, adolescents should consent independently to certain trial components.
2. How was this norm established? According to various statutes, adolescents can consent independently to a number of health-related interventions, such as:
 - a. **Terminations of Pregnancy** at any age (s 5, Choice of Termination of Pregnancy Act, No. 92 of 1996)⁴. However the Act requires providers to advise adolescents to "consult with their parents, guardian, family members or friends" before the termination (s 5, Choice of Termination of Pregnancy Act)⁴
 - b. **HIV testing** from the age of 12 (s 130, Children's Act, No. 38 of 2010)⁵ and even children below 12 can consent independently to such testing if they have "sufficient capacity"
 - c. **Medical treatment** from the age of 12, including STI and HIV treatment provided the child has "sufficient maturity". In other words the child should be 12 and have the mental capacity

- to understand the benefits, risks, social and other implications of the treatment; and (s 129, Children's Act No. 38 of 2010)⁶
 - d. **Contraceptives** and contraceptive advice, including emergency contraceptives from the age of 12 (s 134, Children's Act, No. 38 of 2010)⁷
 - e. **Circumcision** at the age of 16⁸. If boys are below the age of 16, then consent must be obtained from their parent or legal guardian. The Act also requires that boys below 16 can only be circumcised for 'religious' or 'medical reasons on the recommendation of a medical practitioner' whereas those above 16 may undergo circumcision for any reason. Boys over 16 must receive counselling prior to the circumcision, and they have the right to refuse circumcision. (s12 (8) and s12(9-10) of the Children's Act No. 38 of 2005)
 - f. **Surgical operations** at the age of 12 provided he/she (i) has 'sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation', and (ii) is assisted by a parent or guardian. (See section 129(3) of the Children's Act No. 38 of 2005).
3. Another factor that is relevant to consent by adolescents within HIV prevention trials is the age at which they **can lawfully engage in sex**. This is set at 16 in the Sexual Offences Act (s 15, Criminal Law (Sexual Offences and Related Matters) Amendment Act, No. 32 of 2007). See section 7 for more detail.
 4. Currently in prevention trials this means that:
 - a. Adolescents, who need to be tested for pregnancy regularly as part of a prevention trial, can give their own consent for pregnancy tests from the age of 12 and could receive a TOP at any age with their own consent, provided they have the capacity to consent;
 - b. Adolescents, who need to be tested for HIV regularly as part of the study, can give their own consent for these HIV tests from 12;
 - c. Adolescents, who need to be tested regularly for STIs, can give consent on their own from 12 for STI testing and treatment, if required, provided they meet the capacity requirements (which could vary according to the medical condition or procedure); and
 - d. Adolescents wanting access to male or female condoms or other forms of contraceptives or contraceptive advice could receive these on their own from the age of 12.

3: Adolescents should enjoy confidentiality for key trial components

1. The third norm is that adolescents should enjoy confidentiality for key trial components. How was this norm established?
2. Firstly, adolescents have the right to confidentiality for the range of health-related interventions that they have consented to independently. That is:
 - a. Adolescent TPs of 12 years and older (and not their parents) should receive HIV test results;
 - b. Adolescents of 12 (who have capacity) and older (and not their parents) should get the results of STI tests;
 - c. Adolescent TPs of 12 years and older should enjoy confidentiality for access to contraceptives;
 - d. Adolescent TPs (and not their parents) should get results of pregnancy tests and/ or enjoy confidentiality for TOPs.
3. Secondly, adolescents have a right to privacy if there is an expectation of privacy that society regards as reasonable. Where the law is silent on whether a right to privacy exists, one can use the "legitimate expectation test" to establish if something should be kept private.
 - a. It can be argued that adolescents who are 16 years and older have the right to confidentiality regarding their sexual risk data. That is, older adolescents (and not their parents) should get the results of sexual risk assessments. This is on the grounds that older adolescents would

have an expectation of privacy (which most would hold as reasonable) because adolescents can lawfully consent to sex at 16. For adolescents who are under 16, the above rationale may not hold, however, parents can agree not to be informed on the grounds that safeguards (such as counseling and access to services) will be built in to the trial.

4: Adolescents' right to confidentiality can be limited and adolescents could be asked to disclose otherwise confidential information to a trusted adult in certain instances

1. The fourth norm is that even though adolescents have rights to confidentiality, these rights can be limited.
2. How was this norm established? In law, a child's right to confidentiality regarding their health status can be limited where this is in their "best interests" (s 13(1)(d), Children's Act). In ethics, respect for emerging autonomy can be balanced by the need to minimize harms and promote welfare. In law, South African courts have generally held that the best interests of children require a wide range of factors to be considered in decision-making, including those which promote a child's physical, moral, emotional and spiritual welfare.⁹ This means decision-makers must evaluate, weigh and balance these competing factors. They must also take into account the child's wishes.
3. In prevention trials, adolescents, who acquire conditions or a health status with long-term complications that need on-going support, should be asked to disclose to a trusted adult within a reasonable time-frame, because this is in their best interests. For example, maintaining confidentiality regarding a child's HIV status or their pregnancy may not be in their best interests as these are chronic, long-term conditions that require specialist treatment and emotional support.

5: Parents/ LGs and adolescents should understand what information will or will not be made available to parents/ LGs

1. The fifth norm is that both parties must understand what information will be kept confidential and what will be disclosed to another party.
2. How was this norm established? In law, consent is valid only if it is based on a full appreciation of information that most people would consider very important to know. In ethics, consent is only meaningful if it is based on a full understanding of the personal implications of research participation. In prevention trials, it is possible that the parent/ guardian may refuse enrolment when they understand these matters, or the child may refuse to take part.

6: If adolescents are being abused or neglected, this should be reported to authorities and adolescents should be assisted

1. The sixth norm is that adolescents' right to confidentiality is expressly limited where they are being abused or neglected, or are identified as being in need of care and protection.
2. How was this norm established? In terms of s 110 of the Children's Act (2010)¹⁰ there is a broad range of persons who must report any child that has been sexually abused, deliberately neglected or abused in a manner causing physical injury.
3. The category of persons who must report such abuses includes medical practitioners, nurses, psychologists, social service professionals, social workers and members of staff or volunteer workers at a drop-in centres or child and youth care centres.

4. Reports must be made to designated child protection organisations, the provincial department of social development or police officials. While all research staff are not expressly included in this list, some members of the team will fall into these designated categories and are obliged to report.
5. Even if staff do not fall within a designated category obliging them to report, the Act also states that any person who, on reasonable grounds, believes that a child is in need of care and protection **may** report that belief to the provincial department of social development, a designated child protection organisation or a police official.
6. In addition, researchers should assist children by referring them for various kinds of support. Assistance could involve encouraging adolescents to reach out for all forms of adult support, including their reaching out to their parents, where this seems helpful.
7. Trial sites could partner with professional organisations to assist them to make determinations of abuse or neglect.

7: If adolescents are engaged in sexual offences, this should be reported to the authorities and adolescents should be assisted

1. The seventh norm is that adolescents' right to confidentiality may be expressly limited when they disclose conduct which constitutes a sexual offense.
2. How was this norm established? In ethics, respect for emerging autonomy can be balanced by the need to minimize harms and promote welfare. In law, the Criminal Law, Sexual Offences and Related Matters Amendment Act, No. 32 of 2007¹¹ requires any person who is aware of a sexual offence having been committed against a child to *report this to the South African Police Service (SAPS)*.
3. Sexual offenses include commercial sex work; rape and consensual sex/ sexual activity **between the ages of 12 and 16 ('under-age sex/ activity')**. As set out earlier, children can lawfully engage in sex only at 16, according to the Sexual Offences Act (s 15, Criminal Law [Sexual Offences and Related Matters] Amendment Act, No, 32 of 2007). When children below 16 engage in sex/sexual activity they are engaged in a sexual offence, according to current law, and both parties to the sexual act (which may be an adult or another child) will be committing a sexual offense.
4. This memo recommends that all instances the sexual offenses of rape and commercial sex work should be reported to SAPS. In terms of rape, it is important to note that all sex with persons under the age of 12 is rape in terms of the Sexual Offences Act. Therefore, even if a child participant discloses 'consensual' sex under 12, this will have to be reported as a rape.
5. However, this memo recommends a more nuanced approach to the reporting of consensual underage sex/ sexual activity. The issue of underage sex is very complex because it may take various forms.
 - a. Firstly, under-age sex/ sexual activity can be "consensual" but exploitative. In such cases, an under-16 year-old adolescent may describe agreeing to a sexual relationship or conduct, but the relationship involves a large age differential and one party appears to be taking significant advantage of the other party. For example, a 13 year-old participant may describe that she is having a sexual relationship with a 22 year-old man, who is paying for her siblings to attend school.
 - b. Secondly, under-age sex/ sexual activity can be "consensual" and non-exploitative. In such cases, an under-16 year old adolescent may describe agreeing to the conduct or relationship

and both parties are from the same peer group. For example, a 14 year-old is in a sexual relationship with a 16 year-old.

6. In prevention trials, we recommend that researchers elect to treat the sexual offense of consensual, non-exploitative under-age sex/ activity differently to exploitative sex/activity, and elect not to report these to the police. Such an approach ought to only be adopted with caution as it requires researchers and RECs to agree to not apply one portion of the Sexual Offences Act (2007) and accordingly means that researchers, in failing to comply with the Act, have themselves committed an offence.
7. Nevertheless, reporting consensual underage sex/activity appears to be in direct conflict with the principles articulated in the Children's Act (2005) which expressly allows children under the age of 16 to access services such as contraceptive advice and methods, HIV testing, and medical treatment, therefore, it may be possible to defend such an approach. This nuanced approach can also be defended on ethical grounds that harmful activities (non-consensual or exploitative) are reported, but that non-harmful activities (consensual and non-exploitative) are not reported because this is unlikely to protect children, may erode trust in adult or authority figures and may decrease the veracity of disclosures children make to research staff – impeding the ability to steer them to appropriate services.
8. We argue that this approach is supported to some extent by the text of the Sexual Offences Act (2007) which provides that prosecution of underage sex, where the age difference between the parties is 2 years or less, will only occur with special permission from the National Director of Public Prosecutions, indicating that prosecution of underage sex that is non-exploitative will not take place in the ordinary course of events.
9. This approach requires trial sites to undertake an assessment of exploitation. Site staff should consider the age differential as well as other aspects of the relationship such as where one party assumes an unfair level of benefit relative to another party. There is no easy formula for this assessment.
10. Sites may wish to partner with professional organisations to assist them to make such determinations.
11. If adolescents are aware that certain categories of sexual activity, including 'exploitative' sex, may be reported to authorities, they may elect not to disclose this to site staff.
12. [Note: The constitutionality of sections of the Sexual Offences Act are currently being challenged by a number of NGOs who argue that they infringe children's constitutional rights. See copies of the court papers and background on the application at the Child Law Centre's web site at <http://www.centreforchildlaw.co.za>].

8: There is no legal obligation to report other offenses but adolescents should be assisted

1. The eighth norm is that where adolescents are acting in a way that contravenes other laws, there may be no legal obligation to report this, but there is an ethical responsibility to assist. Again, such assistance could involve encouraging adolescents to reach out for forms of adult support, including their reaching out to their parents where this seems helpful.

2. How was this norm established? The South African Schools Act (1996)¹² requires all children between the ages of 7 – 15 to attend school. The Basic Conditions of Employment Act (1997)¹³ asserts that it is illegal for children under the age of 15 to work, or those between the ages of 15 and 18 to perform unsuitable work (work that places their well-being, education, physical or mental health, or spiritual, moral or social development at risk).
3. Currently, in HIV prevention trials:
 - a. A researcher is not under a legal obligation to report **truancy** from school to any authority. However given that parents are required to ensure that children under 15 attend school and they may be unaware that their child is not attending, researchers may wish to inform parents of under 15 year-olds of truancy, so that parents can act to fulfil their duty. Children should also get assistance, advice and appropriate referrals. Trial attendance should not interfere with the school attendance.
 - b. A researcher is not under a legal obligation to report **child labour or inappropriate work**. There may however be an ethical obligation to act in the best interests of the child by providing assistance, advice and appropriate referrals.
 - c. A researcher is not under a legal obligation to report information regarding a child participant who has **committed, or is committing, crimes** (e.g., abusing substances, committing theft). However, where a child, involved in a criminal offense, is being exploited, this should be reported to the police or other relevant authorities because this amounts to ill-treatment (e.g. where a child is being forced to sell drugs by an adult). However, in the instance of criminal activity, researchers should intervene through advice and appropriate referrals.
 - d. A researcher is not under a legal obligation to take further steps when a research participant informs the researcher of a **third party**, who has been the “victim” of a crime or has “committed” a crime. However, they may be under an ethical duty if a child is in clear and imminent danger, for example from a violent and abusive parent. In such a case they should assist the child research participant to report this information to the local police or social workers for further investigation.

9: Parents/ LGs and adolescents should consent to confidentiality limits posed by reporting to authorities

1. The last norm is that both parties (parent and adolescent) must understand what information will be kept confidential and what will be disclosed to authorities.
2. How was this norm established? In law, consent is valid only if it based on a full appreciation of information most people would consider very important to know. In ethics discourse, consent is only meaningful if it is based on a full understanding of the personal implications of research participation.
3. In prevention trials, it should be explained to parents that the researchers are not necessarily required by law to tell parents if a report is made to authorities. However, each case will be approached on a individual basis with the best interests of the child being the basis for deciding whether parents should be informed by researchers.
4. In all instances, the adolescent will receive assistance, support and appropriate referrals.
5. It is possible that the parent/guardian may refuse enrolment when they understand these matters, or the child may refuse to take part.

CONCLUSION

1. Ethical-legal norms for adolescent HIV prevention trials should be understood by, and acceptable to, key stakeholders such as participating communities. Where high levels of objection to trials are anticipated, it may not be feasible to run such trials. It may be helpful to research the acceptability of such norms among participating communities.
2. It may also be helpful for researchers implementing such norms in prevention trials to monitor “events” such as mandatory reports to authorities and direct disclosures to parents to estimate frequency and impact.
3. In the long run, success of adolescent prevention trials will, in part, involve identifying and partnering with range of adolescent service organisations around sites, to assist researchers to implement their responsibilities.

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- ³ Section 71 of the National Health Act No. 61 of 2003
- ⁴ Section 5 of the Choice on Termination of Pregnancy Act No. 92 of 1996
- ⁵ Section 130 of the Children's Act No. 38 of 2005
- ⁶ Section 129 of the Children's Act No. 38 of 2005
- ⁷ Section 134 of the Children's Act No. 38 of 2005
- ⁸ Section 12(8) and section 12(9-10) of the Children's Act No. 38 of 2005
- ⁹ Section 110 of the Children's Act 38 of 2010
- ¹⁰ Section 15 of the Criminal Law (Sexual Offences and Related Matters) Amendment Act No. 32 of 2007
- ¹¹ South African Schools Act No. 84 of 1996
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Appendix 11: Guidelines for authors

International Perspectives on Sexual and Reproductive Health: formerly *International Family Planning Perspectives*

International Perspectives on Sexual and Reproductive Health is a peer-reviewed research journal serving researchers, policymakers, program administrators and service providers in developing countries. The journal invites submissions based on qualitative or quantitative research on such topics as contraceptive practice and research; fertility levels, trends and determinants; adolescent pregnancy; sexual behavior; HIV and other sexually transmitted diseases; public policies and legal issues affecting family planning and childbearing; program operation, development and evaluation; information, education and communication activities; reproductive, maternal and child health; and abortion.

We receive manuscripts with the understanding that they are not under consideration elsewhere and that the substance of the data or analysis has not been published previously. Submissions undergo a two-tiered review. They are screened initially by the editorial staff for overall quality and interest; about 70% are rejected at this stage, and the author is notified within eight weeks of submission. The surviving submissions undergo double-blind peer review by at least two experts in the field. Authors of articles sent for review can expect to receive critiques of their manuscript four months after submission, with guidance from the editors as to whether to proceed with a revision.

Basic Requirements

We expect manuscripts to be double-spaced, with pages numbered, and prefer submissions to be made electronically. The title page should include the names, titles and affiliations of all authors; we limit the number of authors to eight. (Multicenter clinical studies may have up to 10 authors.)

Use active voice when writing the text. Stick to plain English, and avoid jargon known only to academic or professional subspecialties. In particular, describe the study's methodology clearly and simply, keeping in mind that some readers may not be familiar with specific statistical techniques. Dispense with arcane acronyms as well as brand names; if brand names are important to the research, give them on first mention in the methodology section, then use generic designations.

Subheads to delineate the sections of the paper are welcome, but they must fit within one journal column. First-level heads should be no more than 27 characters, and second-level heads no more than 50 characters. Third-level sub_heads may be used if the text merits; these are run-in clauses, in italics and preceded by bullets.

The maximum number of tables and other graphic elements is eight. Place each table and chart on a separate page at the end of the text. All line graphs and charts should be accompanied by their respective data points so that they can be replicated by the journal's production staff.

Reference lists should indicate that you are familiar with the relevant literature, as well as provide citations for all data and factual observations. Most articles have 10-30 references. References in the initial submission need not be in any particular format; however, if we are interested in the article, the correct referencing style must be incorporated with other requested revisions before it will be accepted for publication.

International Perspectives on Sexual and Reproductive Health follows a reference style based on the citation-sequence system of the Council of Science Editors. References are numbered in the text, and are listed in numerical order at the conclusion of the article. A reference may contain only one citation. When a source is cited more than once, the same reference number is used each time; this is a change in the journals' style, effective at the start of 2007. If there are more than three authors, list the first author and add "et al."

The following examples illustrate the format of the most common types of references. For other types, refer to any recent issue of the journal as a guide.

1. Henshaw SK and Van Vort J, Abortion services in the United States, 1991 and 1992, *Family Planning Perspectives*, 1994, 26(3):100-106 & 112, Table 4.
2. Hatcher RA et al., *Contraceptive Technology*, 16th ed., New York: Irvington Publishers, 1994, p. 209.

Footnotes and references are separate elements and should not be intermingled. Used sparingly, footnotes are appropriate for parenthetical or explanatory information that cannot be smoothly accommodated in the text. To distinguish them from references, use symbols or letters to designate them.

Acknowledgments should include funding information, as well as any employment, appointments or financial arrangements that might be perceived as a conflict of interest. Acknowledgments should not be used to thank anonymous reviewers, study participants or coworkers who provided no special technical or intellectual expertise.

Journal Sections

The journal contains a number of sections to which you may submit your manuscript or to which it may be assigned by the editors. The majority of submissions appear in the "Articles" category. Articles deal with never-before-published data or analyses of a research endeavor, survey, program evaluation or academic exercise. Articles should contain all the standard elements: structured abstract (of no more than 250 words), introduction, methodology, results and discussion. Extensive literature reviews are not needed for our specialized audience. The abstract summarizes key data; therefore, the results should not be summarized again in the discussion. Rather, you should draw conclusions about what the results mean for the field and what specific and practical applications can be made of them. A word count is mandatory; we look unfavorably upon articles of more than 6,000 words (not including references or footnotes).

"Comments," too, are usually data-based, but the data may have been compiled from sources other than original research, and the text is an analytic review of some issue or question. Comments may or may not follow the standard structure of a research article, depending on how the author chooses to tackle the subject, but they usually are shorter than an article and have fewer references. Some comments undergo peer review, but others do not.

Although most "Special Reports" are staff-written, an occasional outside submission may land in this section. Special Reports cover a wide range of issues and, for example, may present an in-depth discussion of policy issues relevant to sexuality education, summarize a global conference on maternal mortality, evaluate the adequacy of postabortion contraceptive services or investigate the status of research on a new contraceptive method. Special Reports stop at 4,500 words, do not have abstracts, forgo tables, usually don't contain the standard elements of an article and often are accepted on the basis of the editors' judgment only.

"Viewpoints" follow no specific guidelines and are as individual as the opinions of the people who write them. They are not subjected to peer review, and acceptance is based solely on whether the editors think the opinion is worth airing and the case is cogently made. Viewpoints should be no more than 3,500 words.

We welcome "Letters to the Editor." They should support or take issue with material published in the journal or present some other observation that can be made in 1,200 words or less. Letters are usually sent to the first author of the original paper for a rejoinder, to be published with the letter.

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