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HIV incidence in young girls in KwaZulu-Natal, South Africa- Public health imperative for their inclusion in HIV biomedical intervention trials

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Abstract

Young women are particularly vulnerable for acquiring HIV yet they are often excluded from clinical trials testing new biomedical intervention. We assessed the HIV incidence and feasibility of enrolling a cohort of young women for potential participation in future clinical trials. Between March 2004 and May 2007, 594 HIV uninfected 14–30 year old women were enrolled into a longitudinal HIV risk reduction study in KwaZulu-Natal, South Africa. The overall HIV prevalence at screening in young girls below the age of 18 years of age was 27.6% compared to 52.0% in the women above 18 years, p<0.001. HIV incidence was 4.7 [95% Confidence interval (CI) 1.5–10.9) and 6.9 (95% CI 4.8–9.6)/100 women years (wy), p=0.42 and pregnancy rates were 23.7 (95% CI 14.9–35.9) and 16.4 (95% CI 12.9–20.6)/100wy, p=0.29, in the women below and above 18 years respectively. Retention was similar in both groups (71.0% versus 71.5%, p=0.90). This study demonstrates that the inclusion of young girls between the ages of 14 and 17 years in longitudinal studies is feasible and their inclusion in clinical trials would maintain scientific integrity and power of the study.

Keywords

young girls; biomedical HIV prevention research; South Africa

Introduction

Worldwide an estimated 33.3 million people are living with HIV and nearly five million of these are young people aged 15–24 years [1]. In Sub-Saharan Africa, a notable and unique feature of the HIV epidemic is the age-sex differences in HIV acquisition with young girls

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All authors declare that they have no competing interests.

Author contributions

QAK and SSAK contributed to the study concept and design. ABMK contributed to the study design, was responsible for the study oversight at the urban site, analysis of data and writing the manuscript. JAF contributed to the study design, was responsible for the study oversight at the rural site. LW performed the statistical analysis of the data. MM and BTM were responsible for site operations, clinical management of participants and quality assurance of the data. All authors critically reviewed the manuscript and have read and approved the final version.

acquiring HIV infection about 5–7 years earlier than men; and having a 3–6 fold higher rate of HIV infection compared to young boys in the same age group [2]. South Africa has the largest number of people living with HIV/AIDS and more than 60% of all infected adults acquire their infection before age 25 years. The majority of new infections are heterosexually transmitted and young women between the ages of 20–24 years have the highest HIV prevalence and incidence rates [3–4]. Although the national HIV prevalence estimates in prenatal women have stabilised, the continuing high prevalence in younger pregnant girls is of concern. In young pregnant 10 to 14 year old girls the HIV prevalence has increased from 7.9% [95% confidence interval (CI) 3.7–14.6] in 2009 to 9.1% (95% CI 5.1–15.8) in 2010, whilst the prevalence in the 15–19 year old girls increased from 13.7% (95% CI 12.9–14.7) in 2009 to 14.0% (95% CI 13.1–14.9) in 2010 [5]. Data from the national population-based survey conducted in 2008 estimated HIV prevalence in young people aged 15–24 years to be 15.3% (95% CI 11.8–19.7) in the province of KwaZulu-Natal compared to the national estimate of 8.7% (95% CI 7.2–10.4). The prevalence in young girls aged 15–19 years was 6.7% compared to 2.5% in boys of the same age group [6]. These data repeatedly underscore the importance of heterosexual transmission driving the epidemic in this region influenced by several key epidemiological factors such as age, gender, mobility, sexual partner profile, and the presence of other sexually transmitted infections (STIs).

Reducing sexual transmission of HIV is a major challenge. Despite wide scale improvement in HIV prevention efforts through male and female condom promotion, treatment of STIs, HIV counselling and testing, risk reduction counselling and medical male circumcision [7], these are insufficient and inadequate for young girls. Many young girls are often unable to remain abstinent, or negotiate mutually monogamous relationships or rely on consistent condom use, and have little or no options to reduce their risk of acquiring HIV infection [8–9]. Thus, to prevent the sexual transmission of HIV in young girls the need for new technologies is unambiguous.

The search for a female-controlled HIV prevention technology has been marred by several disappointing results. However, results from clinical trials testing antiretrovirals (ARV) as early treatment [10], pre-exposure prophylaxis (PrEP) [11–13] or as topical vaginal microbicides [14] has provided renewed hope that HIV prevention technologies for women are possible. Despite these promising results, two additional trials conducted among women - the FEM- PrEP trial and the VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial - have produced contradictory results. These studies found no protection against HIV in women using daily oral truvada (TDF/FTC) and tenofovir (TDF) respectively[15] [16]. Although no data are available yet to explain the VOICE trial outcome, since the TDF/FTC arm is continuing and results are not expected until 2013, data on plasma drug concentrations from the FEM-PrEP trial have shown the adherence levels in the FEM-PrEP trial were too low to allow for an assessment of efficacy [17].

Therefore, the use of ARVs for HIV prevention, if used as prescribed, has the potential to substantially reduce HIV transmission. Whilst the safety and tolerability of ARV's in PrEP and topical vaginal microbicide trials has been established in those 18 years and older [14, 18]; this information is not known for young girls below the age of 18 years. Despite their vulnerability to HIV infection, this important group has been excluded from clinical trials assessing biomedical interventions because of significant regulatory, ethical and socio-behavioural and community-level challenges [19–20]. Including young girls below the age of 18 years in clinical trials for HIV prevention provides an opportunity to establish product safety, tolerability, as well as an understanding of and acceptability of biomedical interventions. This information is urgently needed to protect younger girls who are at high risk of HIV acquisition.

It is imperative that young girls be included in research within the context of the ethical principles which govern such studies [20–21]. Several different ethical dilemmas may arise during behavioural and clinical research in younger adolescents and these include but are not limited to the country legal framework [22–23], the cognitive ability of young adolescents, and informed consent procedures. Parental consent may be desirable but unobtainable if parents or guardians are deceased [24–26]. Extra caution is required in protecting young adolescent participants from physical and psychological harm and more importantly from deception and potential social harms that may result from a breach of confidentiality [27].

The purpose of this study was to determine the HIV incidence rate and the feasibility of accruing and retaining sexually active girls below the age of 18 years in a longitudinal study for potential inclusion into HIV biomedical prevention trials.

Methods

Ethics review and oversight were provided by the Biomedical Research Ethics Committee (BREC) of the University of KwaZulu-Natal. BREC determined that in the absence of a biomedical intervention and given the nature of the longitudinal study, approved the inclusion of young girls 14 to 17 years of age. This prospective open cohort study recruited volunteers between March 2004 and May 2007 from a public sector rural family planning (FP) clinic and an urban STI clinic in the province of KwaZulu-Natal, South Africa [9]. All screening, enrolment and follow-up procedures were conducted at the CAPRISA research facilities adjoining the FP and STI clinics. Prior to screening and enrolment, research staff discussed the content of the informed consent, responded to questions, assessed literacy based on the participant's ability to read a paragraph either in the English or IsiZulu. To assess cognitive skills and comprehension, participants were required to respond and answer to study related questions prior to any consenting or study procedures. Following individual written informed consent, sexually active, HIV uninfected women aged 14 to 30 years were enrolled. Interviewer administered structured questionnaires were used to collect demographic, clinical, reproductive and sexual behavioral data at baseline and at each monthly follow-up visit. Pregnancy and HIV testing were conducted at these visits with contraceptive counselling and provision. HIV infection was ascertained by two on-site HIV rapid antibody tests (Determine HIV-1/2 - Abbott Laboratories, Illinois, United States of America and HIV-1/2 SmartCheck assay - Globalemed.LLC, World Diagnostics, Inc), confirmed with an antibody [Enzygnost* Anti-HIV 1/2 Plus (Dade Behring, Marburg, Germany)] and HIV-1 RNA [COBAS AmpliPrep/COBAS TaqMan (Roche)] test. All participants who screened HIV positive or became infected in this study were provided the option of accessing care through the CAPRISA AIDS Treatment Programme at their respective sites or at the nearest public sector treatment clinic.

To assist with retention locator information such as physical residential address and contact numbers were updated at each visit. Monthly retention rates were calculated and participants missing visits were tracked telephonically on the expected visit date or through a home visit using the locator information.

Categorical cut-points for age were used in the descriptive analysis and a time-to-event analysis for the multivariable proportional hazards model. Recruitment, retention rate, HIV infection, demographic and sexual behavior characteristics were stratified to age groups (<18 and ≥18 years). Comparison of individual measures from baseline and follow-up were undertaken using Student's t- and Fisher's exact tests, as appropriate. Generalized estimating equation (GEE) models were used to compare binary outcomes between time points within age groups and between age groups overall, while adjusting for repeated measures. HIV incidence rates were estimated using the number of confirmed seroconversions, calculated

per 100 women years at risk (wy). Data were analysed with SAS statistical package (version 9.2; SAS Institute Inc., Cary).

Results

Of the 1941 volunteers screened, 174 were younger than 18 years and 1767 were 18 years or older. A total of 388 women (28 who were <18 years and 362 who were ≥ 18 years) were not enrolled because they did not return for their enrolment visit, were planning to relocate or were not sexually active. A further 961 were excluded because they were HIV-infected. HIV prevalence at screening was lower among girls younger than 18 years compared to those 18 years and older (27.6% versus 52.0%; p value <0.001). Of the 594 HIV-negative participants enrolled, 100 were <18 years of age and 494 were ≥18 years. The mean number of months of follow-up (12.8 versus 12.0; p=0.36) and the mean number of missed visits (3.9 versus 3.6, p=0.55) were similar for both groups. The girls younger than 18 years old were more likely to be in school (92.0% versus 61.9%, p<0.001) and not living with their current sexual partner (96.0% versus 89.5%, p=0.04), but were similar in terms of being in a stable partnership (94.9% versus 93.1%, p=0.66) and knowing that their partner had other sexual partners (20.2% versus 20.2%, p=0.98).

There were no differences in the pregnancy and HIV incidence rates for the two groups. The pregnancy rate in the girls younger than 18 years old was 23.7/100wy compared to 16.4/100wy for the women 18 years or older (p=0.29). Similarly the HIV incidence rate was 4.7/100wy in the girls younger than 18 years old compared to 6.9/100wy for women 18 years or older (p=0.42). There were no significant differences in the monthly or overall retention rates (71.0% versus 71.5%; p=0.90) and reasons for non-retention for both groups (Table 1).

There were no differences in terms of demographics, and rates of retention among rural and urban girls younger than 18 years old. However, the urban women who were 18 years or older were more likely to complete secondary education (p<0.001), be living with partner (p=0.01), have knowledge of their partner having other partners (p=0.005) and higher retention rates at month 12 (p<0.001).

Notable changes in self-reported sexual risk behaviors from baseline to months 6 and 12 included increase in abstinence or monogamous relationships; decline in anal sex rates, increase in condom and contraceptive use and reduction in the use of any vaginally applied products in both girls younger than 18 years old and those 18 years and older. Reported symptoms of genital discharge, ulceration and bleeding also declined over time (Table 2).

Discussion

The high HIV incidence and pregnancy rates in girls younger than 18 years old underscores the urgent imperative for their inclusion in HIV biomedical intervention trials. Although young girls comprised 16.8% of the cohort, they contributed to more than 10% of new HIV infections and including young girls in studies of HIV prevention technologies should not be delayed. Given that contraceptives were provided as part of the study, the high pregnancy rates and decision-making on method choice in young girls needs to be better understood. It is not known whether the promotion of condoms for prevention of STIs including HIV and pregnancy creating a false sense of protection. Furthermore, it is also not known whether there are any myths and concerns that young, nulliparous girls have about longer acting and more reliable methods of contraceptive methods and future fertility impact.

This study demonstrates that it was feasible to obtain first person consent from sexually active girls younger than 18 years old and retain them in longitudinal studies at similar rates

to those 18 years and older. Furthermore, the similarities in attendance of scheduled study visits, completion of study visit procedures and the quality of data obtained from interviewer administered questionnaires indicates that the inclusion of young girls would not compromise the scientific integrity and study power [28]. In South Africa, girls as young as 12 years of age can access HIV testing, contraception, termination of pregnancy and other health care without parental consent [29], however, current legislation precludes their inclusion in research without parental consent [30]. Nevertheless, ethics committees in South Africa have developed a useful ethical framework to provide guidance on the inclusion of young adolescents in clinical trials [20].

The high numbers of young girls screened out because of already being HIV infected is also cause for concern and highlights the need for early school-based HIV testing programs so that young people can learn of their HIV infection early and access care and treatment appropriately. Furthermore, it is important to understand HIV pathogenesis, disease progression and to enhance guidance on when to start antiretroviral treatment in young adolescents.

Some concerns have been raised about cognitive ability of adolescents to provide first person consent [31]. In this study we recruited sexually active young girls already utilizing and accessing health services to obtain contraceptives or for the management of STIs. We enhanced our informed consent process by having separate screening and enrolment visit allowing sufficient time to consider study participation, completing a comprehension assessment to determine understanding, completing the process in the language of their choice and obtaining consent through trained peer nurse counsellors. While this study provides a good signal on the feasibility of including young girls in longitudinal studies, this is a relatively small cohort from urban and rural settings with a modest follow-up period and generalizability may be limited. Although there was a decline in the reported sexual risk behaviours over time, the information collected at each monthly visit may have been influenced by social desirability and biased in response to the risk reduction counselling provided. Nevertheless this is an important population to understand in terms of behaviours and risk of HIV acquisition. More importantly if risk behaviour is truly affected over time by risk reduction counselling through study participation, these changes need to be taken into account for sample size calculations and study duration. Our study provides epidemiological evidence for the inclusion of this important population against the growing body of literature on ethical imperatives for inclusion of adolescents in HIV biomedical prevention trials [20].

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Table 1

Screening, enrollment, baseline sociodemographic characteristics and retention rates of study participants

Variable	Overall	Age group		*p-value*
		<18 years	≥18 years	
Screening				
Number screened	1942	174	1768	
Number HIV positive (n, %)	959 (49.4)	48 (27.6)	911 (52.0)	<0.001
Number not returning, planning to move away, not sexually active, overage* (n, %)	388 (20.0)	26 (15.0)	362* (20.0)	0.09
Enrolment				
Mean number (±SD) enrolled per month	22.0 (11.1)	5.3 (2.3)	18.3 (9.8)	<0.001
Total number enrolled	**594**	**100**	**494**	
Follow-up				
Mean number (±SD) months of follow-up	12.1 (8.2)	12.8 (8.2)	12.0 (8.1)	0.36
Mean number (±SD) of missed visit	3.7 (2.9)	3.9 (3.4)	3.6 (2.8)	0.55
% missing more than 3 visits	22.4%	23.0%	22.3%	0.90
Demographic characteristics				
% not completing secondary education	67.0	92.0	61.9	<0.001
% in stable partner relationship	93.4	94.9	93.1	0.66
% not living with partner	90.6	96.0	89.5	0.04
% having knowledge of partner having other partners	20.2	20.2	20.2	0.98
Pregnancy rate				
Pregnancies n/wy	96/543.4	22/92.8	74/450.6	
Incidence rate/100wy (95%CI)	17.7 (14.3–21.6)	23.7 (14.9–35.9)	16.4 (12.9–20.6)	0.29
HIV incidence rate				
HIV infections n/wy	39/602.0	5/107.0	34/495.0	
Incidence rate/100wy (95%CI)	6.5 (4.6–8.9)	4.7 (1.5–10.9)	6.9 (4.8–9.6)	0.41
Participants retention				
% at Month 3	80.2	81.9	79.8	0.78
% at Month 6	73.4	68.5	74.4	0.25
% at Month 9	68.2	67.0	68.4	0.81
% at Month 12	68.3	70.3	67.9	0.71
% overall retention rate	71.4	71.0	71.5	0.90
Reasons for non-retention				
% loss to follow-up	2.4	2.0	2.4	1.00

Variable	Overall	Age group		*p-value*
		<18 years	≥18 years	
% refused further participation	14.5	15.0	14.4	0.88
% relocated	5.7	10.0	4.9	0.06

%=percentage; SD=standard deviation; CI=confidence interval; wy=women years at risk

Table 2

Participant characteristics at enrolment, months 6 and at month 12[#]

	Age group														
	<18 years							≥18 years							
	Enrolment		Month 6		Month 12			Enrolment		Month 6		Month 12			
	n	%	n	%	n	%	*P* value	n	%	n	%	n	%	*P* value	*P* value Comparing age groups
Sexual risk behaviour															
Having 1 or no sex partner	96	96.0	63	100	64	100	†	471	95.3	308	96.0	275	98.9	<0.01	0.18
Engaging in anal sex	2	5.7	5	7.9	1	1.6	0.19	10	5.3	12	3.7	4	1.4	0.04	0.26
Always using male condoms	45	45.0	46	71.9	41	64.1	<0.01	196	39.7	181	56.2	156	55.9	<0.01	0.01
Using any vaginally applied products	15	15.0	7	11.1	7	10.9	0.68	118	23.9	44	13.7	33	11.8	<0.01	0.08
Contraceptive use															
Hormonal injectable or oral use	31	31.0	28	43.8	33	51.6	0.03	254	51.4	181	56.2	163	58.4	0.14	<0.01
Genital symptoms															
Presence of genital discharge	29	29.3	3	4.3	4	6.5	<0.01	121	24.6	26	7.5	27	9.3	<0.01	0.90
Presence of genital ulcers	5	5.1	0	0.0	2	3.2	†	10	2.0	7	2.0	5	1.7	0.95	0.30
Any genital bleeding	3	3.0	4	5.7	1	1.6	0.44	40	8.1	20	5.8	6	2.1	<0.01	0.16
Any symptoms of STI	44	44.4	8	11.4	6	9.7	<0.01	207	42.1	58	16.8	44	15.2	<0.01	0.50

[#]% are calculated on the number of responses at each time point

†Model cannot calculate p-value because of 100% or 0% responses at certain study visits