Older, Wiser, Safer?

Evaluation of the long-term impact of an adolescent sexual health intervention programme (MEMA kwa Vijana) in Mwanza, Tanzania.

Aoife Margaret Doyle

Doctor of Philosophy

London School of Hygiene & Tropical Medicine

Author's Declaration

I, Aoife Margaret Doyle, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

19th August 2010

Abstract

Background: The UNGASS target to reduce HIV prevalence by 25% among 15-25 year olds living in the most affected countries by 2005 has not been met. In the absence of a vaccine or cure, behavioural interventions are the main strategy for HIV control. The ability of specific behaviour-change interventions to reduce HIV/STI incidence and unplanned pregnancies in young people remains unproven.

Methods: Since January 1999, an adolescent sexual and reproductive health (SRH) intervention has been implemented in 10 randomly selected intervention communities in rural Tanzania, within a community randomised trial. The intervention consisted of teacher-led, peer-assisted in-school education, youth-friendly health services, community activities and youth condom promotion and distribution. Process evaluation in 1999-2002 showed high intervention quality and coverage. From June 2007 to July 2008, in the specific research reported in this thesis, the long-term impact of the intervention was evaluated among 13,814 young people aged 17-27 years who had attended trial schools between 1999 and 2002.

Findings: Prevalences of HIV and HSV2 were 1.8% and 25.9% in males and 4.0% and 41.4% in females, respectively. The intervention did not significantly reduce risk of HIV (males adjusted prevalence ratio(aPR)=0.91; 95%CI:0.50-1.65; females aPR=1.07; 95%CI:0.68-1.67) or HSV2 (males aPR=0.94;95%CI:0.77-1.15; females aPR=0.96; 95%CI:0.87-1.06). The intervention was associated with a reduction in number of lifetime sexual partners reported by males (aPR=0.87; 95%CI:0.78-0.97) and an increase in reported condom use at last sex with a non-regular partner among females (aPR=1.34; 95%CI:1.07-1.69). There was a clear and consistent beneficial impact on knowledge, but no significant impact on reported attitudes to sexual risk, reported pregnancies or other reported sexual behaviours.

Interpretation: SRH knowledge can be improved and retained long-term, but this intervention had little effect on reported behaviour or HIV/STI prevalence. Youth interventions integrated within intensive, community-wide risk reduction programmes may be more successful and should be evaluated.

Table of Contents

List of Tables

List of Figures

List of Boxes

List of Appendices

Acronyms

AMREF	African Medical and Research Foundation
ANC	Antenatal clinic
ART	Antiretroviral treatment
ARVs	Antiretroviral drugs
ASRH	Adolescent Sexual and Reproductive Health
BCC	Behaviour Change Communication
CI	MkV1FS Census Interviewer
CPE	MkV1 Class Peer Educator
CRT	Cluster randomised trial
CSO	Civil society organisations
CT	Chlamydia trachomatis
CTL	MkV1FS Census team leader
DCI	Development Co-operation Ireland (now called Irish Aid)
DFID	UK Department for International Development
DHS	Demographic Health Survey
EC	European Commission
ELISA	Enzyme-linked Immnunosorbent Assay
FHI	Family Health International
FM	MkV1FS Fieldwork Manager
FS	MkV1FS Fieldwork Supervisor
GPS	Geographical Positioning System
HALIRA	Health and lifestyles research programme
HIV	Human Immunodeficiency Virus
HSV2	Herpes Simplex Virus 2
ICPD	International Conference on Population and Development
IEC	Information, Education, Counselling
LSHTM	London School of Hygiene & Tropical Medicine
MEMA	Mpango wa Elimu na Maadili ya Afya kwa Vijana
MITU	Mwanza Intervention Trials Unit
MkV1	MEMA kwa Vijana Adolescent Sexual and Reproductive Health Intervention
MkV1FS	MEMA kwa Vijana Trial Further Survey
MkV2	MEMA kwa Vijana larger-scale implementation and operations research

MO	MkV1FS Mobilisation Officer
MRC	Medical Research Council
NG	Neisseria gonorrhoeae
NGO	Non-governmental organisation
NIMR	National Institute for Medical Research
PCR	Polymerase chain reaction
PDA	Personal Data Assistant
PMTCT	Preventing Mother-to-Child Transmission of HIV
PSI	Population Services International
RCT	Randomised Controlled Trial
RI	MkV1 FS Registration Interviewer
SD	MkV1FS Study Director
SI	MkV1FS Survey Interviewer
SOP	Standard Operating Procedures
SRH	Sexual and Reproductive Health
SSA	Sub-Saharan Africa
STD/STI	Sexually Transmitted Disease/Infection
THIS	Tanzanian HIV/AIDS Indicator Survey
THMIS	Tanzanian HIV/AIDS and Malaria Indicator Survey
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session
USAID	United States Agency for International Development
VC	MkV1FS VCT counsellor
VCT	Voluntary Counselling and Testing for HIV
WHO	World Health Organization
YFHS	Youth friendly sexual and reproductive Health services

Acknowledgements

I am very grateful to the young people of Mwanza Region, Tanzania who participated in MkV1 further survey. Through sharing their experiences they have improved our understanding of sexual and reproductive health in rural Mwanza Region and I hope that their communities will benefit in the future from the findings of this research.

I would like to thank the Medical Research Council, UK who funded me for the first 3 years of this PhD and DFID and Irish Aid who funded the survey and my salary in recent years. I am also grateful to the Tanzanian Ministry of Health and Ministry of Education, National AIDS Control Programme, and Medical Research Co-ordinating Committee, and the Ethics Committee of the LSHTM, for permission to carry out and publish the results of this study. I am also grateful to the Regional Medical and Education Officers of Mwanza and the National Directors of NIMR and AMREF for their support.

I would like to thank my colleagues at the NIMR, Mwanza and Mwanza Intervention Trials Unit for their advice, support and dedication during the data collection phase of the project. In particular I would like to thank Jacqueline Jackson, Erick Mgina, Tony Ao, Shelley Lees, Celia Barberousse, Clemens Masesa, Kathy Baisley, Aura Andreason, Kaballa Maganja, Yesse Mazanda, Leocardia Mmari, John Marijani, Jenny Renju, Pieter Remes, Basia Zaba, David Beckles and Innocent Rwegasha for their support and friendship. I am especially grateful to John Changalucha and Saidi Kapiga for their wisdom and guidance and for having their doors always open.

I would like to express my gratitude to my PhD advisory committee David Mabey, Richard Hayes, Mary Plummer, Debby Watson-Jones, Claire Cook and Sheena McCormack. In particular, I would like to thank Mary and Sheena for their enthusiastic words of encouragement, Debby for her assistance with the setting-up of the fieldwork and to Richard for his support and advice. I would like to thank Annabelle South, Frankie Liew and Lucy Bradshaw who provided invaluable advice and assistance in London. I am also grateful to David Schellenberg for his advice re PDA, Helen Weiss for her advice on the analysis and to Danny Wight and James Hargreaves for their helpful comments and suggestions. I would like to especially thank David Ross, my supervisor, for his support, advice, encouragement and for guiding me through the many challenges that I faced during this PhD research.

Throughout my time as a PhD student I have met many wonderful fellow students who have made this experience all the more enjoyable and who have offered much needed encouragement and advice. I would like especially to thank Isolde Birdthistle, Clare Tanton, Ally Wringe, Anita Ramesh, Ekua Yankah, Sara Nam, Atsumi Hirose, Wei Huang, Emily Somers, Marieke Schoonen, Andrew Thompson and Suzanna Francis.

And finally I would like to thank my family and friends who have supported me through every step of this PhD with kind words and cups of tea while in the back of their mind wondering how a PhD could ever take so long. I thank especially my parents for their encouragement and words of wisdom and Mike for his love, friendship and for the sacrifices made in the name of this PhD. Last but not least I would like to thank little Cormac for brightening up every day and helping to keep everything in perspective.

Chapter 1 - Introduction

1.1 Introduction

In June 2006, 25 years after the first documented case of HIV, the UN General Assembly adopted a resolution, a political declaration on HIV/AIDS, in which they stated:

'We note with alarm that we are facing an unprecedented human catastrophe; that a quarter of a century into the pandemic, AIDS has inflicted immense suffering on countries and communities throughout the world; and that more than 65 million people have been infected with HIV, more than 25 million people have died of AIDS, 15 million children have been orphaned by AIDS and millions more made vulnerable, and 40 million people are currently living with HIV, more than 95 per cent of whom live in developing countries........ We express grave concern that half of all new HIV infections occur among children and young people under the age of 25, and that there is a lack of information, skills and knowledge regarding HIV/AIDS among young people.'[1]

Was this political hyperbole? Unfortunately, the answer then and now is 'No' as the official UNAIDS figures confirm the continuing devastating impact of the pandemic and especially the impact on young people.[2, 3] Young people aged 15-24 years make up approximately 24% of the world's adult population (15 yrs +),[4] and approximately 40% of all new adult infections (15 yrs+).[2] Approximately 12% of the world's population live in Sub-Saharan Africa (SSA),[4] yet an estimated 1.9 million (35%) of the 2.7 million new infections worldwide occurred in SSA in 2008.[2] These figures demonstrate the disproportionate risk of HIV infection among young people, and especially among young people living in SSA. Furthermore, two-thirds of the estimated 33.4 million people living with HIV worldwide in 2008 were living in SSA,[2] including an estimated 3.2 million young people aged 15-24.[5] Also striking is the fact that 78% of the young people living with HIV in SSA are female.[5] In the United Republic of Tanzania, the setting for the specific research reported in this thesis, females aged 15-24 years are three times more likely than males of the same age to be living with HIV.[6]

Despite the high levels of new and current infections, the global spread of HIV is thought to be on the decline, with the spread estimated to have peaked in 1996.[2] A number of countries in SSA, including Tanzania, have seen a recent decline in HIV prevalence.[2] It is likely that these decreases in rates of infection are due, at least partly, to the extensive prevention efforts that have taken place over the last 15 years. The battle is far from over, however, and male circumcision[7] and the male condom (used consistently and correctly)[8] are the only interventions that have been conclusively shown to be effective in the prevention of the sexual transmission of HIV.

HIV prevalence rises rapidly after the age of 15 years, rises more rapidly among women than men and, in Tanzania, reaches a peak among women in their early 30s and men in their late 30s.[6, 9, 10] Young people have an increased biological vulnerability to HIV and other STIs and have higher rates of morbidity and mortality associated with pregnancy.[11-13] Furthermore, low levels of education, limited access to family planning and health care and the low status of young people in society can make them more prone to other adverse reproductive health outcomes.[12] Young people are at the centre of the epidemic in terms of new infections and opportunities for halting the transmission of HIV[14] and they have been described as potential 'agents of change' within the HIV pandemic.[3, 15] Effective interventions targeted at youth could potentially impact greatly on the HIV epidemic and improve young peoples' overall sexual and reproductive health, especially if interventions motivate informed, safer behaviour from the start.[16]

In this thesis the results of the long-term evaluation of a multi-component adolescent sexual and reproductive health intervention in the rural Mwanza Region of Tanzania within a cluster randomised trial are presented. The use of a rigorous evaluation design, biological outcomes and a long length of follow-up, make this study unique in the field and the research results are of great policy importance.

This introductory chapter provides an overview of sexual and reproductive health (SRH) interventions among young people, a description of SRH in Tanzania, a brief history of the MEMA kwa Vijana intervention and a rationale for the specific research reported in this thesis. Evidence on the effectiveness of SRH interventions among young people is summarised briefly in Chapter 1, however, in Chapter 2 the evidence is discussed in more detail and the quality of the evidence is critically appraised. In the review of the literature in both this chapter and chapter 2, the focus is on Tanzania and sub-Saharan Africa and particular attention is paid to studies among young people. The commonly used definition of young people is all those aged 10-24 years.[17] This definition includes both adolescents (10-19 years) and youth (15-24 years).[17] The long-term evaluation survey presented in this thesis was planned in 2005, and, following delays in receiving funding, was implemented from December 2006 to July 2008

(Appendix 1). Some of the literature presented, therefore, was published either during the implementation or following the completion of the research study. The inclusion of literature right up until the present provides a good background for the discussion of the results of the specific research reported in this thesis.

1.2 Sexual and reproductive health: International initiatives and prevention interventions

1.2.1 Young People

Young people are a diverse group with different needs according to their age, sex, school and family circumstances and stage of development.[12] Dixon-Mueller suggests that 'adolescence' should be broken up into three distinct stages that each have gender-specific physiological characteristics, sociocultural meanings and policy implications: early adolescence (ages 10-14 years, or 10-11 and 12-14), middle adolescence (15-17 years) and late adolescence (18-19 years).[18] Adolescents are at the cross-roads between childhood and adulthood and the transition between the two has been described as 'a period of momentous social, psychological, economic and biological transitions'.[19] The current generation of young people have been born into a world that is characterised by globalisation. Globalisation has resulted in cheaper and easier travel, cheap and fast communications, rapid urbanisation and a trend towards democracy, increased school enrolment and the rise of civil society.[19] In sub-Saharan Africa, the availability of mobile phones and the internet have increased knowledge transfer and increased exposure to other cultures. The impact of globalisation varies greatly between rural and urban communities with many communities in SSA still relatively unexposed to mass media.

Adolescent sexual and reproductive health (ASRH) is a sensitive area which requires acceptance of the fact that many young people are sexually active. The highest incidence of many sexually transmitted infections (STIs) are found in this age group.[20, 21] Untreated STIs often result in both short and long term adverse effects for the young person and/or their offspring but there is also strong evidence that STIs can enhance HIV transmission.[22] High rates of unintended pregnancies, the adverse consequences of which are well recognised, are also found in this age group.[20, 23, 24] In most countries in SSA, a girl has to leave school if she becomes pregnant.[25] Abortion is illegal in most African countries and if a girl chooses to have an abortion it is often carried out in unsafe conditions. Young adolescents are at higher risk of morbidity and mortality associated with childbearing, and babies born to adolescent mothers are at higher risk of mortality. A 2004 report examining the implications of 'children having children' found complications from pregnancy and childbirth to be the leading cause of death for young women aged 15-19 years in developing countries.[13]

Young people in SSA have an increased vulnerability to adverse SRH outcomes due to early sexual debut, early marriage, age-disparate sex, gender disparities, limited knowledge, and lack of life skills to protect themselves against sexual violence and exploitation. Young people who are orphans, who are poor or otherwise disadvantaged, are also particularly vulnerable.[11, 26] Structural factors that increase the vulnerability of young people include high mobility due to a migratory labour system, poverty, low educational status and social instability.[3, 27] Also, young people make up an important part of the most-at-risk populations including sex workers and their clients, men who have sex with men and injecting drug users. There is increasing interest in the important 'transitions' in the lives of young people as these periods of change represent a time when young people are most vulnerable. In Tanzania, for example, leaving primary school is a big transition and often heralds a woman's entry into marriage and childbearing.[28] Becoming sexually active and becoming a mother for the first time are other important transitions. Lloyd and colleagues, argue for increased efforts to ensure a successful passage to adulthood for young people in developing countries. This will require improvement of the health and education of young people and increasing opportunities for productive livelihoods.[19]

1.2.2 International initiatives

The important role played by young people in the propagation of the HIV epidemic has led to an upsurge in interest in ASRH during the past fifteen years and recognition of the urgent need for effective interventions to improve ASRH.[27, 29] In the late 1990s and early 2000s, the number of new infections was rising fast among young people and young people received specific mention in several international initiatives.[30-35]

The International Conference on Population and Development (ICPD) held in Cairo in 1994 formulated a programme of action to improve reproductive health which included improved treatment of STIs, provision of information, education and counselling on safer sexual practices and the promotion and reliable supply of high-quality condoms.[30] Five years later this programme was further elaborated upon and a number of key targets were set (ICPD+5) including increasing young peoples' access to information and services and the goal of reduction of HIV prevalence in 15-24 years olds by 25% by 2010 ***(Box 1.1)***.[32] These targets have had an important influence on ASRH policies and programming.

In 2000, the Millennium Development Goals were formulated, among other things, to aid development and eradicate poverty. Goal 6 was to halt and reverse the HIV/AIDS epidemic by 2015 ***(Box 1.1)***.[35] The Millenium Project was commissioned by the UN Secretary-General in 2002 to recommend a concrete action plan to achieve the Millennium Development Goals. The report published by this group in 2005 provides new goals for 2015 ***(Box 1.1)*** and practical solutions for meeting these goals.[36]

The political will of Heads of States and Governments to tackle HIV/AIDS among young people was demonstrated when the declaration of commitment on HIV/AIDS was adopted by the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in June 2001. By signing this declaration countries committed themselves to meeting a number of key goals based on the ICPD and ICPD+5 recommendations ***(Box 1.1)***.[33] Additional goals addressed gender discrimination and the problems of young people who are at particularly high risk of HIV infection. The Abuja Declaration signed by African leaders around the same time pledged to combat HIV and other infectious diseases and included an emphasis on youth and stressed the importance of education.[37] The UNGASS goals that related to adolescents were reiterated at a UN Special Session on Children in 2002 ***(Box 1.1)***. [38] The UNGASS goals represent the most important policy commitment on HIV and have guided funding and research priorities for the last ten years. However, progress towards these goals has not been easy or universally successful.

Box 1.1: A summary of the main international recommendations and goals regarding the prevention of HIV/AIDS among young people

Source	Goals/Targets
ICPD+5 (1999)[32]	• Reduction of HIV prevalence rates in 15-24 year olds globally by 25% by 2010. • Provision of access to the information, education and services necessary to develop the life skills required to reduce their vulnerability to HIV infection for at least 90% of young people by 2005 and 95% by 2010
Millenium Development Goals (2000)[35]	• Goal 6 Have halted by 2015 and begun to reverse the spread of HIV/AIDS (HIV prevalence in pregnant 15-24 yr olds as an indicator)
UN Millenium Project (2005)[36]	Reduce prevalence of HIV among young people to 5% in the most affected countries and by 50% elsewhere by 2015 Ensure that 100% of young people have access to reliable information about the epidemic and how to protect themselves by 2015
UNGASS (2001)[39]	By 2003, establish time-bound national targets to achieve the internationally agreed global prevention goal to reduce by 2005 HIV prevalence among young men and women aged 15 to 24 in the most affected countries by 25 per cent and by 25 per cent globally by 2010, and intensify efforts to achieve these targets as well as to challenge gender stereotypes and attitudes, and gender inequalities in relation to HIV/AIDS, encouraging the active involvement of men and boys. By 2005, ensure that at least 90 percent, and by 2010 at least 95 per cent of young men and women aged 15 to 24 have access to the information, education, including peer education and youth-specific HIV education, and services necessary to develop the life skills required to reduce their vulnerability to HIV infection, in full partnership with young persons ,parents, families, educators and health-care providers. By 2005, ensure a wide range of prevention programmes in all countries that are culturally sensitive and available in local languages; reduce risky behaviour; encourage responsible sexual behaviour; reduce harm related to drug use; expand access to male and female condoms, clean injecting equipment, safe blood supplies, treatment for sexually transmitted infections, and voluntary and confidential counselling and testing.
UN General Assembly Special Session on Children (2002) [38]	Develop and implement national health policies and programmes for adolescents, including goals and indicators, to promote their physical and mental health Access through the primary health-care system to reproductive health for all individuals of appropriate age as soon as possible, and no later than 2015.

In May 2004, a global WHO consultation was held at Talloires in France, to review the evidence on the effectiveness of policies and programmes to achieve the HIV-related UNGASS and Millennium Development Goals related to young people.[15] The consultation identified persisting low levels of knowledge and self-efficacy; high rates of STIs, substance use, and gender-based violence; and continuing violations of the human rights of young people.[15] In the same year, the ten year review of the programme of action of the International Conference on Population and Development (ICPD) documented significant progress but also found major challenges to the full implementation of the targets addressing HIV/AIDS. They reaffirmed the programme of action and the key actions.[40] A special summit of the African Union on HIV/AIDS, Tuberculosis and Malaria in 2006 reviewed the progress made towards achieving the targets agreed at Abuja in 2001. They found that since 2001 most countries had put in place multi-sectoral national HIV/AIDS programmes for the coordination of the response and the donor support. However, progress towards the targets was slow and they called for an intensified effort.[41]

At the G8 summit in Gleneagles in 2005, in the face of poor progress on the ICPD, Millenium Development Goals and UNGASS targets, the G8 leaders agreed to take concrete actions to develop and implement a package of HIV prevention, treatment and care and to aim for universal access to treatment by 2010. This commitment to universal access was elaborated on at the UN world summit later that year and received commitment from African leaders at summits in Gaborone in 2005 and Brazaville in 2006. The '3 by 5' campaign, launched by UNAIDS and WHO in 2003, was a global campaign to provide 3 million people in low- and middle- income countries with life-prolonging antiretroviral treatment by 2005 and has been very successful, albeit with the target of 3 million on treatment being reached a couple of years late. This success was thanks to the financial support and political impetus that resulted from these high level commitments.

Progress towards these international goals is closely monitored and the UNGASS report this year will be important to see if the universal access targets for 2010 have been reached and to see if we are on target to reduce HIV by 2015. Already the indications are that, at the current rate of progress, we are unlikely to meet several of the Millenium Development Goal targets. For example, in SSA, on average, only 31% of young men and 19% of young women aged 15-24 years have comprehensive HIV knowledge[42] and it is clear that the UNGASS goal of 95% with this knowledge will not be met by 2010. While the ambitious targets set in the early 2000s are unlikely to be met in their entirety, progress has been made. The challenge will be to maintain momentum and interest not only for HIV treatment and care but more importantly for HIV prevention.

1.2.3 Focus on prevention

In contrast to the international campaign to expand treatment, global prevention has, in the past, lacked clear momentum and has been underfunded.[43, 44] This is notwithstanding the efforts of groups such as the Global HIV Prevention Working Group who have, since 2002, pushed for global mobilisation on HIV prevention. In their 2002 'Blueprint for action' report they provided a roadmap for rapidly scaling up prevention programs.[34] An increased emphasis was placed on prevention following the publication of the 2005 UNAIDS Policy position paper on intensifying HIV prevention. The paper posited that *'HIV prevention actions must be evidence-informed, based on what is known and proven to be effective and investment to expand the evidence base should be strengthened'.*[45] One of the eleven essential programmatic actions for HIV prevention was a focus on HIV prevention among young people. The Millenium Project also stressed the need to 'reinvigorate prevention' and highlighted the fact that prevention goals needed the same sense of urgency and excitement as the '3 by 5' WHO/UNAIDS initiative.[36] The WHO/AFRO region in their Maputo Declaration called on member states to declare 2006 a year of accelerated prevention. Different prevention terminology emerged: 'Comprehensive' prevention involving all the strategies required to prevent transmission of HIV and 'Combination' prevention involving the strategies to prevent sexual transmission of HIV.[46] The emphasis was on choosing the right mix of prevention actions and tactics.[3, 47] 'Know your epidemic, know your response' was the rallying cry led by UNAIDS.[26] In a special issue of The Lancet journal in 2008 Peter Piot, the UNAIDS Executive Director, made a 'call to action for HIV prevention'[16] and the editors described as 'scandalous' the fact that the access to medicines had not been matched by an access to prevention campaign.[48] Stover and colleagues, using mathematical modelling estimated that preventing new infections would produce a net financial savings as future costs for treatment and care would be averted.[49]

There is political will to improve ASRH and the UNGASS goals provide targets for the campaign to prevent HIV infection, but what exactly should be done? A wealth of research in the area of HIV prevention and sexual behaviour change has been conducted in the last 15-20 years and our understanding of effective interventions and what might be effective in the future is rapidly increasing. The Millennium Project recently identified seven interventions they consider to be effective in preventing HIV transmission ***(Box 1.2)***.[36] While these interventions are currently widely advocated, the strength of evidence for each intervention varies enormously. Existing interventions can be divided into the three main categories: behavioural, biomedical, structural. It is important to note, however, that biomedical interventions involve behaviour change and behaviour change often involves partner notification and treatment and/or use of condoms.[50]

Box 1.2: Essential Prevention Interventions identified by UN Millennium Project, 2005[36]

1	Education and Communication campaigns (basic facts about HIV/AIDS and its transmission, promotion of behavioural change, combating of harmful myths and stigma)
2	Control of sexually transmitted infections
3	Programs focused on groups at high risk of HIV infection
4	Access to the technical means of prevention: male and female condoms; sterile needles and syringes
5	Voluntary counselling and testing
6	Prevention of mother-to-child transmission using antiretrovirals and nutritional interventions
7	Precautions to prevent transmission in healthcare settings, such as through safe blood transfusion, screening of other blood products, use of sterile equipment etc.

1.2.4 Behavioural interventions

Heterosexual sex is estimated to be responsible for 80% of all new infections worldwide[47] and remains the primary mode of transmission in sub-Saharan Africa.[2] Behavioural interventions have the goal of reducing behaviours that result in the transmission and acquisition of HIV infection. Interventions attempt to change behaviours by improving knowledge, changing attitudes, and developing skills and self-efficacy. The risk of sexual acquisition of HIV can be reduced by delaying the onset of sexual intercourse, reducing the number of sexual partners and reducing the incidence of unprotected sex by encouraging the use of condoms. The combination of these three strategies has become known as 'ABC'. Some groups argue that abstinence should be the only message for young people; however, the evidence for the effectiveness of such 'abstinence only' interventions remains weak.[51]

Evaluation of ASRH behaviour change interventions provides evidence that such interventions can lead to reductions in reported risk behaviours but there is little evidence of an impact of interventions on actual rates of HIV or other STIs.[15] However, recent reductions in the rates of HIV in Uganda,[52-54] Zimbabwe,[55] and Thailand[56] have been associated with reductions in reported risk behaviours. In Benin (urban), Burkina Faso, Cote D'Ivoire (urban), Kenya, Malawi (urban) and Zimbabwe (urban) significant declines in HIV prevalence in the early 2000s of more than 25% among pregnant women aged 15-24 yrs were accompanied by an increase in reported safer sexual behaviour (data from national surveys).[57] Using a mathematical model, Hallett and colleagues showed that the observed decreases in HIV prevalence in Uganda, urban Kenya, Zimbabwe and urban Haiti were consistent with declines associated with changing sexual behaviour and not the natural course of the epidemic.[58] Other studies using data from national population-based surveys have observed general decreases in reporting of risky sexual behaviours.[9, 57, 59] The consensus seems to be that behavioural intervention strategies played a role in reductions in HIV in these countries. Detailed analysis of the reductions in HIV rates in Uganda have found that increased communication about HIV through social networks and the involvement of high-level political and community leaders may have been important in facilitating behaviour change.[60]

Knowing ones HIV status is thought to be important not only for early access of treatment services but also for motivating behaviour change. The overall data on the effectiveness of voluntary counselling and testing for HIV (VCT) to reduce the rates of HIV show mixed results.[61, 62] A major trial is underway in South Africa, Tanzania, Zambia and Thailand to test the effectiveness of an enhanced VCT intervention that involves community outreach and post-test support.[63]

1.2.5 Biomedical interventions

Padian and colleagues recently reviewed the evidence for the effectiveness of biomedical interventions to prevent HIV infection. The authors highlighted the fact that no vaccine or topical prophylaxis would be available in the foreseeable future and even if and when they are available they are unlikely to be 100% effective.[64] In the absence of a vaccine or effective microbicide, circumcision is an important prevention intervention. It is hypothesised that circumcision protects chiefly because the foreskin, which contains a high density of HIV-specific cellular targets, has been removed.[61] A Cochrane review of the evidence on the effectiveness of circumcision from the three clinical trials that have been conducted found that male circumcision reduces the acquisition of HIV by heterosexual men by between 38% and 66% over 24 months.[65] Some countries are developing plans for country-wide scale up of circumcision and it will be essential that such scale-up is carried out by trained surgeons in sterile conditions.[64] There is a lot of interest in the potential effectiveness of oral and vaginal antiretroviral drugs to reduce the infectiousness of those infected by HIV and also for pre-exposure prophylaxis (PrEP), and these strategies are currently being evaluated.[64]

The risk of sexual transmission of HIV increases in the presence of other STIs [22] and treatment of other STIs has been tested as a HIV prevention measure. One study in Mwanza, Tanzania found that syndromic management of STIs through government-run primary health care units reduced HIV incidence by 38%.[66, 67] In Uganda, however, a trial in Rakai found that the periodic mass treatment of all adults for STIs did not significantly impact on HIV incidence,[68] while in Masaka a behavioural intervention accompanied by syndromic management of STIs was no more effective than the behavioural intervention alone.[69] It is now believed that treatment of STIs for the prevention of HIV may be most effective early in the epidemic and in areas with high prevalence of other treatable STIs and risky sexual behaviour.[70, 71] Despite these mixed results, treating STIs could be an effective strategy. A modelling study carried out using data from sites in west and east Africa suggests that, even in mature epidemics, up to a third of all new cases of HIV could be attributed to curable STIs.[72]

Other biomedical interventions that are believed to be effective in preventing HIV include use of the male condom, use of the female condom, male circumcision, post-exposure prophylaxis (PEP), and the prophylactic use of drugs or contraceptives to prevent unwanted pregnancies and to reduce mother-to-child transmission (MTCT). HIV risk can be reduced through behavioural and biomedical interventions among intravenous drug users by reducing or eliminating the incidence of drug injecting and sharing needles, syringes and other drug devices and by treating drug addiction[61]; however, a discussion of these kinds of interventions is beyond the scope of this thesis.

1.2.6 Structural interventions

This group of interventions (also called social strategies or environmental interventions) attempts to create social conditions that facilitate health promotion or risk reduction.[61] Structural factors associated with HIV risk and prevention can be broadly defined to include physical, social, organisational, community, economic, legal or policy aspects of the environment that impede or facilitate persons' efforts to avoid HIV infection.[73] The structural factors that facilitate HIV transmission and help explain the epidemiology of infection have been grouped into 3 broad but interconnected categories: economic underdevelopment and poverty, migration/mobility, sex inequalities.[74] Auerbach stresses that these are not necessarily drivers on their own but in conjunction with particular social arrangements and certain context and stresses that the causal pathways through which structural and social factors confer vulnerability or protection are very complex.[75]

Box 1.3: UNAIDS Prioritised HIV prevention measures for young people[26]

What?
Peer education and outreach to young people out-of-school, children and adolescents involved in sex work, street youth.
HIV, gender, sexual and reproductive health and drug use issues included in school curriculum; gender inequalities addressed through life skills building for boys and girls.
Address inter-generational and transactional sex through campaigns for social change
Ensure access to comprehensive sex education.
Ensure access to youth-friendly health services and HIV counselling and testing.
Remove legal barriers to accessing prevention and care services including condoms.
Involve parents and adults in community in school-based HIV awareness and prevention activities.
Promote mass media campaigns to raise awareness, promote public debate, reduce stigma and promote gender equality.
How?
Using mass media accessed by youth and social mobilisation of young people.
School-based programmes that provide sexuality education.
Access to out-of-school youth through existing youth services and organizations such as youth clubs, workplace programmes, tailor-made programmes/services for most-at-risk young people.

1.2.7 Interventions targeted at young people

It is recognised that in the absence of a vaccine or cure, reducing risk behaviour will remain the main strategy for HIV control in the short to medium term, especially amongst youth.[76] In 1995, a global consultation called for the application of a package of 'actions' to promote health development in adolescents and to prevent and respond to health problems. The actions included: the creation of a safe and supportive environment, the provision of information, building life-skills and the provision of health and counselling services.[77] In 2007, UNAIDS published practical guidelines for intensifying HIV prevention which included more specific guidance on what needs to be done and how it should be done. They included a list of HIV prevention measures that should be prioritised for young people ***(Box 1.3)***.[26] However, the effectiveness of the interventions and the specific policies needed to ensure access to these interventions by the groups who need them are unclear.

1.2.8 Current opinion on HIV prevention

Various themes have emerged within the recent HIV prevention literature:

Context and stage of the epidemic

The importance of context is constantly highlighted and it is clear that an intervention that works in one setting might not necessarily work in another.[78] Interventions also need to be tailored to the stage of the epidemic.

Community and domestication of the response

Many authors highlight the importance of community involvement, community networks for transmission of knowledge and indigenously developed intervention approaches.[36] One key lesson of family planning programs, highlighted by Cleland and colleagues, is that behaviour will change only when the definition of problems and solutions are 'domesticated'.[79] It is now well accepted that community norms and traditions can facilitate or inhibit a young person's ability to practise safer sex. Interventions that work with the community, such as through the use of opinion leaders or peers, may help to communicate information, stimulate discussion and actions to prevent HIV, and also change any social norms that hinder HIV prevention success.

Political leadership

Early and high-level political leadership have been associated with prevention success in Uganda and also in the San Francisco gay community in the 1980s.[36] Appropriate leadership can also help to combat stigma and fear of discrimination that prevents people accessing services.[80]

Empowerment of women and girls

Young women have been shown to be at higher risk of HIV than young men.[5, 81, 82] The empowerment of women and girls has been a recurrent theme in the last decade.[36, 83] The recent 'Girls Count' series of reports from the Center for Global Development call for better data on girls to make them more visible, investment in girls in strategic areas of need, provision of girls with a fair share of resources and opportunities,[84] and for HIV prevention to be focused on adolescent girls.[85] The important role of men in empowering women and girls and obtaining gender equality has been recognised.[86]

Prevention messages tailored to the target group

Married couples and those in long-term relationships have been identified as a group that need special attention as in many countries in SSA a considerable proportion of HIV transmission now occurs within stable relationships.[87, 88] Current prevention approaches such as the use of condoms are incompatible with a desire for childbearing and many believe that use of condoms within stable relationships indicates mistrust in their partner. In younger and non-married populations, fear of pregnancy is often greater than fear of HIV and the use of condoms for the prevention of pregnancies should be emphasised in messages.[89, 90]

Prevention with positives

As the epidemic matures and ART becomes more widely available, there are an increasing number of people living with HIV who are healthy enough to continue their sexual lives. It is important that these people are encouraged to practice safer sexual practices to protect themselves and others, and to adhere to their drugs to keep their viral load down and avoid the emergence of drug resistance.[91] Linked with this is the requirement for an increase in VCT so that more people know their HIV status.[92]

Comprehensive prevention strategies

A comprehensive approach to prevention is needed. Biomedical interventions should be integrated with other modes of prevention in order to maintain adherence and avoid sexual disinhibition.[64] Individual-level interventions need to be linked with interventions that address the broader determinants of sexual behaviour.[78]

Integration of HIV and reproductive health services

There needs to be a continuing integration of HIV prevention interventions with HIV treatment and other reproductive health services and to ensure that these programs are mutually reinforcing.[36]

Use of best available evidence to roll-out interventions and the need for further and higher quality evaluation

Rigorous evaluation of interventions and implementation strategies is essential for governments, policy makers, programme implementers, research institutions and funding organisations to make the most strategic use of funds.[93] Unfortunately, very few interventions have been rigorously evaluated in the developing world and there are varying opinions as to whether interventions shown to be effective in Europe and North America would be as effective in resource-poor countries with a very different cultural background.[29, 94] In the absence of strong evidence on the effectiveness of prevention interventions, policy makers must use the available evidence to select the most appropriate interventions for their settings.[95] However, implementation must be accompanied by evaluation so that over time the international community can improve the effectiveness of their response. In 2008, the Global HIV Prevention Working Group reviewed the evidence on the effectiveness of behavioural interventions to prevent HIV and called for additional research to assess the effectiveness of HIV prevention programs in the field. They also called for an improvement in the quality of evaluations and recommended an increased use of biological endpoints and an increase in the length of time over which study participants are followed.[96]

1.3 The sexual and reproductive health of youth in Tanzania

The following sections focus on Tanzania and provide background information, describe the epidemiology of HIV and other STIs and discuss the social, behavioural and biological determinants of sexual and reproductive health. The major source of demographic and health data on Tanzania are nationwide population-based surveys. The most recent of these have been the 2007/8 Tanzanian HIV/AIDS and Malaria Indicator Survey (2007/8 THMIS), the 2004/5 Demographic Health Survey (2004/5 DHS) and the 2003/4 Tanzanian HIV/AIDS Indicator Survey (2003/4 THIS). Frequent reference will be made to these surveys throughout the next sections. Additional information is available from nation-wide surveillance among antenatal clinic attendees. There has been considerable research activity in Tanzania over the last 20 years and a wealth of data exists on various geographical regions and population groups including data from demographic surveillance systems, clinical trials, observational quantitative studies and a wide variety of qualitative studies.

1.3.1 Tanzanian Context

Socioeconomic environment

Tanzania is the largest country in East Africa with an estimated population of 45 million in 2010 with young people aged 15-24 years making up 20% of the population.[4] The Tanzanian population consists of about 125 ethnic and language groups. Swahili is the national language and is the language of instruction in primary schools.[97] The country shares borders with Kenya and Uganda to the north, Burundi, Democratic Republic of Congo, Rwanda and Zambia to the West, Malawi and Mozambique to the south and is bordered to the east by the Indian Ocean.[98]

Tanzania mainland is divided into 21 regions which are further divided into 120 administrative districts.[98] Tanzania has a tropical climate and is rich in natural resources. Tanzania has a largely rural economy and it is estimated that 30% of young people live in rural areas.[99] Despite recent economic growth, Tanzania remains a very poor country with an estimated one third of the population in 2007 living on less than Tsh 500/day, equivalent to approximately US$0.40.[100]

Mwanza Region lies in the northwest of Tanzania and stretches along the southern shores of Lake Victoria. The region has an estimated population of 3 million (2002 Regional census). Mwanza city, with an estimated population of 500,000 lies on a major truck and bus route between Kenya and central Africa and relies mainly on the fishing, textile and brewing industries. The eight districts in the Region each have a semi-urban administrative headquarters. The population reside in lakeside fishing villages, busy roadside settlements, mining communities, and traditional inland farming areas with small villages and widely scattered compounds (a compound is a group of houses occupied by one or more families, and surrounded by their farm land).[101] The major ethnic group is the Sukuma and subsistence farming is the main means of livelihood. Swahili is the official national language but the main language in the Region is Sukumu.

Collaborative research in the area of HIV and STIs has been carried out by the National Institute for Medical Research's (NIMR)'s Mwanza Research Centre, the London School of Hygiene & Tropical Medicine (LSHTM) and the Tanzania-Netherlands Support on AIDS (TANESA) Project in Mwanza since the late 1980s. A number of population-based surveys and a large clinical trial [102] have collected data on the seroprevalence of STIs and HIV in the Region at various time points over the last 15 years. In addition to the wealth of background information, there is a strong research capacity with the NIMR's Mwanza Research Centre in Mwanza city.

Migration

In rural areas of Tanzania, many young people migrate from their village. Females often migrate to their husband's village when they get married and both males and females migrate to larger urban areas to study or find employment. There is also migration to other rural areas such as near mines or fishing areas. Where people migrate in search of work they often return to their villages during the farming season. In the 2007/8 THMIS, 45% of respondents aged 15-

49 years reported having travelled away from home in the past 12 months and 13% of females and 15% of males had been away for more than one month in the previous year. [6]

Religion

Identifying with a religious group is very common in Tanzania and participation in a religious group is a social outlet for many. At the latest DHS survey in 2004, 30% of respondents were reported to be Muslim, 29% Catholic, 29% Protestant and only 12% reported having no religion.[103] Qualitative research in Mwanza in the late 1990s did not find that religion emerged as a prominent factor that shaped sexual norms,[104] but those few young people who reported abstinence generally attributed it to their religious beliefs.[105]

Marriage and family

Marriage and childbearing are held in high regard. The parents of a girl receive a bridewealth when their daughter marries and the value of this can be influenced by the girl's reputation.[104] Tanzanian society places great importance on respect of the older generation and as a result young people traditionally have a lower status. However, in recent times young people tend to be less economically dependent on their parents and often support their families financially and this has challenged conventional intergenerational relationships.[106] Exposure to mass media has led to a desire to lead a 'modern' life and in recent times the importance of extended-family and collective structures has diminished.[106]

Data from the recent 2007/8 THMIS show that, nationally, 21.3% of females aged 15-19 years and 68.2% of females aged 20-24 years were currently married. In contrast, young males were less likely to be married, with only 1.4% of those aged 15-19 years and 28.1% of those aged 20-24 years married. [6] The median age at first marriage was reported to be 18.8 years for women and 24.3 years for men,[6] and was similar to the median age recorded during the 2003/4 THIS.[107] Polygamy is common in rural Tanzania where 26% of women reported co-wives and 13% of men reported more than one wife.[6] Young women usually marry older men and in 2004, 21% of females aged 15-24 years in Mwanza Region reported that their current husband/cohabiting partner was ten or more years older than themselves.[99]

Nationally in 2004, only 51% of those aged 10-14 years lived with both parents, 18% lived with their mother only, 8% lived with their father only and 23% lived with neither parent. [99] Data from the 2007/8 THMIS suggest that 11% of children under the age of 18 years in Tanzania have lost one or both parents,[6] and 18% of children under the age of 18 are classified as orphans or vulnerable children (live in a household where a parent or adult is, or in the last year, has been too sick to work or undertake normal activities).[6]

Fertility

Nationally, the median reported age at first sex in 2007 was 17.3 years for women and 18.5 years for men and was similar to the median ages reported in 2003. [6] Fertility has not declined in Tanzania for over a decade and, in 2007, the total fertility rate was estimated to be 5.6 births per woman. Women who have low levels of education, who have low socioeconomic status or who live in rural areas had much higher fertility rates.[6] The maternal mortality ratio is high at 578/100,000 live births.[108]

Health

Life expectancy at birth in Tanzania is increasing slowly and is currently 55 years for males and 56 years for females.[4] Child mortality has decreased dramatically since 1999 but still one in 9 children die before they are 5 years old.[108] Many children are malnourished and only three-quarters are fully immunised.[108] Government and parastatal facilities do not charge user fees but those treated at private-for-profit and faith-based facilities will pay for consultations, contraceptives and tests. Many in Tanzania choose to use private health facilities as they perceive the quality to be better and/or they have experience of drug shortages at government health facilities. Modern family planning (at least one of: contraceptive pills, injectables, implants, IUD, male condoms, spermicides or diaphragm) is available in 84% of the health facilities in Tanzania's Lake Zone area (includes Mwanza Region).[108] Only 27% of facilities that offer family planning routinely provide treatment for STIs.[108]

Circumcision

Levels of male circumcision in Tanzania vary according to ethnic group. Men, when they circumcise, are often circumcised in their late teens and early twenties.[109] The main ethnic group in Mwanza Region, the Sukuma, are traditionally a non-circumcising group; however, there is some evidence that circumcision is becoming more popular especially in urban areas and among boys who have been to secondary school.[109] In-depth interviews with young men in Mwanza Region revealed a high level of tolerance and respect for circumcision and a widespread belief that it was beneficial for penile hygiene and disease prevention.[109, 110] During the recent THMIS, two-thirds of men aged 15-49 years reported that they were circumcised. Levels of circumcision were higher in those living in urban areas, among those who were wealthier and among those with higher education.[6] In Mwanza Region, 56% of men aged 15-49 years reported that they were circumcised.[6]

Education system

Since the Jomtien Education for All declaration in 1990, there has been a considerable international effort to increase educational opportunities. Tanzania has been working towards universal primary education (Millenium Development Goal no. 2) and has also been working to reduce gender and other disparities in relation to increased access, retention and completion of basic education. The official age for entry into primary school is 7 years. There are seven grades in primary school (Standard 1-7) and six years in secondary school (Form I-VI). Primary school fees were abolished in 2001 and net primary school enrolment, which was 49% in 1999, had increased to 95% by 2006.[97] DHS data from 2004 show that only 27% of females aged 15-19 years were in primary school and an additional 9% in secondary school. A higher proportion of males of this age are in primary school (44%).[99] In 2007 twice as many females living in rural areas (31%) had never been to school compared to urban areas (15%). However, reflecting increased school enrolment in recent years, in the youngest cohort (aged 10-14 years), only 7% of females reported having no education.[6]

Secondary school attendance in Tanzania remains very low, even for SSA. In 2007 only 10% of females and 12% of males aged 25-29 years reported some secondary school education with, in this age group, only 1% of males having completed secondary school and only 2% of females and 3% of males having more than secondary education.[6] Progress also needs to be made in the area of literacy. In 2004, approximately 30% of females aged 15-24 years were illiterate (could not read a sentence in either Swahili or English).[99]

Major challenges to the improvement of the education system include addressing the quality of content, methodology and the pedagogic capacity of the teachers.[97] In rural Tanzania, additional challenges identified include low enrolment and attendance rates, limited teacher training, little access to teaching resources and official and unofficial practices that may alienate pupils and their parents such as corporal punishment, pupils being made to do unpaid work, forced pregnancy examinations, and some teachers' alcohol or sexual abuse.[28] Furthermore, material conditions are also very poor with few schools having running water, electricity, or other basic facilities. Class sizes are large, many children do not speak Swahili well and teaching methods are didactic. [28] Early marriage and childbearing have been identified as two major factors that prevent young women from continuing in education.[25] In rural Mwanza, additional reasons for students dropping out of school included work obligations, inability to pay school fees, illiteracy, fear of punishment and frequent illness.[28]

1.3.2 Prevalence and incidence of sexually transmitted infections

HIV

The first cases of HIV were reported in Kagera Region in 1983 and by 1986 all Regions were reporting cases. Tanzania Mainland has a generalized HIV epidemic and the primary mechanism for HIV transmission in the country is unprotected heterosexual intercourse, which is estimated to constitute about 80% of all new infections.[6] In recent years, Tanzania has begun to see a decline in HIV prevalence. The adult prevalence of HIV peaked at 8% in 1995.[111] In 2003 the prevalence of HIV infection in Tanzania Mainland among 15-49 year olds was estimated at 7.0%; 7.7% among females and 6.3% among males.[107] In 2007, the HIV prevalence was 5.7% overall, 6.6% in women and 4.6% in men.[6] Estimation of incidence using the 2003/4 and 2007/8 AIDS indicator survey data suggest a significant decrease in incidence in Tanzania, especially among males.[112] Evidence of decreases in HIV prevalence in national surveys has been supported by small decreases in HIV prevalence among antenatal clinic attendees.

Prevalence has been lower in rural areas with 5% of women and 4% of men testing positive in 2007.[6] However, between the 2003 and 2007 surveys, HIV prevalence decreased by 20% in urban areas but only by 11% in rural areas. Within rural areas, HIV prevalence decreased by 16% among males but only 8% among females.[6, 107] Analysis of 10 years of data (1994-2004) from the Kisesa open-cohort study in Magu District, Mwanza Region revealed that, between 2001 and 2003, small decreases in the incidence of HIV were seen in roadside villages but that the incidence in rural areas had risen slightly.[113]

Regional variation exists and is believed to be largely due to differing levels of circumcision and differing proportions of the population living in urban areas.[111] In Mwanza Region the prevalence for females was 7.1% in 2007, and no change was seen from the 2003 survey. However, among males, HIV prevalence decreased from 7.5% in 2003 to 3.7% in 2007.[6] Antenatal clinic surveys in Mwanza Region found HIV prevalence to be 10.7% overall in both the 2000 and 2002 surveys.[114] In 2006, a survey in the same clinics found the HIV prevalence to have decreased to 7.4% overall. The prevalence in rural clinics was 4.6%, similar to the 2000/2002 level.[115]

Among young people, the national HIV prevalence in 2007 was 1.3% and 0.7% amongst young females and males aged 15-19 years respectively, and 6.3% and 1.7% among females and males aged 20-24 years.[6] Between the 2003 and 2007 national surveys, HIV prevalence had decreased by approximately 50% among young people aged 15-19 years and by 60% among males aged 20-24 years. However, the prevalence among females aged 20-24 years increased slightly from 6.0% in 2003 to 6.3% in 2007.[107] In Mwanza Region in 2007, HIV prevalence among females and males aged 15-24 years was 5.9% and 1.4%, respectively, above the national averages of 3.6% for females and 1.1% for males.[6] A survey carried out in the early 1990s found that HIV accounted for 53% of deaths among 20-29 year olds in rural Mwanza.[116]

HSV2

Herpes Simplex virus type 2 (HSV2) infection is almost exclusively sexually transmitted and is the major cause of genital herpes.[117] Seropositivity is associated with high-risk sexual behaviour and the HSV2 antibody may be a suitable biological marker of risk behaviour among young people.[118] A meta-analysis of data from 18 longitudinal studies found that prevalent HSV2 was associated with a three-fold increased risk of HIV acquisition among both men and women in the general population.[119] The seroprevalence of HSV2 in Mwanza Region during the STD/HIV trial in the early 1990s was estimated to be 32.3% (95% CI 20.9-45.3%) in 20-24 year old males and 51.6% (95% CI 41.0-62.1%) in 20-24 year-old females. The seroincidence was estimated to be 5-10% per year.[120] Other studies in Tanzania have found similarly high levels of HSV2 prevalence among young people attending STD clinics,[121] an urban primary health care clinic,[122] a hospital outpatient clinic in Dar es Salaam,[123] and young women working at food and recreational facilities.[124-126]

Syphilis

Syphilis is usually acquired by sexual contact, can have serious sequelae if left untreated and women may transmit the infection to their foetus *in utero*.[127] The Mwanza STD/HIV trial found the prevalence of active syphilis (TPHA+ and RPR+) among 14-54 year olds in rural communities to be 8.9% in males and 9.2% in females. TPHA positivity was significantly associated with HIV infection in women.[102] In 1993, the prevalence of active syphilis among 15-19 year olds in Mwanza, was 2.0% and 6.6% in males and females, respectively, and among 20-24 year olds, 8.0% and 10.5% in males and females, respectively. The incidence of TPHA seroconversion was estimated to be about 2.4%/yr in 15-19 year old males and 3.4%/yr in females of the same age.[128] A national survey of antenatal clinic (ANC) attendees in 2006 found a syphilis prevalence of 6.9% (95% CI 6.6-7.1) with a higher prevalence of 9.7% in rural clinic attenders. The prevalence among 15-24 year-olds was 6.5%.[6] In 2006, a separate survey among ANC attenders in Mwanza Region found the prevalence of syphilis (RPR+) to be 16% among rural, 7% among urban and 13% among rural roadside residents. There was no correlation between the prevalence of HIV and syphilis. The prevalence of syphilis in remote rural areas was similar to that found during the 2002 survey at the same ANC clinics.[114, 115]

Chlamydia and gonorrhoea

In a 1997/8 household survey carried out among 15-19 year olds in rural Mwanza, Obasi and colleagues found the prevalence of *Chlamydia trachomatis* (CT) to be 2.4% among females and 1.0% among males. No association between CT, measured by PCR on urine samples, and HIV infection was found in either sex, though the numbers with HIV were relatively small.[10] Data from the Mwanza STD/HIV trial found the prevalence of CT among 15-39 year olds to be 2.3% among males and 13.0% among females. The prevalence of *Neisseria gonorrhoeae* (NG) was slightly higher in males at 2.8% and much lower in females at 2.3%.[129]

Nationally, the prevalence of any STI remains high and in 2007, 6% of women and 7% of men who ever had sex reported having an STI, genital discharge or genital sore in the 12 months prior to the survey, a slight increase since 2003.[6]

1.3.3 Social determinants of the SRH of young people

Social norms in relation to sexual behaviour

Norms in the general society, community of residence and within the family can influence a young person's willingness and ability to reduce their sexual risk. In Tanzania, as in many other parts of the world, sexual behaviour still largely remains a taboo subject. In Tanzania, early attempts to teach young people about the use of condoms were met with resistance.[130] Recent data from the 2007/8 THMIS suggest that there now seems to be reasonable, but not universal, acceptance of ASRH education for young people with 56% of rural women and 67% of rural men considering it acceptable for children aged 12-14 years to be taught about using a condom to avoid AIDS.[6]

In Tanzanian society, women are of lower status and both economic and gender roles empower men.[104] Expectations for sexual behaviour often differ for males and females. A recent systematic review of qualitative research on sexual behaviour among young people by Marston and colleagues, found a number of themes that were common in many countries and among different cultures. One finding was that sexual relations were often negatively sanctioned for women but encouraged for males, with vaginal penetration often marking the transition from boyhood to manhood. Communication about sex was more difficult in the presence of these social expectations. For example, a woman may not want to say 'Yes' to sex in case she seems too forward, however, this then means that there can be difficulty in the interpretation of 'No'.[131] Marriage and childbearing are often held in high regard and failure to have children or a failed relationship can damage a woman's reputation.[131, 132] Qualitative research carried out in rural areas of Mwanza Region in the late 1990s found contradictory sexual norms and expectations. On the one hand, community norms approved of school pupil abstinence, female sexual "respectability", and taboos around discussion of sex. On the other hand, a number of widely held expectations existed: sexual activity is inevitable unless prevented, sex is a female economic resource, restrictions on sexual activity were relaxed at festivals and social gatherings, and young men's esteem and prestige grows through sexual experience. The result of these contradictory norms was that sexual activity, especially among young, unmarried people, was highly secretive and often opportunistic. Men often have more decision-making power within a sexual partnership than young women.[104] It was not uncommon for a young girl to have pressure from parents to have a sexual relationship with an older man in order to get money and household necessities as well as to marry and bring in bridewealth.[104, 133] However, young women are not always coerced into relationships with older or wealthier men and often choose such relationships as they have limited other options to feed and clothe themselves and to obtain luxury items; to achieve an adult identity; and/or to enhance esteem among their peers.[86, 104, 106, 134]

More recently, qualitative research has found that key factors influencing young people's SRH include low parental monitoring, low parental provision, low levels of SRH (both youth and parents) and beliefs about ASRH.[106] At the community level there was a lack of community-based communication channels for ASRH information, lack of collective efficacy, poor communication between parents and schools/committees, contradictory social norms regarding ASRH, lack of coordination from village authorities, risky leisure and recreational activities, poverty, and unequal power and gender relations.[106, 135]

Socioeconomic status

The relationship between HIV infection and socioeconomic status is complex,[136, 137] and risk of HIV may be associated with economic and gender inequalities as opposed to poverty *per se*.[138] In Tanzania, HIV does not demonstrate the same pattern of association with poverty as with most other diseases and those who are wealthier, have, at least in the past, been more likely to be HIV positive.[111, 139] Analysis of data on a nationally representative sample of adults in 2003 in Tanzania found HIV prevalence to be associated with higher socioeconomic status for both males and females. Within each sex, those with the highest odds of infection were unemployed men and professional women.[140] A more recent analysis of data from Tanzania revealed that between 2003/4 and 2007/8 HIV prevalence had decreased among men and women in the highest wealth quintiles but increased among women in the lowest wealth quintiles.[137]

Education

In Tanzania, as in other countries in SSA, a changing pattern between HIV prevalence and education levels has been observed.[141] Up until 2004, those with a higher level of education were more likely to be infected with HIV.[111] Data from the most recent population level survey suggests that risk is now increasing among those with no education and decreasing among those with secondary level education or higher.[6]

Migration

Migration and mobility have been postulated as risk factors for acquisition of HIV and STIs, but migrants have not always been found to be at higher risk than non-migrants.[142] The risk is thought to be primarily due to an increase in the number of partners as opposed to connection with high risk populations.[143] Some occupations are associated with higher mobility such as petty trade, fishing etc. Also, young people often migrate to earn money to support the family when a parent dies or a marriage breaks up. In Tanzania, women who travelled away from home five or more times in the previous 12 months were twice as likely to be HIV-positive (12%) as those who did not travel. The total time spent away was not an indicator of HIV risk.[6] Data from Kisesa (Mwanza) and Manicaland (Zimbabwe) demographic and HIV surveillance sites suggest that migration is associated with HIV risk and that rural to rural migration rather than urban to rural migration might make the greatest contribution to the continuing epidemic in rural areas.[144] Analysis of data on couples in Kisesa found that, among men, short term mobility was associated with the highest risk. Interestingly, in couples where one partner was long-term mobile, both partners reported higher risk behaviours.[145]

Family situation

A review of the literature for developing countries found that living with both parents and family stability/connection were associated with delayed sexual debut, increased use of condoms and reduction in pregnancy among young females.[146] Another review found that greater family support and parental monitoring, positive parental attitudes and greater parental communication were all associated with reduced risk behaviour.[147]

The number of orphans and vulnerable children (OVC) due to the HIV/AIDS epidemic in SSA continues to rise.[148]A number of studies focusing specifically on orphans have found that orphaned and vulnerable females had increased rates of HIV, STIs and teenage pregnancies.[149, 150]

Domestic violence

Domestic violence is accepted by many in Tanzania and is often associated with increased risk of STIs and unplanned pregnancies. Data from Mwanza Region, showed that 48% of females aged 15-24 years thought that wife-beating was justified under certain conditions such as if wife goes out without telling her husband, a wife neglects the children, or a wife argues with her husband.[99] However in contrast, there seems to be broad acceptance of a woman's right to protect herself from STIs within her relationship, as 87% of young people aged 15-24 years thought that a woman was justified in refusing sex or asking her husband to use a condom if she believed that her husband had an STI.[6]

Stigma and discrimination

Stigma and discrimination towards people living with HIV and AIDS is widespread and can deter people from accessing prevention, testing and treatment services.[6] The 2007/8 THMIS revealed that only just over half of males and females aged 15-24 years would be willing to buy fresh vegetables from a shopkeeper who had HIV. Half of young males and females said that they would want to keep it a secret if a family member got infected with HIV. The majority were, however, willing to care for a family member with HIV in the family home.[6]

1.3.4 Behavioural determinants of ASRH

Knowledge

It is believed that good knowledge of the causes and consequences of infection with HIV/STIs is necessary but not always sufficient to reduce risky sexual behaviour and increase uptake of STI treatment.[14, 151] Similarly, good knowledge of conception and family planning is thought to be necessary for a reduction in unplanned pregnancies and an increased uptake of reproductive health services. The 1999 Tanzanian DHS found only 22% of rural women (15-24 yrs) had 'Comprehensive knowledge of AIDS' (knowing that consistent use of condoms and having just one uninfected faithful partner can reduce the chances of getting HIV, knowing that a healthy person can have HIV and rejecting the two most common misconceptions about HIV transmission and prevention).[152] The 2003/4 THIS found this proportion to have increased to 39%.[107] Knowledge in the recent 2007/8 THMIS did not show any signs of improvement with only 39% of women and 42% of men aged 15-24 years having comprehensive knowledge of HIV. Knowledge was higher in urban areas, among those in the highest wealth quintiles and among those with a higher level of education. Knowledge was highest among never-married, sexually active young people. In Mwanza Region, comprehensive knowledge of AIDS was lower than the national averages among both young females (29%) and males (35%) and only 46% of young females and 75% of young males knew a source of condoms.[6] Knowledge of PMTCT services was also poor and while, nationally, 80% of women knew that HIV could be transmitted from mother to child, only 53% of women knew that the risk of transmission could be reduced by taking special drugs during pregnancy.[6]

Psychosocial constructs

Perceived self-efficacy is one of the main constructs in Social Learning Theory, a social psychological theory which is often used as a basis for behaviour change interventions.[153] In the context of ASRH, self-efficacy to use condoms or to refuse sex is often measured. DiClemente and colleagues, in their review of the antecedents to sexual behaviour among adolescents found some evidence that higher self-efficacy is associated with reduced reported risk behaviour and lower rates of STIs.[147]

Increased perceived risk of infection and increased personal control have been found to be associated with decreased reported risk behaviour and increased reported use of condoms,[146] whereas depression, increased impulsivity and sensation-seeking and lower self-esteem have all been found to be associated with increased risk behaviour and higher rates of STIs among adolescents.[147]

Early sexual debut

Early sexual debut has been found to be associated with increased risk of HIV [154] and teenage pregnancies.[155] Recent data from Tanzania show that 11% of young women and 10% of young men aged 15-24 years reported that they had had sex before the age of 15 years. Over half the women and 43% of the men aged 18-24 years reported that they had had sex before the age of 18 years. There was little change between 2003 and 2007 in the proportion of those reporting sex before the age of 15yrs or before 18 yrs.[6] Early sexual debut was slightly higher than the national average in Mwanza Region with 12% of females aged 15-24 years reporting sex by the age of 15 yrs and 67% of those aged 18-24 years reporting sex by the age of 18 years.[6] A strong negative relationship between age at first sex and education level was observed. Young women from poorer households were more likely to report having had sex before the age of 15 years.

There does, however, seem to be a general increase in reported abstinence, and between 1999 and 2007 the proportion of never-married young people who reported never having had sex increased by 35% among men and 8% among women. Increases in reported abstinence were especially evident among those living in urban areas and those with secondary school level education or higher. In contrast, the proportion of young people who were sexually active increased during this time for young males living in rural areas and young males and females with no education.[111]

Partners and partnerships

Young people have sex for a variety of reasons, including for their own pleasure, the pleasure of their partner, to strengthen a relationship, peer pressure, to obtain money or gifts, to avoid violence or to become pregnant.[131, 156] The number and type of sexual partners and partnerships that a young person has can greatly influence their risk of acquiring a STI including HIV. Marston and colleagues found that sexual partners had an important influence on sexual behaviour and the adoption of safer sexual practices. Young people often assessed their potential sexual partners as 'clean' or 'unclean'.[131] A review of the literature on the antecedents to sexual risk behaviour and STI/HIV acquisition found that a longer length of relationship and older age of partner were associated with an increase in risk behaviour.[147]

Early marriage has been associated with increased risk of HIV in SSA due to increased coital activity, decreased condom use and because it is very difficult for a married girl to abstain from sex. There is also an increased risk of HIV during marriage due to the potential for early exposure to a newly infected partner.[87, 88] In Tanzania, early marriage was found to be associated with subsequent marital instability and polygamy.[157] Young married women can also have more difficulty accessing health services as they rely on husbands and/or mothers-in-law for access to care.[158] Globally, there has been a shift towards later age at first marriage [78, 159] resulting in a greater period of pre-marital sexual activity. Late marriage can also be associated with increased risk of HIV infection due to a longer period of pre-marital sexual activity.[160] Analysis of ANC data from Mwanza found that the odds of HIV infection increased by 10% for every year spent sexually active before marriage. The odds of infection also doubled in women who had more than two marriages.[115] In the 2007/8 THMIS, the HIV prevalence among females aged 15-24 years varied according to marital status with prevalences of 2.3%, 5.6% and 10.3% for women who were never married but sexually active, married, and divorced/separated/widowed, respectively. Among males the prevalences were 0.9% for never married but sexually active, 1.1% for married and 1.8% for those who were divorced/separated/widowed.[6]

Having multiple sexual partners is associated with higher risk of HIV and other STIs. Risk increases when these partners are 'higher-risk' i.e. non-marital and non-cohabiting partners. In 2007 in Tanzania, among young people who reported sex in the previous 12 months, 4% of women and 22% of men reported at least 2 partners in the previous 12 months and 32% of women and 80% of men reported sex with a higher risk partner. HIV prevalence was higher for both young males and young females who reported greater than one non-marital, non-cohabiting partner in the previous 12 months.[6] Between 2003 and 2007 a reduction in reported number of sexual partners was seen for both and men and women, though changes were most visible for women.[111] Comparison of data from ANC surveys carried out in 2002 and 2006 in Mwanza also suggest that the number of sexual partners has decreased among women.[115]

High rate of partner turnover and/or having concurrent partners (more than one partner at a time) both increase the chance of being exposed to an infected individual during the acute infection.[161] The risks associated with concurrency are complex. A hierarchy of risk in sexual partnerships has been proposed with lowest risk in long-term mutually monogamous partnerships and highest risk in regular partnerships, with one or both partners having regular concurrent partners and when this pattern is common in the wider society.[161]

The characteristics of the sexual partner can also increase risk of HIV infection. Young women often have sex with men who are much older and such age-disparate sex leads to increased risk as older men are more likely to be infected than younger men and women may have less power to insist on condom use with them.[162] In the 2007/8 THMIS, 8% of women aged 15-19 years reported that they had had non-marital sex in the 12 months preceding the survey with a man who was 10 years or more older than themselves.[6] Antenatal surveys in Mwanza Region found that having a partner less than 10 years older was associated with lower odds of infection than having a partner at least 10 years older.[114] In Tanzania, data from the 2004/5 DHS showed that 9.5% of males aged 15-19 years reported having paid for sex, with 46% reporting having used a condom.[103] In 2007, the proportion reporting paid sex decreased to 5% and condom use increased to 56%.[6]

Condom use

Condoms are an effective method of preventing acquisition and transmission of HIV and other STIs and an effective form of contraception when used correctly and consistently.[163] Unfortunately, the use of condoms is frequently stigmatised. If a young person requests the use of condoms this is often taken to mean that they do not trust their partner or that they themselves are diseased. Carrying or buying condoms can suggest sexual experience which can be negative for women but sometimes positive for men.[131, 164] A partner's negative attitude to condoms/contraceptives has been associated with decreased use.[146]

Young people can engage in unprotected sex to prove fertility, because they have not considered using contraception, they fear possible side-effects, they are misinformed about the risk of pregnancy/STIs, or because they are more concerned about the safety of condoms than the safety of unintended pregnancy.[132] Young people often report use of condoms only with 'risky' partners or only early in sexual relationships.[131] Condoms are often used for pregnancy prevention more than for prevention of STIs.[89, 131] Reported use of condoms at last sex increased from 19% to 28% in 19 African countries between 1993 and 2001[89]and the level of use seems to be continuing to increase in many countries.[78] In 1999 in Tanzania, only 12% of rural females (15-24 yrs) and 23% of rural males (15-24 yrs) reported use of a condom the last time they had sex with a non-regular partner.[152] The 2007/8 THMIS found these figures had risen to 41% and 43% in rural females and males (15-24 yrs), respectively.[6] Condom use in non-marital relationships was higher for those living in urban areas, among those with higher education and among those in higher wealth quintiles.[6]

Access to and use of male condoms is increasing gradually in Tanzania. According to the recent UNGASS progress report, 10% of nightclubs, 94% of bars and 80% of beer groceries stock condoms. The PSI brand Salama represent 74% of the condoms available.[165] 94% of health facilities stock male condoms.[108] Condom use seems to be on the increase but many young people still do not know where to get a condom.[6]

Use of contraceptives

A systematic review of qualitative research on ASRH found that women, not men are seen as responsible for pregnancy prevention.[131] However, adolescent girls often have greater difficulty in obtaining modern contraceptives as they often have insufficient knowledge, limited access to services and sometimes are discouraged by health personnel because of their young age.[11] There is evidence that communication with a partner is associated with increased contraceptive use.[146] Use of modern contraceptives is relatively low in Tanzania with pills and injectables the most widely used forms of modern contraception. The national average for use of any modern method of family planning by married women is 20%; however, this figure is only 9% for Mwanza Region.[108]

HIV testing

Knowing ones HIV status should lead to earlier treatment and may influence decisions regarding sexual behaviour. Globally, there has been a push to increase access to VCT. In 2007 in Tanzania, 37% of women and 27% of men reported having had had a HIV test and received the results at some point.[6] The uptake of testing increased between the 2003 and 2007 surveys and was highest among those in urban areas and those who were wealthiest and better educated.[6] Among those aged 15-24 years who had had sex in the previous 12 months, 23% of females and 15% of males in the Lake Zone (contains Mwanza) reported having received a HIV test result in the previous 12 months.[6]

1.3.5 Biological determinants of ASRH

The main biological determinants of adverse ASRH outcomes are young age, circumcision and the presence of other STIs. Girls younger than 15 years as well as later-maturing older adolescents have immature reproductive and immune systems which puts them at increased risk of acquisition of STIs and HIV and increased problems during childbirth.[12, 18] Circumcision has been shown to be protective against acquisition of HIV for men. In Tanzania in 2007, HIV prevalence was 3.7% among circumcised males and 6.4% for non-circumcised males.[6] Infection with an STI can put a young person at increased risk of infection with HIV and adverse reproductive health outcomes. Some STIs can be treated effectively but access to effective STI treatment and family planning services can be limited,[166] especially for unmarried persons.[167] HIV infection has additional social stigmas that can deter young people from seeking help. Many STIs are asymptomatic, especially in females, and go untreated. Symptomatic STIs can also go untreated because young people don't know the difference between normal and abnormal conditions or can be embarrassed or may feel guilty to seek treatment.

1.3.6 ASRH initiatives in Tanzania

Key government strategies and policies

In 1990 the Tanzanian government declared HIV a national disaster.[168] Early in the epidemic (1985-2002), AIDS control activities were coordinated by the National AIDS Control Programme of the Ministry of Health. More recently the Tanzanian government have put in place policies and programmes in the areas of HIV/AIDS treatment, care and prevention according to the Three Ones principle. The Three Ones principle involves having one HIV & AIDS coordinating body, one national multi-sectoral strategic framework and one monitoring and evaluation framework. In 2001, the Tanzanian Commission for AIDS (TACAIDS) was set up as the one HIV & AIDS coordinating body with the role of providing strategic leadership and coordination of the multisectoral response. TACAIDS are also tasked with monitoring and evaluation, research, resource mobilisation and advocacy.[6] The response in Tanzania has been regionalised and multisectoral AIDS committees have been set up at the District, Ward and Village levels. [165] The total budget for HIV/AIDS in 2007/8 was 596 billion Tanzanian shillings (£283.5 million at exchange rate on 9th Feb 2010), 95% of which was received from development partners. It is estimated that HIV/AIDS donations represent a third of all aid to Tanzania.[165]

The Tanzanian response is guided by the National HIV/AIDS Policy (2001) and the National Multisectoral Strategic Framework. The National HIV/AIDS Policy outlines the government's commitment to tackling the HIV epidemic and includes the recommendation that 'Reproductive and sexual health should be incorporated in the school curricula'.[169] In the early 1990's, the National AIDS Control Programme was active in Mwanza and established a number of interventions to prevent the transmission of HIV, focusing mainly on condom promotion and health education aimed at modifying risk behaviour.[102] Some of the challenges faced by the response in Tanzania, as outlined in the National Adolescent Health and Development Strategy, included:

- Insufficient and ineffective Information, Education and Communication (IEC) and behaviour change communication (BCC) material
- Issues of stigma are not being addressed sufficiently
- Existing health services are not adolescent-friendly and many are inaccessible to young people

Despite government commitment, improved national policies and increases in spending on HIV/AIDS, the recent UNGASS progress report showed that there is still more progress to be made. [6] The report noted that the Tanzanian IEC campaigns had used TV, radio, newspapers, posters and billboards and had focused more on condoms than abstinence and being faithful.[165] A weak link between IEC and health services was noted.[165] The authors reported as a major challenge: *'Existing IEC/BCC interventions have minimum impact on the desired behavior change among the adolescents'* (page 33)[165]

Pre-marital VCT is common and emphasised in all religions in Tanzania.[165] The Tanzanian President, Kikwete, launched a national HIV testing campaign in July 2007 which included the opening of new testing sites and the use of media and posters. At the end of 2007, 3.2 million people, 78% of the target number and 13% of the adult population (15 yr+), had been tested.[165]

PMTCT started being offered in 2002 and the proportion of HIV-infected pregnant women receiving this treatment had risen from 9% in 2005 to 28% in 2007. However, the numbers accessing this service remain low and there is poor integration of PMTCT into existing community health services.[165] In 2004, the government introduced the National Care and Treatment Plan[168] and by the end of 2007 there were approximately 97,000 people on treatment.[165]

Sexual and Reproductive Health Education

The Ministry of Education and Vocational Training (MoE)[a] is responsible for the provision of education in Tanzanian schools. In the early 1990s, the MoE began the process of developing a Family Life Education curriculum for primary schools that included a focus on AIDS prevention. The national policy at the time allowed the integration of information on reproductive health matters into the curriculum but information on condoms was only provided in secondary schools.[170] In 1993 the MoE in Tanzania initiated a school HIV/AIDS programme and in 1996 a new suite of primary syllabi were developed to include SRH topics in science and guidelines for implementing HIV/AIDS programmes in schools were developed. The topics had a strong bias towards the more biomedical aspects of SRH.[171]

[a] This Ministry was formally known as the Ministry of Education and Culture. For simplicity I will refer to it in this thesis as the Ministry of Education (MoE).

In 2001, the MoE published an information manual on sexual and reproductive health and family life education for schools and teacher training colleges.[172] The following year, the MoE sent a circular which called for guidance and counselling services to be set up in schools and the formation of an AIDS Education Committee (MOEC circular No 11, 2002). The implementation of these recommendations was poor, however, even where teachers were elected for this role, few had been given any training or guidance and even fewer had been active (D Ross, personal communication).

In the first National Multisectoral Strategic Framework (2003-2007) school-based prevention for primary and secondary level was strategic area 11. The policy highlights that *'appropriate curricula are still missing as well as capacities by teachers to guide the young people'*[173] A UN-led survey of the coverage of essential HIV/AIDS prevention services estimated that in 2003 only 19% (910,000) of the 4,787,000 primary school students in Tanzania and 5% (11,000) of 227,000 secondary school students received HIV/AIDS education. These figures for primary school coverage were low compared to neighbouring Kenya (60%) and Uganda (90%).[174] In their report they did not attempt to measure the quality of the education provided.

In 2005 a new science syllabus was released which allowed for the demonstration for proper condom use in standard 6 of primary school and again within family planning in standard 7 but removed STIs as a standalone topic. Further, another subject was added, namely personality, development and sports which has a strong focus on life skills and 66% of the subject is amenable to addressing psychosocial factors that underpin SRH. The new science syllabus is being phased into standards 5, 6 and 7 between 2009 and 2011.[171]

In 2008, an assessment of Tanzania's progress toward the UNGASS goals found that the situation had greatly improved and that 75% of schools now had provided life skills-based HIV education in the previous academic year.[165]

1.4 The MEMA kwa Vijana Adolescent Sexual and Reproductive Health Intervention

1.4.1 Background

A number of studies in the early 1990s reported high prevalence of STIs, teenage pregnancies and high risk sexual behaviour among young people in Mwanza Region. [67, 102, 175] Two separate surveys carried out in rural Mwanza in 1990 and 1991 found the HIV prevalence among 15-24 year olds to be 3.6% and 3.9% among females and 0.6% and 1.4% among males.[102, 176] In 1996, the African Medical & Research Foundation (AMREF), an East African non-governmental organisation, in collaboration with the National Institute for Medical Research (NIMR) and the London School of Hygiene & Tropical Medicine (LSHTM), carried out a cross-sectional survey among a random sample of 892 school-going adolescents in the district capitals of Mwanza Region.[156] The results showed that 80% of primary school boys and 68% of primary school girls reported that they were already sexually active with the median age at first sexual intercourse of 15 years for both boys and girls. Among the 209 primary school girls who reported having sex, 28% reported having forced sex and 14% had been pregnant at some time. 33% of primary school boys and 29% of primary school girls reported ever having had an STI.[156] In 1997/8, a household survey in Mwanza among 9445 15-19 year olds in 23 rural communities found an overall HIV prevalence of 2.4% in females and 0.6% in males.[10] The results of this survey revealed the rapid rise in the prevalence of both HIV and *Chlamydia trachomatis* (CT) between the ages of 15 and 19 years ***(Table 1.1)***. The results of these two surveys emphasised the vulnerability of school-going adolescents in Mwanza Region and the need for an ASRH programme.

Table 1.1: Prevalence of HIV-1 and *Chlamydia trachomatis* (CT) in adolescents in rural Mwanza by age and sex, 1997/8[10]

	HIV-1		CT	
Age (yrs)	Females % (95% CI*)	Males % (95% CI*)	Females %(95% CI*)	Males %(95% CI*)
15	0.9 (0.4 – 1.6)	0.2 (0.0 – 0.6)	1.8 (1.1 – 2.8)	0.4 (0.1 – 1.0)
16	1.2 (0.6 – 2.1)	0.3 (0.1 – 1.0)	2.3 (1.4 – 3.5)	0.7 (0.2 – 1.4)
17	2.2 (1.3 – 3.6)	0.8 (0.3 – 1.7)	1.7 (0.9 – 2.9)	0.6 (0.2 – 1.5)
18	3.3 (2.2 – 4.6)	0.6 (0.2 – 1.3)	3.0 (2.0 – 4.2)	1.8 (1.0 – 2.8)
19	4.6 (3.4 – 6.1)	1.0 (0.5 - 1.9)	3.2 (2.2 – 4.5)	1.7 (1.0 - 2.7)
15-19	2.4 (2.0 – 2.9)	0.6 (0.4 – 0.8)	2.4 (2.0 – 2.9)	1.0 (0.8 – 1.4)

*Exact binomial confidence intervals

At the time, there were few appropriate mechanisms in place for young people to learn about how to protect themselves from adverse reproductive health outcomes.[156] The church-run

VEMA project held discussions and other activities with young people who attended Catholic churches in a few divisions of Sengerema District, Mwanza. In addition, a number of NGOs were involved in delivering AIDS education in schools (MEUSTA in Tanga, GTZ in Mbeya, TANESA in Magu District, Mwanza, SPW in Iringa, CCBRT in Dar es Salaam) but they were mostly small-scale projects and had not been rigorously evaluated. Challenges to the introduction of quality SRH education into Tanzanian primary schools included minimal funding, poor teacher training, sexual harassment of students by teachers and little involvement by parents and youth.[28] Inherent conservatism existed within the Tanzanian education system, which constrained the design of ASRH interventions and had the potential to reduce coverage and delivery.[177]

It was against this backdrop of poor sexual and reproductive health and an unmet need for ASRH education in Tanzania in the late 1990s that the MEMA kwa Vijana intervention was developed. The MkV1 intervention was developed and evaluated in Mwanza Region for a number of reasons: good background information including HIV prevalence data was available, the communities were distinct and well-separated allowing them to be selected and randomised easily, out-migration was less of a problem in the rural area and there had been few other initiatives specifically targeting adolescent sexual health.

1.4.2 Development of the Intervention

MEMA kwa Vijana (MkV1) started on the 1st Oct 1997. The programme name in Swahili is *Mpango wa Elimu na Maadili ya Afya (MEMA) kwa Vijana*, which roughly translates as 'Programme of education for health-related behaviour for young people'. *Mema* means "good things" and the short form of the project name indicates "Good things for young people".[178]

The MEMA kwa Vijana programme had three objectives:

1. To develop and implement a sexual health intervention programme for adolescents in Mwanza.[179]
2. To measure the intervention process and the impact of the intervention on biomedical and behavioural outcomes.[178]
3. To evaluate the cost-effectiveness and feasibility of the programme.[180]

The in-school component of the MkV1 intervention was proposed as a means of providing SRH education in Tanzanian schools and built on previous work on ASRH carried out by the African non-governmental organisation (NGO), AMREF, and others. The in-school component of the intervention was designed based on the education curriculum of the Tanzanian MoE and the policies of the Tanzanian Ministry of Health and the National AIDS Control Programme at that time (1997/8). Development of the intervention began in 1997 and involved reviews of local and international best practice materials and strategies, reviewing evaluations of local programmes (the AMREF pilot programme in four District capitals in Mwanza Region; Kuleana secondary school education programme; TANESA Primary School Peer Education Programme; and the MEUSTA (Tanga), GTZ (Mbeya) and SPW (Iringa) programmes) and pre-testing of the programme in three schools. A modified programme was then pilot-tested in a further six schools in order to assess feasibility, acceptability, appropriateness, and the impact of the intervention on student knowledge using observation, questionnaires, and group discussions.[179, 181]

The key behavioural objectives of the intervention were to:

(i) Delay sexual debut among youth who were not yet sexually active
(ii) Reduce the number of sexual partners among those already sexually active
(iii) Promote the correct and consistent use of condoms among those sexually active
(iv) Increase the uptake of STI and family planning services.

The curriculum was developed based on Social Learning Theory[105] and aimed to encourage behaviour change by addressing key cognitions:

- Providing basic knowledge of reproductive and sexual health
- Improving students' perceptions of their own risk and the perceived benefits of safer behaviours
- Improving students' perceived self-efficacy to perform safer behaviours
- Discussing perceived barriers to safer behaviours and improving perceived social support for the safer behaviours
- Providing students with sexual negotiation skills
- Discussing and challenging commonly held gender stereotypes e.g. the widely held belief that girls cannot refuse sex if they have received a gift, or if they are approached by a teacher or older member of the community.

Box 1.4: Topics covered during the MEMA kwa Vijana in-school teacher-led peer-assisted sessions (approximately 12 forty-minute sessions per school year)

Year 5
What is reproductive health and why is it important?
Leaving childhood: Puberty
What are HIV and AIDS?
The facts about AIDS
The facts about sexually transmitted diseases
Girls and Boys have equal abilities
Misconceptions about sex
Refusing temptations
Saying No to sex
Sexually Transmitted Diseases: Going to the clinic
Year 6
Review of last years' learning
How HIV infection causes AIDS
How Sexually Transmitted Diseases are spread
The relationship between HIV and Sexually Transmitted Diseases
Reproductive organs and their functions
Pregnancy and menstruation
Respecting other people's decisions
Recognising and avoiding temptations
Protecting yourselves: What are condoms?
Revision
Year 7
Review of previous years' learning
How to avoid HIV infection and AIDS
Sexually Transmitted Diseases and their consequences
Making good decisions
Practising saying 'No'
Being faithful
Achieving your future expectations
Planning for your future
Protecting yourself: Correct use of condoms & the truth about condoms
Revision

The topics covered during the in-school teacher-led peer-assisted sessions are shown in ***Box 1.4***. One of the core objectives of the intervention was to teach young people to resist harmful pressure. This included the following lessons: refusing temptations, saying 'No' to sex, girls and boys have equal abilities.[179] A number of key environmental influences, identified during preparatory research were also addressed:[179] (i) community resistance to the discussion of ASRH[104] (ii) the importance of sex as a source of income for girls[182](iii) the widespread stigmatisation of condom use;[183](iv) limited condom availability in rural areas;[184]and (v) young people's fear of censure and exposure by health workers if attending with an STI or family planning request.[185]

During the period 1999-2002 the MEMA kwa Vijana intervention, known as MEMA kwa Vijana Phase 1 or MkV1 during this period, had four major components which were designed to be mutually reinforcing and to act synergistically on ASRH behaviours:[179, 181, 186, 187]

(i)**In-school sexual and reproductive health education** in standards 5, 6 and 7 of primary schools through a teacher-led, peer-assisted programme.

The programme was designed to be run over a 3 year period with 10-15 40-minute lessons each year. Teachers were trained (5 days/year) to deliver the series of participatory lessons that included the use of drama, stories, role-play, games and internalisation exercises. Teachers were provided with a teacher's classbook and flipcart and were assisted by trained peer educators who had been elected by classmates and who participated in the role-plays and drama serial. The teacher's classbooks included detailed learning objectives and lesson plans for each school lesson. For Years 1 and 2 of the intervention, the Class Peer Educators (CPEs) were trained to do the dramas by older youth from the community known as Trainers of Peers. For Year 3, this role was taken over by the teachers. The curriculum includes the key characteristics that had been found to be important for effective in-school programmes in terms of behaviour change in previous studies.[188]

(ii) **Youth-friendly sexual and reproductive health services (YFHS)**, through training of the health workers in government health facilities on how to provide attractive and effective sexual & reproductive health services for youth.

In each government health facility 2-4 health workers were trained for one week in the provision of YFHS (Feb-Mar 1999). The participatory training focused on empathy, confidentiality and the rights of young people to access health services. They were supervised quarterly by supervisors who had been specifically trained in YFHS supervision. Both supervisors and health workers received a 3-day refresher training course in Jun-Jul 2000. Health workers made visits to local primary schools and visits of students and their class teachers to clinics were arranged. Facilities in both the intervention and comparison communities offered family planning services and improved case management of STIs and drugs and other supplies were ensured during the trial (April 1999-Dec 2001).

(iii) **Community-based condom promotion and distribution, for and by youth.**

Young people, 4-5 per village, were elected by other youth in the community and trained (2 days) in the social marketing of condoms. This component of the intervention was started following a needs assessment at the end of the first year which suggested that existing sources (health units and village shops) were not popular with young people. They reported concerns about confidentiality that might deter them from using either of the existing sources, and that the condom purchase price might be prohibitive for most young people. During the second year of the trial (early 2000), in collaboration with Population Services International (PSI), young people were trained to promote and supply condoms to young people at an affordable price (US$0.08 for a pack of 3 condoms).

(iv) **Community-wide activities to create a supportive environment** for the adolescent sexual health interventions and to begin to address socio-cultural barriers to adolescent behaviour change.

In each intervention community, in late 1998, there was a one-week initial mobilisation of parents, religious leaders, local government authorities and women's groups. Advisory committees, elected by community stakeholders, monitored activities at the local level and elected community peer educators (3 males and 3 females per community, also known as Trainer of Peers). In addition, the health workers, in collaboration with the ward advisory committee and the teachers, were encouraged to hold an annual youth health week and twice-yearly youth health days at the government health facilities. During youth health weeks there were competitions between primary schools (drama, story-telling, songs, football, netball, etc), clinic open days for youth, drama presentations, discussions, market meetings, and condom promotion activities. All these activities were attended by community youth and adults, and focussed on issues related to the SRH of adolescents. Carefully-selected videos related to SRH health topics were screened in the evenings after the other youth health week activities as well as during condom distributor supervision rounds and were open to all community members.

No practical or pictorial demonstrations of methods of condom use were permitted in primary schools.[179] Condoms were mentioned in the second and third years of the in-school intervention but not in the first year. During the youth health days, based at health units, young people had the opportunity to see condom demonstrations.

Following the start of the trial, the MkV1 intervention continued to be modified through an iterative process of formative evaluation.[181] In the first year of intervention implementation school years 5, 6 and 7 got the same teaching (Year 1 curriculum). Towards the end of the first year, demand in intervention communities led to the development, piloting and implementation of peer condom social marketing initiative (described above). In the second year of implementation a year 5 in-school curriculum was developed and years 6 and 7 got the same teaching (Year 2 curriculum). In the third year of implementation, separate prototype courses for years 5, 6 and 7 were used. In the fourth year, an almost final version of the intervention was implemented with a separate curriculum and set of teacher's guides for each of the three school years (5-7). This version was then subsequently edited, finalised, translated, back-translated and sent to Ben & Co. Publishers for printing.

1.4.3 Implementation and process evaluation

The intervention was implemented by AMREF and the Ministries of Health and of Education through existing government political, education and health systems, and was specifically designed to be sustainable and replicable in resource-constrained settings.[179] The average annual cost of the intervention was almost US$30,000 per community during the trial phase, including all start-up and capital costs. The cost per adolescent (aged 12-19 years) was estimated to be US$10 per year. If the programme was scaled up as part of a district-wide programme then the estimated cost/adolescent would decrease to US$7.30 in the first year and to US$1.20 in subsequent years.[180]

In addition to the main quantitative cohort evaluation survey with two follow-up surveys (described below), there were a number of other qualitative and process evaluations ***(Box 1.5)***.[178]

Box 1.5. MEMA kwa Vijana- 12 years of experience

MkV1	Intervention Development	1996-1998
	Intervention Implementation	1999-present
	Process Evaluation (HALIRA)	1999-2004
	Impact Evaluation within Cluster Randomised Trial -Baseline survey (1998) -Interim survey (2000) -3-year impact evaluation survey (2001/02)	1999-2002
	Bridging phase	2002-05
MkV2	Intervention scale-up and process evaluation (MkV2)	2004-08
	Formative research to expand community intervention (MkV2)	2004-10
MKV1FS	Long-term (9-year) impact evaluation within Cluster Randomised Trial (MkV1FS)	2007-08

The MRC-supported Health and Lifestyles Research Programme (HALIRA) ran from January 1999 to June 2004, collecting qualitative data on perceptions of the intervention and the sexual behaviour of the target group. This work had a specific focus on intervention process evaluation, sexual norms, condom use, exchange of sex for gifts or money and traditional beliefs related to sexual health. The following data were collected:

1. At annual **teacher** training, questionnaires were given to trainees before and after each training session and there were group discussions and interviews with select groups of teachers. Qualitative researchers also observed teacher training.
2. **Class Peer Educator (CPE)** training was observed by qualitative researchers. Focus group discussions and some follow-up interviews were held with a selected group of CPE and some pupils from 2 schools per district in late 1999.
3. **Quarterly supervision visits** to every intervention school and clinic involved observation of in-class sessions, clubs and clinic sessions and checks on exercise books to see which sessions had been taught.
4. **Quantitative cross-sectional process evaluation surveys** took place in late 1999 and late 2000. These quantitative surveys involved interviews at district, ward, health facility and school level, in both the intervention and control communities. Data were

collected on attitudes towards youth SRH problems, programme training, supervision and service provision.

5. Data on outpatient **attendance at health facilities**, attendance for STI symptoms and condom uptake were analysed prior to the start of the YFHS component (Jan 98- Mar 99) and during the intervention (Apr 99-Dec 01).[187]
6. At 18 health facilities, **'Simulated patient'** evaluation was used to assess the quality of intervention delivery.[185]
7. Three rounds (158 person-weeks) of **participant observation** with pupil participants in 4 intervention and 5 comparison community villages (99-02) with the bulk of the interviews taking place in 2 intervention and 2 comparison villages.[28]
8. Two rounds of **in-depth interviews** (204 interviews) with 72 cohort members from 36 different schools (1999-2000, 2002).
9. Thirty-eight **Focus group discussions** held with class peer educators, pupils or out-of-school young people in 3 villages on the following topics: 'Reasons why girls have sex', 'Pregnancy prevention and termination', 'Range of sexual acts' and 'STDs and condoms'.
10. Focus-group discussions (21) held with **community peer educators**.

There were also a number of external evaluations by national and international experts:

- Peer-educator training component (late 1998)[189]
- Peer education component (mid-1999 to mid 2000)[190]
- Teacher related activities[191, 192]

Other evaluation activities included the evaluation of the use of an assisted self-completed questionnaire in a sub-sample of the survey cohort,[133, 193] evaluation of community condom promotion and provision, and evaluation of the cost-effectiveness of the intervention from the providers' perspective.

The results of the process evaluation showed that the intervention was being delivered to a high standard and with high coverage.[186]

1.4.3.1 In-school education

Training

Observation of teacher and CPE training found that they were implemented with a high quality and consistency across the four districts. Most teachers reported that they were enthusiastic about the material and training and this enthusiasm was also observed during training. Teacher knowledge and reported attitudes improved considerably with initial training. The researchers observed challenges associated with the wide spectrum of teacher's abilities and risky sexual behaviours on the part of the teachers.[105] CPE training was successful and they were enthusiastic about songs and games. However, the relationship with trainers was like formal school teaching relationships and some CPE were confused by the skill-building exercises which were beyond their conceptual level.[105, 181]

Coverage

In the 2000 process evaluation survey, head teachers in all 11 surveyed intervention schools reported that lessons on reproductive health had taken place. Over 80% of sessions had been taught 2-3 months before the end of each school year during the trial. The authors noted that supervision and examination (in std 7) legitimised the subject and ensured quality and coverage.[194] During participant observation and group discussions, pupils in intervention schools consistently reported that they had participated in MkV1 lessons once a week for most of the school year.[105]

Fidelity

Supervision visits showed that most teachers taught the sessions well. Evidence from the teacher session report forms for the first year of the intervention suggest that the vast majority of teachers did not skip or change any part of the sessions.[105] The teaching on SRH and biology was good, however, many found the new teaching styles difficult.

CPE

Supervision visits showed most class peer educators were able to perform the brief dramas that were used as discussion starters; however, the ability of CPEs to communicate educational information outside the classroom seemed limited.[105] The minor incentives that peer-educators received such as meals during training, T-shirts, may have undermined status as 'peers' and hence their validity as role models or educators.[190] CPE were often thought of positively but sometimes negatively and there was gossip about CPE sexual behaviour.[105]

Link with health facilities

In a questionnaire survey in the second year of teacher training, 89% of the 106 teachers who had been taught in the first year said that health workers had visited their school to discuss MkV1 activities, and 92% said that students had been taken to visit the health facility.[179]

Impact

A qualitative study confirmed that the teaching was well received by most pupils and communities.[105] In the 1999 process evaluation survey the only notable knowledge or attitude difference between teachers in trial arms was that intervention teachers were more likely to report that respecting a young persons' confidentiality is important.[105] Pupils generally enjoyed the classes and the new teaching styles but some found the messages about abstinence too unrealistic and the threat of AIDS irrelevant for young people.[105] Also, some students felt that teachers and CPEs did not follow the behaviours that they were promoting. There seemed to be some confusion over whether condoms were allowed for young people.[105] The paucity of female teachers and girls' traditional inhibition in participating in mixed group discussions or drama meant that girls may have experienced the intervention differently to boys.[190]

1.4.3.2 Youth Friendly Health facilities

Overall, the investigators report increased awareness of STI services[179] and a high level of support for preserving the confidentiality of adolescents seeking STI treatment in the intervention communities.[195] A simulated patient study at the end of 2000 found that health workers in intervention communities were more respectful and empathic to youth than in comparison communities. However, privacy and discussion of condoms was still poor in both intervention and comparison health units.[185] Analysis of health facility attendance data showed that attendance increased in both arms over the trial period with attendance for STI symptoms by young males greater in the intervention communities. Few condoms were distributed in intervention health facilities but this number was greater than health facilities in comparison communities.[187]

1.4.3.3 Condom promotion and distribution

In total, over 57 500 condoms were sold by the youth condom promoters/distributors over the 2 year life-span of this component of the intervention.[186] Investigators reported an increased awareness of condom services in the intervention communities.[179] However, relatively low levels of condom sales were reported. By the end of the initial phase of the trial in 2001, only

1/3 of the condom promoters were still active, 1/3 had left and the remaining 1/3 were inactive. Furthermore, there were anecdotal reports that the condom promoters/distributors did not use condoms themselves. This component of the intervention was dropped in the middle of 2002 as it did not fully meet its goals, was thought not to be sufficiently cost-effective and because there was no mechanism for the government to continue it.

1.4.3.4 Community activities

In the communities, attitudes to the interventions varied considerably. In one community, a religious group disrupted the implementation of the programme by condemning the discussion of sexual matters in class and burning a project t-shirt. Following discussion with the group, the investigators were able to reverse the hostility.[181] In the process evaluation surveys, over two thirds of the interviewed community members thought STIs (including HIV/AIDS) to be a major health problem for adolescents. Less than 30% felt that girls in their community were able to refuse sex with an older man. The external evaluation of the peer-education component of the intervention found that many community members were still unaware of the MkV1 activities.[179, 196]. Video shows were well attended, however, investigators noted sub-optimal coverage of the community activities. For example, annual health weeks were only held in 7 of the 10 intervention communities in 2001 (4th Annual Report, unpublished). Parents, siblings and out-of-school friends and sexual partners had marginal exposure. Despite low levels of community involvement, the community activities were sufficient to gain parental permission for the participation of students in MkV1.[105]

1.4.3.5 Summary

Overall, the response was very positive to the intervention. SRH had been taught in all schools in the intervention and 84% of medical staff had been trained in youth-focused SRH services. There was a high level of support among the health workers for preserving the confidentiality of adolescents seeking STI treatment in the intervention communities.[195] Training courses were of high quality and consistent across the four project districts.[105]

The results of this process evaluation should be interpreted with caution given the potential for the following:

1. **Evaluation and reporting bias**

The MkV1 implementation team collected process data and may, therefore, have either judged it too harshly or too leniently. Furthermore, MkV1 teachers, health workers and peer-educators developed relationships with trainers and supervisors and this may have impacted on the way that they reported activities to them.

2. Evaluation as intervention

Evaluative group discussions with teachers may have motivated them to perform to levels that would not have been achieved otherwise.

1.4.4 Impact evaluation

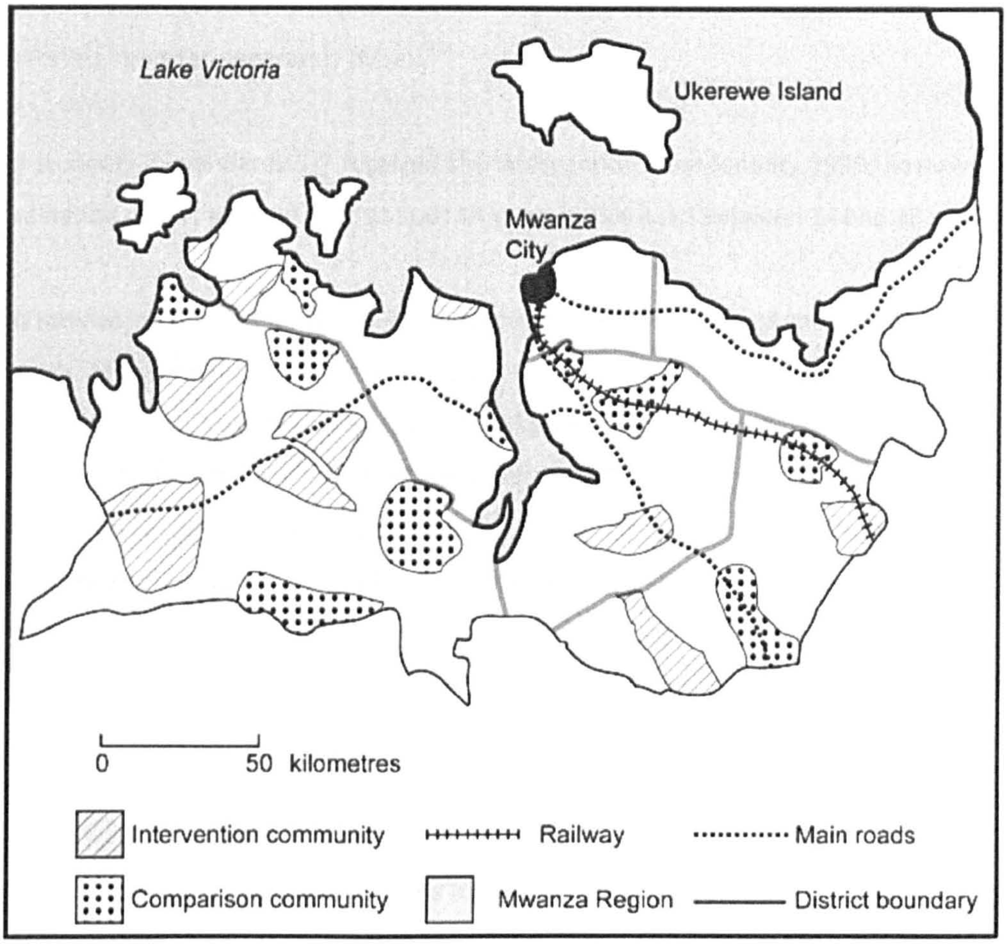
The MkV1 community randomised trial was funded by the European Commission (EC), Development Cooperation Ireland (DCI), and the UK Medical Research Council (MRC), with additional support from the UNAIDS and the UK Department for International Development (DFID).

Starting in January 1999, restricted randomisation was used to allocate the twenty trial communities to intervention or comparison arms.[178] Communities were grouped into three strata based on expected risk of HIV infection (6 low risk, 8 medium risk, 6 high risk). Expected HIV risk was based on HIV and Chlamydia prevalences in 15-19 yr olds[10] and on geographical characteristics of the communities (e.g. remote rural villages or close to towns, major roads or gold mining areas).[178] Within strata random allocation to the two study arms was restricted to ensure an adequate balance on prior HIV prevalence, prior Chlamydia prevalence and a balanced distribution of intervention and comparison communities in each administrative district. Each trial community was roughly equivalent to an administrative "ward", which is the smallest unit of local government. Communities were selected from the 23 communities surveyed in 1997/8 [10] and were scattered across Sengerema, Geita, Kwimba and Missungwi districts of Mwanza region ***(Figure 1.1)***. The trial communities were geographically distant from each other and intervention and comparison communities were usually separated by other non-trial 'buffer' communities.[197]

A total of 58 primary schools and 18 health facilities in the 10 intervention communities received the MkV1 intervention and 63 primary schools and 21 health facilities in the comparison communities did not receive the MkV1 intervention, but were included in the evaluation. If the intervention was shown to be effective, the plan was that every effort would be made to obtain the necessary resources to ensure that all comparison communities would receive the intervention as soon as possible after 2002. In practice, this was achieved in ~

2005. Government health facilities in comparison communities received a regular supply of STI drugs and other supplies.

Figure 1.1 Map of Mwanza Region, Tanzania, showing intervention and comparison communities



During the period from January 1999 to March 2002, the intervention's impact on HIV, other STIs, unintended pregnancies, reported attitudes and sexual behaviour, and on SRH knowledge was evaluated within a cohort of 9,645 adolescents ***(Box 1.5)***.

An **enrolment survey** was carried out between August and December 1998. Basic demographic information was collected on all pupils registered in standards 4-6 and who were present on the days of the survey. Those born before 1 January 1985 (aged approximately 14 years and over) were invited to participate in the survey. This date of birth restriction was used because the initial survey showed a low HIV prevalence in young people aged < 17 years it was decided that all cohort members should be >= 17 years at the end of cohort follow-up ***(Table 1.1)***.[10]

Enrolled students took part in a **baseline survey** which involved the collection of information on their knowledge, attitudes and reported behaviour and collection of a urine sample for testing for HIV, CT, NG and, for females, pregnancy.[198] Relatively low levels of HIV, CT, NG and pregnancy were present among pupils in years 4 to 6 of primary school. Differences in the baseline characteristics of males and females were seen and subsequent trial results were therefore reported separately by sex.[186]

All students in standards 5-7 received the intervention from January 1999; however, the trial evaluation cohort were all aged at least 14 years (>95% aged between 14 and 18 years).

An **interim survey** was carried out from February to June 2000, 18 months after the baseline survey. At the interim survey an additional ~400 young people were recruited into the cohort. These additional young people had been eligible for recruitment at baseline but had been missing on the day the team visited their school. All survey participants completed a questionnaire (face-to-face) and provided blood spot and urine samples. In addition, a subsample completed an assisted self-completed questionnaire.

A **3-year follow-up survey** was took place between October 2001 and April 2002. During this survey, a number of additional steps were taken to trace cohort members not presenting to the study team and hence to maximise follow-up:

(i) All communities were revisited for a second time towards the end of the survey period (March- April 2002).
(ii) Up to three visits were made to the homes of cohort members at each of the two periods when the survey team was in their community.
(iii) An attempt was made to trace cohort members reported to have moved within the same ward or within 30 minutes drive of the ward boundary.
(iv) In April 2002, a survey team visited major migration points in Mwanza Region and neighbouring regions in an attempt to trace cohort members who had been reported to have moved to these locations.

The primary outcomes during Phase 1 of the trial were HIV incidence (seroconversion among cohort members who were HIV-negative at enrolment, Ag/Ab ELISA), and seroprevalence of HSV2 at second follow up (2001/2). Secondary outcomes included prevalence of syphilis seropositivity (by TPPA), NG, CT and (in women only) *Trichomonas vaginalis* (TV) by PCR.[186]

Pregnancy was measured as prevalence at the 2001/2 survey using a IPAS urine dipstick and as reported incidence during follow-up. Knowledge and attitudes regarding sexual health, and reported sexual behaviour including age of sexual debut, number of sexual partners and use of condoms were recorded by means of an interviewer-administered structured questionnaire. This was the first randomised controlled trial anywhere in the world that measured biological outcomes to assess the effectiveness of an ASRH intervention in preventing HIV and other STIs. In 2001/2, 73% of the 9645 eligible cohort members were seen with higher follow-up rates among males and younger participants of both sexes.[186] The results of the 3-year evaluation showed an improvement in knowledge, reported attitudes and behaviour in the cohort members in the comparison communities. However, the MkV1 intervention had led to a significantly greater improvement in knowledge, reported attitudes and some, but not all, reported behavioural outcomes, especially among males in the intervention communities. There was a trend towards greater effect in those receiving all three years of intervention. Improvements in knowledge were greater in unmarried compared to married young people.[186] The results of the evaluation of biological outcomes were inconclusive, at least partly because, by that time, the trial lacked the statistical power to detect effects of public health importance on HIV and some of the other STIs measured. There were only 5 HIV seroconversions in males and 40 in females, in whom the adjusted rate ratio was 0.75 (95% CI: 0.34, 1.66). Overall HSV2 prevalence at 3-year follow-up was 11.9% in males and 21.1% in females, with adjusted prevalence ratios of 0.92 (95% CI: 0.69, 1.22) and 1.05 (95% CI: 0.83, 1.32), respectively. There was no consistent impact on other biological outcomes, though there was a significantly higher prevalence of NG in females in intervention communities ***(Appendix 2).***

The results of a special examination in year 7 of primary school confirmed that those in the intervention schools had much higher levels of knowledge and desirable reported attitudes compared to those in the comparison schools. In July 2002, 84% of the 2445 intervention community students in year 7 and 50% of the 2262 comparison community students in year 7 passed the examination (obtained at least 50%). In the intervention communities, the pass rate was higher among males (88%) compared to females (80%). A quarter of students in the intervention communities and only 0.6% of students in the comparison communities scored 80% or more in the examination.[186, 199]

1.4.5 Interpretation

The MkV1 intervention trial demonstrated that such interventions are feasible and sustainable and can be implemented to a high standard through existing government health and school structures. Unfortunately, the substantial increases in knowledge, desired attitudes and reported reductions in risk behaviours did not, after 3 years of implementation, lead to a decrease in rates of HIV, STIs and unintended pregnancies.

The qualitative research team wrote a summary report of its process and impact findings prior to analysis of the quantitative trial results. Qualitative data collected through participant observation and in-depth interviews suggested that while knowledge and communication about sexual matters had improved, this did not seem to translate into greater perceived self-efficacy to reduce risk behaviours. The intervention did not appear to increase perceived susceptibility to risk or negative outcome expectations. Investigators felt that secrecy about sexual relations and ignorance about partners' sexual history may have impeded realisation of risk. For example, some subjects of the participant observation reported that they were not at risk of HIV or STIs as they only had one sexual partner. The subjects of the participant observations rarely reported any behaviours promoted by the intervention (e.g. reduced number of sexual partners or condom use) and some reported that they were too afraid of poor confidentiality to attend the health facility for treatment. The research team predicted that the intervention would have led to improved knowledge, might have led to an increase in reporting of desired attitudes and behaviours but that it was unlikely to have substantially changed actual attitudes and behaviours.[105] Participant observations and in-depth interviews found that students reported that it was too difficult for males to give up the pleasure and females to give up the material gain associated with sex. Very few young people reported that they had reduced their number of sexual partners or had used condoms.[105]

A number of limitations of the intervention and intervention evaluation were identified. The follow-up rate was 73% and those who were lost to follow-up may have had a different experience. It is likely that those who do not complete interventions are older, have less exposure to HIV/AIDS information at baseline, and are more likely to participate in high-risk sexual activity.[170, 200] Reported attitudes and behaviours following an intervention can also be subject to differential social desirability bias with those in the intervention arm reporting what they think they should say. It has been suggested that measures of intention may be more subject to this kind of bias.[94] It is not clear to what extent this bias may have influenced the results, highlighting the importance of objective biological measures.

Some challenges to the implementation of ASRH interventions in primary schools in Mwanza have been discussed above. Furthermore, compromise on some key aspects of intervention design was required (e.g. the Tanzanian national guidelines require the promotion of abstinence and do not allow condoms to be shown). The intervention itself was limited to the last 3 years of primary school and did not target out-of-school youth, include traditional healers nor incorporate mass media (to avoid contamination). Income generation was not included in the intervention.[179] Gender and age differentials are difficult to change quickly and complementary strategies may be needed to access out-of-school youth and the wider community.

1.4.6 Developments between 2002 and 2005

The trial team, the four participating district councils, the Tanzanian Ministries of Education & Culture, and Ministry of Health, and the funding agency, DCI, felt that the positive results in terms of improvements in knowledge, reported attitudes and reported behaviours justified continuing the intervention in these 10 communities. Between 2002 and 2005 (**Bridging phase, Box 1.5**) the in-school SRH education, support and supervision for the YFHS, and the community-wide activities (mainly community video campaigns) were maintained in the 10 intervention communities only, with support from Irish Aid (formerly DCI). A review of activity reports between 2002 and 2005 and discussions with implementers suggests that there had only been a slight decrease in implementation intensity during that period, however, the following was noted:

- The condom promotion component of the intervention had been dropped
- One internationally recruited staff member (A Obasi), who had been seconded to AMREF by LSHTM from 1997-2001 had not been replaced with her role taken on by her locally-recruited counterpart.
- The teachers had not received annual refresher training workshops.

1.4.7 MEMA kwa Vijana Phase 2

MEMA kwa Vijana Phase 2 (MkV2) ran from June 2004 until June 2008 ***(Box 1.5)***. The specific objectives of MkV2 were to[201]

1. Provide technical support to the planning and implementation of the district level HIV/AIDS response
2. Expand the MkV intervention to all 620 primary schools and 179 health facilities in the four districts involved in MkV1

3. Conduct in-depth process evaluation to assess the extent and quality of intervention implementation and integration at the district level
4. Carry out policy work to ensure a favourable environment for the implementation of MkV2 in the four districts, and to ensure that the lessons learnt from MkV2 were used to inform the development of health policy in Tanzania and internationally
5. Carry out formative research to develop and evaluate complementary interventions aimed at strengthening the effect of the MkV2 intervention.

The key activities included:[202]

- Training of technical staff at regional and district government level to implement the scale up of MkV interventions.
- Technical assistance to the districts for an initial 4-year period, through the provision of a district advisor for each district council.
- Support and supervision of 3-year scale-up of core MkV2 intervention activities in 649 schools and 179 health units (650 head teachers, 3,500 teachers, 20,000 peer educators, 600 clinicians)
- Operations, process, policy and formative intervention development research conducted by a dedicated social science research team. Formative research was carried out on further complementary interventions including community activities targeting young men, innovative condom distribution partnerships, video-based harm reduction initiatives, interventions with HIV+ individuals and interventions through parent groups.

Between the middle of 2005 and the middle of 2007, the MkV2 intervention was implemented. A quarter of the schools and health facilities were covered in 2005, 50% in 2006 and the remaining 25% in 2007. The intervention started in the trial comparison communities in 2006. The MkV2 intervention primarily targets those adolescents (mainly aged between 13 and 16 years of age) who are in the last three years of primary school and is very similar to MkV1 intervention though it does not include the condom promotion component.[203]

Evaluation of the scaled-up intervention found that high coverage was achieved, however, with lower dosage and fidelity levels than in trial conditions. Results from serial cross-sectional surveys revealed that the scaled-up intervention also had a substantial impact on HIV and reproductive health knowledge and reported attitudes.[203] Operations research highlighted that the design of the scale-up, including technical assistance from AMREF staff, ensured high coverage but the project struggled to integrate into existing systems.[204] The investigators recommend that the scaling-up of future interventions should be conducted as part of a national level directive and should include addition support and capacity-building at district and local levels.[205]

1.4.8 Rationale for the long-term impact evaluation survey

One of the potential explanations for the lack of any consistent impact on the biological outcomes during the original MkV1 trial period, despite the substantial differences in knowledge, reported attitudes and reported sexual behaviours, is that the interventions may have needed more time to work. It is possible that behaviour change would only take place when a critical mass of young people in the communities had been exposed to the interventions. Drawing on the Diffusion of Innovations Theory, the hypothesis was that through making contact with a proportion of the population the impact of an intervention would in time reach a 'tipping point' and spread to all the community through a ripple-like social transmission or diffusion of new ideas.[206]

The follow-up period of three years that was available for the original phase of the trial led to the following unavoidable limitations:

1. The highest risk group (standard 6 at recruitment) represented 41% of the trial cohort, but received only one year of the in-school intervention. Only 27% could receive all three years of the programme.

2. There is a substantial difference in the average age of males and females in sexual partnerships in this population.[207] The older male sexual partners of the young women in the cohort had not been exposed to the in-school intervention and, conversely, some of the sexual partners of the young men in the cohort may have been too young to have been exposed to the in-school intervention. Given the power differentials between men and women, it may be the case that both partners, or at least the male partner, need to have been exposed to the interventions before substantial behavioural changes will take place.

3. The trial cohort had a lower than projected HIV incidence possibly because the groups at highest risk were among the 27% that were lost to follow-up. Also, sample size

calculations were based on data from a household survey which included recent in-migrants to the communities. The trial involved follow up of a closed cohort of primary school students, in whom the HIV incidence may be lower.[178]

A long-term evaluation survey in 2007/8, the **MkV1 Further Survey (MkV1FS)** was planned in order to evaluate the longer-term impact of the MkV1 intervention. MkV1FS had several advantages relative to the earlier phase of the trial. Firstly, participants in five of the six school year groups in the intervention communities who were included in the survey would have had the opportunity to receive at least 2 years of the in-school intervention. Secondly, many of the male partners of the young women in the survey would have previously received the MEMA kwa Vijana in-school component, and this may have been translated into stronger effects in these women. Both the total number of young people and the mean HIV prevalence in this older population would be higher and the study would, therefore, have a greatly enhanced power to detect differences in HIV prevalence. Members of the original trial cohort would be included, and so the long-term effects on knowledge, attitudes and other frequent outcomes could be measured in this subgroup. Those eligible to participate in the MkV1 Further Survey would have left primary school by the end of 2004 and so young people in the comparison communities who have been exposed to MkV2 in-school component of the intervention would not be included (NB if they repeated std 5, 6 or 7 then they may have left primary school after 2004, but were very unlikely to still be in primary school in 2006 when the MkV2 interventions started in the comparison schools).

This survey was carried out 8 years after the introduction of the MkV1 intervention and was able to examine the impact of this intervention in the long-term, when it had had the chance to affect several consecutive cohorts of young people. The survey, however, retained the advantages of the original community randomised controlled trial design.

1.5 Hypothesis underlying the specific research reported in this thesis

The hypothesis underlying the specific research reported in this thesis was that in the longer-term the MEMA kwa Vijana (MkV1) intervention would lead to an improvement in sexual and reproductive health and a reduction in HIV and other STIs among young people exposed to the intervention.

1.6 Aims and Objectives

1.6.1 Aim

To investigate whether there is a significant long-term impact of the MEMA kwa Vijana (MkV1) intervention on the sexual and reproductive health of young people.

1.6.2 Objectives

The **primary objective** is to investigate whether the intervention had an impact on the primary outcomes, HIV prevalence and HSV2 antibody prevalence

The **secondary objective** is to investigate whether the intervention had an impact on the secondary outcomes:

- Three sexual health knowledge scores and one sexual health attitudes score (each score based on 3 questions, as used in the previous MkV1 surveys)
- Reported sexual behaviours: sexual debut, lifetime number of sexual partners, number of different sexual partners in previous 12 months, condom use with last partner and last non-regular partner in the previous 12 months, ever use of other contraceptives, use of other contraceptives at last sexual intercourse, more than one partner in the same time period in the previous 12 months, more than one partner in the previous 4 weeks.
- Reported clinical and biological outcomes: Genital discharge (in the previous 12 months), genital ulcer (in the previous 12 months), visit to health facility for most recent STI symptoms (in the previous 12 months), lifetime number of reported pregnancies, reported pregnancy while in primary school, reported unplanned pregnancy.
- Biological outcomes: Syphilis seroprevalence (TPPA+), Active syphilis prevalence (TPPA+, RPR+), Prevalence of *Chlamydia trachomatis* (CT), Prevalence of *Neisseria gonorrhoeae* (NG)

1.7 Structure of thesis

This thesis is composed of six chapters. This introductory chapter has set the scene and provided the background and rationale for the long-term evaluation of the MEMA kwa Vijana Adolescent Sexual and Reproductive Health (ASRH) intervention in Mwanza, Tanzania. In the literature review, Chapter 2, the current evidence on the effectiveness of interventions to improve the SRH of young people in sub-Saharan Africa is presented. At the end of the chapter some research priorities are highlighted and it is explained how the specific research reported in this thesis will attempt to fill important gaps in our knowledge of 'what works' in the area of ASRH and, in particular, HIV prevention among young people. Chapter 3 details the research methods used and includes discussion of some key design issues. The results of the long-term evaluation survey are presented in Chapter 4 along with a brief comparison of these new results with the results of the 2001/2 impact evaluation (described in ***Section 1.4.4***). The results and the limitations of the research design are discussed in Chapter 5 and the results are compared with the findings from other similar research. In Chapter 6, the lessons learnt and recommendations for policy makers and researchers on possible future directions of research are presented.

1.8 Role of the candidate

The candidate and the Principal Investigator David Ross (PhD Supervisor) co-led the design of the MEMA kwa Vijana Trial Further Survey (MkV1FS) including the design of the data collection tools. The candidate coordinated the long-term evaluation phase of the trial in Mwanza, Tanzania and conducted the analysis presented in this thesis. The systematic review of the effectiveness of HIV prevention intervention in young people in sub-Saharan Africa was conducted jointly by the candidate, Sue Napierala Mavedzenge (Research Fellow) and David Ross. The candidate developed the search strategy for the systematic review, and conducted the initial search for relevant citations based on title, abstract and/or key words for relevance. Sue Napierala Mavedzenge reviewed 10% of all citations from this initial search, conducted a search of additional electronic resources, and reviewed references from selected citations. The candidate conducted a full-text review of relevant citations and determined studies for final inclusion jointly with co-authors of the systematic review all of whom participated in the writing of the review.

Chapter 2 - Literature Review

In this chapter the current evidence on the effectiveness of Adolescent Sexual and Reproductive Health (ASRH) interventions in sub-Saharan Africa (SSA) is presented, providing the background against which the results, which are presented in Chapter 4, will be discussed. The focus will be on behavioural interventions and as a background to such interventions the various theories of behaviour change and their role in ASRH intervention development and evaluation are discussed briefly in section 2.1. Section 2.2 provides an overview of the different types of ASRH interventions and is followed later in section 2.4 by a more detailed critical appraisal of the evidence on the effectiveness of ASRH interventions in SSA. The focus throughout this chapter is on sub-Saharan Africa, however, data from other African, developing and developed country settings are provided where data are not available for sub-Saharan Africa or where such data illustrate additional important points. Section 2.3 highlights the importance of the evaluation of interventions and details the criteria for evaluating the effectiveness of interventions. Section 2.4 gives an overview of reviews on the effectiveness of ASRH interventions and includes a systematic review of HIV prevention interventions in schools, health facilities and geographically-defined communities carried out in sub-Saharan Africa and reported between January 2005 and December 2008. Section 2.5 briefly summarises what is known about the effectiveness of behavioural interventions implemented outside sub-Saharan Africa. Section 2.6 gives a short overview of the role of mathematical modelling studies in the evaluation of interventions and prediction of intervention effects. The concluding remarks in section 2.7 stress the need for rigorous evaluations of ASRH interventions especially evaluations that include longer-term follow-up and that measure biological outcomes.

2.1 Behaviour change theories and their role in ASRH interventions

Many of the interventions that aim to improve ASRH fall into the category of behavioural interventions. These interventions aim to establish behavioural patterns that will reduce the risk of sexual transmission of HIV and STIs and of unwanted pregnancies i.e. delay onset of sexual intercourse, reduce number of sexual partners, and reduce the incidence of unprotected sex. Such interventions are often founded in one of the theories of behaviour change and frequently focus on improving knowledge and attitudes, which are often hypothesised to be on the pathway to behaviour change.

2.1.1 Main concepts and theories

Most individual behaviour change interventions that claim to be theoretically based draw on social-psychological cognition theories. Theories focus on a number of the following factors that are thought to be important in explaining sexual behaviour:[151, 153]

- Intentions and planning
- Personal susceptibility to risk
- Perceived benefits and barriers
- Social Approval and Norms
- Perceived self-efficacy
- Modelling behaviour
- Skills (interconnected with perceived self-efficacy)

Self-esteem and empowerment are thought to be two key theoretical concepts that are important to behaviour change. Self-esteem is important in promoting a sense of purpose and control over one's life. High self-esteem is associated with positive choices for healthy lifestyle and self-assurance to resist pressure from peers. However, self-esteem is unlikely to be sufficient to change all behaviours and sometimes self-esteem is gained from engaging in an unhealthy lifestyle.[153] Empowerment is mutually supportive with self-esteem. 'Empowerment-based practice' needs to address problems lay people themselves define as important[208] e.g. the Stepping Stones intervention starts with problem identification and priority setting. Lay people should actively participate in deciding how problems are solved and then in solving them using techniques like group discussions or participatory drama.[153] However, young people may not have a sufficiently advanced cognitive level to make well-informed decisions and cannot always anticipate what might be useful to them in the future. Sex education programmes that emphasised clear behavioural values and norms have been found to be more likely to be effective[209] which goes against 'informed choice'.

The two main sociological ideas underpinning sexual health programmes are the gendered construction of sexuality and the diffusion of innovations. In the social sciences, sexuality is understood to be largely learnt and to be learnt differently according to ones gender.[153] Sexual health programmes often help young people to understand how sexuality is socially constructed and help them to understand sexual issues from the viewpoint of the opposite sex. Interventions often attempt to modify the norms that perpetuate gender inequality and provide the skills necessary to empower women in their personal and sexual relationships.[153] Interventions using the concept of diffusion of innovation[206] target individuals who are thought to be 'change agents' who can influence key opinion leaders and in turn other community members. Diffusion of innovation is the best explanation of how peer-education might work and there have been some successes in using this approach.[210-212]

Behavioural change theories are either general theories, health-specific theories or theories specific to the health problem e.g. HIV/AIDS. Theories vary in their complexity, the empirical support for the theory and the proximal determinants of behaviour that they prioritise. Some theories are stage models i.e. assume that change is a process and that different factors affect movement through different stages of the process.[151] Often social-psychological cognition theories have overlapping concepts.[213] Some of the most commonly used theories for ASRH interventions are the **Health belief model**[214, 215] the **Theory of Reasoned Action**[216], **Social learning theory**[217] and the **AIDS risk reduction Model (ARRM)**[218].

Most theories stem from the **Health Belief Model.**[214, 215] This model assumes that people will engage in preventive behaviour if they feel susceptible to the health condition, believe the condition is characterised by a high level of severity and feel that the costs of engaging in preventive behaviour are outweighed by benefits.[151] In addition, this model often involves cue stimulus (symptoms, knowing others, mass media) and the concept of self-efficacy. The empirical support for association between the Health Belief Model constructs and levels of HIV preventive behaviour is mixed and critics highlight the fact that the relationships between the variables in the model remain unconceptualised and unspecified (i.e. the model is essentially a list of constructs rather that a model per se).[151]

The **Theory of Reasoned Action**[216] has been widely used to study STI preventive behaviours. Behaviour is determined by intention to perform that behaviour. Intention is influenced by attitude towards the behaviour and the individual's subjective norm or perception of support for the behaviour. Empirical support for the use of this theory in HIV prevention is generally good, especially for increasing the use of condoms,[151] however, a major limitation to the theory is that it does not address the fact that an individual may lack perceived control over HIV preventive acts.[151] The **Theory of planned behaviour** developed by Ajzen and Madden is an extension of this theory which attempts to influence intentions but also prioritises goals and plans for realising those goals. [151]

Social learning theory and its sequel **Social Cognitive Theory** emphasise modelling behaviour and self-efficacy. The emphasis is on the development of self-efficacy, intentions and planning and modifying social approval.[217] Bandura specifies that an effective behaviour change intervention should involve four components: (i) an informational component to increase awareness and knowledge of health risks and to convince an individual that they have the ability to change their behaviour (ii) the development of self-regulatory and risk reduction skills (iii) the enhancement of these skills to increase self-efficacy (iv) the development or engagement of social support for the individual to make the behaviour change. This model has been widely used as a basis for HIV prevention interventions, however, the interrelations between the theory constructs remain unspecified.[151]

The **AIDS risk reduction Model (ARRM)** is a stage model of behaviour change.[218] The three stages are recognition of one's risk, commitment to reducing that risk, and following through with that commitment by seeking solutions. This model assumes that change is a process that individuals must go through and that different factors affect movement through different stages of the process. The achievement of each stage is considered a meaningful outcome. This model however provides very few ideas on how to actually change behaviour as the description of factors associated with the enactment stage is limited.[151] Factors associated with the attainment of one stage may be associated with attainment of another stage. Empirical support for this model has been somewhat equivocal.[151]

2.1.2 The use of theories in the development of ASRH interventions

During intervention development, a theory of behaviour change can be embedded in a larger causal model that specifies the hypothesised causal relationship between the proposed intervention, the determinants of behaviour, the target behaviour and the main health outcome.[213] Interventions can be designed to target different components of the model. This model can then be used when defining intervention evaluation outcomes. Wight provides a good overview of the history of the use of behavioural theories in SRH research.[153] He highlights the fact that those theories of behavioural change with the greatest empirical support, that is social psychological theories, prescribe the content of sex education programmes more than the mode of delivery.

Many recent ASRH interventions have been based on a number of different theories. The LoveLife programme in South Africa was based on diffusion of innovations, ecological theory[219] and the Theory of Reasoned Action.[220] The MEMA kwa Vijana intervention in Tanzania was based on Social Learning Theory though it was also influenced by the Theory of Reasoned Action.[105, 181]

In 2000, Fishbein published a paper describing an 'Integrative model' that integrated several leading theories of behavioural prediction and behaviour change (Theory of reasoned action, Social cognitive theory, Health Belief Model).[221] This model was used as the basis for the Project RESPECT intervention in the US that led to a reduction in STIs[222] and the AIDS community demonstration projects, also in the US, that resulted in an increase in reported use of condoms.[223]

Having a theoretical framework that guides programme design and evaluation is considered essential for successful school-based ASRH programmes in both developed and developing countries.[224, 225] A review of 40 ASRH intervention evaluations in the US published between 1983 and 1995 found that the use of a behavioural theory was significantly correlated with intention to use condoms and tended to be positively associated with other outcomes. The 'successful' sexual risk programmes were associated with the following theories: Social learning theory, Social cognitive theory, Health belief model and Theory of reasoned action.[226] However, reviews of school-based programmes in SSA[94] and community-based interventions in developing countries[227] have not observed this association. Some authors argue that additional research is needed to clarify the mechanisms by which sexual health promotion works, which in turn should contribute to more empirically based theory.[153] For example, the major outcome is often intentions and not enough attention is given to the relationship between intentions and actions.

Existing theories of behaviour change have been criticised for being based on western concepts of decision making which might not be applicable in different cultures. The importance of context has been highlighted by other authors who criticise psychological models (e.g. social cognitive, AIDS risk reduction model) for assuming that behaviour is individual, rational, and under the control of the individual, and that risk is context free. Furthermore, individual-level models sometimes overlook the situational factors that might shape sexual behaviour such as availability of condoms, effects of drugs, power differentials etc.[153] Theories often emphasise negotiation and communication within relationships but the rights of partners in a relationship vary between cultures.[228] Some have argued for the development of culture-specific theories following formative anthropological research.[229]

However, Fishbein believes that existing theories provide us with the tools to change behaviour and that research should focus on improving the understanding and utilisation of existing theories, within different contexts, instead of trying to create new theories.[221]

Through the development and testing of these behavioural change theories much has been learnt. It is now commonly accepted that changing specific behaviours such as condom use, is more effective than changing general patterns of behaviour e.g. 'safer sex'.[221] In the context of ASRH, trying to change existing behaviour is likely to be much less effective than encouraging the development of healthy patterns of behaviour by targeting young people prior to their sexual debut and before patterns are established.[230, 231] The suitability of an individualistic approach is increasingly being questioned in contexts, especially in SSA, where a spirit of collectivism prevails.[232] Community participation and community mobilisation are increasingly being recognised as strategies of change that are important to the success of interventions.[221] Successful interventions are likely to address not just individual self-efficacy but also collective efficacy and identify environmental impediments and facilitators to behaviour change and hence promote change at a socio-cultural level.

2.1.3 Key messages used by ASRH interventions

An example of a clear message generated in Uganda and now promoted widely is 'The ABC of prevention: Abstain from sex until marriage; if not abstaining, Be faithful to one, uninfected partner; if this is not possible, use a Condom'. Despite being one of the most effective ways to protect against HIV and other STIs, condom promotion and use still remains controversial. Community resistance or national guidelines have prevented practical demonstrations of the use of condoms in schools[179, 233] or have even led to their exclusion from many programmes.[130, 234] The alternative message proposed is one that focuses on abstinence before marriage, as the most appropriate message for young people. Secondary abstinence e.g. no partner in the last 12 months if previously sexually active (MEASURE DHS) is proposed for those who are unmarried but have already been sexually active. However, there has been little rigorous evaluation of these programmes and a recent systematic review of school-based interventions carried out in developing countries between 1990 and 2005 found only three 'Abstinence only' programmes that fitted their criteria for selection.[235] Another recent systematic review, evaluating secondary school teen pregnancy prevention programmes carried out in the United States, found only three randomised controlled trials (RCT) that had evaluated abstinence-only programmes in secondary schools and only one of these studies showed any significant impact on reported sexual behaviour.[236] Others promote abstinence as the best means of preventing acquisition of HIV but also encourage condom use and reduction of partners for sexually active youth. A recent Cochrane review of 'abstinence-plus' programs in high-income countries found no evidence that such programmes can reduce rates of STIs but that they have been shown to reduce **reported** risk behaviour. The authors call for trials comparing abstinence only, abstinence-plus and safer-sex interventions.[237] While this suggestion will please some in the field, it is shocking that 'abstinence-only' programmes, which deny young people information on all the different ways that they can protect themselves, are still encouraged. In addition to messages regarding sexual behaviour, interventions often promote uptake of health services including the identification and treatment of STI, VCT and family planning.

2.2 Types of interventions aiming to change behaviour of young people

ASRH interventions vary considerably not only in terms of their theoretical basis but also in setting, target group and methods of implementation. Furthermore, the implementation and impact of an intervention can vary by setting according to the resources available and risk profile of the target population. Intervention setting is most frequently used when trying to group and classify the diverse spectrum of interventions. The main types of interventions are described here according to the following settings: Schools, Health Facilities, Communities, other settings. Interventions targeted at high risk groups and structural factors that can be targeted by interventions are then briefly discussed. Prevention interventions among young people who are HIV positive 'positive prevention' and the effectiveness of VCT on its own as an intervention are beyond the scope of this review and are not discussed.

2.2.1 Schools

In this thesis, "schools" are defined as any establishment providing formal education or training, in this case, to people 25 years or younger. Schools have emerged as a leading setting for ASRH Interventions because schools are seen as established settings at which interventions are easy to implement and replicate[238] and the majority of children in SSA enrol in school at least at primary level.[239] Schools have great potential for HIV prevention education in that students are expected to attend regularly, and the great majority begin attending prior to becoming sexually active.[235, 240] Also, some of what a young person "learns" while in school affects their lifelong norms, attitudes and behaviours. Schools may therefore play a vital role in HIV prevention among young people, both while they are within the young person's age group (10-24 years) and after that.

School-based reproductive health (RH) education programmes vary considerably in terms of curricula, content and delivery format.[241] Interventions have been tried in primary, secondary and evening schools and programmes have been curriculum, group or peer based or been based on small media. Many interventions are based on interventions developed in the West e.g. Fitzgerald/Stanton intervention in Namibia based on US intervention 'Focus on Kids'.[228] Interventions are often curriculum-based and such interventions are typically more intensive, and based on theory and previous research, often with pilot testing. Non curriculum-based interventions are often less structured, and can involve a wide variety of activities such as dramas, competitions, and health fairs.[235]

In addition to imparting knowledge, schools provide opportunities for young people to develop life skills. Life skills are abilities for adaptive and positive behaviour that enable individuals to deal effectively with the demands and challenges of everyday life.[242] In particular, life skills include communication and interpersonal skills, decision-making and critical thinking skills and coping and self-management skills. Life skills may be directed toward personal actions or actions toward others, as well as toward actions to change the surrounding environment to make it conducive to health.[242] Recent evaluations have shown that life skills interventions for HIV prevention are most effective when directed specifically to skills related to HIV risk reduction.[225] Examples of HIV risk reduction life skills include practical skills such as how to use a condom, interpersonal skills such as how to negotiate condom use or to refuse sex and personal skills such as how to be more assertive or to communicate better in a relationship. Such life skills that focus on specific health behaviours are often better described as skill-based health education.

In terms of mode of delivery, teacher-delivered education is a popular approach. This approach involves the teacher targeting cognitions in a systematic way, with a consistent behavioural message and ensuring that the target group receive exercises. Teachers or other adults are likely to have more knowledge, skills and experience to help them to lead a sexual health intervention. Teacher-led interventions are typically logistically manageable, more often curriculum-based, and highly replicable. Teachers may be in a better position to challenge dominant norms but are, however, unlikely to be regarded as credible role models and may not be appropriate in some settings.[28] Young people may not want to ask questions or reveal and discuss sensitive issues, or may not respect what they advise in terms of sexual behaviour because of the major gap in age and lifestyle. From the teacher's point of view, the teaching techniques are often new to developing country schools[243] where didactic techniques are more common. Insufficient teacher training and/or lack of availability of teachers, large class sizes, lack of curricular materials, and access to other financial, material and technical resources can hamper teacher-led programs.[28] Cultural and social norms of both the local communities and the schools themselves can make it difficult for teachers to discuss sexuality and especially condoms.[235, 244, 245]

Peer educators are often used as an alternative/adjunct to teachers/other adults. Peer educators, especially outreach rather than formal school-based peer educators, may be successful at facilitating the development of self-esteem and empowerment and at facilitating diffusion of innovation. Peers can relate more closely with young people but are likely to be less knowledgeable and less likely to have the skills to teach. Peer-led interventions have often been less intensive and less structured, and when the peers are other students from the same institution, will necessarily require frequent training of a new cohort of peer educators, usually annually or once every two years.[235, 246] Also, one of the greatest challenges to the principle of peer education is the social heterogeneity of pupils, and there are strong practical arguments in favour of teacher delivery of interventions.[153]

A review of evidence on the effectiveness of school-based interventions in the US led to the identification of ten key characteristics of effective sex and HIV education programs[209] These characteristics have now been updated based on evidence from both developed and developing countries and the resultant 17 "Kirby characteristics" of effective in-school, curriculum based programs that pertain to the curriculum development, content and implementation, and have been advocated as "best practice" ***(Box 2.1)***.[51] School-based HIV/AIDS education programmes have been the subject of a number of recent UN-led guidance briefs and technical support tools that are targeted at those responsible for implementing such programmes.[247-249]

In summary, school-based HIV prevention programmes are seen by many as an essential step to protect the general population from further infection[238, 250] and, increasingly, countries are including SRH education in their school curricula. However, in places where a large proportion of young people do not attend school, or when interventions target young people who have already become sexually active, school-based interventions are likely to be less effective.

Box 2.1 The 17 characteristics of effective in-school, curriculum based programs that pertain to the curriculum development, content and implementation, and have been advocated as "best practice".[51]

The Process of Developing the Curriculum	The Contents of the Curriculum Itself	The Implementation of the Curriculum
	Curriculum Goals and Objectives	
1. Involved multiple people with different backgrounds in theory, research and sex/HIV education to develop the curriculum	1. Focused on clear health goals – the prevention of STD/HIV and/or pregnancy 2. Focused narrowly on specific behaviors leading to these health goals (e.g., abstaining from sex or using condoms or other contraceptives), gave clear messages about these behaviors, and addressed situations that might lead to them and how to avoid them	1. Secured at least minimal support from appropriate authorities such as ministries of health, school districts or community organizations
2. Assessed relevant needs and assets of target group	3. Addressed multiple sexual psychosocial risk and protective factors affecting sexual behaviors (e.g., knowledge, perceived risks, values, attitudes, perceived norms, and self-efficacy)	2. Selected educators with desired characteristics (whenever possible), trained them and provided monitoring, supervision and support
3. Used a logic model approach to develop the curriculum that specified the health goals, the behaviors affecting those health goals, the risk and protective factors affecting those behaviors, and the activities addressing those risk and protective factors	**Activities and Teaching Methodologies** 4. Created a safe social environment for youth to participate 5. Included multiple activities to change each of the targeted risk and protective factors	3. If needed, implemented activities to recruit and retain youth and overcome barriers to their involvement, e.g., publicized the program, offered food, or obtained consent
4. Designed activities consistent with community values and available resources (e.g., staff time, staff skills, facility space, and supplies)	6. Employed instructionally sound teaching methods that actively involved the participants, that helped participants personalize the information, and that were designed to change each group of risk and protective factors	4. Implemented virtually all activities with reasonable fidelity
5. Pilot-tested the program	7. Employed activities, instructional methods and behavioral messages that were appropriate to the youths' culture, developmental age, and sexual experience 8. Covered topics in a logical sequence	

2.2.2 Health Facilities

Health facilities are another important setting for ASRH interventions.[251] The importance of access to health services for young people was reinforced when the UNGASS on HIV/AIDS made this an explicit goal for young people's health and development *(Box 1.1)*. There is widespread agreement about the elements that make up an effective package for health services for adolescents in the general population, and for vulnerable groups of adolescents.[243, 252-255]

In terms of ASRH, the key services that can be provided for adolescents at health facilities do not differ from those that are provided for adults and include:[253]

- Reproductive health information, education and counselling
- Distribution of condoms (both male and female) and other contraception
- Sterile injecting equipment and other services for intravenous drug users
- Diagnosis and treatment of STIs
- Male circumcision
- Voluntary counselling and testing for HIV (VCT)
- Antenatal, delivery and post-natal care
- Treatment, care and support services for young people living with HIV (including prevention of mother-to-child transmission of HIV (PMTCT))

However, young people often to not have effective access to these important services. Barriers to access range from practical issues such as cost of services, inconvenient hours, long distances and poor transportation to motivational factors and personal concerns about privacy and confidentiality, fear and embarrassment, and attitudes of staff. Community attitude to the health facility can also be a major influence on young people's willingness to avail themselves of the services.[244, 256] For health services to be optimised, they must be tailored to the specific age, gender and socio-cultural needs of young people. This does not require the setting up of parallel services for youth but requires the existing services to be more responsive to the specific needs of young people. Interventions aim to improve service quality at health facilities and increase utilisation by making health facilities more 'youth-friendly'.

The key qualities of youth friendly health services (YFHS) are:[77, 256-260]

- **Accessibility:** putting the services in reach and making them potentially useable by all young people who need them;

- **Acceptability:** making the services such that young people will be willing to use them, by ensuring privacy and treating young people who access these services with respect;
- **Effectiveness:** providing appropriate, high-quality prevention, care and treatment services to young people.

Provider attitudes and confidentiality may be two of the most important factors in making health services 'youth-friendly'. However, a user friendly health service may be a necessary but not a sufficient condition to ensure service utilisation by adolescents[77, 254] and stigma and fear can remain strong deterrents. Innovative approaches to increasing service use include outreach (taking the services to target groups), social marketing and social franchising and voucher schemes and greater involvement of the private sector.[252, 258] A high proportion of youth already use the private sector for RH services and pharmacies, and private sector health services are increasingly seen as an important setting for intervention.[244] Private services may be more socially acceptable to young people as they are often thought to provide increased privacy and confidentiality and better supplies.[244] In order to increase knowledge of STIs and the services available, a number of health services interventions have been linked with school programmes[179, 233, 261] or have involved mass media and social marketing.[244, 256] The use of schools and health services is often accompanied by the constraints of resource limitations, regulations or institutional cultures all of which can have an impact on intervention content and delivery.[179]

Box 2.2: Standards for Adolescent Friendly Reproductive Health Services in Tanzania.[262]

1	All adolescents are able to obtain sexual and reproductive health information and advice relevant to their needs, circumstances and stage of development
2	All adolescents are able to obtain sexual and reproductive health services that include preventive, promotive and curative services that are appropriate to their needs
3	All adolescents are informed of their rights on sexual and reproductive health information and services whereby these rights are observed by all service providers and significant others
4	Service providers in all delivery points have the required knowledge, skills and positive attitudes to provide sexual and reproductive health services to adolescents effectively and in a friendly manner.
5	Policies and management systems are in place in all service delivery points in order to support the provision of adolescent friendly sexual and reproductive health services
6	All service delivery points are organized for the provision of adolescent friendly reproductive health services as perceived by adolescents themselves
7	Mechanisms to enhance community and parental support are in place to ensure that adolescents have access to sexual and reproductive health services

Many countries in SSA have introduced national guidelines on YFHS e.g. Tanzania[262] and South Africa.[263] The Tanzanian standards are listed in ***Box 2.2.*** South Africa has introduced an 'Essential Services Package', in an attempt to establish a good standard of adolescent health care services at primary care level throughout the country. Health services can gain accreditation by reaching 10 nationally recognised standards with 41 associated criteria.[263] Training[264] and assessment guides[255, 259] have been developed to assist in the implementation of YFHS and in the monitoring of standards.

2.2.3 Communities

Communities can be geographically-defined (everyone living within a defined geographical location) or socially-defined (people with common social attributes).[265] Interventions in geographically-defined communities are discussed in this section. Community involvement, participation and engagement has great potential for improving health.[266] Community level interventions have the potential to change established norms, values and traditions that may impede HIV prevention and care. In addition, community-based interventions may increase support for young people, and increase access to necessary information and services. Interventions based in the community are promising as they can target diverse groups including out-of-school youth and those not accessing the health services. The advantage of interventions in this setting is that they encourage the participation not only of youth but also parents and community leaders. Despite their potential, community interventions face a number of challenges, including the inherent difficulty in changing established norms, community diversity, sustainability, and difficulty with monitoring and evaluation of these interventions, and the dearth of community development workers in most low and middle income countries.

Interventions in the community are very diverse and can be targeted, for example, for out-of-school youth or involve more widespread community mobilisation and health education. Interventions often involve counselling, workshops and the use of peer educators or popular opinion leaders. Youth development programmes focus on life options and skills, educational aspirations, vocational opportunities and psychosocial development.[244] Community outreach programmes provide clinical services in a non-clinical setting. Social marketing programmes use techniques borrowed from commercial advertising, market research and the social sciences and aim to increase access to health services and bring about changes in health behaviour and practices.[244] These programmes can reach large numbers of people by making condoms, over the counter contraceptives and other products available at subsidised, affordable prices and at places where young people congregate.[77] Peer programmes recruit and train a core group of youth to serve as role models and to take health messages or health products to other young people of similar age and background.[77, 244, 267] These programmes encourage the involvement of young people in programmes designed for them and help the promotion of social norms and values supportive of positive attitudes and health behaviour.[244] The primary impact is often among youth attending schools and on peer educators themselves. Peers tend to be in contact with youth like themselves and so lots of different peer educators may be needed for community-wide coverage.[244] The sustainability of such programmes has been questioned due to the high turnover of peer educators, the payments for services and the lack of a pre-existing managed structure that can support the programme.[77, 267] Also, adults may be better than peers at conveying factual information and receipt of information from adults or more distant peers may be more acceptable to youth in some settings.[267] Other types of community interventions include those involving youth-serving organisations, livelihood programs and parental programs.[256]

Following their review of peer-led community based programmes in low and middle income countries, Maticka-Tyndale and colleagues concluded that the elements of a successful peer education programme include: a community needs assessment (unless current data are already available from another source), well-thought out peer educator selection (preferably with input from youth/community stakeholders), adequate peer educator training, monitoring and supervision, involvement of youth and community stakeholders in programme development and implementation, a structure for programme delivery, peer educator retention efforts, a system to locate and train replacement peer educators, and a system for sustainability.[267] An earlier review of all types of community-based interventions by the same author recommended that interventions should focus on gaining entry to the community and developing strategies to deal with adverse reactions to programme components. Interventions should focus on the use of participatory learning activities and ensure that there is a sustainable means of obtaining programme supplies. Importantly, the authors highlight the need to build links between components of complex interventions e.g. referral systems.[227]

2.2.4 Other intervention settings

A number of types of ASRH interventions do not fit into one of the above three settings. For example a number of multi-component interventions have used different forms of **mass media** to enhance the impact of the intervention. Mass media involves the use of radio, video, television, internet and/or print media, and can be used for community mobilisation, behaviour change communication and social marketing. The success of a mass media intervention is dependent on a suitable message being targeted and delivered to the appropriate audience.

In 2006, as part of the Steady, Ready, Go! review (see ***Section 2.4*** for more details), Bertrand and colleagues reviewed the strength of evidence on the effectiveness of the three most common types of mass media interventions: radio only, radio with supporting media, or radio and television with supporting media.[268] The authors concluded that there was evidence of the effectiveness of mass media interventions to increase the knowledge of HIV transmission and prevention, improve self-efficacy in terms of condom use, influence social norms about the acceptability of young people discussing RH, increase interpersonal communication about HIV and prevention behaviours, increase the use of condoms, and boost awareness of health providers. Disappointingly, there seemed to be very little impact on delaying age at first sex or on decreasing the reported number of sexual partners.[268, 269] On the other hand, all four studies in the review that looked at a dose-response found that, for some of the outcomes, the impact varied according to level of exposure.[269] More recently, an evaluation of the 'Straight Talk' mass media programme in Uganda showed the intervention to be associated with greatly improved ASRH knowledge, communication with parents and some decrease in reported sexual risk behaviours. However, there was no real control group and this evaluation, based on dose-response of reported exposure, does not represent strong evidence of impact.[270] A recent observational study in Kenya also found that a mass media campaign was associated with increased attendance at VCT services.[271] While mass media is an attractive method for reaching youth and becomes an increasingly important component of intervention programmes as they are scaled-up, the sustainability of such programmes has been questioned.[77, 268]

The **workplace** is another potential setting for ASRH interventions. Workplace programmes provide youth with information and services at or through their place of employment, often using a peer-education approach. Programmes can be initiated and run by the workplace or the workplace can accept a programme run by a NGO or other group. Programmes have been tried at a wide range of sites including hotels and other recreational facilities, plantations, merchant ships, mines and brothels. Workplace programmes are important as they can target out-of-school youth and those who are at higher risk of HIV e.g. truck drivers, those who are away from home. Workplace settings (including apprenticeship and vocational training programmes) are ideal for imparting life skills, providing HIV information and education, and influencing behaviour. Workplaces provide an environment where young people may come together with adults to discuss, interact and learn from each other.[272] If the employer recognises the advantages of maintaining a healthy workforce then they often pay for some or all of the services offered. Workplace programmes, however, are less likely to be successful for HIV prevention among young people in countries where few young people are employed in the formal sector.[256]

Speizer and colleagues included workplace interventions for youth in their review of studies reported between 1990 and 2002 and found only four studies in developing countries, all from Asia.[241] A study in Thailand targeted male conscripts into the Thai army encouraging 100% condom use among visitors to brothels. The authors found a reduction in HIV incidence but there was no control group and it is difficult to know the relative impact of the army programme and other Thai HIV prevention activities.[273] In India, the quasi-experimental evaluation of an intervention among female sex workers found improvements in knowledge, the likelihood of insisting on condom use and a reduction in the incidence of HIV and syphilis infections.[274] Two studies (in Cambodia and Thailand) offered RH education to female factory workers and both found improvements in knowledge, but neither had behavioural outcome measures.[275, 276] In 2008 the Inter-Agency Task Team on HIV and Young People produced a guidance brief on HIV interventions for young people in the workplace. In this guidance brief they provide a number of examples of workplace interventions involving behaviour change communication, access to health services and the creation of a safe and supportive environment.[272]

The idea of **youth centres** which offer reproductive health as one of many recreational and other services is very appealing. Youth centres often include peer educators who refer youth in the community to the youth centre. Centres provide a supportive non-threatening environment where youth can have access to counselling, contraceptives, clinical prevention services, and sometimes, treatment. One benefit to this approach is that youth come into contact with 'influential peers' and connect with an institution.[244] Centres can also attempt to address many of the non-sexual risk factors, including smoking and alcohol use. However, several evaluations have found that youth centres are a relatively expensive and potentially ineffective way to provide reproductive health care to young people.[256, 277]

2.2.5 Young people at risk

Targeting the groups most at risk of infection is an attractive public health strategy and is employed successfully in many developed countries. However, the categorisation of individuals into high and low risk groups is less clear in areas with generalised epidemics and especially where young people are already at higher risk than other members of the population. In countries in SSA where there are generalised epidemics, young girls, men who have many sexual partners, the women who are married to them, prisoners and young people in detention centres, mobile young people, and groups living in relative poverty have also been identified as groups at higher risk.[278] The interventions mentioned above that are based in schools and health-facilities will often not involve these young people who are most at risk. Community-based interventions may be more successful but may still miss these high risk young people. A recent review of studies focusing on young people most at risk in developing countries found only 11 studies reported between 1990 and 2005, all in programme reports or in the grey literature.[278] The majority of the reports were from Latin America and focused on sex workers. In the absence of good evidence from interventions among high-risk young people in developing countries, Hoffman and colleagues used data from studies that targeted high-risk people of all ages. They conclude that the strongest evidence of effectiveness exists for interventions that have outreach as well as facility-based information and services.[278] The authors stress that interventions that decrease the overall vulnerability of these groups will also be important.[278]

In summary, interventions among high risk groups have the potential to impact greatly on the HIV epidemic. However, implementing and evaluating interventions among these high risk populations is particularly difficult due to high mobility, the illegal nature of some of the practices and the potential risk of increasing stigma towards these already marginalised groups.

2.2.6 Structural Factors

Over the last fifteen years an increasing amount of attention has being given to structural factors ***(Section 1.2.6)*** and how they can be altered to prevent HIV. There have been calls to 'enrich the mix' of interventions so that the structural and social environment can support rather than impede new and existing prevention approaches.[279] Proposed interventions to reduce structural barriers include changes in laws and policies to fight discrimination against people living with HIV/AIDS and to protect the rights of vulnerable populations at high risk of HIV; increased services for populations at risk; changes in provider practices; changes in funding priorities; increased participation by the private sector; increased community participation; and the economic empowerment of women.[73] Structural interventions may either facilitate enactment of existing motives to avoid HIV transmission or make enacting risk behaviour more difficult.[280] Structural interventions have the potential to improve the effectiveness of existing individually-focused interventions. For example, existing interventions would benefit from long-term and stable funding for existing interventions and consistent policies and legislation that encouraged the distribution and use of condoms. Sometimes structural interventions would actually be based in one of the above settings, for example, changes in provider practices at a health centre or a change in government policy to allow condom demonstrations in schools, but in other cases not ,for example, legislation to ban pornographic videos. Structural interventions may work in different ways and combinations of such interventions or of structural and individually-focused interventions may be additive, multiplicative or subtractive.

Examples of structural interventions that have been successful in reducing risk behaviour include aspects of the 100% condom use campaign among sex workers in Thailand[281] and increasing access to sterile injecting equipment for intravenous drug users.[282] As Auerbach and colleagues point out, the challenge faced when evaluating structural interventions is that complex social phenomena-such as gender, poverty, economic equality- are not easily reduced to a few variables that can be modified or controlled for testing in an experimental design. Such intervention evaluations often, by necessity, are carried out without a suitable contemporaneous control group which makes attribution of effect difficult.[61]

Structural interventions leading to economic empowerment would potentially be very effective in improving SRH among young people.[283, 284] Economic development would allow young people to stay at school longer which has been shown in some settings to be associated with decreased risk of HIV and unplanned pregnancies.[141] Improved employment opportunities for young people would provide them with more positive expectations regarding their future and hopefully encourage them to see the importance of remaining healthy and avoiding pregnancies at a very young age. Reviews of the evidence of interventions to empower young women economically and reduce women's vulnerability to HIV found that targeting microfinance to adolescent girls might not be as successful as microfinance programmes aimed at older target groups.[284, 285] For example, in Kenya, the Population Council Tap and Reposition Youth (TRY) savings and microcredit programme for out-of-school adolescent girls and young women found that some young women did not like the pressure of having to take out and repay loans and were more interested in voluntary savings.[286, 287] Kim and colleagues identify a shift away from rigid microfinance schemes and towards livelihood training (e.g. vocational training, literacy programmes) as a way to economically empower young girls.[284] However, such programmes may not be cost-effective and sustainable because the investment per girl can be high and the kinds of girls who are likely to complete such a programme are unlikely to be those who are at highest risk. One recent initiative by the World Bank, the Adolescent Girl Initiative, seeks to address the economic needs of adolescent girls and young women in poor or post-conflict countries while also improving their wellbeing. A pilot programme in Liberia aims to combine interventions including job skills, life skills, and entrepreneurship training with linkages to microfinance combined with activities on gender-based violence and reproductive health.[288]

Some interventions have tried to change social norms in addition to improving economic wellbeing. The Intervention with microfinance for AIDS and gender equity (IMAGE) study in South Africa sought to determine whether the involvement of women in the programme would improve household economic wellbeing, social capital, and empowerment and reduce intimate partner violence. Young people were not the direct recipients of this intervention but the project hoped to reduce the vulnerability of young people living in households where an older woman was involved in the programme. The project led to improvements in household wellbeing, social capital and empowerment (other outcomes discussed in ***Section 2.4*** below).[289, 290]

Structural factors are promising targets for intervention efforts and offer renewed hope for the area of HIV prevention among young people. However, the evidence on the effectiveness of structural interventions is very limited. One of the challenges in developing effective structural interventions is that they their impact will be context specific. In their review of the evidence for effectiveness of structural interventions, Rao Gupta and colleagues argue that intervention development should only take place following careful mapping of the social, political, economic and environmental factors influencing both vulnerability and risk and call for research into methods to evaluate structural interventions.[291] Intervention development has usually tried to take the local context into account, though the deeper evaluation suggested by Gupta and colleagues, while important, may make the development of effective structural interventions an expensive and slow process.

2.3 Evaluation of interventions- methodological considerations

Resources for HIV prevention in all countries are limited, and there are competing programmes and activities, including an increased demand for treatment. Evaluation of the effectiveness of interventions is important to allow maximum deployment of effective interventions, to stop harmful interventions being further developed and implemented, and to maximise the cost-effectiveness of interventions.[93] It should be clear whether the evaluation is of intervention efficacy (impact under ideal conditions) or, more likely, intervention effectiveness (impact when delivered through real-life channels). One of the key challenges in intervention evaluation is determining whether an intervention is deemed to be unsuccessful because the evaluation failed to detect an impact or because the intervention was poorly delivered. Often many different pieces of evidence are needed in order to be confident that an intervention has been effective.[292, 293]

Evaluating the evidence on the effectiveness of HIV prevention interventions in young people is inherently difficult. Interventions are complex, often with multiple components, and with different types of evidence of varying quality. Some interventions target the individual, while others target communities or other groups of individuals. Cultural differences, variation in duration and intensity of the intervention, and length of follow-up will have implications on the effectiveness and generalisability of study findings. There is increasing emphasis on the need for rigorous evaluations especially of complex interventions.[294, 295] Where RCTs are not possible or suitable then evaluation can be based on the careful use of surveillance data, observational studies and modelling.[296] A recent WHO consultation reviewing the evidence for policies and programmes to achieve the global goals on young people and HIV/AIDS suggested the following criteria for evaluating the evidence on the effectiveness of public health interventions: (1) Level of evidence, (2) quality of the intervention, (3) quality of the outcome measures, (4) process evaluation of the intervention and (5) the context in which the intervention is delivered.[15]

2.3.1 Level of evidence

The level of evidence on the effectiveness of an intervention relates mainly to the quality of the research design and the methodological quality of the evidence.

Research design

The reported impact of an intervention must be interpreted within the context of the quality of the research design.[94] The main objective of an evaluation is to influence decisions and Habicht and colleagues argue that the complexity or simplicity of an evaluation must depend on who the decision maker is and on what types of decisions will be taken as a consequence of the findings. Based on the types of decision that may be taken, they propose a framework for deciding upon the appropriate evaluation design.[292] One of the main factors influencing the decision on design should be the type of inference to be made. Habicht and colleagues propose the following hierarchy of evidence:

Adequacy 'supportive' evidence: the intervention was implemented and the expected changes occurred

Plausibility evidence: the effects related to the programme were greater than could be explained by any other external influences

Probability evidence: there is only a small statistical probability that the programme's observed effects could have occurred by chance. Probability evidence can only come from RCTs.

This idea of relating the level of evidence to the needs of the audience was taken up by Ross and colleagues when they defined the 'thresholds of evidence' that are needed for different kinds of interventions. The threshold will depend on the interventions' feasibility (including cost), potential for adverse outcomes, acceptability, potential size of the effect and other health or social benefits.[95]

Whether an intervention is to be delivered at the individual or at the community level will also have profound implications for the design and interpretation of a study to evaluate its impact.[293] In clinical research the 'gold standard' study design is a randomised controlled trial in which study subjects are assigned to intervention and control groups at random. Randomisation seeks to balance out external influences between groups so that the true effect of the applied intervention is detectable.[294, 297] This 'experimental' design minimises bias and allows for control of known and unknown confounders. RCTs are criticised as being difficult to conduct for complex interventions, are sometimes not ethical, and that the results are difficult to interpret.[298] Opinion varies as to whether sexual health interventions are suitable for experimental evaluation.[197, 292, 298-300] There is also a feeling that prioritising evidence from experimental designs belittles the value of interventions that cannot be randomised such as mass-media or interventions initiated by community groups. Nevertheless, the RCT is the only design that provides 'probability' evidence, the strongest evidence for causality.

When RCTs are not possible or desirable then quasi-experimental designs, with comparison groups chosen by non-random methods, are often used.[297] These studies can provide evidence of association, especially if they record time series data, but cannot fully control for confounding factors (e.g. other interventions in the community), and are more open to selection bias. On average they will tend to overestimate the impact.[93, 241, 301] Another alternative is to use a pre and post test evaluation only or time-series analysis.[297] However, without an adequate concurrent control group the evidence from such studies is weak and at best provides 'plausibility' evidence as any changes in the prevalence of risk factors or the study outcome might have occurred over time in the absence of the intervention.[95, 293, 302] However, their strength can be increased by careful elimination of other potential factors that could have caused any changes measured, to increase the plausibility that the changes were actually due to the interventions being evaluated. Other study designs using case studies, partner and network studies, or the use of surveillance data provide suggestions but not evidence of impact. In such observational designs, confounding is a problem which must be dealt with as effectively as possible in the design and analysis and which must be considered when interpreting the findings of the study. Ethnographic and qualitative studies provide supportive 'adequacy' evidence, can improve our understanding of the mechanisms by which an intervention has worked and should accompany quantitative evaluation.[164, 295] In the absence of epidemiological and qualitative research evidence, informed judgement provides the weakest evidence. Another important design issue is the length of follow-up post-intervention. This will contribute to the strength of evidence, as time is often needed before improvements are seen and conversely improvements can be transient or diminish over time.[303]

Methodological quality of the evidence

It is also essential to assess the methodological quality of the research undertaken. A RCT can only be considered as high quality evidence if the research was carried out to a high standard. The aims, objectives and study methods must be clear and transparent and the data should be analysed correctly and all pre-defined outcomes and mediating factors presented. The results should be interpreted following critical analysis of the representativeness of the data and objective assessment of the internal and external validity of the indicators used. Alternative potential explanations for the findings should be considered and deemed less likely.[95]

2.3.2 Quality of the intervention

Only high quality interventions that have been shown to be effective should be considered for further investment and large-scale implementation. Assessment of the quality of an intervention is possible when all details of the intervention are available (i.e. objectives, target population, characteristics and mechanisms underlying their characteristics).[304] A full description of the intervention may seem like an obvious request, however, reviews of the evidence of HIV prevention have found that the documentation of the rationale and processes of intervention design, development and implementation is often poor.[94, 305]

It can be helpful to assess the quality of the intervention according to the following criteria:[95]

- Experiential base- the extent to which interventions are developed in the light of previous experience
- Theoretical basis- explicit and plausible theoretical mechanism by which the intervention is postulated to work
- Careful pilot testing- in the target group and in order to modify and improve the intervention
- Feasibility- whether the intervention is acceptable, logistically viable and cost-effective
- Quality and completeness of implementation

One example of the importance of careful pilot testing and assessment of feasibility comes from Zimbabwe where prior to intervention implementation investigators carried out a well-resourced and carefully planned feasibility study. This feasibility study incorporated both formative and process evaluation and paid particular attention to the context of the proposed intervention. The results showed that the ASRH intervention, as originally conceived, was unlikely to be deliverable and both the content and the delivery of the proposed intervention were changed substantially prior to formal evaluation through a RCT.[306]

The relevance of the intervention to the specific health problem in the specific context should also be taken into account when deciding on the appropriateness of an intervention.[95] Any special considerations that need to be addressed when delivering the intervention to different target groups should be provided.[304]

2.3.3 Quality of the outcome measures

Smith and Morrow in their classic book on field trials of health interventions in developing countries stress that a high quality outcome measure should be of public health significance, the probable effect on that outcome should be large enough to be of interest and it should be accurately recorded.[307] These criteria are a good guide but there can be other reasons for including specific outcome measure, for example interventions based on a theoretical model of behavioural change might include mediating factors on the path to behaviour change as outcome measures. Aral and Peterman stress that careful choice of the study outcome measure(s) is crucial and that it should take into account the context of measurement (e.g. intervention evaluation, programme evaluation etc.) and also the level of measurement (individual vs. population).[302]

Programmes targeting ASRH are usually evaluated by measuring a combination of SRH knowledge, SRH attitudes, perceptions of SRH norms, self-efficacy and self-reported sexual and health-seeking behaviour and, occasionally, biological outcomes. Evaluations of community-based studies have also included community level outcomes such as change in community norms.[227] Evaluations of health service based interventions have mainly looked at the achievement of 'Youth friendliness' and/or access to YFHS by measuring coverage of health services and in particular ASRH services. Evaluation has focused more on whether the services were used and less on whether use of the services made a difference in terms of reproductive health outcomes. The measurement of service use can be problematic as attendance at health facilities is not always for reproductive health services. Commonly used outcomes can be broadly divided into the following three categories:[61, 308]

Psychosocial: knowledge, self-efficacy especially in terms of condom use and negotiating sex, perceived risk, personal or interpersonal skills, attitudes towards safer sex behaviours, attitudes towards people living with HIV/AIDS (PLWA), intentions to adopt risk reduction behaviours, influence of peer and social norms, communication with partners, social support.

Behavioural: Delayed initiation of sexual intercourse, frequency of sex, number of sexual partners (non-regular, new, concurrent etc), use of contraception (ever, always, last sex), number of pregnancies, use of condoms (ever, always, last sex, last sex with non-marital non-cohabiting partner), number of unprotected acts of sexual intercourse, unprotected sex with primary partner/secondary partner, reported STI symptoms, reported treatment for STIs, reported testing for HIV.

Biological: measured rates of STIs including HIV, measured pregnancy.

The quality of the outcomes refers not only to choice of the outcome but also to the reliability and validity of the measurement of the outcome. The reliability of a test or instrument is its ability to give consistent results over many tests. Internal consistency, the consistency of an individual's responses to the same or similar questions within, for example, a questionnaire is also a measure of reliability. Validity on the other hand is a measure of how well a test or instrument measures what it purports to measure. Valid data are data that are as close to the truth as possible.[304] As pointed out by Aral and Peterman, it is more important to have a valid outcome measure than to have a reliable outcome measure that has poor validity.[302]

Measurement of some of the above outcomes such as skills and vulnerability is particularly challenging. There has been much debate surrounding the use of subjective outcomes such as self-reported intentions and behaviours as they can be subject recall and desirability bias.[133, 193, 309-312] Social desirability bias occurs when study participants do not answer questions honestly because they perceive the truth to be socially unacceptable or undesirable.[304, 310] The results of a number of studies in SSA suggest that in the context of a sexual behaviour survey, women tend to underreport their number of sexual partners whereas men tend to over-report.[313, 314] This kind of bias is more likely to be differential in the context of intervention evaluation where respondents exposed to the intervention are more likely to be aware of what the desirable response than those not exposed to the intervention.[61] Recall bias is common when questions relate to the timing and frequency of behaviours and especially when questions relate to a more distant time period such as the past year. Furthermore, respondents can understand and define behaviours differently, for example, the definition of first sex.[315, 316]

The quality of the data collected often depends on the interview methods. Quantitative methods are commonly used for intervention evaluation where plausibility or probability evidence is sought. Traditionally questionnaires are administered face-to-face with an interviewer asking the respondent a series of pre-defined questions. Alternative methods such as the use of audio or computer assisted self-completed questionnaires[193, 317-319] and confidential voting[320] have been developed in an attempt to improve reporting of sensitive information. The comparison of data collected during face-to-face interviews with data collected using these alternative methods suggests that some sensitive behaviour are reported more frequently with the alternative methods but that the validity of reported behaviours recorded by either method remains questionable. Qualitative methods such as in-depth interviews, participant observation, can get more in-depth but not necessarily more valid information on sexual behaviours.[133] Measuring community-level outcomes can be more challenging and some work is being done to develop alternative outcome measures. For example in Zimbabwe the use of risk mapping is being explored in order to measure more subtle changes caused by community level interventions.[321]

The problems associated with the reliability and validity of self-reported behavioural outcomes and technical advances during the last decade have led to a growing interest in objective outcomes such as biological markers.[322, 323] In intervention evaluation the incidence (number of new cases in a fixed period) of a biological marker is a more valuable biological marker than prevalence (current number of cases). Nevertheless, prevalence is often the chosen outcome especially when the large sample sizes needed to collect incidence data are not feasible. The measurement of intervention impact on other STIs apart from HIV is important as STIs are associated with considerable morbidity and have also been shown to facilitate HIV transmission.[22] While changes in rates of other STIs can be used to demonstrate that sexual transmission of the pathogen has been interrupted by an intervention, it should not be assumed that they can reliably be used as a proxy for rates of HIV.[302, 324] The use of biological markers as outcome measures is not always feasible and biological tests are technical, intrusive and expensive.[322] Furthermore, the sensitivity and specificity of the STI laboratory test can have an impact on the ability of a study to demonstrate intervention impact especially in low prevalence populations.[325]

Both behavioural and biological measures are important outcomes for studying the efficacy or effectiveness of behaviour change interventions and both provide useful information.[323, 324, 326] However, behavioural and biological outcome measures cannot substitute, nor validate, one another, and neither serves as a true surrogate for HIV prevalence or incidence. Biological markers don't always correlate with reported behaviour and the relationship between the two is often complex.[296, 314, 322, 323, 327-329] This complexity largely stems from the fact that different STIs have different age and sex prevalence rates, different transmission rates, different durations, and are differentially affected by condom use and use of other forms of contraception.[323, 330] A modelling study using data from a HIV intervention trial in high-risk populations in 7 cities in the US found that limiting the number of sex partners was a more effective strategy for reduction of the transmission risks for highly effective STIs such as gonorrhoea, than for reduction of HIV risk. In contrast, condoms were found to be more effective for low transmission STIs such as HIV.[331] Ecological comparison of results from cross-sectional population-based studies in four African cities found high-risk sexual behaviour patterns in all four cities. The authors concluded that the variation in rates of HIV between these cities could be explained by other factors such as rates of circumcision, ulcerative STIs and perhaps variation in HIV sub-types rather than sexual behaviour.[332, 333] Shain and colleagues argue that the link between behaviour and biology can be clarified when behavioural measures incorporate context and are considered simultaneously.[326]

2.3.4 Process evaluation of the intervention

Poor implementation and monitoring of an intervention can have an impact on its measured effectiveness. Process evaluation involves the assessment of a programme's content, scope or coverage, together with the quality and integrity of implementation.[334] The results of process evaluations along with information on the cost of the intervention and reception by target audience and implementers are of particular interest to programmers. In clinical research the mechanism by which the intervention is assumed to work is usually established. However, the mechanisms by which behavioural interventions work are far less well understood.[181] Process evaluation should always accompany the outcome evaluation of complex and behavioural interventions so that the facilitators and barriers to implementation and acceptance of the interventions can be assessed and to inform as to when and where findings might be applicable.[93] Such process evaluation can also help to determine which component of a complex intervention was best delivered and had the best response from the target group.[181] However, process evaluation will not necessarily be able to identify which component of a package of interventions was most effective and may only be able to identify the components that could *not* have been effective as they were not delivered, or not accessed by those who needed them.

2.3.5 Context in which the intervention is delivered

The importance of the context in which the intervention is delivered is usually even more important for behavioural or social interventions than for biomedical interventions (e.g. medicines or vaccines). The specific context is of particular interest to policy makers who need to decide whether an intervention would be effective in their setting.[335] Pawson and Tilley in their discussion of evaluation stress that Mechanism + Context = Outcome i.e. the contextual conditions necessary for triggering programme mechanisms are integral to the outcome of the intervention.[336] Ingham urges researchers to move from considering individual risk takers to vulnerable situations.[337] Context includes the target population characteristics, prevailing social, cultural and economic environment (gender norms, relations between different age groups, social norms, value systems, economic status, consumerism, geography, beliefs around health and illness, presence of other HIV/AIDS control programmes) and epidemiological characteristics of the HIV epidemic (stage of the epidemic, core groups, HIV prevalence). The epidemiological characteristics of the HIV epidemic (stage of epidemic, core groups, STI prevalence) have been identified as an important factor in the effectiveness of HIV prevention interventions.[15] This has been seen in the Mwanza[66], Rakai [68] and Masaka[69] trials of STI treatment for the prevention of HIV where there were differences in study populations with respect to sexual risk behaviour, STI rates and stage of HIV epidemic ***(Section 1.2.5)***. Another example of where context was shown to be important was the 'Gay Heroes' peer-education programme which led to a reduction in unsafe sex among gay men in small towns in the US in the early 1990's.[211] This same intervention did not have any impact when repeated in the cities of Glasgow[338] and London[339] in the late 1990's or in low and middle income countries between 2002 and 2007.[340] Process evaluation indicated that failure of this intervention in the UK was likely to have been due to a reluctance to discuss sexual practices in bars and gyms in larger cities, problems with attrition of peer educators and perhaps a less urgent concern about the HIV epidemic at a time when ART was becoming available.[341, 342]

2.4 Evidence on the effectiveness of ASRH interventions in sub-Saharan Africa

2.4.1 Introduction

In sections 2.1-2.3, the main types of interventions that have been deployed in sub-Saharan countries in an effort to prevent HIV, STIs and unplanned pregnancies among young people have been highlighted. This section contains a summary of the evidence on the effectiveness of ASRH interventions in developing countries. This summary is based on a general review of the literature and also includes the results of a systematic review that was recently carried out of ASRH studies conducted in SSA and reported between January 2005 and December 2008. The results of the long-term evaluation of MEMA kwa Vijana were included in the systematic review, but these results are not be presented in this chapter. All intervention impact results presented below were statistically significant ($p<0.05$), unless otherwise specified.

A compelling case can be made for the need for focussed interventions for young people, but it is less clear how this should be done. Over the last fifteen years, there have been almost as many reviews of the accumulating evidence for the effectiveness of ASRH interventions as there have been high quality studies evaluating interventions. Reviews have either focused on studies carried out in developed countries and in the US especially[209, 226, 236, 303, 343-348], both developed and developing countries [50, 225, 231, 349-355] or developing countries only.[29, 94, 241, 267, 335, 356-360] Overall the quality of the reviews is good but the extent to which they critically appraise the quality of the studies they included varies considerably. Reviews also vary according to the type of interventions included, the intervention setting, the type of outcomes and the quality of the study design. Some of the more recent reviews have attempted to identify the characteristics associated with successful interventions.[94, 225]

One of the earliest reviews was published in 1994 by Choi and Coates. They did a comprehensive review of the impact of HIV prevention interventions among different populations in both developed and developing countries in the late 80's and early 90's. In their discussion the authors state *'Those sceptical of the potential of preventive interventions to bring about change should be encouraged by the data presented here'*. Their optimism is unlikely to be based on results from studies among adolescents where they found mixed results in the seven intervention evaluations (4 school-based; 3 clinic-based) among this population that had measured behaviour change (all US studies). None of the evaluations among adolescents had measured impact on biological outcomes.[231]

Considerable progress in terms of the number and quality of studies was seen when almost ten years later, Speizer and colleagues, found 41 developing country studies, carried out between 1990 and 2002, which they considered to provide 'sufficient scientific basis for making inferences concerning causality'.[241] This review was a follow-up to previous work reported by the FOCUS on Young Adults program[244, 361] and is more a description that a critical appraisal of the selected studies. Of the 22 school-based studies that they included in their review, 17(77%) improved knowledge and attitudes, 4/11 reported a delay in sexual initiation, 3/6 a reduction in sexual partners, 6/10 increased contraceptive use and only 1/3 increased use of services. The authors found only five school-based studies that had an experimental design, measured reported sexual behaviour (as opposed to just knowledge or other mediating factors) and were carried out in SSA.[170, 200, 362-364] Three of these five studies showed a positive impact on reported sexual behaviour with all showed improvements in knowledge or other mediating factors. The same review identified only 4 health-facility based programmes with what the authors considered to have a strong evaluation design, 2 of which had been carried out in SSA.[365, 366] Neither programme had a positive impact on utilisation of services but one programme, which also included a mass-media programme, did result in an increase in reported communication by parents and youth about sex.[365] Only five community-based interventions were included in the review. There was consistent evidence for an increase in contraceptive use with 4/4 studies showing positive impact. Positive intervention impact was also seen in the one study that looked at impact on initiation of sex and the one study that looked at access to services. Three of these five studies took place in SSA; all in West Africa.[367-369]

The following year a review was published by Gallant and colleagues covering the same time period but focusing only on school-based studies in sub-Saharan Africa.[94] No criteria were set for study design but only studies published in a peer-reviewed journal (1990-2002) were included. The authors critically appraised the selected studies but their conclusions are limited by the paucity of studies that measured behavioural outcomes. Out of the four studies that measured reported condom use, only one study found an increase. Similarly, only one of five studies found a decrease in reported sexual behaviour. Only four of the included studies had an experimental design.[170, 200, 363, 364] The study in Zimbabwe reported by Mbizvo and colleagues and colleagues, included in the Speizer review, was not included by Gallant perhaps due to the poor description provided of methods and results.

One of the most comprehensive reviews of curriculum-based sex and HIV education programmes was carried out by Kirby and colleagues in 2005. The authors restricted their review to studies with a reasonably strong experimental or quasi-experimental design with both intervention and comparison groups and both pre-test and post-test data collection. A total of 83 evaluation studies were identified including only 18 in developing countries, 9 of which took place in SSA. Two-thirds of all the studies reviewed found a significant positive impact on one or more of the sexual behaviours they measured or on rates of pregnancy or STIs. Twenty three of these studies measured impact on pregnancy or STI rates, and of these, only nine used laboratory tests to measure these health outcomes. Only 3 out of these 23 studies found significant positive effects on biological outcomes. The MEMA kwa Vijana Trial was the only intervention evaluation in a developing country to include biological outcomes.[178, 186] Only 9 of the 83 studies evaluated the impact beyond 3 years with the longest follow-up at just less than 5 years. The review included results from five evaluations of interventions in SSA that had been published subsequent to the Speizer and Gallant reviews.[186, 370-372]

In 2004-2006, the Department of Child and Adolescent Health and Development of the WHO collaborated with the London School of Hygiene & Tropical Medicine (LSHTM) to lead a major systematic review of interventions to prevent HIV among young people in developing countries, which was released in full as an issue of the WHO Technical Report Series.[254] Though historically there has been a broad consensus as to what types of interventions are key to preventing HIV in young people, this was the first time that different types of HIV interventions for young people had been systematically reviewed alongside each other, in a transparent way, and graded for their effectiveness. The review was based on a new methodology for reviewing the available research for policy makers and programmers, which recognised that decisions need to be taken *now* despite the fact that the evidence-base is not perfect, and where multiple interventions are likely to be needed to achieve the desired outcome of decreased HIV incidence. Known as the *Steady, Ready, Go!* approach, the methodology is based on the premise that different strengths of evidence are needed to be able to recommend different types of interventions for wide-scale implementation, and that the strength of the empirical evidence available from research and evaluation studies needs to be assessed in relation to these defined evidence "thresholds". Interventions were assessed in terms of the specific goals and targets relating to HIV and young people that were endorsed by the UNGASS on HIV/AIDS, namely increased access to the information, services, and skills young people need to be able to reduce their risk of HIV, as well as their impact on reported sexual behaviours and, where available, HIV incidence. The review was based on interventions in schools, health services, geographically-defined communities, the media, and targeting young people most at-risk of HIV (specifically young sex workers, men who have sex with other men and young injecting drug users). Studies included in the review took place in all developing countries and were completed or published between 1990 and June 2005. The review of interventions within schools was limited to studies with an experimental or quasi-experimental study design, while reviews of interventions in other settings had less strict criteria in terms of study design. An explanation of the Steady, Ready, Go! recommendations is provided in ***Box 2.3***.[17] and the recommendations generated from the review are summarised in ***Appendix 3***.

Box 2.3: Explanation of 'Steady, Ready, Go!' recommendations.[17]

Go	Take these interventions to scale NOW!
	Sufficient evidence to recommend widespread implementation on large scale now, with careful monitoring (coverage & quality... & cost)
Ready	Implement widely but continue to evaluate
	Evidence suggests interventions are effective, but large-scale implementation must be accompanied by further evaluation to clarify impact and mechanism of action
Steady	More research and development still needed
	Evidence is promising, but further intervention development, pilot testing and evaluation urgently needed before they can move into the "Ready" or the "Do not go" categories
Do not go	Not the way to go.....
	Strong evidence of lack of effect or of harm

In summary, these early reviews present mixed evidence on the effectiveness of school, health-facility and community-based interventions to impact on SRH knowledge, mediating factors and reported behaviours. It is important to note that other reviews restricted to studies with stronger study designs, such as experimental and quasi-experimental designs, have also shown conflicting results.[94, 225, 359] Encouragingly, there has been a move towards the use of reported behaviour as an outcome though up until 2005 MEMA kwa Vijana was the only ASRH study in a developing country that had been able to include the more objective biological outcomes of STI and pregnancy rates.[186]

In view of the urgency of improving prevention programmes for young people it was timely to re-evaluate the evidence for HIV prevention in young people. This review provides updated guidance for policy makers, programmers and funders on the most promising, evidence-based interventions to prevent HIV among young people that can be taken to scale, and updated recommendations for priorities for research. This review update follows closely the methodology of the *Steady, Ready, Go!* (SRG) review published in 2006. In the following sections the review methods are first presented and then the results of the review for interventions in the three social settings most relevant to the research described in this thesis are presented: schools, health facilities, geographically-defined communities. The review focuses on studies reported during 2005-2008 but earlier studies are discussed where they illustrate important points. This updated review is timely as the results of several major RCT of adolescent HIV prevention interventions conducted in SSA have been reported since the first SRG review. Unlike the previous SRG review, mass media interventions or interventions targeting most at-risk groups have not been evaluated as the MkV1 intervention did not contain these components. Neither has a systematic review been conducted of the evidence on the effectiveness of interventions that aim to reduce the non-sexual transmission of HIV or structural interventions such as legislation, economic investment, taxation etc. However, in order to provide a complete overview of effective interventions for young people, the evidence for these alternative interventions has been briefly summarised in ***Section 2.2*** above.

2.4.2 Systematic review of evidence from studies in sub-Saharan Africa (2005-2008)

2.4.2.1 Objectives

The overall goal was to systematically review and update the evidence on the effectiveness of HIV/AIDS prevention interventions in young people in SSA. The studies included aimed specifically to improve ASRH either by improving knowledge, education, skills and behaviour or by controlling STIs. All studies included in this review must have measured at least one biological or reported sexual behaviour outcome, including use of reproductive health services. This updated review focused on interventions carried out and/or published from January 2005-December 2008. Evidence-based recommendations were made based on the impact of interventions on biological and/or reported sexual behaviour outcomes only. Recommendations were based on studies identified in this review but also based on studies that were conducted prior to 2005 i.e. those included in the first SRG review. The recommendations in this report are specifically made for SSA.

2.4.2.2 Methods

Evaluating the evidence

The *Steady, Ready, Go!* approach is a systematic method to assess the strength of evidence of effectiveness in HIV prevention interventions, and to make policy recommendations based on whether the strength of evidence meets the predefined threshold of the strength of evidence needed for that type of intervention in that particular setting ***(Box 2.3)***.[17, 95] In this review a similar methodology is used, briefly described here:

1. Interventions are categorised by the 'setting' in which they are implemented, and then, within each setting, by the type of intervention. For this review they have been categorised into interventions in schools, health services, and geographically-defined communities;
2. The theoretical strength of evidence needed for widespread implementation of each type of intervention, or the 'evidence threshold' is defined as low, moderate or high, based on an explicit assessment of the following key factors: feasibility, cost, potential for adverse outcomes, acceptability, potential size of effect, other health or social benefits ***(Box 2.4)***. Considerations for defining the evidence threshold in this report are similar to those described in the first SRG review,[95] with the exception of dissociating cost from the consideration of feasibility. Each type of intervention in each of the settings covered in this review – schools, health services and geographically-defined communities – was considered separately to determine the strength of evidence that would be needed to recommend its widespread implementation. Consideration of the required strength of evidence was determined prior to evaluating the individual studies included in this report. Interventions in each setting are further divided into categories of interventions and tables are included in the respective results sections of this report showing the required threshold of evidence for each category of intervention.
3. Studies are selected based on pre-defined inclusion/exclusion criteria and are then critically reviewed (see below);
4. The strength of empirical evidence for each type of intervention within a setting is summarised based on the type of evidence available. This takes into consideration factors such as study design, process evaluation and quality of implementation, analysis, and feasibility of the intervention in achieving the desired outcomes (in relation to the UNGASS goals). This is then compared against the theoretical evidence threshold required to recommend widespread implementation;
5. Evidence-based recommendations are derived from this comparison for each type of intervention within a given setting and allocated to one of four groups ***(see Box 2.3)***: 'Do not go' if the evidence threshold has been met and there was evidence of a lack of effectiveness or harm, 'Steady' if the threshold of evidence needed to recommend widespread implementation had not been met, 'Ready' if the evidence threshold had been partially met, or 'Go!' if the evidence threshold had been reached.

The "Do not go, Steady, Ready, Go!" recommendations are particularly important for policy makers, and programme implementers. However, they also have important implications for researchers, as the "Steady" and "Ready" recommendations indicate types of interventions that should be a priority for further evaluation research in order to move them either to "Do not Go" or "Go!".

Box 2.4: Evidence threshold for widespread implementation in sub-Saharan Africa for the six key attributes of an intervention

Threshold of evidence needed	Feasible	low cost	Low risk of adverse outcomes	Acceptable	Large potential size of effect	Other health or social benefits
Low	√	√	√	√	D	D
Medium	D	√	√	√	D	D
High	x	D	X	X	X	X

Key: √= necessary; D=desirable; X= not necessary

Search strategy

From a total of approximately 70 available databases, those most likely to contain relevant citations were selected. A computerized search of the Medline, Embase, PsychINFO, GlobalHealth, Popline, ERIC, Cochrane and Web of Science databases was conducted, searching for publications between January 2005 and December 2008. The search was restricted to studies in SSA, and with no restriction on language. The detailed electronic searches included terms from each of the following key concepts: Intervention study design, Preventive health services , HIV/STIs/Reproductive health, Adolescents and sub-Saharan Africa. Non-published studies, identified during the literature review, in the references of a published paper, or through prior knowledge of current ongoing research, were included where possible in order to avoid publication bias. In order to refine the search criteria, initial searches included the years 1990-2004 and results were checked to see that relevant studies included in the first SRG review had been identified. The initial search strategy was also refined to ensure that pre-identified relevant studies published from 2005-2008 had been identified. In addition to the database search, a number of electronic resources were searched for additional citations: www.clinicaltrials.gov, www.controlled-trials.com, the HIV Prevention Trials Network website, the Reproductive Health Library, ELDIS and id21. Two completed RCTs were identified that had not yet published results from their final evaluation. Authors from both studies were contacted to request additional information. The author from one of these studies ("Grannies do AIDS speak: a randomized controlled trial of empowerment of female elders in rural South Africa") responded but unfortunately the results were not ready to be shared. The second author did not respond to our request ("Let us protect our future: a cluster-randomized controlled trial of a HIV/STD risk-reduction intervention for young South African learners"). Finally, the references from all relevant studies were examined for any additional relevant citations.

Study identification

Criteria for inclusion in this review are shown in ***Box 2.5***. Briefly, the review was limited to studies with a contemporaneous comparison group or time series analysis in the intervention group and with measurement of the impact on biological outcomes or on reported sexual and reproductive health behaviour. Evaluations needed to be carried out in at least 100 people and at least 3 months post-intervention. There must have been both pre- and post-intervention data, or if there were only post-intervention data an effort must have been made to exclude other reasons for any differences seen.

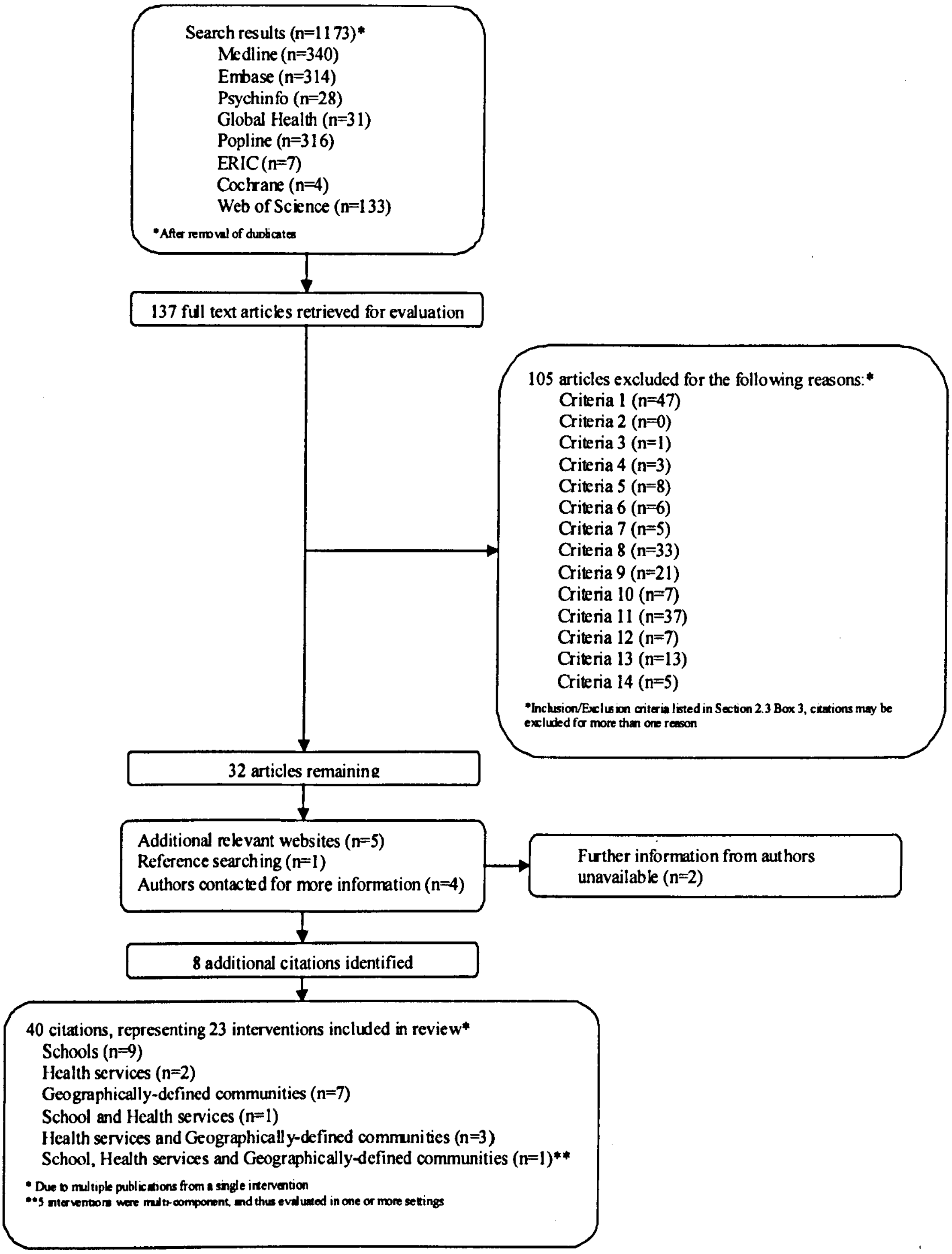
Initially, the citations identified were evaluated for relevance on the basis of their title, abstract, and key words. Non-relevant papers, such as curriculum manuals, and policy documents were excluded. Ten percent of all citations were evaluated by a second reviewer as a quality control measure. Search of additional electronic resources was also conducted. The full text of potentially relevant papers was read by the first reviewer. The first reviewer documented and subsequently discussed with the second reviewer each study in terms of the inclusion and exclusion criteria. The second reviewer reviewed the full text of any papers where eligibility for inclusion was not clear-cut (19 studies). A third reviewer was available in the event of disagreement between reviewers. The study selection process is shown in ***Figure 2.1.***

Data from studies selected for final inclusion in this review were extracted using a standardised format adapted from one developed by Kirby and Laris (Doug Kirby, personal communication). Completed data extraction forms were sent to the authors for verification of accuracy and completeness. The authors of 12 of the 22 included studies responded and minor changes to the data extraction forms were suggested for 8 studies.

Box 2.5 Inclusion Criteria

1. Is the report of an intervention evaluation?
2. Were the evaluation results released 2005-2008?
3. Was at least one of the intervention settings in sub-Saharan Africa?
4. Was the intervention based in a school, and/or health facility and/or geographically-defined community?
5. Does the target population include young people aged 10-24 years (or part of that age group)? If it also includes other ages, is there an analysis of the impact of the intervention in the young people (10-24y) age range or at least part of that range?
6. Is the study population largely representative of the general population of young people (as opposed to a specific subgroup e.g. young commercial sex workers)?
7. Does the intervention focus on one of the following: (i) Improving sexual and reproductive health skills and behaviour (ii) Controlling sexually transmitted diseases (iii) Reducing unintended pregnancies (iv) Increasing utilisation of health services for treatment of STIs and/or behaviours related to more appropriate service utilisation?
8. Does the evaluation design include a contemporaneous comparison group or a before-after/time series analysis in the intervention group?
9. Does the evaluation include pre and post intervention data, or if only post-intervention data then has an effort been made to exclude other reasons for any differences seen?
10. Was the evaluation carried out in at least 100 people and at least 3 months after the start of the intervention?
11. Did the evaluation outcomes include at least one of the following: (i) Prevalence or incidence of HIV (ii) Prevalence or incidence of another STI (iii) Prevalence or incidence of pregnancy (measured by lab test or clinically-observed) (iv) Reported SRH behaviour (including treatment seeking behaviour)?
12. Are there sufficient details on the content of the intervention to assess its type within the setting?
13. Are there sufficient details on the design and methods of the evaluation to assess Criteria 6-10? (>2 Unclear = Exclude)
14. Were the data analysed appropriately (or are there sufficient details to be able to do that)?

Figure 2.1. Systematic Review study selection



Data synthesis

In the following sections the evidence on the effectiveness of ASRH interventions implemented in one of more of the three social settings most relevant to the MkV1 intervention is summarised: Schools, Health Facilities and Geographically-defined communities.

Within each setting, studies were further classified according to type of intervention. The typology is described in detail in the results section for the relevant setting. The authors of the first SRG review made an effort to choose a typology that they felt reflected the key choices that policy makers and programme managers needed to make as to what they should invest in within that setting. Although the resulting typologies are not the only way that studies could be classified, in order to provide a basis for comparison with the first SRG review, the typology used in that review was retained.[227, 235, 254] As an impact on biological outcomes is the main public health objective of interest, the results from the group of studies which used biological measurements are presented in a separate section of this chapter.

Some studies evaluated multi-component interventions conducted in more than one setting (e.g. in schools, health facilities and geographically-defined communities). Where this happened, the results from one study are reported under two or more settings. An intervention was considered as having an effect (positive or negative) if one or more significant results were found from among all of the relevant outcomes measured.

Following presentation of the results for this review update, summary and overall recommendations for the combined results of the first and current SRG reviews are then presented. For simplicity, a p-value of ≤ 0.05 was considered significant for all reported outcomes in all settings, based either on the entire sample or the sub-sample stratified by gender. This will potentially overestimate the number of true effects (beneficial or harmful) that are reported, since a p-value of 0.05 means that there is a one-in-twenty probability that the observed difference was due to chance, and some individual studies included at least 20 such comparisons. Nevertheless, if the vast majority of statistically significant observations are in the same direction, for example show a positive impact, then it is unlikely that they would have all occurred by chance. In some studies, multiple waves of data were collected. Unless otherwise noted, results are presented for the last data collection point. Most studies measured a number of variables, for which only a small number were significant. To avoid reporting bias, results for all sexual behaviour outcomes measured are presented here, and results for all variables measured including factors mediating sexual behaviour such as knowledge and attitudes are presented in the expanded study descriptions in the review report (www.memakwavijana.org/publications/2010.html).

2.4.2.3 Sex and HIV education interventions in schools

Classification

For the purposes of this review, to be categorised as 'In-School' a major component of the intervention must have been set in schools or other learning institutions such as colleges or universities, or the in-school component of the intervention must have been evaluated separately. For this review a typology similar to that of the first SRG review was used, classifying interventions in schools into curriculum versus non curriculum-based, and adult versus peer-led. All of the curriculum-based studies included in this review contained all or most of the "Kirby characteristics" ***(Section 2.2.1, Box 2.1)***, and therefore interventions have not been further divided based on this criterion. The various types of school-based interventions were adjudged to require a low threshold of evidence ***(Appendix 3, Table A3.1)***.

Evidence from the first SRG review

In the first SRG review, Kirby and colleagues included 22 school-based studies with experimental or quasi-experimental design that measured reported behaviour.[235] Twelve of the 22 in-school interventions evaluated were conducted in SSA and 8 of these 12 studies had an experimental design.[170, 186, 200, 233, 362-364, 373]

An increase in knowledge was detected in all in-school sexual and HIV education intervention studies, and these were therefore awarded a clear 'Go' for knowledge. Sixteen of the 22 interventions reviewed had a significant desired impact on at least one of the following: initiation of sex, frequency of sex, use of condoms or contraceptives, incidence of unprotected sex. Curriculum-based interventions led by teachers were generally effective in inducing positive reported behaviour change, and were awarded a 'Go' rating. Both non-curriculum-based and peer-led interventions warranted a 'Steady' rating for reported behaviour change, though this was due in part to the limited number of studies of these types. Only one among the 22 interventions studied was associated with an increased reported sexual risk behaviour,[369] providing strong evidence that focused sexual and HIV education programmes are very unlikely to lead to increased reported risky sexual behaviours. Only the MkV1 study[186] reported detailed intervention cost data or included cost-effectiveness analyses.[180] ***Table A3.2*** in ***Appendix 3*** summarises the results from the first SRG review of interventions in schools.

Evidence from the recently updated review of interventions in schools

Excluding MkV1, 10 studies of interventions in schools in SSA that were reported between 2005 and 2008 met the criteria for inclusion in this update of the SRG review (Studies B, E-M).[374-383] Five were in South Africa, three in Kenya, and there was one intervention study each in Uganda and Zimbabwe. ***Tables 2.1 and 2.2*** summarise the studies included in this review and their impact on sexual behaviour outcomes.

Characteristics of studies and interventions

Seven studies were teacher-led and curriculum-based. One study (Study B) was described by the authors of the original study as being peer-led and was curriculum-based, though the "peers" in this intervention were not current students but rather young people who were nationally-recruited and were in their 'gap year' between A-levels and university. They were rigorously trained as peer-educators during a 5 week residential training, and then sent to live and work in the intervention communities. The final two studies (Studies L and M) were peer-led, non curriculum-based interventions. Two interventions were implemented in primary schools (Studies J and K), 7 were implemented in secondary schools (Studies B, E, F, G, H, I and M) and one intervention was implemented at a university (Study L).

Two of the 10 studies employed an experimental study design (Studies B and K) and 8 were quasi-experimental, where assignment to study arm was not random. While 8 of the 10 studies had fairly large sample sizes, 2 studies (I and L) clearly lacked statistical power to detect a programmatic effect on sexual behaviour, with sample sizes of less than 700 and further stratification by gender. These studies have been retained in this review because they included other measurements where they had sufficient power. In interpreting the overall results of this review, it will be important to bear in mind that inclusion of these studies negatively biases the results pertaining to reported sexual behaviour.

Table 2.1. Details of interventions included in the systematic review

Study, location and programme	Type	Target population and primary objectives	Description
B - Zimbabwe, Regai Dzive Shiri (Cowan et al unpub)[374]	**Schools:** Older peer-led, Curriculum-based **Health facility:** Type 1c (service providers, community, other sectors) **Community:** Type 3 (community-wide, traditional networks)	* Youth with mean age 15 years in rural areas * Targeted sexual initiation, condom use, number of partners, use of health services * Multi-component intervention * Health service objective: Increase access to high quality sexual and reproductive health services for young people * Community objectives: Raise issues related to adolescent sexuality among adults, improve communication between parents and youth, improve community safety for young people, enable adults to support youth to reduce risk	* In-school programme led by older, highly trained peers * Covered refusal skills, self-efficacy, self-esteem, STI/HIV, sexuality, contraception, abstinence, access to reproductive health care, social values, respecting individual rights, gender * Highly participatory curriculum offered to all in- and out-of-school youth wishing to participate (not just study cohort) * 10-15 lessons per year over 3 years * Five-day clinic staff training for at least one nurse per clinic to improve youth friendliness of clinic staff, and re-training after 2 years *On-site training for remaining clinic staff *Monthly clinic support visits by project staff for clinic assessment and additional training, as necessary * Two modules of eleven 3-hour session each delivered to community members by trained and supported community facilitator *Community awareness-raising sessions for parents and adults * Sessions were participatory, designed to maximise ownership of learning points, encouraging development of life skills and attitude change * In year 4 a 24-session out-of-school youth programme was implemented
C - South Africa, Stepping Stones (Jewkes et al, 2008)[384]	**Community:** Type 2 (youth, own system and structure for delivery)	* Youth aged 15-26 years in rural areas * Targeted condom use, number of partners (total,casual,transactional), intimate partner violence, drinking and drug use	* Peer-led sessions for in- and out-of-school youth * Peer group meetings * One community-wide meeting
D - South Africa, loveLife (Pettifor, 2005)[385]	**Community:** Type 2 (youth, own system and structure for delivery)	* Youth aged 15-25 years in rural and urban areas * Targeted sexual initiation, condom use, number of partners, gender and social norms	* Promotion of HIV risk reduction and positive lifestyle through media programmes including billboards, television, radio and printed materials * Comprehensive, interactive educational programmes for youth, parents, organisations and communities

Table 2.1 (CONTINUED) Details of interventions included in the systematic review

Study, location and programme	Type	Target population and primary objectives	Description
E - Uganda, Voluntary Counseling and Testing and School Health Education (Dente et al, 2005)[375]	**Schools:** Adult-led, Curriculum-based	* Youth aged <16-19 years * Targeted HIV/AIDS, sexual behaviours, knowledge and access to condoms * Multi-component intervention	* In-school teacher-led programme * HIV/AIDS education was incorporated into the standard government health education curriculum * Included participatory activities for students such as art competition, drama, poetry, posters
F - South Africa, Life skills education (Magnani et al, 2005)[379]	**Schools:** Adult-led, Curriculum-based	* Youth aged 14-24 years * Targeted sexual debut, secondary abstinence, number of sex partners, condom use	* In-school teacher-led programme * Based on national curriculum but each school developed their own programme, implemented to varying degrees in all schools * Covered STI/HIV, community assistance, self-efficacy, living HIV-positively, caring for people living with AIDS, coping with loss * Sessions at least once per week for 20 weeks
G - South Africa, Department of education life skills programme (James et al, 2006)[377]	**Schools:** Adult-led, Curriculum-based	* Youth aged 12-21 years * Targeted sexual behaviour, condom use	* In-school teacher-led programme * Covered HIV/AIDS, attitude to condoms, people living with AIDS, gender, perceptions about sexual behaviour * Used didactic and interactive teaching, group work and role-play
H - South Africa, HealthWise Program (Smith et al, 2008)[382]	**Schools:** Adult-led, Curriculum-based	* Youth mean age 14 years * Targeted sexual debut, sexual activity, condom use, number of sexual partners, substance use	* In-school teacher-led sexual health and substance use programme * Covered sexual activity, condoms, multiple substance use * Youth Development Specialists were also hired to liaise between schools and communities * 12 lessons in grade 8 and 6 booster lessons in grade 9, each lesson taking 2-3 class periods to deliver

Table 2.1 (CONTINUED) Details of interventions included in the systematic review

Study, location and programme	Type	Target population and primary objectives	Description
I - South Africa, US alcohol/HIV prevention curriculum adapted for South Africa (Karnell et al, 2006)[378]	Schools: Adult-led, Curriculum-based	* Youth mean age 16 years * Targeted sexual debut, condom use, alcohol use, alcohol-related problems	* Teacher-led curriculum along with peer-assistance for group discussions * Covered HIV and alcohol, consequences of alcohol and sex, self-efficacy, avoiding risky situations * Curriculum was 10 units of 30 minutes each over 8 weeks
J - Kenya, Kenya national primary school HIV education (Maticka-Tyndale et al 2007)[380]	Schools: Adult-led, Curriculum-based	* Youth aged 11-16 years * Targeted sexual debut, sexual activity, condom use	* In-school teacher-led programme * Covered HIV/AIDS, self-efficacy, stigmatization, care for people with AIDS *Used role modelling, activities to build self-efficacy, didactic instruction * Set up school health clubs
K - Kenya, Education and HIV/AIDS Prevention (Duflo et al, 2006)[376]	Schools: Adult-led, Curriculum-based	* Primary school grades 6-8 * Targeted unprotected sex	* Teacher-led intervention where schools received one or a combination of the following: Training teachers in HIV/AIDS curriculum, debates and essay writing, reduced cost of education, information on HIV rates by age and sex * Covered STI/HIV, caring for people with AIDS, pregnancy and STI prevention * Set up school health clubs in schools receiving teacher training
L - Kenya, I Choose Life (Miller et al, 2008)[381]	Schools: Peer-led, Non-curriculum based	* Youth ≥18 years, Years 1-4 of university * Primary or secondary abstinence, faithfulness and condom use	* In-school peer-led programme with no curriculum * Used behaviour change communication groups, outreach to people living with AIDS and AIDS orphanages, could choose to enrol in a 4-week life skills course * Abstinence messages and purity pledging, encouraged faithfulness and condom use * Also included mobile VCT clinics and annual HIV testing day
M - South Africa, peer education (Visser et al, 2007)[383]	Schools: Peer-led, Non-curriculum based	* Youth aged 12-19+ years * Targeted sexual initiation, condom use, promote respectful relationships, communication	* In-school peer-led programme with no curriculum * Peers provided health-related information, communication skills, facilitate discussion on sexual behaviour, influence peer group norms * Peers developed their own programme including plays, guest speakers, awareness days, drama, song, posters, newsletters, peer discussion, peer support offices

Table 2.1 (CONTINUED) Details of interventions included in the systematic review

Study, location and programme	Type	Target population and primary objectives	Description
N - Ghana, African Youth Alliance (AYA) (AYA 2007)[386]	**Health Facility**: Type 2c (service providers, clinic, community, other sectors) **Community:** Type 4 (community-wide, community-wide activities)	* Youth aged 17-22 years * Health service objective: Increase access to and enhance sexual and reproductive health services for young people, increase contraceptive use * Community objectives: sexual initiation, condom use, number of sex partners * Multi-component intervention	* 65 clinics were established or enhanced to improve their youth-friendliness, including staff training and activities in the clinic * Peer-educators provided information at health facilities, in the community and in 'youth talks' * Multi-faceted media and interpersonal communications campaign to promote adolescent reproductive health, including television, radio and a youth magazine * life skills planning and enter education activities such as poetry, sports, drama and clubs * Included policy and advocacy component and institutional capacity building
O - Tanzania, African Youth Alliance (AYA) (AYA 2007)[387]	**Health Facility**: Type 2c (service providers, clinic, community, other sectors) **Community**: Type 4 (community-wide, community-wide activities)	* Youth aged 17-22 years * Health service objective: Increase access to and enhance sexual and reproductive health services for young people, increase contraceptive use * Community objectives: sexual initiation, condom use, number of sex partners * Multi-component intervention	* 58 clinics were established or enhanced to improve their youth-friendliness, including staff training and activities in the clinic * Peer-educators provided information at health facilities, in the community and in 'youth talks' * Also included an extensive community behaviour change communication component * Multi-faceted media and interpersonal communications campaign to promote adolescent reproductive health, including television, radio and a youth magazine * life skills planning and enter education activities such as poetry, sports, drama and clubs * Included policy and advocacy component and institutional capacity building

Table 2.1 (CONTINUED) Details of interventions included in the systematic review

Study, location and programme	Type	Target population and primary objectives	Description
P - Uganda, African Youth Alliance (AYA) (AYA, 2007)[388]	**Health Facility:** Type 2c (service providers, clinic, community, other sectors) **Community:** Type 4 (community-wide, community-wide activities)	* Youth aged 17-22 years * Health service objective: Increase access to and enhance sexual and RH services for young people, increase contraceptive use * Community objectives: sexual initiation, condom use, number of sex partners * Multi-component intervention	* 96 clinics established/enhanced to improve their youth-friendliness, including staff training and activities in the clinic (20 clinics were staff training only) * Peer-educators worked at health facilities, in the community and in 'youth talks' * Also extensive community behaviour change communication component * Multi-faceted media and interpersonal communications campaign to promote adolescent reproductive health, including television, radio and a youth magazine * life skills planning and enter education activities (poetry, sports, drama and clubs) * Included policy and advocacy component and institutional capacity building
Q - Botswana, African Youth Alliance (AYA) (AYA, 2005)[389]	**Health Facility:** Type 2c (service providers , clinic, community, other sectors)	* Youth aged 17-22 years * Health service objective: Increase access to and enhance sexual and RH services for young people, increase contraceptive use * Multi-component intervention	* 58 clinics were established or enhanced to improve their youth-friendliness, including staff training and activities in the clinic * Peer-educators worked at health facilities, in the community and in 'youth talks' * Also included an extensive community behaviour change communication component
R - Madagascar, Top Reseau (Top Reseau, 2007)[390]	**Health Facility:** Type 2c (service providers, clinic, community, other sectors)	* Youth aged 15-24 years * Increase access to high quality sexual and reproductive health services for young people	* A network of 146 private, franchised youth-friendly clinics was established in 7 urban sites that were affordable, high quality and confidential * Clinics had integrated service delivery and health communication * Community outreach was conducted to promote the clinics and motivate young people to practice safer behaviour, including peer education sessions, mobile video units, youth debates, radio and television spots
S - Cameroon, 100% Jeune (Plautz et al, 2007)[391]	**Community:** Type 2 (youth, own system and structure for delivery	* Youth aged 15-24 years in urban areas * Targeted safer sex, promoting community dialogue about adolescent reproductive health	* Multi-faceted media & interpersonal communications campaign to promote ASRH * Peers targeted in- and out-of-school youth with informative shows conducted at schools and youth hang-outs * Campaign themes were encouraged by radio shows, billboards, brochures and print ads, as well as a monthly magazine. Also network of youth-friendly condom outlets

Table 2.1 (CONTINUED) Details of interventions included in the systematic review

Study, location and programme	Type	Target population and primary objectives	Description
T - Guinea, Youth campaign (Fonseca-Becker et al, 2005)[392]	**Community:** Type 4 (community-wide, community-wide activities)	* Youth aged 15-24 years in rural and urban areas * Targeted sexual initiation, condom use, reproductive health communication	* Behaviour change communication campaign to prevent STI/HIV and unwanted pregnancy * Condom use demonstrations conducted by peer educators, tailors, hair dressers and health providers * Dissemination of posters and brochures, along with community campaign events such as theatre and soccer matches * Peer educators trained to reach and refer youth to ASRH information * Advocacy meetings with community, government, religious and youth leaders
U - Uganda, condom promotion (Kajubi et al, 2005)[393]	**Community:** Type 1 (youth, existing organisations or events)	* Youth aged 18-30 (75% 18-24 years) in peri-urban areas * Targeted barriers to condom use	* Participants attended at least one 3-hour session condom use skills workshop * All participants were given coupons for free condom redeemable from volunteer distributors in the community
V - Zambia, peer education (Svenson et al, 2008)[394]	**Community:** Type 1 (youth, existing organisations or events)	* Youth aged 15-24 years in rural and urban areas * Targeted sexual initiation, number of sexual partners, condom use, knowledge, stigma against PLWHA, treatment and care of HIV/STIs	* Peer targeted in- and out-of-school youth using focus group discussions, dramas, counselling, sensitization programs, videos, debates, quizzes, media programs, and printed materials. Peer educators had clear objectives and workplan, but activities varied across sites * Work at clinics providing referrals for youth at youth-friendly corners * Community participation an essential component
W - South Africa, IMAGE (Pronyk et al, 2006 & 2008)[289, 290]	**Community:** Type 4 (community-wide, community-wide activities)	* Youth aged 14-24 years in rural areas * Targeted sexual initiation, condom use, number of partners, gender and social norms, communication of reproductive health, HIV testing	* Microfinance for establishment of small businesses among older women (not targeted to youth) * Gender and HIV training curriculum * Community mobilization to engage young people and men * Clinic health workers received training in HIV testing, care and support

Table 2.2. Evaluation results for studies included in the systematic review

(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
B	**Design:** Experimental (randomised by community) **Sample size:** 6791 baseline, 4672 at last follow up *15 intervention communities and 15 control communities * Cohort design, baseline and interim surveys, cross-sectional surveys at 36 and 48 months *Baseline, 36 and 48 months follow up	***At 48 months***				**Strengths:** Rigorously evaluated RCT with large sample size; long term follow-up; use of biological outcomes. **Limitations:** Due to excessive out-migration the original cohort was not followed for 48 months, rather a population-based survey was conducted
		HIV prevalence:		0	0	
		HSV2 (genital herpes) prevalence:		0	0	
		Pregnancy prevalence:		0	0	
		Reported pregnancy during follow-up:			+	
		Sexual initiation during follow-up:		0	0	
		Two or more partners in last 12 months:		0	0	
		Two or more lifetime partners:		0	0	
		Sexual debut at 17 or younger:		0	0	
		No condom use at last sex;		0	0	
		No pregnancy prevention with first partner:		0	0	
		No pregnancy prevention with last partner:		0	0	
		No pregnancy prevention with any partner:		0	0	
		Went to clinic in last 12 months:		0	0	
		Sought treatment for STD symptom:		0	0	
		Knowledge of HIV acquisition:		0	0	
		Knowledge of STD acquisition:		+	+	
		Knowledge of pregnancy prevention:		+	+	
		Condom self-efficacy:		0	+	
C	**Design:** Experimental (randomised by community) **Sample size:** 2776 baseline, 2058 at last follow up *35 intervention communities and 35 control communities * Cohort design, pre, 12 and 24 months post test surveys *Baseline, 12 and 24 months follow up	***At 24 months***				**Strengths:** Rigorously evaluated RCT with large sample size, medium term follow-up; use of biological outcomes. **Limitations:** Low power to detect changes in HIV incidence
		HIV incidence:		0	0	
		HSV2 incidence:		+	+	
		At 12 & 24 months				
		Number of partners in past year:		0 0	0 0	
		Any transactional sex with a casual partner:		+ 0	- 0	
		Pregnancy (or impregnated, for men):		0 0	0 0	
		Correct condom use at last sex:		0 0	0 0	
		Any casual partner:		0 0	0 0	

Table 2.2.(CONTINUED) Evaluation results for studies included in the systematic review
(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
D	**Design**: Cross-sectional survey (no comparison group) **Sample size:** 11,904 with analysis among 7691 sexually experienced * Nationally representative population-based survey 4 years after start of intervention	HIV prevalence: - Participated in a loveLife program - Participated in a youth group in the past month		+ +	+ 0	**Strengths:** Large sample size; use of biological outcome. **Limitations:** Cross-sectional survey design; those exposed to intervention could be fundamentally different from unexposed
E	**Design:** Quasi-experimental (randomised by school) **Sample size:** 1312 * 22 schools with 3 intervention arms: VCT and health education, health education only, or none. Data from health education only vs none presented here * 4 schools received VCT services at baseline and two 6-month intervals * Post-test data only, collected ~3 years after start of intervention	Ever had sex: Age at first sex: Lifetime partners: Partners in the past year: % casual partners in the past year: Always use condom with regular partner: Always use condom with casual partner:	0 + 0 0 + 0 0			**Limitations:** post-intervention assessment only; no randomised assignment of intervention; not stratified by gender; no data on utilization of health services
F	**Design:** Quasi-experimental (randomised at the household level) **Sample size:** 3052 baseline, 4185 at last follow up * Analysis based on dose-response as all youth were exposed to the intervention * Baseline and 24 months follow up	***Overall change/Exposure effect*** Sexual initiation: Secondary abstinence: >1 partner in last month: >2 partners in last year: Used condom during first sex: Always use condoms: Condom use at last sex:		+ + + 0 0 0 + 0 0 + + 0 + 0	+ 0 + 0 0 0 0 0 + + 0 + 0 +	**Strengths:** Large sample size; relatively long term follow-up; well-conducted analysis **Limitations:** Intervention was introduced in all schools so not possible to have a matched controlled trial; youth were not exposed to life skills at random (though attempted to control for this)

Table 2.2. (CONTINUED) Evaluation results for studies included in the systematic review
(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Female	Factors affecting strength of evidence
G	**Design:** Quasi-experimental (randomised by school) **Sample size:** 1141 baseline, 844 at last follow up * 11 intervention and 11 control schools * Pre-test and multiple post-test cross-sectional surveys of 2 classes within each school * Surveys at baseline, 6 and 10 months	***At 6 & 10 months*** Reported ever had sex: Reported had sex in recall period*: Reported condom use at last sex: * 6 mths at 6 mth follow-up; 3 mths at 10 mth follow-up	 0 0 0 0 0 0			**Limitations:** Surveys were not among a cohort, intervention was not fully implemented in 4 of 11 schools; not stratified by gender; no attempt to control for confounding
H	**Design:** Quasi-experimental (randomised by school) **Sample size:** 2383 baseline, 1350 at last follow up * 4 intervention schools and 5 control schools * 5 surveys waves every 6 months in cohort	***At wave 5 (30 months)*** Sexual intercourse in lifetime: Sex in the past month: Always used condom during sex:		 0 0 0	 0 0 0	**Strengths:** Relatively large sample size **Limitations:** non-random assignment; intervention and control differed by race and sexual initiation at baseline
I	**Design:** Quasi-experimental (randomised by school) **Sample size:** 661 baseline, 535 at follow up * 3 intervention schools and 2 control schools * Cohort design, baseline and 5 months surveys	***Sex at pretest/no sex at pretest*** Condom use at last sex: Alcohol use concurrent with sex:		 0 0 0 +	 0 0 0 +	**Limitations:** Short-term follow up, final survey was 8 weeks after conclusion of curriculum; sample size insufficient to detect change in sexual behaviour by gender
J	**Design:** Quasi-experimental (randomised by district and school) **Sample size:** 3452 at baseline, 3940 at follow up * 40 intervention schools and 40 control schools matched for district and academic standing * Cross-sectional surveys at baseline and 18 months	Sexual debut during program: – program effect: – exposure effect: ***Pre-program virgins /non-virgins*** Sexual intercourse in past 3 months: – program effect: – exposure effect: Condom use at last sex: - program effect: – exposure effect:		 + + 0 0 0 0 0 0 + +	 + 0 + 0 0 0 0 0 0 0	**Strengths:** Large sample size; matched intervention and control schools; rigorously conducted analysis **Limitations:** Cross sectional data and large influx of previously out-of-school youth in year 2 due to change in government policy

Table 2.2. (CONTINUED) Evaluation results for studies included in the systematic review

(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
K	**Design:** Experimental (randomised by school) **Sample size:** 74,000 at baseline • 328 schools assigned to receive various combinations interventions including teacher training for sex ed, free uniforms for girls, condom debate/essay •Cross-sectional surveys at baseline and >2 years	***Teacher Training***				**Strengths:** Large sample size; long term follow up; attempt to evaluate effect of various intervention components **Limitations:** interventions began at different times so some had greater follow up than others
		Has ever had sex:		0	0	
		Has had more than one partner:		0	0	
		Has ever used a condom:		+	0	
		Used condom at last sex:		0	0	
		Has started childbearing:		0	0	
		If started childbearing, is married:		0	+	
		Reducing cost of education				
		Has ever had sex:		0	+	
		Has had more than one partner:		0	0	
		Has ever used a condom:		0	0	
		Used condom at last sex:		0	0	
		Has started childbearing:		0	+	
		If started childbearing, is married:		0	0	
		Condom debate/essay				
		Has ever had sex:		0	0	
		Has had more than one partner:		0	0	
		Has ever used a condom:		0	0	
		Used condom at last sex:		+	0	
L	**Design:** Before-after **Sample size:** 632 at baseline, 746 at follow up • 2 cross-sectional surveys of students selected from halls of residence at baseline and 24 months	Ever had sex:				**Limitations:** no control population; different control population in before and after surveys; low uptake of the intervention; sample size insufficient to detect change in sexual behaviour when stratified by gender
		Number of sexual partners in previous 6 months:		0	0	
				0	0	
		Among those ever having sex				
		Ever used condom:	+			
		Frequency of condom use:	+			
M	**Design:** Quasi-experimental (randomised by school and class) **Sample size:** 1918 at baseline, 2168 at follow up • 13 intervention schools and 4 control schools • Cross-sectional surveys at baseline and 18 months	Ever had sex:	+			**Strengths:** Large sample size **Limitations:** non-random assignment; baseline differences between control and intervention schools; intervention implemented to varying degrees in schools
		Had sex in past 3 months:	+			
		More than one partner in past 3 months:	-			
		Used condom every time had sex in past 3 months:	0			

Table 2.2. (CONTINUED) Evaluation results for studies included in the systematic review

(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
N	**Design:** Cross-sectional survey **Sample size:** 3416 * Post-evaluation survey only 2-3 years after start of intervention * 65 health facilities in total * Purposefully selected intervention and matched control sites, based on level of AYA implementation	Had delay of sexual debut:		0	+	**Strengths:** Large sample size; uptake of health services measured through clinic records **Limitations:** Non-random assignment; post-evaluation data only
		Abstains from sex:		-	+	
		Had fewer than two sex partners (past 12m):		0	+	
		Had condom use at first sex:		0	+	
		Had condom use at last sex:		0	+	
		Ever used condom with current partner:		0	+	
		Always uses condom with current partner:		0	+	
		HIV/AIDS knowledge: (spontaneous/prompted)		+ 0	+ 0	
		Knows condom is protective against HIV/AIDS:		0	0	
		Has positive attitude toward condom users:		+	-	
		Is confident could put on condom correctly:		+	-	
		Used modern contraceptive first sex		0	+	
		Used modern contraceptive at last sex		0	+	
		** Steady increase in clinic attendance over five quarters, but then a drop in the final quarter (no statistical tests carried out)*				
O	**Design:** Cross-sectional survey **Sample size:** 1900 * Post-evaluation survey only 2-3 years after start of intervention * 58 health facilities in total * Purposefully selected intervention and matched control sites, based on level of AYA implementation	Had delay of sexual debut:		0	0	**Strengths:** Large sample size; uptake of health services measured through clinic records **Limitations:** Non-random assignment; post-evaluation data only
		Abstains from sex:		0	-	
		Had fewer than two sex partners (past 12m):		0	0	
		Had condom use at first sex:		+	+	
		Had condom use at last sex:		0	+	
		Ever used condom with current partner :		0	+	
		Always uses condom with current partner:		+	+	
		HIV/AIDS knowledge: (spontaneous/prompted)		0 0	+ 0	
		Knows condom is protective against HIV/AIDS:		0	0	
		Has positive attitude toward condom users:		+	+	
		Is confident could put on condom correctly:		0	+	
		Used modern contraceptive at first sex		+	+	
		Used modern contraceptive at last sex		0	+	
		** Increase in clinic attendance (from 24 clinics) in 1st quarter and then a levelling off for subsequent quarters (no statistical tests carried out)*				

Table 2.2. (CONTINUED) Evaluation results for studies included in the systematic review
(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
P	**Design:** Cross-sectional survey **Sample size:** 3176 * Post-evaluation survey only 2-3 years after start of intervention * 96 health facilities in total * Purposefully selected intervention and matched control sites, based on level of AYA implementation	Had delay of sexual debut: Abstains from sex: Had fewer than two sex partners (past 12m): Had condom use at first sex: Had condom use at last sex: Ever used condom with current partner: Always uses condom with current partner: HIV/AIDS knowledge: (spontaneous/prompted) Has positive attitude toward condom users: Is confident could put on condom correctly: Used modern contraceptive at first sex Used modern contraceptive at last sex * Non-statistically measured steady decrease in clinic use		0 0 0 0 0 0 0 + 0 0 0 0 0	0 - 0 + + + + + 0 0 0 + +	**Strengths:** Large sample size; uptake of health services measured through clinic records **Limitations:** Non-random assignment; post-evaluation data only
Q	**Design:** Cross-sectional survey **Sample size:** N/A * Post-evaluation survey only 2-3 years after start of intervention * 18 health facilities in total * Purposefully selected intervention and matched control sites, based on level of AYA implementation		* Non-statistically measured steady increase in clinic attendance			**Strengths:** Large sample size; uptake of health services measured through clinic records **Limitations:** Non-random assignment; post-evaluation data only
R	**Design:** Two cross-sectional surveys **Sample size:** 4041 baseline, 9364 follow up * 146 health facilities in total * Random household sampling from 4 sites at baseline and 7 sites at follow up 2 years after start of intervention	Never had sex Secondary abstinence in past 12 months	+ +			**Strengths:** Large sample size **Limitations:** No control population; no data on utilisation of health services

Table 2.2. (CONTINUED) Evaluation results for studies included in the systematic review
(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
S	**Design:** Cross-sectional multi-stage population-based survey (no comparison group) **Sample size:** 2097 at baseline, restricted to 1956 unmarried; 3627 at last follow up, restricted to 3370 unmarried * 12 neighborhoods at baseline and 20 neighborhoods at 18- and 36-months after start of intervention	***At 18 months/ 36 months***				**Strengths:** Large sample size; long term follow up **Limitations:** No control population (though dose-response analysis conducted); evidence that other on-going programmes also contributed to outcomes
		Had sex in the past year:		0 0	0 0	
		2 or more partners in past year:		0 0	- 0	
		Ever using condoms:		+ +	+ +	
		Condom use at last sex with regular partner:		+ +	+ +	
		Condoms effective for FP:		+ +	0 +	
		Condoms prevent HIV:		0 +	0 +	
		Knows correct condom use:		+ +	+ +	
		Friends support youth condom use:		0 +	+ +	
		Parents support youth condom use:		+ +	+ +	
		Discussed STI/AIDS with friends in past year:		+ +	+ +	
		Discussed STI/AIDS with others in past year:		- 0	- +	
T	**Design:** Cross-sectional survey **Sample size:** 1008 * 9 health districts * Post-intervention survey only 12 months after start of intervention, with DHS data from 15 enumeration areas acting as proxy baseline data	Ever used condom:		+	+	**Strengths:** Relatively large sample size **Limitations:** No randomised assignment of intervention; differences in intervention and control groups at baseline; proxy baseline data not necessarily representative
		Condom use at last sex:		+	+	
		Knows how to use condoms:		+	+	
		Willing to use condoms:		+	+	
		Advocate for condoms:		+	+	
		Knows at least one mode of HIV transmission:		0	0	
		Knows how to prevent HIV:		+	+	
		Perception of community's willingness to discuss RH:		+	+	
U	**Design:** Quasi-experimental (randomised by community) **Sample size:** 498 baseline, 378 follow up * 2 communities * Surveys at baseline and 6 months after start of intervention	Abstinence:		0		**Limitations:** Small sample size; short term follow up
		Consistent condom use:		0		
		Consistent condom use with casual partner:		0		
		Abstaining from any casual partner:		0		
		Unprotected sex with a casual partner:		0		
		Overall number of partners:		-		
		Reduction in casual partners:		0		
		Number of unprotected casual sex partners:		0		
		Distribution of condoms:		+		
		Proportion of men redeeming condoms:		0		

Table 2.2. (CONTINUED) Evaluation results for studies included in the systematic review
(Results categorised as: 0, no significant change; +, significant desirable change, - significant undesirable change)

Study	Design and sample size	Evaluation results	All	Males	Females	Factors affecting strength of evidence
V	**Design:** Cross-sectional survey, post-test only **Sample size:** 1695 * Nationally representative population-based survey ~1 year after start of intervention	Age of sexual debut: Ever had sex: Number of sexual partners in last 4 weeks: Condom use at last sex: Always uses condom with most recent partner: Ever had an HIV test: Knowledge: Intention to use condoms: Stigma against PLWHA:	0 0 0* + + 0* + + +			**Strengths:** Fairly large sample size; cost-effectiveness analysis **Limitations:** Post-intervention survey only; not a randomised trial; no dose-response evaluation; results not stratified by gender
W	**Design:** Experimental (randomised by community) **Sample size:** 647 in cohort 2, 1303 in cohort 3 *8 intervention communities and 8 control communities *3 cohorts in each community, at the (1) individual - did not target young people, (2) household and (3) community levels *Baseline and survey at 2 years follow up in cohort 2 and 3 years in cohort 3	***Cohort 2/ Cohort 3*** HIV incidence: Sexual debut: > 1 sexual partner in last 12 months: Unprotected sex non-spousal partner (last 12m) : Communication with household members about sex in past 12 months: Comfortable discussing sex in the home: Knowledge that healthy-looking person can be HIV+: Have had an HIV test: Participation in collective action against HIV/AIDS:	 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0			**Strengths:** Rigorously evaluated RCT, medium term follow-up; use of biological outcomes. **Limitations:** Low power to detect changes in HIV incidence in subset of young people, direct programme participants (cohort 1) were not young people, not powered to stratify by gender in this subgroup analysis

Impact on reported sexual behaviours

Reported sexual debut, or initiation of sexual activity, was measured in 8 of the 10 intervention studies. Five demonstrated a delay in sexual debut overall, or in either males or females in sub-group analyses (Studies E, F, J, K and M). Importantly, none of these demonstrated earlier reported sexual initiation in the intervention versus the comparison arms. Six studies measured the number of sexual partners in the previous 1 - 12 months (Studies B, E, F, K, L, M). None of these studies showed a significant beneficial effect on this outcome. However, Study M demonstrated an increase in the reporting of multiple partners in the intervention arm during the previous 3 months. The number of casual partners was measured in one study (Study E), and this study detected a significant decrease in reported sex with a casual partner in the past year.

All 10 studies included some measurement of reported condom use. Two studies measured whether a condom was ever used (Studies K, L), and both reported increased condom use in the intervention arm, among both males and females and overall. Whether a condom was reported to have always been used was evaluated in four studies (Studies E, F, H and M). Three showed no increase in this measure of reported condom use in the intervention versus control arm. The fourth study (Study F) demonstrated an overall increase in males reporting always using a condom, and an increase among females with higher intervention exposure. Due to recall errors, condom use at last sex is an important proxy for overall condom use. This was measured in 5 studies (Studies B, F, I, J, K). Two studies showed no effect on condom use at last sex (Studies B and I). Two studies showed an overall increase in condom use at last sex in males, but not females (Study J and K). The fifth study demonstrated an increase in condom use in males, and among females with higher intervention exposure (Study F). None of the studies detected a decrease in condom use in the intervention versus control arms.

Overall, 8 of the 10 studies reviewed had a positive effect on at least one measure of reported behaviour. One of the intervention studies demonstrated a negative impact on the number of multiple partners (Study M), however this study had a weak design with no reported adjustment for baseline differences and its results should be interpreted with caution. None of the other intervention studies demonstrated a negative impact on any reported sexual behaviour variables. Two studies, G and H, had no impact on reported behavioural outcomes. Poor intervention implementation probably explains this failure in Study G. The authors of Study H, a relatively intensive teacher-led intervention, suggest that baseline differences in sexual experience may explain the failure to see an impact on reported behaviours. This study used PDA to collect self-administered questionnaire data and perhaps the results reflect responses less subject to desirability bias.

Knowledge, attitudes, and other mediating factors

Other potential mediating factors for HIV prevention include knowledge, attitudes, values, self-efficacy, peer norms, communication about sexual health and alcohol use. At least some of these potential mediating factors were measured in all 10 studies. Seven studies measured the impact of the intervention on knowledge of HIV, STIs, pregnancy prevention or other sexual and reproductive health topics. Of these, 6 studies (Studies B, E, F, G, J and K) had some impact on one or more measurements of knowledge in males, females or both. As findings from developing countries have repeatedly shown school-based sex education interventions can improve knowledge, what is in fact surprising here is that one study (Study I) reports that no increase in knowledge was detected. The authors discuss but do not present the results for knowledge and so it is difficult to know whether this could be explained by baseline differences between the groups or other problems with the intervention or study design.
Results of other mediating factors measured included:

- 2 out of 4 intervention studies demonstrated an improvement in attitudes related to sex or condom use (Studies J and L);
- 5 out of 7 intervention studies demonstrated increased self-efficacy related to sex or condom refusal or other measures of perceived personal control (Studies B, F, H, I, J);
- 2 out of 3 intervention studies demonstrated a reduction in reported alcohol use (Studies H and I);

Among the 10 studies, two studies showed a negative impact on one or more mediating factors. Study H was a sex and substance use education programme, and the authors report that there was an increase in reported lifetime marijuana use in males in the intervention versus the control arm though they do not present data to support this statement. Study M demonstrated an increase in reported sex without consent following a peer sexual health education programme. Though these alarming findings cannot be disregarded, in both of these studies baseline rates of these outcomes were higher in the intervention arm which may have contributed to the differences post-intervention.

A summary of the strength of evidence for the effectiveness of each type of intervention is presented in ***Table 2.3.***

Table 2.3: School-based interventions- results and strength of evidence

Evaluation design	Effect on reported behaviour +	Effect on reported behaviour 0	Effect on reported behaviour -	Effect on other mediating factors +	Effect on other mediating factors 0	Effect on other mediating factors -	Strength of evidence (for biological and/or reported sexual behaviour data)
Curriculum-based interventions							
Adult-led							Strong: positive effect
RCT (≥6 clusters)	K	-	-	K	-	-	
Quasi-experimental	E, F, I, J	G, H	-	E, F, G, H, J	I	H*	
Peer-led							Moderate: weak positive effect
RCT (≥6 clusters)	B	-	-	B	-	-	
Non curriculum-based interventions							
Peer-led							Weak: mixed results
Before-after	L			L			
Quasi-experimental	M	-	M***	M	-	M**	

Key: + signficant positive change; 0, no significant change; -, significant negative change
An intervention was considered as having an effect (positive or negative) if ≥1 significant results were found from among all of the relevant outcomes measured
Where interventions are classified in more than one column it is because they had mixed results, see Table 2.2 for details
* Increased reported lifetime marijuana use; ** Increased reported sex without consent; *** Increased reporting>1 parters in past 3 months

Cost-effectiveness

Among the intervention studies in schools, 2 included some discussion or analysis of cost (Studies B and K). Study K evaluated the cost of reported pregnancies averted through training teachers for sex education in schools, reducing the cost of education by providing free uniforms for girls, and informing girls of the age-profile of HIV prevalence in men. This preliminary cost-effectiveness analysis suggested that the teacher training intervention was least cost-effective at $525 per reported pregnancy averted, followed by the reduced cost of education at $300 per reported pregnancy averted, while informing girls of the HIV age-profile of men cost just $91 per reported pregnancy averted. Study B trained older peer-educators to live and work in intervention communities. While this intervention is expensive, costing $500 per educator per year, each peer educator could potentially reach hundreds of youth and adults in a community.

Overall recommendation for interventions in schools

Table 2.4 shows the strength of evidence on the effectiveness of all intervention types in the first SRG review. The table then shows overall recommendations for each intervention type in schools in SSA, based on biological and reported sexual behaviour results from a combination of this updated review and the first SRG review i.e. 1990-2008. Interventions in schools were largely successful at demonstrating reductions in reported sexual risk behaviours. Curriculum-based, adult-led interventions were the most common interventions seen, and showed strong evidence of effectiveness for these outcomes. Similar results were found in the first SRG review, and this type of intervention was given a 'Go' recommendation overall. The first SRG review did not identify any curriculum-based, peer-led interventions in SSA, and due to the lack of data a 'Steady' recommendation was given. There was one recent experimental evaluation of a curriculum-based intervention led by older young people, who were defined as peers by the authors of that study, identified for the current review, which proved effective at reducing reported pregnancies (Study B). It is important to remember that this particular evaluation was of an intervention that used nationally-selected older peers who were given an intensive 5 week residential training, whereas most "peer-led" interventions have used locally-recruited peers from within the same school who have been given very limited (e.g. one or two weeks) training. Though this was a well-conducted RCT, the limited available data for this type of intervention, and lack of effect on any of the biological or reported sexual behaviour outcomes, except reported pregnancies, led to a 'Steady' recommendation overall. Non-curriculum based interventions in schools provided weaker evidence of effectiveness and similar to the first SRG review, this type of intervention resulted in a "Steady" recommendation. Overall, in-school interventions are a logical and promising means to impart necessary information and skills to school-going young people. However, the evidence from the MkV1 Trial[186] and the recent trial in Zimbabwe, discussed in detail above (Study B), that included an assessment of the impact of schools-based interventions (linked to interventions in health facilities and in the communities surrounding the schools in both cases) on HIV and other biological outcomes suggest that such interventions may not be sufficient to reduce the risk of HIV, other STIs or early pregnancies, at least in the short to medium term (2-3 years).

Table 2.4. Interventions in Schools: impact on reported sexual behaviour and biological outcomes

		First SRG review (Developing countries, 1990-2004)			Revised SRG (SSA, 1990-2008)		
Evaluation design	**Threshold of evidence required**	**Strength of evidence**	**SRG recommendation**	**Explanation**	**Strength of evidence**	**Overall Recommendation**	**Explanation**
Curriculum-based interventions with Characteristics of Effective Programs							
Adult-led	Low	Very strong	Go	Large number of studies; strength of evidence for some of the individual studies is stronger than for the studies in other categories; interventions consistently had a positive effect on behaviour	Strong: positive effect	**Go!**	Large number of studies with positive effects
Older peer-led				No studies	Moderate: weak positive effect	**Steady**	One strong RCT with weak positive effect
Peer-led	Low	Weak	Steady	Only one study		**Steady**	No studies
Curriculum-based interventions without Characteristics of Effective Programs							
Adult-led	Low	Weak	Steady	Only two quasi-experimental studies, one with positive effect and one no impact		**Steady**	No studies
Peer-led	Low	Weak	Steady	One RCT with weak positive results		**Steady**	One RCT with weak positive results
Non curriculum-based interventions with Characteristics of Effective Programs							
Adult-led	Low					**Steady**	No studies
Peer-led	Low					**Steady**	No studies
Non curriculum-based without Characteristics of Effective Programs							
Adult-led	Low	Weak	Steady	Few studies (2 RCT, 2 quasi-experimental); mixed results		**Steady**	No studies
Peer-led	Low	Equivocal	Steady	One quasi-experimental study showing negative impact on one behavioural outcome, positive on others	Weak: mixed results	**Steady**	3 studies all with weak designs and mixed effect

2.4.2.4 Interventions to improve health services

Classification

In order to evaluate the capacity of interventions in health services to impact HIV in young people, the studies included in this review examined not merely access to health services, but also the use of health services by young people. This takes into account accessibility, but also the acceptability of the health services. Measuring effectiveness against HIV was not possible, as the studies did not have adequate data to assess this. However, at least some of the specific health services interventions, such as condom use and STI treatment, have been shown to be effective if used, justifying the focus on uptake of services rather than the effectiveness on HIV prevalence and incidence themselves.[258] Male circumcision has recently been shown to be highly efficacious for reducing HIV acquisition,[65] but none of the intervention studies identified for this review included the provision of male circumcision as a major component of their interventions.

Further to this, interventions also had to include interaction between a young person and a clinically-trained health-care worker, such as a doctor, nurse or other clinical officer to be included in this review. Interventions comprised only of interaction with people who were not clinically-trained staff, such as condom distributors, counsellors or peer-educators were not included.

Interventions in health services were classified according to the typology used in the first SRG review:[254]

- *Training service providers* ***(Type 1)***: These interventions only provide training to clinic staff to improve their knowledge, skills and attitudes, in order for them to be able to respond more appropriately to the needs of young people.
- *Training service providers plus implementing other interventions in the health facilities to make them more youth-friendly* ***(Type 2)***: In addition to training clinic staff as in Type 1 interventions, these interventions also implemented specific actions to further accommodate young people, such as extended clinic hours, reducing prices, or taking measures to increase their privacy.

Each of these two Types of interventions were then coupled with a means to bring information to young people. This could be accomplished in one of three ways:

- *Activities conducted within the community (a):* These included any type of community outreach activities directed at providing youth with health information, such as meetings with youth, meetings with community leaders, or distributing posters or advertisements.
- *Activities conducted with other sectors (b):* For example, in-school education programmes or mass media.
- *Activities conducted within the community and with other sectors (c):* These interventions included a combination of the above two strategies.

Assigning interventions to these categories was not always straightforward due to insufficient information. The various types of health services interventions were adjudged by the first SRG review authors to require a low to moderate threshold of evidence ***(Appendix 3, Table A3.3)***.

Evidence from the first SRG

Dick and colleagues reviewed 16 health-facility based studies that measured access to youth friendly health services (YFHS), 12 of which were carried out in sub-Saharan Africa.[254] All but one offered services in public facilities only. All of the studies included in this review had training of health service providers, and all had some type of activity in the community. Descriptions of the content of training and the activities in both the health facilities and in communities were limited in the original studies. Activities in health facilities included reducing fees, subsidising commodities and modifying the physical environment to increase privacy or appeal to young people. Community activities that were most frequently implemented included holding public meetings and advertising the facility using posters or pamphlet distribution. Peer educators were also employed by many studies to provide information, referral, or to increase demand.

Of the 12 SSA studies, only 2 were RCT[186, 233], 4 had a quasi-experimental [395-398] and the rest had weaker designs without control groups.[365, 399-402] Many of the included studies provided no more than 'adequacy' evidence i.e. a service was provided and it was used by young people. The importance of comparison groups was highlighted in a study in Senegal which showed an increase in service utilisation in both intervention and comparison communities but no significant difference in utilisation between intervention and comparison communities/health facilities.[398] Only one study[233] collected enough data to determine not only whether services were used but also whether services made a difference i.e. whether they were effective in decreasing reported STI symptoms and increasing reported condom use. Analysis was often weak with one study failing to use statistical analysis altogether[395] and others failing to control for clustering [396, 397]. Some studies are thought to have suffered from contamination in the control sites.[397, 398] Overall most studies included in the first SRG review demonstrated an increased use of health services, though the evidence was weak. The authors concluded that there was sufficient evidence to recommend wide scale implementation of interventions that involve the training of service providers, actions in the health facilities and interventions in the community (Types 2a & 2c). ***Appendix 3, Table A3.4*** summarises the results from the first SRG review of health services.

Evidence from the recently updated review of interventions to improve health services

Six studies that had evaluated improvement of health services for young people in SSA, which were reported between 2005 and 2008, met our criteria for inclusion in this update of the SRG review (Studies B,N-R).[374, 386-390, 403-405] There was one intervention each in Tanzania, Botswana, Ghana, Madagascar, Uganda and Zimbabwe. While one study (Study R) did not directly measure uptake of health services, it did measure the impact of implementation of youth friendly health services on primary and secondary abstinence. This was a single component intervention and therefore it is easier to isolate the impact of the intervention, and thus has been retained in the review. ***Tables 2.1 and 2.2*** summarise the studies included in this review and their results in terms of intervention impact on uptake of health services.

Characteristics of studies and results by intervention

All but one intervention (Study R) were multi-component studies. In multi-component interventions, increasing use of health services was one of a number of objectives, and there was often limited description of the improvements made to health facilities or accompanying community activities. Many of the studies implemented improvements in public health services, but four studies implemented services in both public and private sector health services (Studies N, O, P and Q). One study (Study R) established a social franchised network of new private clinics specifically for young people. None of the studies identified in this review attempted to explore the relationship or relative contribution of different aspects of health facility improvements versus community activity, and uptake of health services.

Study B evaluated the impact of a Type 1c intervention. This was an experimental community-randomised trial, and therefore more weight has been put on the strength of evidence from this study. In addition to improved health services, Study B had an in-school intervention and an extensive community component. Study B showed no increase in those reporting having visited the clinic in the past 12 months, or those who reported seeking treatment for STI symptoms. Unfortunately, it did not also measure the numbers of young people attending the health facilities within the health facilities themselves.

The remaining five studies were Type 2c interventions. Four of the Type 2c interventions were part of the African Youth Alliance (AYA) project, a multi-country, multi-component large-scale intervention in Botswana, Ghana, Tanzania and Uganda. The AYA interventions were implemented by a number of government and non-governmental partners, and in addition to attempting to improve health facilities, they also implemented community activities as well as youth advocacy and institutional capacity-building on a national level. Only post-test surveys were conducted in these countries and, therefore, their strength of evidence was considered weak. Data for uptake of health services was not analysed for statistical significance, but trends in clinic use were described. Though multi-component interventions were implemented in all four countries, only the health service component of the intervention was evaluated in Botswana. Broader programme evaluations were conducted in Ghana, Tanzania and Uganda, where data on reported contraceptive use was collected and was presented as a proxy indicator of uptake of health services. Clinic records from Study Q in Botswana showed a steady increase in clinic attendance between April and December 2003, however, it is possible that this was due to a secular trend unrelated to the intervention. In Ghana (Study N) there was a steady increase in clinic attendance over five consecutive quarters, but then a drop in the sixth and final quarter. Quarterly records from Study O in Tanzania indicated an increase in clinic attendance in the first quarter after introduction of the interventions and then a levelling off for the remainder of the intervention period. Study P in Uganda saw a steady decrease in clinic use. There was an increase in reported use of a modern contraceptive at first and last sex in females in Studies N, O and P but no impact in males in Studies N and P. Study O also saw an increase in reported contraceptive use at last sex in females only. Taken as a whole, these four AYA evaluations provide weak evidence that the package of AYA interventions in health facilities and local communities may have been associated with increased use of health services by young people in some, but not all, settings.

Study R was the only single component intervention. The project developed a network of private youth friendly clinics in Madagascar under the franchise name of *Top Reseau*. Their primary function was to provide young people with high-quality family planning and STI treatment and prevention services, and some also offered VCT services. The network of clinics was supported by an extensive complementary communications campaign using mass media, peer educators, youth debates and other strategies to promote the clinics and to encourage young people to adopt safer sexual behaviours. Based on evidence from two cross-sectional surveys in intervention communities, there was a statistically significant increase in both reported primary and secondary abstinence in the past 12 months. Evaluation of clinic attendance was not conducted in Study R, and furthermore this evaluation did not take into account the potential effect of other HIV prevention interventions taking place in the same cities in Madagascar on the outcomes measured, and therefore the strength of evidence from this intervention is considered weak. There were no studies of intervention Types 1a, 1b, 2a or 2b.

Summary

Though most of the evidence from this review of the impact of improvement in health services on their uptake by young people was weak, a number of studies demonstrated increased use of health services and/or a positive impact on mediating factors of reproductive health. Just one study described a decline in health service use (in males), though there was an increase in reported contraceptive use in females observed in this same study (Study P). A summary of the strength of evidence for each Type of intervention is presented in ***Table 2.5.***

Of the interventions that measured use of health services in this review, only those that included training of service providers as well as community activities with involvement of other sectors (Type 2c) showed evidence of increased use. It is particularly difficult with Type 2c interventions to determine which combination of interventions, in the clinic as well as in the community, was most effective or cost-effective. The evidence from this review was weak overall, as clinic use was often not analysed for statistical significance. Also, the large majority of interventions that did statistically evaluate clinic use relied on reported use, where there was likely to be reporting bias. Another issue when interpreting the data is the challenge of differentiating between studies which demonstrate an effective approach to increase the use of health services, and those that show increased use of health services merely because they are filling a provision gap. Though existing evidence is not strong, many studies from this review, and most from the first SRG review demonstrate an increase in use of health services when they are accessible and made more youth friendly. Furthermore, there is no evidence to indicate a reduction in uptake associated with attempts to improve the health services and to make them more youth-friendly.

Table 2.5: Health facility based interventions- results and strength of evidence

Evaluation design	Positive impact: Statistically significant	Positive impact: Statistical significance unknown	No impact: Statistically significant	Negative impact: Statistical significance unknown	Strength of evidence (for increased use of health services data)
Type 1a (service providers, community)					
N/A	-	-	-	-	
Type 1b (service providers, other sectors)					
N/A	-	-	-	-	
Type 1c (service providers, community, other sectors)					Strong: no effect
RCT (≥6 clusters)	-	-	B	-	
Type 2a (service provider, clinic, community)					
N/A					
Type 2b (service providers, clinic, other sectors)					
N/A	-	-	-	-	
Type 2c (service providers, clinic, community, other sectors)					Weak: positive effect
Cross-sectional	N, O, P	N, O, Q	-	P*	
Before-after (no comparison group)	R	-	-	-	

An intervention was considered as having an effect (positive or negative) if ≥1 significant results were found from among all of the relevant outcomes measured

Where interventions are classified in more than one column it is because they had mixed results, see Table 2.2 for details

* Decrease in clinic attendance as per clinic records

Overall recommendation for interventions to improve health services

Evidence on the most appropriate way to deliver health care to young people in order to maximise their effective access to and appropriate use of such services remains incomplete. ***Table 2.6*** shows the strength of evidence for interventions to improve health services from the first SRG review. The table then shows overall recommendations for intervention in health facilities in SSA, based on use of health service results from a combination of this updated review and the first SRG review i.e.1990-2008. Of the six types of potential interventions to improve young people's access to health services that were identified in the first SRG review, only two types were identified for this review. Type 2c interventions, the most commonly reported type, showed the strongest evidence of effectiveness, and were awarded a 'Ready' recommendation overall. There were very few interventions of Types 1a, 1b and 1c, and provided limited evidence of effectiveness garnering a 'Steady' recommendation overall.

Though no Type 2a interventions were identified in this review, the first SRG review did include several interventions of this type. The original recommendation for Type 2a interventions was 'Go!', however there were fewer studies when limited to SSA only, and a 'Ready' recommendation was awarded overall for this Type of intervention. None of the included studies presented data on the cost of the health facility interventions and where an intervention impact was observed this may have been small relative to the overall investment in the intervention.

Table 2.6. Interventions in Health Facilities: impact on use of health facilities

Evaluation design	Threshold of evidence required	First SRG review (Developing countries, 1990-2004) Strength of evidence	SRG recommendation	Explanation	Revised SRG (SSA, 1990-2008) Strength of evidence	Overall Recommendation	Explanation
Type 1a (training service providers with interventions the community)	Low	Equivocal	Steady (or do not go)	*One study with no statistical tests*		**Steady**	*No studies*
Type 1b (training service providers and involvement of other sectors)	Moderate	Equivocal	Steady (or do not go)	*One weak quasi-experimental study, no evidence of increased use and increased access to information*		**Steady**	*No studies*
Type 1c (training service providers, with interventions in the community and involving other sectors)	Moderate	Equivocal	Steady (or do not go)	*One RCT, moderate strength, no evidence of increased use; one quasi-experimental study with weak evidence of increased use*	Strong: little or no effect	**Steady**	*4 studies with moderate to strong designs, little evidence of an effect*
Type 2a (training service provider and actions in the clinic, with interventions in the community)	Low	Weak	Go	*3 studies with weak evidence and 1 study with moderate evidence of increased use*	Weak: weak positive effect	**Ready**	*3 studies all with weak designs and positive effect*
Type 2b (training service providers and actions in the clinic, and involvment of other sectors)	Moderate			*No studies*		**Steady**	*No studies*
Type 2c (training service providers and actions in the clinic,with interventions in the community and involvment of other sectors)	Moderate	Weak	Ready	*8 studies, 6 with weak evidence of increased use of services, 1 RCT with strong evidence of increased use, 1 before/after with no difference*	Weak: positive effect	**Ready**	*11 studies all with weak designs and positive effect*

2.4.2.5 Interventions in geographically-defined communities

Classification

Interventions in geographically-defined communities in the first SRG review were classified according to the following typology:[227]

- *Type 1* interventions target young people and focus on providing information, skills building and behaviour change. They affiliate with existing groups and organisations working with young people to deliver the intervention.
- *Type 2* interventions target young people and focus on providing information, skills building and behaviour change. They create their own mechanism or infrastructure to deliver the intervention.
- *Type 3* interventions target the entire community. They utilise traditional kinship networks to deliver the intervention, and interventions use one-on-one discussion, or small groups of people to disseminate the message.
- *Type 4* interventions target the entire community. They use large-scale community activities to deliver the intervention.

This review has used a similar typology in order to facilitate comparison with the first SRG review. The various Types of community interventions were adjudged by the SRG review authors to require a moderate to high threshold of evidence ***(Appendix 3, Table A3.5)***.

Evidence from the first SRG review

Maticka-Tyndale and colleagues identified 22 intervention studies located in geographical communities in developing countries, targeting youth and addressing prevention of sexual transmission of HIV.[227] Fifteen of these studies were carried out in SSA and they had the following evaluation designs: three RCT,[367, 369, 406] four quasi-experimental,[371, 407-409] one before-after without a control group,[410] five qualitative,[411-415] and two with only anecdotal evidence.[413, 416]

Using peers to deliver the intervention was common, with 17 of the 22 interventions involving peers either with or without adults, and four more interventions used peers informally as educators or role models. Only one community intervention exclusively used trained adult community members to deliver the intervention.

Some of the interventions targeted entire communities e.g. through the use of traditional *Sengas,*[417] Muslim structures,[409] married adolescent mothers as peer educators,[415] or through the use of drama.[414] An interesting study in Uganda based their intervention on the *senga* (father's sister), the traditional channel for socialising adolescent girls into sex and marriage among many ethnic groups. The intervention involved the training of 'modern' *sengas* to provide HIV-related counselling to adolescent girls.[408, 417]

A number of outcomes were measured, including community norms, attitudes and values, skills, HIV incidence, sexual activity and condom use. Only one of these studies[414] explicitly articulated a theoretical framework of behaviour change.

Despite the innovation of the interventions, the evaluations of community-based interventions had, in general, poor quality design and data analysis. None of the interventions resulted in strong evidence of a positive effect. Less than half the studies had an experimental design, few stratified by gender, and many did not control for potential confounding. Only one study used a biological outcome, HIV incidence from sentinel surveillance data[410], but this study had a non-experimental design and it was not possible to determine whether the increase in HIV incidence seen over the intervention period was related to the intervention or just a national trend. It is not surprising, therefore, that the authors could not recommend any intervention type as 'Go' (recommend wide scale implementation). The authors found that the most encouraging results were for programmes that had links with existing structures or organisations e.g. youth centres or youth organisations, with family networks or were part of community-wide festivals and events. They recommend that programmes that have high resource needs or lack the mechanism for ongoing provision should not be implemented. A summary of the results from the first SRG review are shown in ***Appendix 3, Table A3.6***.

Evidence from the recently updated review of interventions in communities

Eleven intervention studies in geographically-defined communities in SSA that were reported between 2005 and 2008 met our criteria for inclusion in this update of the SRG review (Studies B-D, N-P, S-W).[289, 290, 374, 384-388, 391-394] Three were in South Africa, two in Uganda, and there was one intervention each in Cameroon, Ghana, Guinea, Tanzania, Zambia and Zimbabwe. Four of these eleven studies were multi-component interventions (Studies B, N, O and P). ***Table 2.1 and 2.2*** summarise the studies included in this review and their impact on relevant reproductive health outcomes.

Quality of the evidence

Three studies (Studies B, C, and W) were experimental CRT. One (Study U) was a quasi-experimental controlled trial. There were four interventions which only had post-test evaluations, though each attempted to identify a suitable control population, as well as attempting to control for potential confounding factors (Studies T, N, O and P). The final three interventions used cross-sectional population-based surveys to evaluate their impact, two using a single post-intervention survey (Studies D and V) and the other using multiple rounds of survey data (Study S). All but one intervention study stratified results by gender.

Eight of the eleven studies explicitly reported a theoretical basis for the intervention. Peers were used to educate youth, promote activities and services, and/or distribute condoms in 9 of the 11 interventions. Most of the interventions reviewed here described the model of delivery in some detail. Activities included strengthening and expanding work conducted by existing organisations, providing links to health services, education and skills-building workshops/participatory learning modules, condom distribution and extensive communications and media campaigns to promote behaviour change.

Outcomes

The objective of most interventions was to increase knowledge and build skills to promote positive SRH behaviour change. A number of studies attempted to increase condom use through overcoming barriers to their use. Some studies also attempted to strengthen youth support systems within the community, as a means to facilitate self-efficacy and positive decision-making, and several additionally had the objective of raising community awareness and changing community norms. One study (Study W) used a microfinance and education programme for women as a structural approach to reducing HIV incidence and improving mediating factors among the individual participants, their households and their communities.
Eight of the eleven interventions, representing all four Types of interventions, measured gains in knowledge about HIV (general knowledge of HIV, or knowledge about transmission or of HIV acquisition specifically), STI acquisition, pregnancy prevention, and/or condom use (Studies B, N-P, S, T, V, W). Seven of the eight interventions showed at least some gains in knowledge.

Six interventions evaluated reported skills in correct condom use, with varying results. Two studies (S and T) evaluated reported knowledge of correct condom use, and both demonstrated a significant increase in reported ability to correctly use condoms in both males and females. Study B found a significant increase in reported condom self-efficacy in females but not males. Of 3 studies measuring reported confidence in correct condom use, one resulted in no increase (Study W), one demonstrated a significant increase in females but not males (Study O), and one showed a significant increase in males and decrease in females (Study N).

Two interventions measured reported levels of SRH communication. Study S found increased discussion with friends about family planning and STI/HIV in both sexes. Discussion with others increased in females only. Study W showed no increase in either discussion with household members about sex, or in comfort with discussing sexual issues at home.

Seven studies measured changes in attitudes and community norms. Study T found an increase in both sexes in their perception of community willingness to discuss SRH. Study S found that both sexes reported increased perceived support for youth condom use, and Study V noted a reduction in reported stigma towards people living with HIV/AIDS. Attitudes toward condom use were reported in five studies. Study T demonstrated an increase in both males' and females' willingness to use condoms and to advocate for condom use. Study V reported an increase in intention to use condoms. Of the AYA studies, two showed no impact on attitude toward condom use and one study in Tanzania (Study O) demonstrated a positive impact in both men and women.

Four interventions included biological measurements of HIV. Study D demonstrated a statistically significant impact on HIV prevalence. Studies B, C and W did not demonstrate an impact on HIV, however, Study C did impact HSV2 among those exposed to the intervention.
Ten studies evaluated other measures of sexual activity, including reported abstinence, number of sexual partners and condom use. Studies B, C and W showed no impact on any measure of sexual behaviour, and Study U demonstrated a negative impact overall on reported number of sexual partners (this study was only among males). The remaining six studies demonstrated at least one significantly beneficial outcome. Reported condom use increased in studies T, S, and V and among females only in studies O, P and N. In study O only 39% of males believed that condoms were protective yet 65% reported using a condom at last sex suggesting that this study may have suffered from reporting bias. Secondary abstinence increased in females in study N but decreased in females in studies O and P and in males in study N. Females in studies O and N reported lower numbers of sexual partners. Reported modern contraceptive use increased in females in studies P and N and among both sexes in study O.

Cost-effectiveness

Three interventions in geographically-defined communities presented data on costs and/or cost-effectiveness (Studies B, D and V). In Study V they performed a comparative analysis of cost between the five sites where the programme was implemented. They found a strong correlation between programme cost and quality, with higher quality programming being more expensive. Those that were more costly to implement had greater exposure and more referrals to services than the less costly sites. Study D, the national *loveLife* programme in South Africa, had the most comprehensive analysis of its potential epidemic and economic impact among the studies in this review.[418] The authors assessed the potential cost-effectiveness of *loveLife* by estimating HIV infections averted, programme costs, and averted medical costs. They concluded that *loveLife* would avert between 270,000 and 363,000 HIV infections over 10 years. At the programme level, it was estimated that *loveLife* net savings would be between $2.1 billion and $3.0 billion for the infections averted over ten years. Details on the cost-effectiveness of study B are provided in the schools section ***(Section 2.4.2.3)***.

Summary

A summary of the evidence from this review of interventions in geographically-defined communities is shown in ***Table 2.7***.

Table 2.7 Community-based interventions: results and strength of evidence

Evaluation design	Knowledge		Skills			Attitudes/Norms			Sexual behaviour/Condom use			Strength of evidence (for biological and/or reported sexual behaviour data)
	+	0	+	0	-	+	0	-	+	0	-	
Type 1 (targeting youth and delivered using existing organisations or events)												Weak: positive effect
Cross-sectional	V	-		-	-	V	-	-	V	-	-	
Quasi-experimental	-	-	-	-	-	-	-	-	-	U	U***	
Type 2 (targeting youth and creating own system and structure for delivery)												Strong: positive effect
Before-after (no comparison group)	S	-	S	-	-	S	-	-	S	-	-	
Cross-sectional (no comparison group)	-	-	-	-	-	-	-	-	D (HIV)	-	-	
RCT (≥6 clusters)	-	-	-	-	-	-	-	-	C (HSV2)	C	-	
Type 3 (community-wide intervention delivered through traditional networks)												Moderate: positive effect
RCT (≥6 clusters)	B	-	B	-	-	-	-	-	B (reported pregnancy)	-	-	
Type 4 (community-wide intervention delivered through community-wide activities)												Moderate: mixed results
Cross-sectional	N, O, P, T	-	N, O, T	P	N*	N, O, T	P	N**	N, O, P, T	-	N, O, P****	
RCT (≥6 clusters)	-	W	-	-	-	-	W	-	-	W	-	

Key: +, Positive impact; 0, no significant impact; -, negative impact. An intervention was considered as having an effect (positive or negative) if ≥1 significant results were found from among all of the relevant outcomes measured. Where interventions are classified in more than one column it is because they had mixed results, see Table 2.2 for details

* Females were less confident they could put on a condom correctly

** Females had a less positive attitude towards condom users

*** This intervention among males demonstrated an increase in overall number of partners

**** Reduction in abstinence

Table 2.8 Interventions in Geographically-defined Communities: impact on reported sexual behaviour and biological outcomes

Evaluation design	Threshold of evidence required	First SRG review (Developing countries, 1990-2004)			Revised SRG (SSA, 1990-2008)		
		Strength of evidence	SRG recommendation	Explanation	Strength of evidence	Overall Recommendation	Explanation
Type 1 (targeting youth and delivered using existing organisations or events)	Moderate	Equivocal	Ready	*5/10 evaluated with design to produce plausibility or probability evidence sufficient to meet moderate threshold. There was high diversity within this type of intervention and lack of adequate monitoring or process data*	Weak: positive effect	Steady	*7 studies all with weak designs and positive effect*
Type 2 (targeting youth and creating own system and structure for delivery)	High	Weak	Steady (or do not go)	*All 6 evaluations had weak designs, mostly positive results*	Strong: positive effect	Ready	*5 studies with mostly positive effect, weak to moderate study designs, two impacting biologically measured HIV/STI*
Type 3 (community-wide intervention delivered through traditional networks)	Moderate	Weak	Steady	*Only 3 interventions, mixed results*	Moderate: positive effect	Ready	*1 well-designed RCT with positive effect, and 3 weaker studies with mixed effect*
Type 4 (community-wide intervention delivered through community-wide activities)	Moderate	Weak	Steady	*Only 2 studies, weak design, mostly positive results*	Moderate: mixed results	Steady	*6 studies with weak to moderate study designs and mixed results*

The number of studies in each Type of intervention was limited, and due to their study design most studies did not provide strong evidence on effectiveness. Interventions often lacked appropriate control populations, some lacked adequate baseline information, and few appropriately evaluated a dose-response relationship. None-the-less, overall there was some evidence that interventions in geographically–defined communities can have the potential to positively impact a number of RH outcomes in young people. Interestingly, the AYA intervention (Studies N, O and P) was conducted in three countries, and though the study design was similar in each country, the results were not. This implies that the effectiveness of a single intervention may vary substantially in different contexts, or that the same types of interventions were implemented with differing quality or coverage in the different AYA programmes. Several of these interventions were multi-component, but even those that were single-component interventions generally conducted a number of different types of activities. As such it is difficult to disentangle how the various components work together and which aspect or aspects of these interventions were most effective. Furthermore, there was little attempt to evaluate any mechanism of action in the interventions reviewed, and cost-effectiveness analysis was only addressed in Studies B, D and V. Future research would benefit from addressing these facets of community interventions in more detail.

Overall recommendation for interventions in geographically-defined communities

Table 2.8 shows the strength of evidence from all interventions in the first SRG review and then shows overall recommendations for interventions in geographically-defined communities in SSA, based on biological and reported sexual behaviour results from this and the first SRG review combined i.e. 1990-2008.

Interventions in geographically-defined communities were generally the most difficult to evaluate. As compared to the studies available to the first SRG review, more recent reports of evaluations of interventions in geographically-defined communities added in this review were generally of higher quality. Unlike the first review, most identified a theoretical basis for the intervention, provided adequate description of the models of programme delivery, and analysed outcomes stratified by sex. Due primarily to the limited number of intervention studies included in the combined SRG review, none of the intervention types were awarded a 'Go!' recommendation. There were just two Type 1 studies in this review, neither with strong study designs. While one demonstrated positive results for a number of mediating factors (Study V), the other had no effect or a negative effect (Study U). In the first SRG review, there were five studies of this type conducted in SSA with weak study designs and largely positive outcomes. Type 1 interventions were given a 'Steady' recommendation overall. Only three Type 2 studies were identified, all having weak to moderate study designs and positive outcomes. However, there was one community randomised Type 2 intervention (Study C) that showed a statistically significant reduction in incident HSV2 and so a recommendation of 'Ready' was given overall. Type 3 and 4 interventions target the community as a whole, either using traditional networks (Type 3) or large-scale community activities (Type 4) to deliver the intervention. Type 3 interventions, while they can be culturally acceptable, are typically more labour intensive as the intervention is transmitted to one individual or family at a time. Type 4 interventions benefit from a broad reach and uniform message, though there is little attention paid to the individual. Both Types 3 and 4 interventions in the first SRG review were given a 'Steady' recommendation. One strong Type 3 study with a positive impact was identified in this review, and so Type 3 was recommended as 'Ready' overall. Type 4 interventions had mixed results in this review therefore garnered a 'Steady' recommendation. Most of the current recommendations, based on the combined review, differed from those in the first SRG review, highlighting the increase in evaluation studies in this setting and also the difficulty in disentangling the important elements of community-based interventions.

2.4.2.6 Interventions with biological outcomes

Since the first SRG review was completed in 2005, there have been four studies of interventions in one or more of the three settings that have reported the impact on HIV prevalence and other biological outcomes (Studies B, C, D and W).[290, 374, 384, 419] Because the primary outcome of reducing HIV prevalence in young people has been measured directly as opposed to using proxy measures such as reported sexual behaviour, knowledge, reported attitudes or self-efficacy, more weight is placed on the strength of evidence from these studies. This section reviews only the evidence from these studies and only considers the impact on the biological outcomes within those studies. The impact on other outcomes measured in these same studies has been reported in the relevant sections according to study setting and type.

Two studies were of multi-component interventions (Studies B and W), and two were in geographically-defined communities (Studies C and D). Descriptions of the interventions and the outcome evaluations are presented in ***Tables 2.1 and 2.2.*** Three studies used an experimental, cluster randomised design, had large sample sizes, had medium to long term follow-up, and were rigorously implemented and evaluated. The fourth study (Study D) was a nationally-representative cross-sectional survey to identify risk factors for HIV, which included exposure to a national community-based intervention.

The Regai Dzive Shiri Trial (Study B), evaluated a multi-component ASRH programme aimed at preventing HIV, STIs and unintended pregnancy among young people in and out of school in rural Zimbabwe within a CRT.[374, 420] In addition to in- and out-of-school health education programmes, this intervention also implemented interventions to increase the youth-friendliness of local government health services and a community awareness-raising component. Impact was evaluated in a cross-sectional survey of young people aged 18-22 years living in the trial communities irrespective of their exposure to the intervention approximately 48 months after the start of the interventions. Blood was collected as dried blood spots and tested for HIV and HSV2 antibodies using ELISA. Urine was collected from females for hCG pregnancy testing. At 48 months follow-up there was no significant impact on the prevalence of pregnancies, HIV or HSV2, however, there was a significant reduction in reported pregnancy in this study. Study B had good power to detect an impact on HIV, however, it suffered from high participant mobility, and ultimately the intervention was assessed in the wider community rather than among intervention recipients only, which is likely to have diluted any true effect of the intervention if it occurred.

The primary objective of Study D was not to evaluate a specific intervention, but rather to identify factors associated with HIV in a nationally representative survey of sexually-experienced young people in South Africa.[419] One of the exposure variables measured in this survey was exposure to the national HIV prevention and sexual and reproductive health programme, *loveLife*. *loveLife* is a multi-component intervention, including a multi-media awareness and education campaign, community outreach, youth centres, and youth-friendly clinics. Study D evaluated HIV prevalence by reported participation in a *loveLife* community programme. Study D was the only study in any of the three settings in sub-Saharan Africa to have demonstrated a significant impact on HIV prevalence. This was found in sexually-experienced males and females. As this study was a cross-sectional observational survey, it is not possible to determine the causal sequence of events, and furthermore it is possible that young people exposed to *loveLife* would have been systematically different from those unexposed with regard to their HIV risk profile. None-the-less, this survey did control for a number of potential confounding factors, and these results are consistent with the hypothesis that *loveLife* had reduced HIV risk in this population.

The Stepping Stones trial (Study C) evaluated a community-based intervention targeting in- and out-of-school youth, with the aim of reducing HIV and promoting safer sexual behaviour in young people in rural South Africa within a cluster randomised trial.[384] Study C measured impact on HIV and HSV2 incidence at 24 months after initiation of the intervention. A blood sample was tested for HIV using rapid tests, with ELISA for confirmation of positive results, and for HSV2 by ELISA. It is important to note that Study C evaluated the impact of the Stepping Stones intervention in small groups of volunteers who self-selected themselves to be involved in an intensive intervention. They were likely therefore to be individuals who were particularly motivated to learn about sexual risks and perhaps to change their own risk behaviours. This study was not adequately powered to detect changes in HIV incidence, as the assumptions of likely HIV incidence in this population that were used to calculate sample size at the trial design proved to be overestimates. However, no significant impact on HIV incidence was seen but there was a significant reduction in HSV2 incidence at 24 months in both males and females. This finding is important in that while HSV2 arguably may not be a good proxy for HIV,[421] it is an important co-factor for HIV transmission and therefore could impact HIV incidence in the longer term.[119]

The IMAGE study (Study W) was a CRT in rural South Africa, evaluating an individual and community-level, structural approach to HIV prevention and reduction of intimate partner violence.[289] Based on the theory that poverty and gender inequity contribute to increasing HIV prevalence in this area, IMAGE intervened through a microfinance programme for women, coupled with a curriculum on gender and HIV education. Notably, this intervention did demonstrate a reduction in intimate partner violence among recipients of the intervention. Though young people were not the direct recipients of the intervention, the impact of the intervention was assessed among young household members of participants (cohort 2) and young people in the communities of participants as a whole (cohort 3). A blood sample was tested to measure HIV incidence in cohorts 2 and 3 using ELISA. A sub-group analysis was conducted among young people in cohort 3, the results of which are presented here. No impact on HIV incidence was observed but the power of Study W was very low to detect changes in HIV incidence among this subgroup of young people.

2.4.2.7 Strengths & limitations of the review

This systematic review of HIV prevention interventions for young people has a number of distinct strengths. The review applies a standard and transparent methodology across settings and types of intervention in each setting. This methodology relies on grading interventions for their strength of evidence, to systematically review interventions alongside each other in order to determine overall effectiveness for each type of intervention within a given setting. The review takes a public health perspective with the major focus of the review being the implications of results for policy and programming. While more weight is placed on evidence from experimental trials, non-randomised interventions have been included where appropriate. Finally, as a similar typology and methodology to the first SRG review has been used, the newly-reported studies can be directly added to the ones already reviewed in the first SRG review. This allows overall recommendations to be made for interventions in SSA in schools, health services and geographically-defined communities based on evidence from 1990-2008.

One limitation to the Steady, Ready, Go! methodology used is this review is that it prioritises the UNGASS goals and hence measures success according to intervention impact on knowledge and reported behaviours. Reported behaviour is problematic and measuring intervention impact on biological outcomes would have been more objective and more in keeping with the ultimate goal of reducing HIV and other STI. However, too few studies measured biological outcomes to make this a very useful exercise. As such, evidence for effectiveness depended primarily, in schools and in geographically-defined communities, on reported sexual behaviours. In health services, evidence for effectiveness depended on utilisation or reported utilisation of services and not the effectiveness of the services themselves on health outcomes. It should be noted that even for interventions with a recommendation of 'Go!' this applies. Interventions in this review were considered as having an effect if an impact was seen on one or more of the biological or reported behavioural outcomes measured, without there being any negative impacts on these same outcomes. This is a limitation as often an intervention shows an impact on only one or a small number of its many outcomes (e.g. reported condom use in Study L and a delay in reported initiation of sex/decreased sexual activity in Studies E and M). Reporting that there was an overall impact for such studies tends to make an intervention appear more effective (or harmful) than it may actually be. The impact on reported behaviour also varied according to sex, both within and between studies. For example, an impact on reported condom use was seen only among males in Studies J and K but only among females in Study F. Similarly, reported initiation of sex was delayed among males only in Studies F and J and among females only in Study K.

The inclusion of studies with non-experimental design can be seen as a strength in that it does not exclude interventions that are not amenable to the use of a randomised controlled design for example the evaluation of the *loveLife* programme in South Africa. However, inclusion of studies with weaker study designs can also be seen as a limitation as confounding and biases are less likely to be controlled for in these studies and the results of the systematic review could have been biased by these weaker studies. In some cases the typology used was too restrictive and some community-based interventions for example Study W, did not fit as well within the pre-defined typology as others. Despite the limitations of this typology, it does create a reasonable framework for evaluating interventions in this setting, and retaining it allows us to combine results from this review with the first SRG review. Another limitation was the omission of other types of interventions including mass media interventions, and interventions among young people most at-risk. This was done because such interventions were not part of the MkV1 intervention package. The data on cost-effectiveness was unfortunately very limited, and did not provide adequate opportunity for comparison, nor for estimates of costs of similar interventions in other settings. One final limitation associated with all reviews of published literature is that there is a possibility of publication bias i.e. researchers may be more likely to report results and have them published if they have a positive result.

2.5 Summary of evidence from studies outside sub-Saharan Africa

2.5.1 Other Developing countries

The above review of the evidence has focused on studies that were carried out in SSA. It is important to consider whether studies from other developing countries provide additional or different evidence on the effectiveness of behavioural interventions among young people. The reviews that have included studies from all developing countries[225, 241, 267, 354, 359, 422] have found similar results to reviews focusing just on SSA.[94, 356, 357] Only a few review authors have commented on the effectiveness of interventions in SSA vs. other developing countries[354] and they have not found any major differences i.e. the evidence of impact from other developing countries is also mixed. For example, two large school-based studies in Mexico, one a cluster randomised trial[423] and the other a quasi-experimental study[424] found an impact on knowledge but no impact on reported sexual behaviour or reported condom use. A much smaller study, also in Mexico, found decreased reported sexual activity at 8 months and increased reported contraceptive use at first sex.[425] A large quasi-experimental study in Chile found improvements in knowledge, reported timing of sexual debut and reported contraceptive use among females.[261] A RCT in Brazil reported a decrease in reported risky sexual behaviour among females but not males, though this study had high attrition.[426] Also in Brazil, a large repeat cross-sectional study found no impact on reported ever having had sex, use of condoms or utilisation of clinics.[427]

All but one of the reviewed interventions that were implemented in developing countries outside of SSA relied on reported behavioural outcomes and none measured biological outcomes.[225, 241, 354] An abstinence-centred intervention in a high school in Chile led to a reduction in clinically-recorded pregnancies though the authors did not present sufficient data to ascertain whether baseline differences between intervention and control groups were important. This intervention taught 'Fertility awareness registration methods' and as neither use of family planning methods nor sexual behaviour were recorded, it was unclear what led to the decrease in pregnancies.[428]

2.5.2 Developed countries

Have developed countries had any more success in reducing risky sexual behaviour?

In reviewing 83 evaluations of school-based interventions in both developed and developing countries, Kirby and colleagues found that programmes were just as likely, if not more likely, to be effective in developing countries as they were to be effective in developed countries.[51, 225] They concluded that the immediate local context was more important for intervention success than the national or global regional context. Kim and colleagues reviewed the evidence on the effectiveness of forty adolescent AIDS risk-reduction interventions in the US published between 1983 and 1995. A positive impact was seen in 88% of studies assessing knowledge, 58% assessing changes in attitudes, 60% assessing intention to use condoms, 73% in reported condom use and 64% in decreasing the reported numbers of sexual partners. None of the included studies seem to have recorded impact on biological outcomes.[226] A meta-analysis of 26 RCT of teenage pregnancy prevention interventions that were carried out in developed countries between 1970 and 2000 concluded that such interventions did not result in a delay in sexual initiation, improved reported use of contraceptives or reduction in the number of pregnancies.[346] Another review, this time of all types of adolescent sexual risk-reduction programmes that were published in the 1990's, concluded that the following four overall factors may impact programme effectiveness: (i)the extent to which programmes focus on specific skills for reducing sexual risk behaviours; (ii) programme duration and intensity; (iii) what constitutes the content of a total evaluated programme including researchers' assumptions of participants' exposure to prior and concurrent programs; (iv) and what kind of training is available for facilitators.[347]

Looking beyond adolescents, in 2005, Manhart and Holmes published a review of the effectiveness of HIV prevention interventions among participants of all ages.[50] Out of a total of 41 RCT carried out before 2004, 22 showed an effect on STI acquisition, transmission or complications. In terms of behavioural interventions, however, they found only one out of 23 individual risk-reduction counselling interventions[222] and three out of nine group counselling and skills building interventions were successful in reducing the acquisition of STI.[50] Among the behavioural interventions reviewed, those that showed no effect were theory-based as often as those that demonstrated benefit and no single underlying theory or approach (e.g. skills building, counselling) was more often successful than another. Many of these studies were carried out in adults of all ages but young people featured strongly in these trials e.g. ~35% of Project SAFE trial participants were aged < 19 years.[429]

The successful individual risk-reduction intervention was Project RESPECT in the US. This was a multi-site RCT designed to evaluate the effectiveness of STIs/HIV counselling and testing among heterosexual men and women attending a STI clinic.[222] The intervention, based on a Fishbein integrative model of behaviour change,[221] was delivered one-to-one in a STI clinic by trained counsellors. The groups who received counselling sessions had an overall reduction in STI incidence (chlamydia, gonorrhoea, syphilis or HIV) of about 30% at 6 months and 20% at 12 months relative to control groups who had received only the 2 brief didactic messages that were typical of the current care at the time. The 2 session counselling arm had a similar impact to the longer 4-session counselling arm. Sub-group analysis revealed a greater relative effectiveness among clients aged 20 years or younger.[222] One of the individual risk-reduction counselling interventions reviewed by Manhart that was not successful was the EXPLORE project. This was a large multi-centre trial in the US among men who have sex with men. The intervention involved ten one-on-one counselling sessions followed by a maintenance session every 3 months and the control was Project RESPECT counselling. HIV incidence was 15.7% lower in the intervention arm after adjustment for baseline covariates. This result was not statistically significant but a statistically significant 20.5% lower self-reported incidence of unprotected receptive anal intercourse with partners who were HIV positive or of unknown serostatus was observed in the intervention arm. The intervention effect may have been muted by the use of Project RESPECT as the control condition.[430]

One of the successful group counselling interventions compared a skills training to a health education intervention for reducing the risk of new STD infections among heterosexual low-income women in the US. Women exposed to the 32 hours of skills training (5-10 participants/group) had an almost 50% lower incidence of STI in the 12 month follow-up than those who received the mainly didactic health education intervention. Self-reported high risk sex was also lower in the skills training group.[431] Another US RCT evaluating Project SAFE found a reduction in rates of chlamydia and gonorrhoea over 12 months. The intervention was targeted at high-risk women and involved 3 small group sessions of 3-4 hours each based on the AIDS Risk Reduction Model.[429] The authors attributed their success to the extensive anthropological work carried out in the study community prior to the intervention implementation and the grounding of the intervention in theory. They also considered that inclusion of a focus on relationships helped the women to bond and encouraged empowerment and action.

Community-level interventions have also shown some success in changing behaviours in the US. One study using popular opinion leaders to target men who have sex with men in US bars found a reduction in reported high risk sexual behaviours at one year follow-up.[211] The CDC AIDS community demonstration projects targeting high-risk populations in 5 cities in the US was based on Fishbein's integrative model and used three techniques: mobilisation of community members to distribute and verbally reinforce prevention messages and materials among their peers, creation of small-media materials featuring theory-based prevention messages in the form of role-model stories, and increased availability of condoms and bleach kits.[223]

In the UK, the RIPPLE study was a large trial comparing the impact of school-based peer-led with teacher-led sex education. The investigators followed-up participants until the age of 20 years but did not find the peer-led intervention to be associated with a reduction in the rate of teenage abortions by age 20 years. The peer-led intervention was associated with a reduction in reported pregnancies before age 18 years and a borderline significant reduction in reported abortions. The discrepancy between the reported outcomes and objective measured outcomes show the importance of the use of biological outcomes.[246] Limitations of this study included poor follow-up of participants in the comparison arm and the absence of a true control group.[246, 432] In Scotland, another RCT compared a theoretically based, specially-designed enhanced teacher-led sex education programme (SHARE) with the intensive existing sex education programme. The enhanced programme was associated with improved practical knowledge of sexual health but did not reduce self-reported or routinely-reported conceptions or terminations. The authors concluded that high-quality sex education should be continued, but to reduce unwanted pregnancies complementary, longer-term interventions that address socioeconomic inequalities and the influence of parents should be developed and rigorously evaluated.[433] Following on from the disappointing results of these 2 large RCT in the UK, Harden and colleagues, reviewed the impact of early childhood interventions and youth development programmes on the rate of teenage pregnancies. The results of 6 controlled trials, all in the US, revealed that combining individual-level and structural-level measures to tackle social disadvantage can lower teenage pregnancy rates.[434]

2.6 Role of modelling studies

The limitations of reported behaviours as outcomes have been highlighted earlier in this chapter. The use of more objective biological outcome measures is often not feasible due to the large sample sizes that would be needed to measure differences in these rarer outcomes, and the considerable costs associated with laboratory tests. In the absence of large high-quality trials, mathematical modelling is a tool that can be used to predict the potential impact of interventions. For example, in 2002 Stover and colleagues modelled the immediate implementation of a comprehensive set of interventions (including VCT, MTCT, mass media, peer counselling, workplace programmes, condom social marketing, STI treatment etc.) and suggested that the UNGASS goal of 25% reduction in HIV by 2010 could be met.[250] Hallett and colleagues modelled the potential impact of circumcision programmes and proposed that if efforts to change behaviour are increased in parallel with the scale-up of circumcision services, then dramatic reductions in HIV incidence could be achieved (at least 10 times greater than the reductions if circumcision programmes are not accompanied by behaviour change).[435] White and colleagues modelled the impact of episodic and suppressive therapy on the incidence of HIV. They found that HSV-2 therapy could potentially have a population-level impact on the incidence of HIV, especially in more concentrated epidemics. However, a substantial impact requires high coverage and long duration therapy if population-wide suppressive therapy was used, or very high symptom recognition and treatment-seeking behaviour if episodic therapy was to be used.[436]

Modelling can also help in the design of trials by predicting the size of effect and the time that it might take to obtain a desired size of effect. A model looking at the impact of an intervention targeted at high-risk groups showed that there was a delay between the behaviour change happening and its full effect being realized in the low-risk group. This suggested that only with unrealistically favourable study conditions would a statistically significant result be likely with 5 years follow-up or less.[437] Models have been used to explain the findings of STI treatment [438] and adolescent behaviour change trials.[439] An ongoing adolescent modelling study is using models to investigate the projected short-term and long-term effects of alternative interventions targeted at adolescents with the aim of providing evidence of how interventions should be tailored to the local context (Richard White, personnel communication).

Mathematical modelling is an important tool but the main limitation is that models can rarely reflect the true complexity of the sexual networks. Sexual health outcomes will depend on the position of individuals in sexual networks and the timing (concurrence) of multiple partnerships.[302] Also, models include lots of assumptions about the levels of the variables included in the model, and, about how they will interact with each other and it is precisely these interactions that we often do not know enough about.

2.7 Conclusions and research priorities

In this chapter the state of knowledge on the effectiveness of behavioural interventions to prevent HIV, STIs and unplanned pregnancies among young people in SSA has been outlined. Between 2005 and 2008 there were 22 adolescent SRH interventions in SSA that met the inclusion criteria for the systematic review. The large number of studies, published in the span of just four years, reflects an increasing recognition of the importance of HIV prevention among young people, and the need for studies to assess the effectiveness of interventions that aim to achieve that goal. Encouragingly, intervention studies in this review, in addition to addressing reported behavioural and/or biological outcomes, have largely addressed the UNGASS goals, in terms of overall objectives and outcomes measured. Overall the quality of studies included here tended to be higher than those identified in the first Steady, Ready, Go! review, however, this review was still hindered by poor study design and lack of analytical rigour in several of the evaluations. The relative dearth of RCT (a total of just 4/22) reflects the fact that many of the evaluations have either been conducted by programme implementers or have been a late addition to the programme design. The strength of evidence is only as good as the evaluation, and future research should plan for a rigorous evaluation process.

The majority of the conclusions and recommendations from the systematic review are based on reported risk behaviours. Ultimately we would like to determine how effective an intervention is in reducing HIV prevalence in young people, but very few evaluations include biological testing for HIV, or even other biologically-measured proxies of sexual risk behaviour such as other STI or pregnancy. As highlighted earlier in this chapter, reported sexual behaviour, especially among young people, is problematic and potentially suffers from low validity due to social desirability and other biases. The lack of a measurable impact on the majority of biological outcomes may be testament to the fact that knowledge alone is not enough to reduce HIV and STIs in young people, and that other social and economic vulnerabilities may pose challenges that outweigh the desire for positive behaviour change.

There is now compelling evidence that well-designed and implemented, curriculum-based interventions in schools that are led by adults, with or without the involvement of peers can have an impact both on knowledge and on reducing self-reported sexual risk behaviours. However, there is increasing concern that this apparent impact on behaviours may actually be due to reporting bias fuelled by the young people's improved knowledge of what they would need to do to reduce their risk, rather than reflecting substantial changes in actual behaviours. The longer-term evaluation of the MEMA kwa Vijana intervention reported below went some way to improving our understanding of the relationship between knowledge, reported behaviour and real improvements in SRH. There is less strong evidence on the effectiveness of interventions to make health facilities more accessible and acceptable to young people, but this updated review concludes that interventions which train service providers and take actions to make the facility more youth-friendly, coupled with activities in the community with or without involvement of other sectors to link or refer young people to health services, can show promise in terms of increasing young people's utilisation of health services. The review of the evidence on the effectiveness of interventions in geographically-defined communities has led to the recommendation that interventions targeting young people and/or other community members are also effective for improving reported sexual and/or biological outcomes.

There is a growing consensus that to achieve HIV prevention in young people it is necessary to provide a range of tools and address a number of barriers, including changing broad community attitudes and norms.[26] To accomplish this, it is necessary to implement interventions in different settings simultaneously, and thus have the capacity to promote change using different approaches on a number of levels. With evaluations of multi-component interventions, however, it is difficult, often impossible, to disentangle the relative contribution of the various components on the measured outcomes. Likewise, for interventions with a range of activities, such as many of the community-based interventions evaluated in this review, it is equally difficult to determine how the various components work together (synergistically or perhaps even antagonistically) and which aspect(s) of these interventions are most effective.

The limited cost data available for ASRH interventions suggests that the recurrent costs of in-school interventions might be quite cost-effective, at least for SRH knowledge outcomes. There is typically an initial expense related to project development and teacher-training, however, the costs of the materials required for in-school sex education are generally limited, and once the programme has been developed and initiated, training of new teachers can be included into pre-service training curricula at little added expense. Peer-led interventions in the community might be affordable but only if they can be designed so that peers do not need to be retrained and/or replaced every year. There is some suggestion that interventions that involve short, sharp messages e.g. the HIV age profile of men in Kenya, might be cost-effective at reducing reported pregnancies[440] and this is an area worth exploring further.

In 2003, Stephenson noted that too many reviews of SRH interventions had concluded that it was not possible to draw firm conclusions about which interventions work and which do not, because of methodological flaws in the conception, design, conduct, and analysis of the available studies. She challenges the research community to *'ensure that systematic reviews of sexual behaviour intervention trials conducted over the next decade do not conclude that the quality of trials in this area remains poor, or that too few interventions have been rigorously evaluated and shown to be effective in improving sexual health'*.[441] Five years later, have we as a research community risen to this challenge? Unfortunately, this review has revealed poor quality evaluations and an absence of sufficient evidence to draw firm conclusions. However, this review, following in the footsteps of the first Steady, Ready, Go! review has made important policy recommendations based on the best available evidence.

In the last few years, a number of less comprehensive reviews have looked at interventions limited to one setting or have looked only at one type of intervention. Kim and colleagues reviewed high quality evaluation studies in order to examine the evidence on effectiveness of peer-led ASRH education in any setting. The authors found that peer-led sex education had a limited impact on reported condom use, pregnancy or new sexual partner acquisition.[355] Maticka-Tyndale and Barnett published a similar review in 2009 but they focused only on peer-led programmes in geographical communities and had less strict study design criteria. They found evidence of a positive impact on the reported use of condoms but few studies that showed an impact on other reported behavioural outcomes. The authors used the probability, plausibility, and adequacy framework devised by Habbicht and colleagues and reviewed the evidence according to the strength of the study design. They conclude that greatest successes were reported in studies with the weakest designs.[267] This relationship was, however, not observed for studies at the top of the quality spectrum as Kirby found that the studies with experimental design had a similar success rate to those with quasi-experimental designs.[225] Reported condom use seems to be one of the outcomes that is most frequently shown to increase as a result of interventions. While this is promising, it is important not to be too optimistic given the high potential for biased reporting associated with this outcome. Again, these reviews point to the need for high-quality evaluations and the inclusion of more objective biological outcomes.

Interventions are often complex in terms of their theoretical basis and mode of implementation and the resultant evaluations are also complex as they strive to measure a variety of outcomes, some of which have dubious validity. There still remains a lot of uncertainty as to the most effective interventions to improve ASRH in developing countries. A number of research priorities have been identified.

(i) Need for rigorously designed trials

It is important to determine if an intervention is having the desired effect or not. As one author pointed out 'If high quality, school-based programs cannot have an impact on behaviour, programs can train teachers to reach the easier goal of increasing knowledge and improving attitudes about HIV/AIDS'.[442] Where feasible, interventions should be evaluated using a randomised controlled design. Failing that a quasi-experimental design should be used with particular attention made to minimising bias and controlling for confounding factors.

(ii) Need for biological outcomes

In the past 20 years or so of HIV prevention research among young people in SSA only five studies have included objective biological outcomes.[186, 290, 374, 384, 419] The unreliability of reported sexual behaviour outcomes and the importance of biological outcomes have been highlighted earlier in this chapter.

(iii) Evaluation of the long-term impact

Little evidence exists on the long-term effects of interventions on behaviours, or on scaling-up and evaluating of long-term programmes. Many interventions are attempting to change behaviours that are intrinsically linked to social norms and traditions. It is unlikely that interventions will change these behaviours significantly in the short-term and researchers should strive to conduct long-term evaluations. It is only through such longer-term evaluations with more than one time-point for evaluation of impact that we can observe transient intervention effects and effects that materialise only when the 'tipping point' has been reached in the study community.

(iv) Combining both quantitative and qualitative approaches

Rigorous evaluation of interventions using a combination of both quantitative and qualitative methods will yield the most informative results and facilitate the improvement of and/or replication of interventions. This will require the inclusion of process evaluation so that we can understand how well the intervention was implemented and other qualitative data collection to help us understand why an intervention did or did not work.

The MEMA kwa Vijana Trial Further Survey (MkV1FS) was a rigorous evaluation of the long-term impact of a multi-component ASRH intervention using both reported behaviour and biological outcomes. As such, the research presented in this thesis attempted to make an important contribution to the field by answering whether the multi-component MEMA kwa Vijana intervention had a long-term impact on knowledge, reported attitudes, reported sexual risk behaviours, and, most importantly, objective biological outcomes.

Chapter 3 - Methods

This chapter outlines the research study methods. The first section describes the study design including details of the sample size calculation and the estimation of study power. A number of key issues that were addressed during the design of the survey are also highlighted in this section. The second section describes the choice and design of the data collection tools. The subsequent three sections provide details of the fieldwork, data management, laboratory and statistical methods. The final sections outline ethical considerations and the methods used to communicate and disseminate the research results.

3.1 Design of study

3.1.1 Study Design

The MEMA kwa Vijana long-term evaluation survey (MkV1FS) was a cross-sectional survey, within a community-randomised trial, of young people living in the 20 MEMA kwa Vijana (MkV1) trial communities (10 intervention, 10 comparison). Data collection took place between May 2007 and July 2008, approximately 9 years after the start of the MkV1 intervention. MkV1FS had 3 main components:

1. Mobilisation of the community
2. Census of all households to identify young people
3. Survey of young people

The following terminology was used:

Invited young person - Potentially eligible young person who had been given an invitation to attend the survey

Attendee - Young person who attended the survey (eligible or non-eligible)

Participant - Young person who was eligible and who participated in the survey

3.1.2 Inclusion and exclusion criteria

To be eligible to participate in MkV1FS, young people had to fulfil the following three eligibility criteria:

1. Currently be considered by the household head to be a member of a household within one of the 20 trial communities i.e. a *de jure* member of a household
2. Attended standard 5,6 or 7 in a primary school within a trial community for at least one year between 1999 and 2002 inclusive (the period when the intervention was implemented most intensively and with the closest supervision)
3. Willing to give informed consent to all the study procedures

Figure 3.1 is a cohort diagram that shows the primary school year groups according to the time since last exposure to the in-school component of the MkV1 intervention. The potential number of years of exposure to the MkV1 in-school component of intervention, by the end of the calendar year, for those in the 10 intervention communities is represented by the number in each cell. Young people who were invited to participate in the 10 comparison communities attended the same standards in primary school, during the same time period, but their number of years of actual exposure to the intervention will have been '0'. The school year groups which include those eligible for the original MkV1 trial cohort are highlighted in yellow. The other school year groups who had the potential to receive at least one year of the in-school intervention during the period when this was being implemented most intensively (i.e. 1999-2002 inclusive) are shown in blue. The school year groups that have been exposed to the MkV2 intervention in both the intervention AND comparison communities are indicated in pink. MkV1FS was carried out in the second half of 2007 and first half of 2008 and included both these school year groups (cross-hatched in row for the end of 2007).

Figure 3.1 Cohort diagram showing those eligible for MkV1FS (2007/8): Number of years exposed and time since last exposure to the in-school component of the intervention and age distribution of those eligible (for further explanation see text on previous page)

Activity		**Primary School**				**Years since left school**								
	Year	**Std 4**	**Std 5**	**Std 6**	**Std 7**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Recruitment survey (Aug-Dec '98)	**Dec-98**	0	0	0										
Intervention started Jan '99	**Dec-99**		1	1	1									
	Dec-00		1	2	2	1								
3-year evaluation Survey	**Dec-01**		1	2	3	2	1							
	Dec-02		1	2	3	3	2	1						
	Dec-03		1	2	3	3	3	2	1					
	Dec-04		1	2	3	3	3	3	2	1				
	Dec-05		1	2	3	3	3	3	3	2	1			
	Dec-06		1	2	3	3	3	3	3	3	2	1		
Long-term evaluation Survey	**Dec-07**		1	2	3	3	3	3	3	3	3	2	1	
Mean age in late 2007 (range) for each schl yr cohort (yrs)- FEMALE		13 (10,16)	14 (11,17)	15 (12,18)	16 (13,19)	17 (14,20)	18 (15,21)	19 (16,22)	20 (17,23)	21 (18,24)	22 (19, 25)	23 (20, 26)	24 (21, 27)	25 (22, 28)
Mean age in late 2007 (range) for each schl yr cohort (yrs)- MALES		14 (11,18)	15 (12,19)	16 (13,20)	17 (14,21)	18 (15,22)	19 (16,23)	20 (17,24)	21 (18,25)	22 (19,26)	23 (20, 27)	24 (21, 28)	25 (22, 29)	26 (23, 30)

3.1.3 Estimated size of potentially eligible population

The population who were eligible for MkV1FS was limited (i.e. must have attended the trial primary schools during the selected time period). Unfortunately, the school registers were not a reliable source of denominator data as the number of students in each class is often exaggerated because school funding is based on the numbers registered. The size of the potentially eligible population was, therefore, estimated ***(Appendix 4)*** and the sample size was based on an estimate of the number of eligible young people who:

(i) Would be aged 17-25 years[b]
(ii) Could be traced during the census and would be able to attend the survey
(iii) Would agree to participate

Based on data from the original MkV1 trial enrolment survey, it was estimated that there would be an average of 720 men and 720 women from each community who had, between 1999 and 2002, completed at least 1 of the final 3 years of primary school in that community and that 90% of these young people would be aged 17-25 years at the end of 2006 ***(Appendix 4)***. During the 2001/2 MkV1 impact evaluation survey, the study team was able to gain full data on 73% of the original trial cohort. The participation rate for those who were identified as being present in the study community was approximately 95%.[186] For MkV1FS, it was estimated that the team would be able to trace 70% of subjects in the study communities and that full data would be obtained on 80% of these. These lower proportions reflected the slightly longer average period since leaving school (3-8 yrs vs. 1-2 yrs).

The total expected number of young people who would be included in the survey was therefore estimated to be 14,520 (363 males and 363 females interviewed per community x 20 communities).

[b] When finalising the protocol (April 2007) the age restriction was removed from the eligibility criteria i.e. eligible young people of all ages could participate in the survey. It had previously been estimated that 10% of the young people who attended the appropriate years in trial schools would be excluded based on age and by removing the age restriction the size of the eligible population would be expected to increase. However, given the uncertainty around the estimates of the number of eligible young people who could be traced during the census and/or the number who would agree to participate no changes were made to the sample-size estimates.

3.1.4 Estimated age distribution of eligible population

The MkV1 trial enrolment data provided the distribution of students by age and sex. In order to extrapolate up to the time of the proposed survey it was assumed that the students in each school year group after that had a similar distribution of ages. Taking an average age distribution for females (or males) based on the distribution in standard (std) 4, std 5 and std 6 (ignoring outlier ages where <0.5% of the class cohort had that age), the age distribution in each school year group was estimated through extrapolation i.e. for those who left school 3 years ago, 4 years ago, etc ***(Figure 3.1)***. The age distribution of the total eligible population was calculated based on the age distribution in each of the 6 school year groups. It was estimated that the population of interest (left school 3 to 8 years ago) would be aged between 16 and 29 years ***(Appendix 4)***. The estimated age distribution was not weighted according to the proportion of each school year group that were expected to be interviewed (i.e. those who left school recently were, on average, younger and may have been more likely to participate in MkV1FS).

3.1.5 Estimated prevalence of primary outcomes

Estimates of the prevalence of STIs in the study population were based on data from other studies among this age group in Mwanza Region.[120, 128, 186] Despite previous work, the greatest uncertainty lay in the estimates of HIV prevalence. The best guess estimates for the prevalence of the primary outcome HIV was 2% for males and 4.5% for females ***(Appendix 4, Table A4.2)***. It was estimated that the prevalence of our other primary outcome HSV2 would be 25% for males and 35% for females ***(Appendix 4, Table A4.3)***.

3.1.6 Estimated power of study

The power of the study to detect a true reduction in the prevalence of the biological outcomes was calculated separately for men and women assuming 363 men and 363 women per community, 10 communities per arm, and k=0.2, where k is the coefficient of variation between communities for that outcome. Power calculations took into account the cluster-randomised design and the formulae are set out in a paper by Hayes and Bennett.[443] Assumptions regarding the coefficient of variation (k=0.20) were based on previous experience from the Mwanza study population.[444]

Using best estimates, it was predicted that the study would have good power (88%) to detect a 40% reduction in HIV prevalence in females, and adequate power (85%) to detect a 50% reduction in males ***(Table 3.1)***. Similarly, the study would have at least adequate power (>80%) to detect differences of 35% in syphilis and of 30% in HSV2, in each sex. If similar effects were found in the two sexes, it would be possible to combine the results from the two sexes to give even greater power.

Table 3.1 Power to detect true sizes of effect for various outcomes

Outcome	Sex	Prevalence (%) in comparison community[1]	Size of effect[2]				
			50%	40%	35%	30%	25%
HIV	**Males**	1	0.60	0.40	0.31	0.24	0.17
		2	0.85	0.64	0.51	0.39	0.28
		2.5	0.90	0.71	0.58	0.45	0.32
	Females	3	0.94	0.77	0.64	0.50	0.36
		4	0.97	0.85	0.73	0.58	0.43
		4.5	0.98	0.88	0.76	0.62	0.45
		5	0.99	0.90	0.79	0.64	0.48
		6	0.99	0.93	0.83	0.69	0.52
		7	1.00	0.95	0.86	0.73	0.56
Syphilis	**Males**	6.5	0.99	0.94	0.85	0.71	0.54
	Females	10	1.00	0.97	0.92	0.80	0.63
HSV2	**Males**	25	1.00	1.00	0.98	0.91	0.77
	Females	35	1.00	1.00	0.98	0.93	0.80

Key:

1 Estimated using prevalence and incidence estimates from other studies in Mwanza Region

2 Difference in prevalence between intervention and comparison communities

Best estimates of the prevalence of each outcome taking into account the expected age distribution of participants. Estimates were based on the prevalences of HIV, HSV2 and syphilis among MkV1 participants in 2001/2,[186] the estimated incidence of HIV based on data from the MkV1 initial survey and the incidence of HIV, HSV2 and syphilis during the STD trial in Mwanza.[102, 120, 128]

3.1.7 Key design issues

Choice of a cross-sectional instead of a cohort design

A cross-sectional survey design was chosen in order to increase the power of the study to detect a difference in the frequency of HIV, one of the two primary outcomes. The original MkV1 trial cohort comprised of 9,645 individuals, approx 55% male and 45% female, who were in standard 5 of primary school in 1997, 1998 and 1999. At the 3-year evaluation survey in

2001/2 73% of the cohort was found. At best, it was estimated that in 2007/8 it would be possible to trace 50% of the original trial cohort. Assuming that 80% of these traced individuals agreed to participate, 3,858 young people (2,143 males and 1,715 females) would be interviewed. In the unlikely event that 60% were traced and 90% of these agreed to participate, 5,208 (2,864 males; 2,344 females) would be interviewed. Even with this more optimistic estimate of follow-up, a cohort study would have only had 34% power to detect a true 50% reduction in HIV incidence among males. Among females there would have been 80% power to detect a 40-45% reduction in HIV incidence; however this dropped to a power of <80% to detect a true difference of 50% in HIV when the best guess estimates of HIV incidence and cohort follow-up were used.

Up until at least 2008, young people in all of the subsequent school year cohorts in the intervention communities also received the MkV1 in-school component of the intervention. However, the most intensive teaching (and probably also more youth-friendly health services) occurred during the period from January 1999 to December 2002 when the supervision by AMREF was at its most intensive, and training courses were held for replacement teachers and health workers if staff left and were replaced. In order to increase the power of the study, a cross-sectional design was chosen that allowed the inclusion of young people in the three subsequent school year groups (std 5 in 2000, 2001 and 2002). Recruitment was restricted to those who had been exposed to the intervention for at least one year between January 1999 and December 2002 ***(Figure 3.1)***.

The MkV1 trial cohort included only those who were born in 1984 or earlier. In addition to including three additional school year groups it was possible to increase the number of potentially eligible young people by including those in the same MkV1 trial cohort school year groups but who were born later than 1984. This cross-sectional design greatly increased the study power to detect a true difference in the primary outcomes of HIV and HSV2 prevalence, and the inclusion of the entire original trial cohort allowed the possibility of sub-analyses restricted to the original trial cohort members.

One disadvantage of the cross-sectional design was that the primary outcomes were prevalence and not incidence of HIV and HSV2. However, as discussed above, because baseline data had not been collected on the additional school year groups, a cohort study would have been severely underpowered for HIV incidence. Also, prevalence at the time of MkV1FS would be a close proxy for cumulative incidence, since HIV-related mortality in recently infected young people would be negligible. While a small number of prevalent HIV infections may have occurred at a very young age, prior to intervention, previous data from this cohort show that this proportion will have been very small. Another disadvantage was that we would need to conduct a census to identify young people potentially eligible for the survey. This census would be labour intensive though it would have also been labour intensive and perhaps largely unsuccessful to try to trace the original trial cohort members by their name and location in 2001/2. The cross-sectional survey with an estimated sample size of over 14,000 was much larger in scale than the previous trial cohort evaluation survey which included ~7500 young people. It was felt that this larger survey was justifiable given the importance of investigating the long-term impact of the intervention on HIV prevalence.

Risk of dilution and/or contamination

One issue raised during the planning of MkV1FS was that the introduction of the MEMA kwa Vijana intervention (MkV2) into the various comparison communities at varying times between July 2005 and December 2007 would lead to contamination of the trial. The most intensive MkV1 intervention component is the in-school programme. The design of the 2007/8 follow-up survey meant that none of the participants from the comparison communities would have received any of the in-school intervention in December 2007 ***(Figure 3.1, PINK highlighting)***. Furthermore, it seemed very unlikely that the behaviour or HIV/STI risk of the older age-groups covered by the survey, who would all have left primary school by July 2005, would have changed appreciably in the short-term as a result of the recent introduction of the intervention which is largely primary school-based.

Another issue raised was that additional ASRH activities in the trial communities would lead to dilution of the intervention effect. The MkV1 team had been monitoring this in both the intervention and comparison communities since the start of the trial in January 1999. Some national, regional, or district-wide initiatives, such as social marketing of condoms through Population Services International (PSI), have continued or been initiated since 1999. However, these should have equally affected participants in both arms of the trial. There had been no important local sexual and reproductive initiatives started within either the intervention or comparison communities during this period, except those provided through the MkV1 trial.

Inclusion of both males and females

Despite the large sample size proposed for MkV1FS, the survey only had adequate power to detect a very large true reduction in HIV prevalence among males (≥50%). Excluding males altogether from this long-term evaluation was considered. One major advantage of excluding males would have been to halve the size of the survey and hence make it cheaper and logistically easier. Despite these arguments it was decided to include males as there were hints from the previous rounds of the trial that male participants may have experienced a larger impact of the intervention than females. Also, males largely control the terms of sexual intercourse and may have found it easier to reduce their risk behaviours in response to the intervention. It would also be worth demonstrating whether there was an impact (or lack of it) on HSV2 prevalence in males as well as in females.

Definition of 'exposure' to the intervention and allocation to trial arm for analysis

Defining 'exposure' to the multi-component MkV1 intervention was not straightforward. Exposure for the purposes of MkV1FS could be broken down into three main components (with decreasing importance):

A. Exposure to the in-school component of the intervention (1999-2002) defined as attending relevant school years during this period
B. Exposure to the in-school component of the intervention (2003-2006) defined as attending relevant school years during this period
C. Exposure to the community component of the intervention (1999-2006) defined as residence in the community during this period

It had already been decided that participants needed to have had at least 1 year of exposure to the in-school intervention between 1999 and 2002, the years when supervision and training were most intense (A). It was also decided that exposure to the in-school intervention between 2003 and 2006 would not be sufficient for inclusion (B). A question remained around the criteria for residence in a trial community (C). It was of interest to evaluate the intervention among those who had some degree of exposure to the community component of the intervention. Residence in the trial communities was important as the intervention may have led to a change in social norms related to sexual and reproductive health which may have facilitated behaviour change by youth. Also, young people living in their original trial community might have been more likely to have a partner who was also exposed to the intervention. Ideally, therefore, young people who had always been living in their trial community would be included. The original idea was only to include those who were currently resident in the trial community where they were educated. The residence criteria could have been relaxed a little to include those educated and living in a community in the same trial arm. Neither of these options was ideal as they would potentially have led to an underrepresentation of certain subgroups of interest who may have been more likely to migrate e.g. married women. The final decision was to prioritise representativeness of the study population and include all those who were educated in a trial school regardless of where they were currently living. They did, however, have to be a 'de jure' resident in a household in one of the trial communities i.e. to be considered by the household head to be a member of the household. The inclusion of those educated in an intervention community but currently living outside an intervention community had the potential to underestimate intervention impact. However, it was thought that the numbers of such individuals would be small. Allocation to trial arm would be based on the first trial school attended between 1999 and 2002.

Choice of biological outcome measures

The primary interest was to evaluate the impact of the intervention on HIV and HSV2, both life-long incurable STI. Secondarily, the impact of the intervention on lifetime exposure to syphilis, a STI that could be tested for using the same serum sample, would be evaluated. It was unclear as to whether it was worth the cost and additional logistics of collecting a urine or vaginal swab sample to test for treatable STI such as *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and/or *Trichomonas vaginalis* (TV). An impact of the intervention on these short-term curable STI might have been less likely, especially given the concerns that the intervention may not have been as intensively implemented over the 2-3 years prior to the survey, and the fact that some interventions would start in the comparison communities during 2005. However, NG and CT have important adverse health effects, especially in young women, and their prevalence should be reduced not only through adoption of safer sexual behaviours but also through improved treatment at youth-friendly clinics. But most importantly, in the 2001/2 impact evaluation, NG prevalence was higher among intervention community females and this difference was of borderline significance.[186] Although the trial team thought that the most likely reason for this difference was chance, it was important to check whether the higher prevalence of NG persisted and was statistically significant. Furthermore, collection of a urine sample from both males and females would be feasible without adding too much extra time to the survey process. However, it was decided not to test for TV because this would have required the young women collecting self-administered vaginal swabs, a procedure which needed careful explanation and added significantly to the lab time per female participant, let alone the subsequent testing time and costs for polymerase chain reaction (PCR).

Identification of young people

One of the major challenges associated with the chosen study design was the absence of any pre-existing mechanism for locating the potentially eligible young people. Names and contact details were available for the MkV1 trial cohort members but this subgroup represented only half of the total target population and they were not necessarily still living at their 2001/2 location. The aim was to interview as many of those exposed to the intervention as possible in the most efficient way possible.

The first option available was to use the existing school registers to identify all the potentially eligible individuals and to solicit the help of village and sub-village leaders and school teachers to locate the identified young people. MkV1 tried to use school registers at baseline in 1998, but there were major errors in some of them. Of 17,084 registered standard 4, 5 and 6 pupils of all ages, 15% were absent on two survey days 5-6 weeks apart.[198] While some pupils who really were attending school on a regular basis may have been truly absent on these days by chance, many school registers were intentionally and unintentionally inaccurate- (a) often the names of pupils who dropped out of school were not deleted from the registers, (b) many pupils had different school and home names, (c) many pupils were given the names of other school pupils to use officially for the rest of their lives (because someone who failed their Std 7 exams is not allowed to re-sit them, so they unofficially pay the teachers to use the name of someone else who had previously dropped out) but whose name remained on the school register (Mary Plummer, personal communication).

The second option was to ask the sub-village leaders (with the help of their balozi (ten-household) leaders) to list all households and then to say which of these households had a currently resident young person within an expanded age range (e.g. 15-30y). Then a fieldworker (census interviewer) would be sent with the sub-village leader to each of these households to check the eligibility of all young people in those households and to invite them to the survey. The disadvantage of this option would have been that the quality and accuracy of the information on young people might have varied from sub-village to sub-village.

The third option was similar to the second but the census interviewer would visit all households regardless of whether the sub-village leader reported a young person was living there or not. This option required all households in the study areas to be visited but had the advantage of being systematic and leaving the screening of young people exclusively to trained field staff. This option would rely on reported schooling but this was likely to be more valid and much easier to use than school register data. This option was chosen as it was likely to result in the location of the largest and least biased sample of young people.

Whether the original trial cohort members (and potentially other identified eligible young people) who had migrated away from the trial communities should be traced was also debated. These young people who migrated away may have been more likely to be infected with HIV and other STI and their inclusion would provide a more representative sample of those exposed to the in-school component of the MkV1 intervention. However, it was known from the 2001/2 follow-up survey, when attempts were made to trace individual cohort members, that visits to major migration points (large towns and business areas) would increase the time and cost of the survey and was unlikely to be very fruitful. It was decided that a limited time and fixed amount of resources would be devoted to the tracing of individuals to the major migration points in Mwanza and neighbouring regions only.

3.2 Design of data collection tools

There were two major stages of data collection (i) the household census to identify and invite potentially eligible young people to the survey (ii) the subsequent collection of sensitive sexual behaviour data from the invited young people.

3.2.1 Decision to use PDA and GPS during the household census

Data collected during the household census were needed by the registration interviewers during the survey which ideally would have taken place within a few days after the census. The study communities were up to 5 hours travel from the main research centre in Mwanza and it would not have been feasible to return the census data to Mwanza, have the data double entered and cleaned and then returned to the survey team within a few days. Leaving a longer period between census and survey i.e. the ~2 weeks needed for such data processing, might have resulted in decreased attendance at the survey if invited young people were to, for example, forget their appointments or leave their community. This would also decrease the amount of time that the census and survey teams were working in the same communities and the benefits of having an overlap of teams in terms of logistics and supervision would be largely lost. It was decided, therefore, to collect the census data electronically using Personal digital assistants (PDA).

The Census questionnaire was developed and pre-tested on paper before being prepared electronically using the Pendragon Forms 5.0 (Pendragon Software Corporation). Two linked forms were developed to collect the small amount of information needed to identify young people potentially eligible for the survey:

(i) Household form- collected information to help identity the household and included the number of household residents and number of resident young people (15-30 years)

(ii) Young person form- this form was filled out for all those aged 15-30 years and recorded information on schools, standards and years attended and whether a survey invitation was given to the young person

Inconsistency checks, ranges of values and required values were programmed into the Pendragon data collection form and this simplified the process of data cleaning. The use of PDA required considerable preparation and training and was associated with some initial teething problems. Nevertheless, our use of PDA was overall successful and allowed rapid transfer of information in the field to the survey team.

Census fieldworkers also used handheld Geographical Positioning System (GPS) devices to determine the geographical location of each household interviewed during the census. These GPS coordinates were manually entered into the household form in the PDA. These coordinates were collected primarily to assist the teams to return to the households of invited young people, for example, to remind them to attend the survey or to deliver the results of laboratory tests. In reality, the teams found that the help of other community members was sufficient for these tasks and the GPS coordinates were not used. A secondary objective was to use the GPS coordinates to investigate the geographical risk factors for HIV, STIs and reported behaviours including utilisation of health facilities, and this analysis is planned for next year.

In addition to information on household composition and potential eligibility of young people, the census fieldworkers collected information on the following:

1. Co-habiting spouse(s)/partner(s) of an eligible young person. If both partners participated in the survey then this information, recorded in the PDA dataset, could later be used to link them during analysis.
2. The existence of and access to facilities/amenities in the sub-village and surrounding area (including health facilities). This information was collected on the **Village Information Sheet** and was used to describe the study settings.
3. Other HIV/AIDS prevention work in the area was also collected on the **Village Information Sheet** in order to identify possible sources of bias or 'contamination' of comparison areas.

3.2.2 Face-to-face questionnaire design

The MkV1FS team developed the main survey questionnaire from Oct 06- Feb 07 ***(Appendix 5- Main questionnaire)***. The main objectives of the survey questionnaire were to determine the extent of exposure to MkV1 interventions, determine how well the MkV1 intervention has fulfilled its objectives ***(Section 1.4.2)*** and to investigate other possible sources of HIV infection.

Data on knowledge, reported attitudes and reported sexual behaviour outcomes were collected during the 2001/2 evaluation survey using a face-to-face questionnaire. It was decided to stick with this type of questionnaire as the use of self-completed or assisted self-completed questionnaires would have been logistically difficult and it was thought that reporting of sensitive information might be less prone to bias with this population of older young people. A number of questions suspected to have dubious validity were included so that comparisons could be made with data from previous MkV1 surveys e.g. lifetime number of partners, number of partners in the last 12 months. Throughout the questionnaire the term either in Swahili or Sukuma which is literally translated as 'Making love' was used for penile-vaginal intercourse. However, the following section was read out (in Swahili) to respondents prior to the first set of questions on sexual behaviour ***(Appendix 5- sub-section 3)*** *'Always when I mention the word "making love" I am talking about having penetrative sex with somebody. This will include sexual intercourse where one of the two has not agreed (one part forced). We know that some young people like you are already having sex and some are not. We are only interested in hearing the truth about young peoples' sexual experience even if you have not ever had sex yet. This discussion is very confidential between you and me, so I hope that you will be free to tell me about your life sexual experience.'*

Questionnaires and forms were designed with the help of materials used during MkV1, other surveys conducted in Mwanza and other surveys measuring sexual and reproductive health. During the design process efforts were made to make the questionnaire more appropriate for this older population of young people many of whom were now likely to be married. The 2007/8 MkV1FS questionnaire differed significantly from the 2001/2 evaluation survey questionnaire in the following areas:

1. **Identification**

In order to identify those survey participants who were involved in previous MkV1 surveys, participants were asked if they had taken part in a health survey before and if so then the name of the survey and survey ID number (if available) were recorded. If the MkV1 Card/ID number were not available then the registration interviewer attempted to match the respondent with a MkV1 cohort member on a list of MkV1 cohort members using name, village, school, date of birth etc. A number of additional questions were added to record the details of primary school, standards and years attended. This information was essential for assessment of eligibility and for analysis stratified by number of years of exposure to the in-school component of the intervention.

2. **Recording of previous sexual partnerships**

A question regarding the number of new partners in the last 12 months was added as this indicator is considered by some to be more important than total number of partners in terms of HIV/STI risk.[445] A module on the last 3 sexual partners in the last 12 months was also included. This module (section 5) contained 15 questions on the characteristics of each partner, and the timing of the first/last sex, and use of family planning including condoms with them. A respondent's willingness to use condoms within a relationship may be influenced by their perception of the type of relationship. In addition to asking about the type of partner (Spouse, Other regular partner, Casual partner, Commercial sex worker) the following question was asked (Q05.11): *What is your current relationship status with this person? (We are still in a relationship and will make love again; Our relationship is not continuing but we might make love again; our relationship has completely ended; Don't know).* In an attempt to determine the partner's exposure to the MkV1 intervention respondents were asked whether their partner had been to primary school in the study community and what the highest standard reached had been. Forced sex is one of the core indicators recommended by WHO in their Guide to indicators for monitoring and evaluating national HIV/AIDS prevention programmes for young people,[304] however respondents may be reluctant to report forced sex. In an attempt to measure unwanted sex the following question was added (Q5.15) *'Has there been an occasion when you did not want to make love with this partner? If YES: What did you do the last time that this happened? (Refused and did not have sex; Refused but still had sex; Did not refuse; Don't remember).*

3. Type of information collected on previous pregnancies

The team were interested in knowing when the young person first was pregnant but were conscious of the unreliability of such age questions. The following question was, therefore, selected 'In what year in school did you first get pregnant?/ first make a girl pregnant?' . In an attempt to get at unintended pregnancies the following question was asked 'Sometimes a girl or young woman becomes pregnant when she does not plan to (not a good time to become pregnant). Have you ever become pregnant when you did not plan to (when it was not a good time)?

Initially, all questionnaires and forms were drafted in English and were then, where appropriate, translated into Swahili and Sukuma and back translated into English. A number of drafts were circulated and useful advice and suggestions were received from staff in Mwanza and also from senior staff at collaborating institutions. A questionnaire workshop, attended by ASRH experts, was held in September 2005 during which the main questionnaire was modified and shortened. A Sukuma/Swahili version of the main questionnaire was pre-tested by interviewing 15-20 young people during visits to villages in Magu district of Mwanza Region on 16th and 22nd February 2007. Following pre-testing, the questionnaire was modified and a revised version was used during the training and pilot study. Final drafts were used during the pilot study and revised before the survey where necessary.

3.3 Fieldwork methods

A brief description of the fieldwork methods is provided in the following sections. A more detailed description of the fieldwork methods including the 'Standard Operating Procedures (SOPs)' are provided in the study protocol which is accessible at: (http://www.memakwavijana.org/about-mkv/mema-kwa-vijana-trial/long-term-evaluation.html).

3.3.1 Partnerships and permissions

A Memorandum of Understanding was signed between London School of Hygiene & Tropical Medicine and Mwanza Intervention Trials Unit (MITU) /National Institute for Medical Research (NIMR), Mwanza. Office and storage space at NIMR, Mwanza was allocated to the survey. Ethical clearance was obtained as outlined in ***Section 3.7***. The permissions obtained at Region, District, Ward and Village level are described in detail in ***Section 3.3.6***.

3.3.2 Procurement and rental of vehicles

IT equipment and clinical/medical supplies that are not readily available locally in Tanzania were purchased in the UK and shipped to Mwanza. All other equipment (including vehicles) were purchased locally in Tanzania. Lease agreements were signed for Land cruiser and minibus hire.

3.3.3 Personnel and training

All positions on the MkV1FS team that could not be filled by existing MITU/NIMR staff were advertised in East African Newspapers (senior positions) and/or on local notice boards. Senior MkV1FS and MITU/NIMR staff shortlisted candidates based on pre-defined person specifications and job descriptions. Tests and interviews were held at NIMR, Mwanza in front of a panel of MkV1FS and MITU/NIMR staff. The majority of staff were employed for a period of 12 months on standard NIMR/AMREF/LSHTM collaborative project contracts. Contracts included a 3-month probation period and standard terms and conditions i.e. allowances for annual, sickness, maternity (paternity) and compassionate leave etc.

Senior MkV1FS staff (Fieldwork Manager and Fieldwork Supervisor and technical field staff (Clinicians, Counsellors, Laboratory Technicians, Drivers) were recruited and trained in February 2007 and March 2007 respectively. A large number of fieldworkers were needed (interviewers, census workers, tracers) and assessment for suitability for the posts was based initially on application letter and CV. A shortlist of 35 male and 35 female applicants were invited to the first week of training in April 2007. The first week of training focused on the survey protocol and the main questionnaire. Only those who did well on the written test at the end of that week and who performed well during group activities were invited to participate in the second week of training (51 applicants). The second week of training focused on the use of PDA and GPS for the census. The final composition of the two field teams was decided at the end of the second week of training. The third and final week of training involved a pilot study. In addition, clinical, laboratory and counselling staff had short-term placements at health facilities/laboratories in Mwanza and spent some time observing staff on other research projects. Throughout the survey, there was ongoing supervision and on the job training. In total, there were 70 MkV1FS field staff: 2 mobilisation officers; 2 census teams each comprising of a team leader, a driver and 10 census interviewers; 2 survey teams with 22 team members each: Team Leader (1), Clinical Officer (1), Counsellors (2), Tracers (5), Attendee Co-ordinator (1), Registration interviewers (2), Interviewers (3 male, 3 female), Lab workers (2), Data Checker (1), Driver (1).

3.3.4 Pre-testing and Pilot study

Pre-testing

Both pre-testing and piloting took place in Magu District in Mwanza Region. In February 2007, senior staff visited the District to have formal and informal meetings with District, Ward and Village leaders, to explore ways to locate eligible young people and to pre-test the census questionnaire. The PDA and GPS procedures were pre-tested with staff at NIMR, Mwanza and during the fieldworker training. The main questionnaire was developed and pre-tested as described in ***Section 3.2.2***.The MkV1FS team also received advice and suggestions from other projects that were currently or had previously worked in the same study areas.

Pilot study and finalisation of questionnaire and forms

Both field teams took part in pilot studies in Nassa Ginnery, Magu District in May 2007. The aim of the pilot studies was to test the materials and questionnaires, and the procedures for mobilisation, registration, interviewing and collecting the data. The pilot studies included a census to find eligible young people, the generation of a list of survey participants, setting up of a survey centre, and collection and transport of laboratory specimens. Pilot study data was entered and analysed, and the results were used for additional team training and finalisation of the survey instruments. The main challenges faced during the first pilot study (14-16 May 2007) related to:

1. Mobilisation - households were not informed that the census interviewers (CIs) would be coming, and community helpers were not present to help the CI.
2. Census - confusion over where the survey would take place (survey site) led to a low attendance and the CI's were still getting used to the PDA and GPS and hence worked slower than expected.

Following feedback on the first pilot study and further training of field staff, a second pilot study was conducted (21-22 May 2007) and an improved attendance of young people was achieved.

3.3.5 Mobilisation

Mobilisation and sensitisation took place prior to the start of the data collection and also before the field team visited each community. Mobilisation took place at the Regional, District, Ward, Village, sub-Village and household level and the main aims were to:

1. Introduce the rationale, aims and procedures of the MkV1FS project and to gain feedback on the proposed plans.
2. Request permission to conduct the survey activities
3. Ensure that the study communities were ready for the arrival of the census and survey teams. This was done primarily through the distribution of a timetable of activities to community leaders and the distribution of information sheets and the survey poster (showing pictures of survey procedures), via the sub-village leaders, to all households

Before the field activities commenced, the mobilisation officers (MOs) and/or senior MkV1FS staff members met with administrative, medical and educational officials at Regional and District level. At the Regional level, individual meetings were held with the key officials. An official request was made to the Regional Planning Authority for an up-to-date map of Mwanza Region. This map was used to plan and monitor the survey. For logistical reasons, MkV1FS used a slightly different order of communities to the MkV1 2001/2 evaluation survey ***(Table 3.2)***. A request was also made to the Regional Education Officer for permission to access and photocopy standard 7 exam results for the years 2002-04 which would be used to verify eligibility during survey registration.

In each of the four MkV1FS Districts and in each of the 20 MkV1FS Wards[c] within those districts, senior MkV1FS staff and the MO organised a half-day information forum. In addition to these formal meetings, the MO spent an initial 2-3 days in each District capital and then ~ 2 weeks in each community just prior to the arrival of the field teams during which time he held informal meetings and carried out various preparatory tasks. In each of the trial communities, the MO also, with the help of local leaders, booked the survey venues, accommodation and

[c] Each of the MkV1 trial communities was approximately equivalent to an administrative Ward.

transport for the field teams. Potential venues for the survey included rented houses, guesthouses, schools (during school holidays only) and 'go downs' (large barns to store crops).

Table 3.2 Order of visiting MkV1 trial communities

Order of communities	Community name & number		Community intervention status *(I=intervention; C=comparison)* & stratum (1,2 or 3)	
	Team 1	**Team 2**	**Team 1**	**Team 2**
1.	Katunguru (5)	Koromije (22)	I1	C1
2.	Kasamwa (11)	Mwagi (23)	I1	C1
3.	Nyang'whale (14)	Malya (24)	C2	I2
4.	Bukoli (13)	Misasi (18)	C1	I1
5.	Katoro (8)	Usagara (21)	I2	C2
6.	Kagu (9)	Nyakaliro (4)	I3	C3
7.	Lubanga (10)	Katwe (2)	C3	I3
8.	Busisi (6)	Nyehunge (3)	C2	I2
9.	Nkome (1)	Fukalo (17)	C3	I3
10.	Ihanamilo (12)	Hungumalwa (16)	I2	C2

Guesthouses were only used if there were no other suitable survey venues. The MO also visited all school head teachers, as well as some religious leaders, traditional healers and other influential individuals such as health NGOs working in the area, as deemed appropriate. In preparation for the census, the MO obtained a list of households in each sub-village from the sub-village leaders. On these lists the sub-village leaders had indicated the households with young people aged 15-30 years. The MO also visited the District Medical Officer in each District to explain that MkV1FS would be offering syndromic management for STIs for participants and would be providing contact slips for partners. The District hospitals and health facilities were told to expect a small increase in the number of people attending for STI treatment. The MO also discussed the referral system for participants who test positive for HIV. In each Ward the MO met with any home based care groups working in that Ward and discussed with them the process for referrals for HIV treatment and other support for those who test positive for HIV. He also visited local health facilities to tell them about the survey and to discuss the possibility that there would be an increase in people seeking treatment for STIs and/or family planning.

Before leaving a community, he revisited and debriefed the Ward Executive Officer and reminded him/her of the upcoming visit of the census and survey teams.

Upon return to Mwanza, the MO submitted a brief written report containing information on villages/sub-villages visited and included names and contact details (mobile phone numbers) of key individuals and groups e.g. sub-village leaders, school and health facility staff, home based care groups. The report also provided information on the selected survey venues and field team accommodation. The information on the size and relative location of villages/sub-villages was then used to produce the final detailed survey timetable for the community. On the first few visits to the communities the MO was accompanied by a senior member of project staff. During the survey the Fieldwork Supervisor (FS) was in contact by telephone with the MO every week. If the MO encountered any difficulties he contacted the FS and/or Fieldwork Manager (FM) as often as required.

3.3.6 Census

Following mobilisation, a household census was conducted in each of the survey communities in order to identify young people eligible to participate in the survey. All those thought to be eligible were given an invitation to attend the main survey which took place at a central location in the sub-village ~2 days later. A community (approximately the same as one Ward) had a radius of 5-10 km, a population of approximately 18,000 and was made up of approx. 6 villages. There were two census teams and each census team worked in 10 communities.

Pre-census preparations

The day after the census team arrived in each community they introduced themselves to the Ward officials, informed them that the survey was about to start in that Ward and provided them with an updated survey timetable indicating the days that census and survey teams would be in each village and sub-village. The census team leader (CTL) travelled to the nearest village (usually the Ward capital) and introduced himself to the village and sub-village leaders. He reminded them of the survey procedures, informed them that the census would start in their village the next day and provided them with the updated survey timetable. The sub-village leaders were requested to mobilise their residents so that as many of them as possible were present in the sub-village on the day that the census team would visit. The CTL asked the sub-village leaders help to arrange for community helpers to assist the CI during the census.

While the CIs were carrying-out the census in one village/sub-village, the CTL arranged a pre-census visit to the next village/sub-village. The CTL also completed the *Village information sheet* with the help of leaders in the community.

Census

The CI travelled to the study site in a Land cruiser (one Land cruiser/team) and then travelled from household to household on foot or by bicycle (project bicycle or bicycle hired during the exercise). Each of the 10 CIs worked 48 hours/week (8 hours/day for 6 days) and needed to interview approximately 150 households(HH)/week each (approx. 20 mins/HH; 25 HH/day/CI). A number of additional days were needed in each village as some of the households had to be visited more than once so it took approximately 3 weeks to complete the census of the ~3000 households in each community.

Using the list of household heads prepared by the sub-village leader for the MO, a CI copied the information on their allocated households onto their own form. Using this form, they went with their community helper to each of these households. If a household was empty then the CI made up to two further attempts to revisit the household (at least 4 hours apart if on the same day). If the CI found some additional household(s) in the sub-village, which were not included in the pre-prepared list, the CI added these to the *List of additional household heads*. In each household the CI and community helper introduced themselves and briefly explained the aim of the census. Informed consent was obtained from the household head or another adult member of the household prior to questioning.

Each CI used a PDA to directly enter information on household members aged 15-30 years. Potentially eligible young people were given an appointment 2-4 days later to attend the survey that would be held in a nearby rented building (4-8 venues per study community). If the eligible young person was not present at the time of the census, the other household members were asked to give the survey invitation to them. The survey invitation contained the following information:

1. Location and time of the survey interview
2. Description of survey procedures, stressing that confidentiality would be maintained
3. Details of travel expenses and incentives that would be paid
4. Request to bring to the survey: invitation, any health survey ID cards and any official documents showing date of birth or age

If the eligible young person was <18 years of age then the parent or guardian was given an additional information sheet explaining the survey procedures and the parent/guardian was asked to sign a sheet to indicate consent for the young person to participate in the survey. If the household members indicated that the eligible young person would not be in the village on the day of the survey then the CI recorded the details of their whereabouts on a *Moved Away Form*. The *Moved Away Forms* would be used later by tracers to try to find young people who had migrated out of their original communities. The CIs used their GPS equipment to record the exact geographical location of the household and entered this location into the PDA. If there were any technical problems that prevented the CI using the PDA to record the census data then the CI used a back-up paper census questionnaire.

Generation of lists for survey team

Each evening, the CTL was responsible for downloading the census data from the PDAs into the laptop, and made a copy of the data collected that day onto a blank CD. The CTL, with the help of the CIs, completed a daily progress report form. If the paper back-up census questionnaire was used then, in the evening, the CTL with the assistance of the CI entered the data into an Access Database. When the census team completed all the households in one village (~every 3 days) the CTL generated and printed lists of eligible young people and a list of Household heads (Lists A1- A3). These lists were then delivered to the survey team (one day before the survey).

3.3.7 Survey

Pre-survey preparations

Each survey team and their equipment travelled from Mwanza to the survey communities in a hired bus (at least a 22-seater bus). Each survey team also had a project Land cruiser that stayed with them and transported them and their equipment from village to village within the community.

When the Survey Team Leader (STL) arrived in the community, he met the CTL and discussed progress with the census and any issues that were important for the survey. The CTL provided the STL with printed copies of the lists of those invited to the survey **(Lists A1-A3)**. The CTL and STL made brief visits to the Ward officials to provide an update on the progress of the census and remind the officials about the survey timetable and procedures. The STL then visited leaders in the first village to introduce the survey team and finalise arrangements for the survey. The CTL and STL kept in regular contact (by text/ phone) about the survey venue and accommodation for field teams.

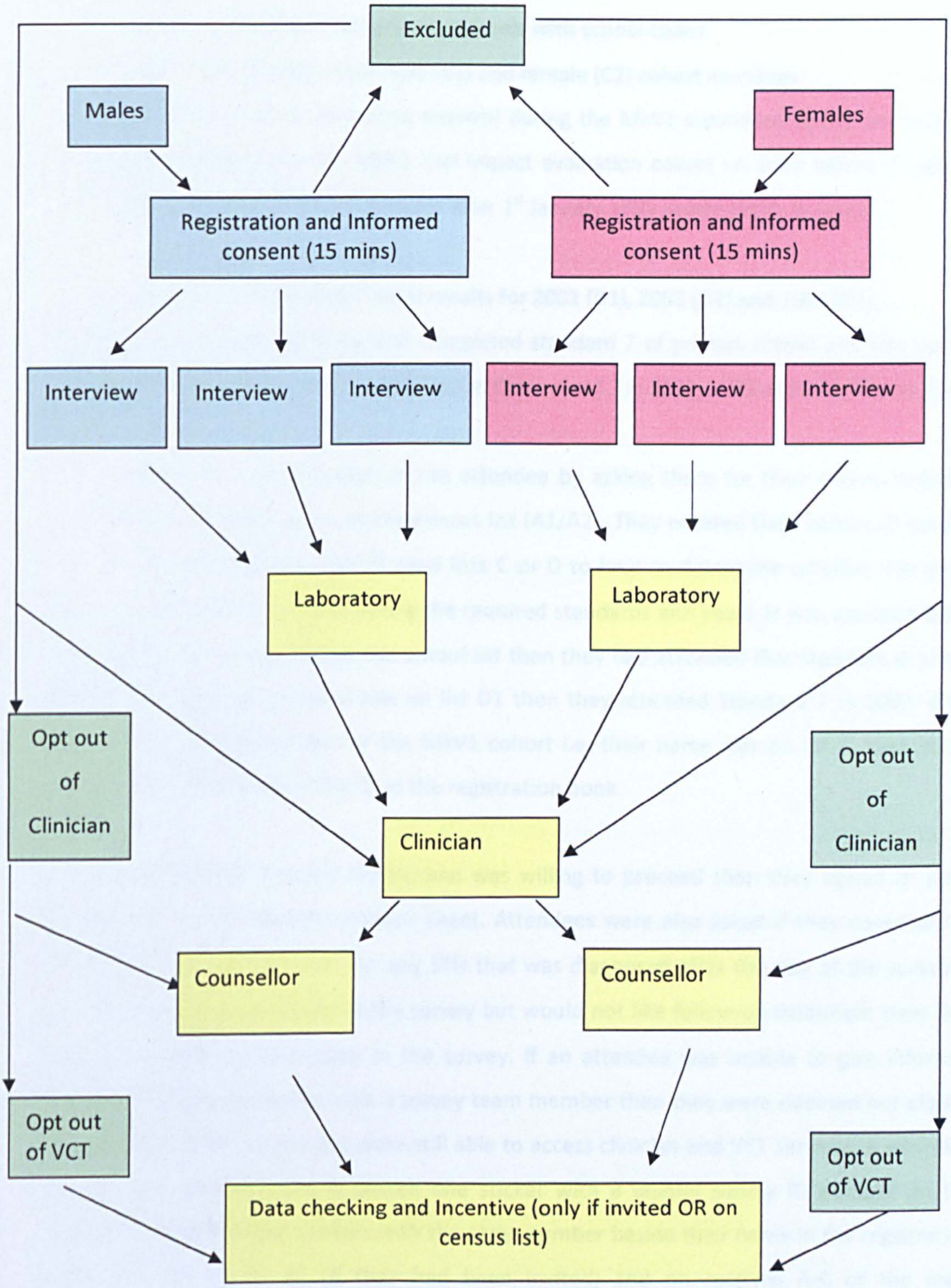
Each survey team arrived in a village approx. 2-4 days after their respective census team and set up a survey centre in the pre-booked guesthouse or house. The survey centre had a registration and waiting area (often outside in a shaded area), 6 rooms for face-to-face interviews, 1 room for the lab technicians, 2 rooms for the VCT counsellors and 1 room for the clinician (10 rooms + registration/waiting area).

It was estimated that there would be ~ 14,500 eligible young adults who would attend the interview sites, giving a mean of 730 per community, and that one team would interview 48 participants /day. Hence, it would take approximately 15 days to interview the 730 eligible young people in a community. The team would spend a couple of extra days in each community so that they could interview those who were unable to attend the survey at the designated time, and to allow for variation in the mean number of eligible young people per community. The survey venue flowchart ***(Figure 3.2)*** shows the steps that a young person attending the survey venue went through and the estimated time each step would take. Taking into account some waiting time between survey steps, the survey was estimated to take between 1.5- 2.5 hours for those participating in all steps of the survey.

Registration

Invited young people were expected to make their own way to the survey centre on the day and time specified on the survey invitation. The census team aimed to invite 64 young people to attend at 08:00 every day. When the invitees arrived they were greeted by the attendee co-ordinator who took them to the registration interviewer (RI). The RI greeted attendees and recorded the date and time of interview, attendee's name, village, sub-village and name of household head in the registration book. Attendees were then shown to the waiting area where they were provided with an information sheet and a Walkman containing a Swahili recording of information on the project. One of the team members showed attendees how to play, pause and stop the recording. When an attendee had read the information sheet and/or listened to the Walkman he/she was interviewed by the RI ***(Appendix 5 – sub-section A)***. The RI used the following lists:

Figure 3.2. Survey Flowchart



- **List A- Lists of males (A1) and females (A2) who were invited to the survey during the census**
- **List B- List of MkV1 Trial primary schools with school codes**
- **List C- Lists of MkV1 Trial male (C1) and female (C2) cohort members**

List C was a list of those who were enrolled during the MkV1 enrolment survey and included those who participated in the MkV1 trial impact evaluation cohort i.e. born before 1st January 1985 (blue MkV1 ID card) and those born after 1st January 1985 (white MkV1 ID card).

- **List D- List of Standard 7 exam results for 2002 (D1), 2003 (D2) and 2004 (D3)**

This was an official list of those who completed standard 7 of primary school and was used to identify eligible non-trial cohort members (i.e. those in std 7 in 2002, 2003 or 2004) ***(Figure 3.1).***

The RI verified the identification of the attendee by asking them for their survey invitation and/or by finding their name on the census list (A1/A2). They entered their census ID number into the registration book. The RI used lists C or D to help to determine whether the young person was in the trial schools during the required standards and years. It was assumed that if a young person's name was on the school list then they had attended that standard in school in that year e.g. if their name was on list D1 then they attended Standard 7 in 2002. If the young person was a member of the MkV1 cohort i.e. their name was on list C, then the RI indicated so in the column 'MkV1' in the registration book.

If the attendee was deemed eligible and was willing to proceed then they signed or put a thumbprint on the informed consent sheet. Attendees were also asked if they consented to receiving follow-up treatment for any STIs that was diagnosed after the day of the survey. If they consented to participate in the survey but would not like follow-up treatment then they were still eligible to participate in the survey. If an attendee was unable to give informed consent following discussion with a survey team member then they were deemed not eligible to participate in the survey but were still able to access clinician and VCT services. If informed consent was obtained, the RI placed one sticker with a unique survey ID number on the consent form and further stickers with the same number beside their name in the registration book, on List A1 or A2 (if they had been invited) and on sections A-C of the main questionnaire. These survey sticker numbers were a sequential series and therefore did not contain any information that could be used to identify the individual. All further data and laboratory samples were identified using this unique sticker number. Later identification of a young person e.g. for tracing to provide laboratory results, could only be done by linking the sticker number with the personal identification information recorded in the registration book. The registration books (and lists A1/A2) were kept in a locked tin trunk while in the field and were placed in a locked filing cabinet when the teams returned from the field. All eligible consenting attendees ('participants') were given a plastic folder containing their main questionnaire and additional stickers and they proceeded to the survey interviewer.

In theory, all young people who came to the survey venue should have been recorded and issued with a survey questionnaire. However, subsequent checks showed that the survey teams were not always consistent in their recording of attendees who had not been invited. When there were a large number of non-invited attendees, the STL occasionally did an initial screening check for eligibility before allowing the non-invited young person to be interviewed by the RI in order to exclude those who would definitely not meet the inclusion criteria. These young people who were screened by the team leader only did not get recorded on a survey questionnaire, so the total number of recorded 'attendees' is likely to be an underestimate of the total number of attendees. If a young person had been invited to the survey then they always reached the RI and it is only the number of 'non-invited, non-eligible attendees' that is likely to have been underestimated.

Face-to-face interview

Participants were interviewed using a face-to-face questionnaire ***(Appendix 5- sub-section B)*** by a survey interviewer (SI) of the same sex and similar age. The interviews took place in a private place, and the completed questionnaires were kept safe at all times. After the interview was completed, the main questionnaire was returned to the participant and they were directed to the Laboratory Technician (LT).

Laboratory

The LT greeted the participant and checked that the stickers on the main questionnaire matched the remaining stickers in the folder. The LT then collected the blood and urine samples for STI testing (including HIV). The LT screened for schistosomiasis by testing the urine for the presence of red blood cells using urine dipsticks. Stickers were placed on the serum and urine tubes, in the laboratory registration book and on the Laboratory Submission Form. The respondent was given the questionnaire and the remaining stickers and directed to the clinician. Female respondents were also given the container containing the remaining urine sample (wrapped in tissue paper).

Clinician

The clinician's primary responsibility was to ensure that the survey participants received the correct treatment or referral for any condition that they might have. Thus during the time of the survey, the clinician only saw the survey participants and invited young people who are ineligible for the survey. After the survey was finished for the day, the clinician was able to see other attendees. The clinician was requested to avoid treating any other members of the community who did not attend the survey and was requested instead to refer them to the nearest government health facility.

The clinician first asked the respondent about the symptoms that the respondent has at the present time. The treatment protocols were described in section C of the main questionnaire ***(Appendix 5 – sub-section C)***, and in the clinician's instructions. All drugs were pre-packed and clearly labelled before the survey started so that the clinician did not waste time counting tablets or searching for drugs. All males received an external genital examination, whereas only females who reported genital ulcers had a genital examination. Females were examined while lying on a mattress on the floor or bed and male participants were examined in a standing position. If a female participant required treatment for a suspected STI then the clinician was required to carry out a pregnancy test (on the urine remaining in the container) before deciding on the most appropriate syndromic treatment. STI diagnosis and all treatment provided was recorded on section C of the main questionnaire and in the clinician treatment register.

All participants treated for STI related complaints were asked about their sexual partners and given contact referral slips. It was not usually possible for the clinician to see the partners within the time they were in that particular village. Partners were therefore asked to go to the nearest health centre or dispensary for their treatment, taking their contact referral letter with them. Condoms were offered to all participants. The Clinician then directed the participant to the counsellor (if they wanted to visit the counsellor).

VCT

Voluntary counselling and testing for HIV was offered by qualified VCT counsellors (VCs). Pre-test counselling was given by the VC and, if after that the participant requested to know their

HIV test results, they signed an HIV Test Request Form. Whereas all consenting participants provided a serum sample for HIV testing at the NIMR laboratory i.e. using ELISA, only those who were interested in finding out their HIV status provided a separate finger prick specimen that was used for VCT. This finger prick sample of blood was tested immediately at the survey site using two independent blood tests (Bioline and Determine). Further counselling was provided during the 15 minute period before the results could be read and post-test counselling provided based on the results. The VC completed a VCT results form and placed a sticker on the form. The VCT results form and the VCT registration book contained a survey sticker but did not contain the name of the participants or any other identifying information. If the rapid HIV test results were discordant (one test positive and the other test negative) then the participant was informed that they would need to wait for a further test to be carried out on their blood at NIMR, Mwanza (double ELISA) and that a member of the field team would return as soon as possible to give them their result. The VC completed a *VCT Discordants Form* in order to request the HIV test results from the NIMR laboratory. All those who opted for VCT were informed that a confirmatory test would be carried out on their serum at NIMR, Mwanza and that they may be contacted again in the unlikely event that that there has been a problem with their VCT HIV test. All those who tested positive for HIV were referred to the nearest health facility offering Antiretroviral Treatment (ART) so that their eligibility for antiretroviral drugs (ARVs) could be assessed. They were given money to cover the cost of three return trips to the nearest HIV treatment & care service. If there was a home based care organisation working in the survey area then they were put in contact with the organisation so that they could receive supportive counselling and nutritional care.

Questionnaire quality control

In order to improve the quality of the data collected using the face-to-face questionnaire, the role of the data checker was introduced in January 2008 (approximately halfway through the survey). Data checkers were selected from the existing SIs based on their suitability for the role and replacement SIs were recruited and trained. Following the visit to the counsellor and before returning to the RI the participant met with the data checker who, according to their SOP, went through the questionnaire to check that all sections were completed correctly. If there were any inconsistencies or omissions they asked the staff member responsible to clarify with the respondent what the answer should be. The data checker also supported the STL with other tasks where necessary.

Participant incentives

When the participants completed the survey they were given an incentive by the Data Checker or the Registration Interviewer. The transport costs and incentives that were offered to the different categories of attendees are shown in ***Table 3.3***.

Table 3.3: Incentives for MkV1FS attendees

	Invitation *OR* on census list	**Eligible for survey**	**STI treatment**	**VCT**	**Incentive and Transport allowance**
1	Yes	Yes	Yes	Yes	4000 Tsh + Large bar of soap (approx. value 1000 Tsh)
2	Yes	No	Yes	Yes	2000 Tsh + Half bar of soap (approx. value 500 Tsh)
3	No	Yes	Yes	Yes	4000 Tsh + Large bar of soap
4	No	No	Only if time after other categories of attendees have availed of services		None

Tracing

There were 5 tracers on each survey team who were responsible for ensuring that the invited young people attended the survey venue. On the first day of the survey in a village the tracing team travelled to the areas where those invited to the survey on that day were living. They made house-to-house visits to encourage the invited young people living in that area to attend the survey venue. On the second and third day of the survey they tried to mobilise those invited on those days and also tried to follow-up on those who had not attend on the previous day(s). When following-up on young people who did not attend they recorded information on their tracing forms.

Census and Survey reporting and field staff supervision

At the end of each day the census and survey team members shared their experiences at a debriefing meeting with their respective teams. Within 2 days of returning from the field the teams attended a debriefing meeting with the project coordinators in Mwanza. The CTL and

STL also completed village summary forms and community report forms. These reports contained information on villages/sub-villages visited, days spent at each survey venue, number of HH visited, number of young people interviewed, problems encountered etc. Reports were submitted to the MkV1FS coordinators when the team returned to Mwanza or during the next sample/data collection visit. While in the field the CTL and STL sent daily updates (numbers of households visited, eligible young people interviewed etc.) by text message to the FS or Study Director (SD).

The NIMR Mwanza-based SD, FM and FS were all involved in the initial supervision of the field teams i.e. during the first few communities. They travelled with the field teams and supervised the setting-up of the survey centres and all steps of the survey including specimen and data collection. They also supervised the CI, in particular ensuring that the team had no problems using the PDAs and creating the list of survey invitees. Subsequent field supervision was carried out primarily by the FS who spent approx. 75% of his time in the field. During a supervision visit the FS spent at least one day with the census team during which he observed a CI at work and conducted blind and non-blind repeat visits to households previously visited by CI. Observations were recorded on the census supervision form. He also spent at least one day with the survey team during which he sat in on some survey interviews, conducted quality control interviews with a sample of young people and prepared a summary of the performance of the team members which he fed back to the STL. During the FS visit to the field, he discussed any problems or concerns relating to the census or survey with local leaders. The SD and FM occasionally accompanied the FS on visits to the field sites. All supervisors from Mwanza (FS, FM, SD, technical support) completed a supervision report form within 2 days of returning to the office.

Data and specimen collection

The LT processed and packaged the blood and urine samples, storing them in a portable freezer prior to transport to Mwanza. An additional project Land cruiser travelled to meet the teams and collect specimens approximately every week (collecting approx. 180 blood and 180 urine samples). Transportation to NIMR, Mwanza was in portable freezer and/or heavy-duty coolbox with fresh ice-packs, so that samples were kept at maximum 4°C. Sample submission forms were filled in for all samples sent to Mwanza and were signed by the staff member who delivered the samples and the Lab Assistant who received the samples in NIMR.

Completed questionnaires and other forms were collected at the same time as the laboratory samples. These forms were transported to the Data section of NIMR/MITU where they were double-entered. All paper forms and questionnaires sent to NIMR were accompanied by a Data Submission Form which was signed by the staff member who delivered the forms and the data manager who received the forms at NIMR.

Post-survey STI treatment

The NIMR lab and data section, within 5 weeks of receipt of laboratory samples, produced a list of participants who had tested positive for a treatable STI (active syphilis or NG or CT) and who were not treated through syndromic management. A dedicated team member (clinician) returned to the communities approximately 2 months after the survey to offer treatment to these individuals. With the help of MkV1FS tracers and the sub-village leaders the clinician invited these young people to the local health facility. Neither local officials nor community members were told that the team were returning to treat for STIs. They explained simply that they were making a follow-up to the survey. The STI diagnosis and treatment was discussed only with the participant and always in private. They provided referral slips for contacts if necessary. Those who tested positive for HSV2 were not visited, as HSV2 is not a curable although it is a treatable infection. During the survey the clinician counselled all participants on the importance of attending a health facility if they have genital ulcers.

In the unlikely event that there was a discrepancy between the VCT test results and the HIV ELISA result then a participant was revisited and VCT was repeated. Only those who chose to avail of VCT during the survey were revisited. In most cases the repeat VCT result matched the NIMR result. Where there was any remaining discrepancy between the VCT result and the NIMR result, the participant was advised to repeat VCT after 3 months. Only where the VCT result remained discordant was the participant told the NIMR result. In all cases, participants were offered further counselling.

3.3.8 Mop-up

Preparations

In April 2008, while the field teams were visiting the last few of the 20 trial communities, the power of the study was reassessed. At that stage, after 8 of the 10 comparison communities, an average of 323 males and 270 females had been interviewed per comparison community. This total of 593 eligible young people per comparison community was 82% of the total target recruitment (89% of expected males, 74% of expected females). Interestingly, on average slightly more eligible young people were being found in the intervention communities and so the overall average number per community after 17 communities was 621 eligible young people i.e. 85% of expected (94% for males, 76% for females).

The trial defined "adequate power" as being >80% and "good power" as being >90%. The HIV prevalence in the first 8 comparison communities was 1.6% for males and 3.7% for females. If these HIV prevalences were a good indicator of what would be observed in all 10 comparison communities then, the study would not quite have had adequate power (75%) to detect a 40% reduction in HIV prevalence in females, and only a moderate power (73%) to detect a 50% reduction in males. Similarly, the study would have had adequate power (>80%) to detect differences of 40% in syphilis (females) and of 25% in HSV2 (both sex). It was decided to put particular effort into recruiting more eligible females during the "mop-up" phase as firstly a lower proportion of the target number of females had been interviewed and, secondly, females had a higher prevalence of HIV and other STIs so there would have been more "gain" per person recruited.

It was estimated that if during the mop-up phase of the study the number of males in each of the comparison communities could be increased by 10% (relative to the number already recruited) and the number of females by 20% then the average number of males and females per comparison community would be 356 and 324 respectively. Assuming the prevalence remained the same then the study would have had adequate power to detect a 55% difference in HIV prevalence in males and a 40% difference in females.

In practical terms this meant that the mop-up teams would have to find an additional 330 males and 540 females in the 10 comparison communities (or residents of comparison communities who moved to migration points). In the 10 intervention communities they would have to find an additional 80 males and 400 females (or residents of intervention communities who have moved to migration points). An equal amount of time was spent in each trial community during the 'mop-up' phase i.e. communities with low numbers recruited were not prioritised.

The total recruitment target for the mop-up phase was 1350 (410 males and 940 females)

Phase 1- Repeat visits to the trial communities

The two original pairs of census and survey teams (total 65 staff) were reduced in size and reorganised into three mop-up teams (total 45 staff) who revisited the 20 trial communities to try to find eligible young people and gather more *Moved Away Forms* and/or improve the quality of information on the existing moved away forms. During this first phase of the 'mop-up' each community was visited for a period of 3 days. The survey procedures remained the same though the survey team was reduced in size with team members carrying out more than one role in the team. There was no census team and all team members were involved in tracing. When a mop-up team reached the community they set up a survey centre in the main village and completed the following tasks:

1. Revisited all households which were not interviewed during the census e.g. because the household members had been absent
2. Revisited all households with a female who had been invited to the survey but who had not attended (and not actively refused to attend).
3. Visited all trial primary schools and with a list of eligible students and the help of the teachers tried to locate females who were not identified during the census/survey.
4. Visited any secondary school in that community to try to find additional eligible females.

If a potentially eligible female or male was found then the fieldworker invited the young person to the survey site or, preferably, accompanied him/her to the survey site if he/she agreed to attend. In order to improve the information on young people who had moved away the order of priority for tracing of young people was those who did not have a *Moved Away Form* (i.e. no information on their current location), then those with an incomplete *Moved Away Form*, then those with a complete *Moved Away Form*. The tracing of females was prioritised but if the team came across a potentially eligible male then they were also interviewed.

Phase 2- Visits to major migration points

Following phase 1, the *Moved Away Form* information was summarised and five geographical areas with high numbers (i.e. 50 +) of potentially eligible females were selected for phase 2. The three mop-up teams then went to these selected major migration points, which lay outside the trial communities, and attempted to trace 3161 young people (1829 males, 1310 females). Within these 5 areas, villages with at least 10 potentially eligible young people were prioritised. When a mop-up team arrived in the major migration point they set up a survey centre. Team members, using the *Moved Away Form* information, tried to contact potentially eligible females (and males). If an eligible young person was found then the fieldworker invited them or, preferably, accompanied him/her to the survey site.

3.4 Data management

A database was created by a data manager based at NIMR, Mwanza. All data were double-entered and checked for discrepancies, which were corrected. No names or other personal identifiers were entered into the database. The pilot study data were examined to assess the appropriateness of the design of the questionnaires and forms and to identify any areas for improvement. The main survey data were entered within 2 weeks of receipt of the data. The first priority was to enter the main questionnaire. Other questionnaires and forms were entered in due course with regular feedback being given to both data entry personnel and the field staff on the quality of the data received, for example, the existence of missing data or inconsistencies.

The census data was comprised of two merged datasets (i) household data (ii) young person data. If the household data was missing for a young person then the community of invitation of that young person was not known.

The laboratory results were entered onto paper forms by the NIMR lab technicians, and these were then double-entered into the study database by the data entry personnel. Periodically, new lab results were merged into the *Main Questionnaire* database with individuals matched on sticker numbers.

Initial data cleaning was carried out by a team of data managers at NIMR, Mwanza. Further data cleaning was carried out by the Study Director prior to data analysis.

3.5 Laboratory methods

All the research laboratory tests were done in the STD Diagnostics Laboratory in NIMR Mwanza Centre.

3.5.1 HIV
Sera were tested for HIV-1 and HIV-2, using 3rd generation Murex HIV 12.0 enzyme-linked immunosorbent assay (LISA) (Abbott-Murex, Dartford, UK) and 3rd generation Vironostika HIV UNIFORM II plus O (Biomeriux, Boxtel, Netherlands) with the two tests done in parallel. Sera with discordant ELISA results were retested up to two more times on both ELISAs. Samples remaining discordant after the repeat ELISA testing were tested for p24 antigen using Biorad Genetic System HIV1 Ag EIA (Biorad, Lacoquette, France). Any samples that were negative for p24 antigen were tested with Inno-Lia HIV1/2 score Assay (Inno-Genetics NV, Gent, Belgium). Inno-lia indeterminate specimens were classified as negative.

3.5.2 HSV2
Sera were tested for antibodies to HSV2 using KALON HSV Type 2 IgG ELISA (KALON biological, Guildford, UK) following the manufacturer's instructions. KALON ELISA indeterminate samples were retested. Persistently indeterminate specimens were classified as negative.

3.5.3 Syphilis
Lifetime exposure to syphilis was examined using the Serodia *Treponema pallidum* particle agglutination (TPPA) test (Fujirebio, Japan). TPPA indeterminate samples were retested. Those positive on TPPA were further tested for active syphilis using the Immutrep carbon antigen rapid plasma reagin (RPR) test (Omega Diagnostics, Hillfoot, UK). For treatment purposes TPPA indeterminate were considered as positive as the results of repeat TPPA tests were not yet available.

3.5.4 Neisseria Gonorrhoeae (NG) and Chlamydia Trachomatis(CT)
Urine specimens were tested for Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) by Amplicor™ PCR (Roche Diagnostics, Branchburg, USA) according to the manufacturer's instructions during the first half of the survey and pooled with a pool size of 5 during the second half of the survey. PCR positive samples were retested individually up to twice. The final CT result was based on this "two out of three" strategy. NG samples which remained positive following repeat testing were confirmed with an in-house 16S rDNA PCR using primers NG01: 5'-GACGGCAGCACAGGGAAGCTTGCTTCTCGG-3' and NG03M: 5'-TCGGCCGCCGATATTGGCAA-3.[446, 447] Only samples with positive 16S PCR results were reported as positive for NG.

3.6 Statistical methods

Statistical analyses were carried out using Stata version 10.0 (Stata Corp., College Station, Texas, USA).

3.6.1 Survey participation and allocation to trial arm

A flow chart was compiled, by trial arm and sex, to show the number of potentially eligible young people identified during the census who had attended, had been eligible/ non-eligible and had participated (Figure 4.1). Allocation to trial arm for the MkV1FS primary analysis was based on the community where a young person had first attended one of standards 5-7 in a trial school between 1999 and 2002. 'Intention to treat' analysis was conducted i.e. young people who attended intervention primary schools in the correct standards and years were considered to have been exposed to the intervention even though they may not have actually attended any MkV1 sessions if, for example, they were absent from school.

The number of households interviewed during the census was taken as the number of household records in the census dataset. The number of households not interviewed (i.e. absent or refused) was taken from the field team community reports. The number of household members in the interviewed households was calculated using the census dataset. The number of young people invited during the census was calculated as the number of young people who, according to the final census dataset, had either an invitation number or a date of invitation. The number of invited young people who attended the survey site was calculated as the number of young people who either had (i) a census number on the survey questionnaire or (ii) the registration interviewer reported on the questionnaire that they could find the name of this person on List A (the census list of those invited according to the PDA data).

Associations between process indicators (timing of survey, Team) and sex and trial arm were investigated using logistic regression. Within cluster correlation was adjusted for using robust standard errors.[d]

The number of people opting for VCT was the total number of participants with a non-missing VCT result in the survey dataset.

3.6.2 Descriptive Analysis

All analyses were stratified by sex and trial arm. The characteristics of the study population were described according to age group, ethnic group, religion, marital status (current, ever) and highest level of education.

The median age at first sex was calculated using survival analysis. The reported age difference between the participant and their first and last reported sexual partners was tabulated and the mean age difference calculated.

Reports of temporary absence from the study community and reports of blood transfusion and injections in the previous 12 months were summarised. The proportion of male participants with clinically observed circumcision was reported. The association between circumcision and tribe was investigated using a logistic regression model which adjusted for community as a factor in the model.

Years of exposure to the in-school component of the MkV1 intervention was summarised in total number of years of exposure (1999-2004) and in years of exposure during the most intensive intervention period (1999-2002). Participants were also classified according to years since last exposure to the in-school intervention. Mean number of years since last exposure was calculated for each sex within each trial arm. Mean age in each standard of primary school

---

[d] *In cluster randomised trials observations on individuals in the same cluster are likely to be correlated. During analysis it is, therefore, essential to use statistical methods that take such correlations into account. The use of standard statistical methods that assume independence of observations will underestimate the standard errors of the estimates and the significance of any effects will be exaggerated.*[448]

was based on year in each standard and year of birth (or calculated using age and year of MkV1FS interview). Participants were defined as members of the MkV1 trial cohort if their cohort ID number (as presented during registration) could be matched uniquely with a cohort ID number of an individual using previous trial datasets. This may have resulted in an underestimate, as errors in transcription and/or omissions in the recording of the cohort ID number by the MkV1FS RI may have led to some cohort members not being identified.

Age difference between participant and their first and their most recent sexual partners were summarised. The association between mean age difference (between participant and most recent partner) and partner type (spouse, other regular partner, casual partner) was investigated using a linear regression model which adjusted for community as a factor in the model.

3.6.3 Outcomes

Primary and secondary trial outcomes were predefined prior to analyses by trial arm.

The primary outcomes were:

- HIV prevalence
- HSV2 prevalence.

The secondary outcomes were:

Biological

- Lifetime syphilis prevalence (TPPA+, RPR-)
- Active syphilis (TPPA+, RPR +)
- CT prevalence
- NG prevalence

Knowledge

- Knowledge on HIV acquisition
- Knowledge on STD acquisition
- Knowledge on pregnancy prevention

Attitudes

- Sexual attitudes

Each of these knowledge and attitude scores comprised of 3 questions *(Table 3.3)*. Results are presented for each question individually and as the % of participants who had correct responses to all 3 questions.

Table 3.4: Questions used in the composite knowledge and attitudes scores

Question	Correct Answer
Knowledge on acquisition of HIV	
1.1 Can HIV be caught by sexual intercourse (making love) with someone?	Yes
1.2 Can you catch HIV by sharing a plate of food with an HIV-positive person?	No
1.3 Can a person who looks strong and healthy have HIV?	Yes
Knowledge on acquisition of sexually transmitted diseases	
2.1 Can pus or abnormal fluids coming out of the private parts be caught by sexual intercourse (making love) with someone?	Yes
2.2 Can schistosomiasis be caught by sexual intercourse (making love) with someone?	No
2.3 Can an ulcer on the private parts be caught by sexual intercourse (making love) with someone?	Yes
Knowledge on pregnancy prevention	
3.1 Is it possible for a girl to become pregnant the first time she makes love?	Yes
3.2 Is it possible for a person to prevent pregnancy by using a condom while having sexual intercourse (making love)?	Yes
3.3 Is it possible for a person to prevent pregnancy by not having sexual intercourse (making love) at all?	Yes
Sexual attitudes	
4.1 If a man or youth wants to have sexual intercourse (make love) with a girl, can she refuse to have sexual intercourse (make love) with him if he is older than her?	Yes
4.2 If a man or youth wants to have sexual intercourse (make love) with a girl, can she refuse to have sexual intercourse (make love) with him if he is her lover?	Yes
4.3 If a girl accepts a gift from a boy, must she agree to have sexual intercourse (make love) with him?	No

Reported sexual behaviour

- Age at first sex
- Lifetime number of sexual partners
- >1 partner in the last 12 months
- Used a condom at last sex in the last 12 months
- Used a condom at last sex with non-regular partner
- Ever used modern contraceptive (condom, oral contraceptive pill or injectable contraceptives)

- Used a modern contraceptive at last sex
- Greater than one partner in the same time period over the last 12 months
- Greater than one partner in the past 4 weeks

Outcomes relating to the most recent sexual partner in the last 12 months were based on section 5 of the questionnaire (the last 3 partners in the last 12 months module). The most recent sexual partner for analysis was identified using the reported timing of sex with each of the last 3 partners (Q05.09). This was not necessarily the "most recent partner" reported by the participant. As a result, the description of most recent partner is restricted to partners where timing of relationship (i.e. first and last time had sex, Q5.08 & Q5.09) was available.

Reported clinical and biological outcomes

- Lifetime number of pregnancies
- Timing of first pregnancy (pregnant in primary school vs. not pregnant in primary school)
- Unplanned pregnancy
- Went to health facility for treatment of most recent STI symptoms within the past 12 months
- Symptoms of genital discharge in the last 12 months
- Symptoms of genital ulcer in the last 12 months

3.6.4 Unadjusted analysis

The data were analysed as described for stratified cluster-randomised trials (CRTs) in Hayes and Moulton.[448] The cluster-level summary method was chosen over methods based on individual-level regression as there were less than 15 clusters per trial arm and there remains some uncertainty as to the performance of such methods when stratification has been used.[448] The cluster-level method is based on the t-test and hence assumes a normal distribution of the outcome variables. To ensure robustness of the method and to allow for slightly skewed data, analyses were based on log-risk and geometric means.

Analysis followed a two-stage approach:

- In the first phase a summary measure was obtained for each cluster.
- At the second stage the cluster-specific measures were compared by arm, using a stratified t-test

The number of individuals differed slightly for each analysis because of missing results. Within each sex, the overall prevalence for each community was calculated and presented according to trial stratum and arm. For primary outcomes only, if a similar effect of the intervention was seen in males and females then the combined impact on both sexes was examined.

Impact was measured using prevalence ratios. Calculations were based on geometric mean prevalence for the 10 communities in each arm or based on arithmetic mean prevalence if an outcome had zero cases in at least one community. For continuous outcomes such as age at first sex, the overall mean (if normally distributed) or median for each community was calculated. P-values and the confidence interval (CI) for the prevalence ratio were obtained using a 2-way ANOVA of log-prevalence on intervention arm and stratum with 14 degrees of freedom[•]. This is the stratified design analogue of the t-test, which has been shown to be more robust for the analysis of CRTs with small numbers of clusters than alternative methods such as generalised estimating equations.[448] The results were interpreted in terms of the strength of evidence (strong, weak etc.) with less emphasis placed on whether the result was significant or not, for example, evidence was strong when $p<0.05$ and weak when $p>0.05$ and $p<0.1$.

3.6.5 Adjusted analysis

Covariates were allowed for in the analysis by carrying out individual-level logistic regression at the first stage of analysis. For each community, the fitted model was used to compute the ratio of observed to expected events (O/E). The adjusted prevalence ratio was obtained as the ratio of the geometric mean of these O/E estimates for the two study arms, and variances and CI were obtained from an ANOVA of log(O/E) on stratum and study arm.

The regression model included terms for the adjustment factors (age group, stratum, and ethnic group (Sukuma/non-Sukuma)), but not study arm. *A-priori,* age group, ethnic group and stratum were adjusted for as an imbalance in these covariates was seen at trial baseline. There was no substantial imbalance in other potential confounders between trial arms. Factors that were on the causal pathway e.g. knowledge, attitudes and reported sexual behaviours, were not adjusted for. Analysis was not adjusted for circumcision as information was not available as to when circumcision took place in relation to infection with an STI.

[•] Number of clusters (20)- number of combinations (2 arms, 3 strata) (Ref 448: Hayes & Moulton, 2008)

3.6.6 Sub-group analysis

The intervention may have had a greater impact in certain sub-groups of young people, for example, those who were younger or those who were unmarried. Given the relatively long time since exposure to the intervention, it was possible that the impact of the intervention would have been strongest in those who were exposed more recently. It was also important to investigate whether there was a dose-response effect of the intervention. Effect-modification of intervention arm by the following factors was, therefore, assessed using the method of Cheung and colleagues.[449]:

- Age group at further survey (categorical)
- Marital Status (binary)
- Level of exposure to the in-school component of the MkV1 intervention
    - yrs in trial school, std5-7, 1999-2004 (trend)
    - yrs in trial school, std5-7, 1999-2002 (trend)
- Years since left trial primary school (trend)

For the binary variable (marital status), a t-test was carried out to compare the difference in prevalence within each community between arms. To assess effect-modification of dose-response for the other variables, Cheung's method was extended by using linear regression to estimate the dose-response for each community, and conducting a t-test of the regression coefficients between arms. These analyses were conducted for the adjusted prevalence ratio (i.e. outcome is log O/E).

3.7 Ethical considerations

3.7.1 Ethical clearance

Research and ethics clearance for MkV1FS was obtained from the Government of the United Republic of Tanzania through its Medical Research Coordination Committee and from the LSHTM Ethics Committee ***(Appendix 6)***.

3.7.2 Informed consent

All participants provided written informed consent prior to participation ***(Section 3.3.7)***. Signed consent from a parent or guardian was also obtained for those participants who were aged less than 18 years.

3.7.3 Participant incentives

The transport costs and incentives **(Table 3.3)** were chosen to represent reasonable compensation for the participant's time and travel expenses spent to participate in the survey, rather than as an incentive as such.

3.7.4 Confidentiality and sample collection

The interviewers were not aware of the participants' HIV status, which was only known by the counsellor conducting the test.

3.7.5 HIV testing and treatment of STI

Free HIV testing and counselling was offered to eligible participants. Following national Tanzanian guidelines, any participant treated for a suspected STI was offered "contact slips" for all their reported sexual partners, and were encouraged to ask these partners to take the contact slip to their nearest government health clinic where they would receive free STI syndromic management.

The participants who opted to know their HIV status after pre-test counselling were given post-test counselling according to a protocol that had been developed within previous MkV1 survey rounds, and within other field studies in Mwanza Region. This included a careful discussion of the future implications of the test result for themselves and their past, current and future sexual partners and children. Participants were not given their HSV2 test results, as there was no recommended treatment for those who were HSV2 seropositive under Tanzanian national guidelines for treatment of STIs at the time of the survey.

3.7.6 Standard of care in comparison communities

The interventions that were currently recommended and implemented in the four project districts were the "standard of care" for the comparison communities. These included syndromic management of STIs, the standard teaching in schools related to sexual and reproductive health, and any other interventions that the government and other organizations implemented (e.g. social marketing of condoms). In 1999, the study team ensured that all government health facilities in both intervention and comparison communities had at least

Chapter 4 - Results

4.1 Participation in the census and survey

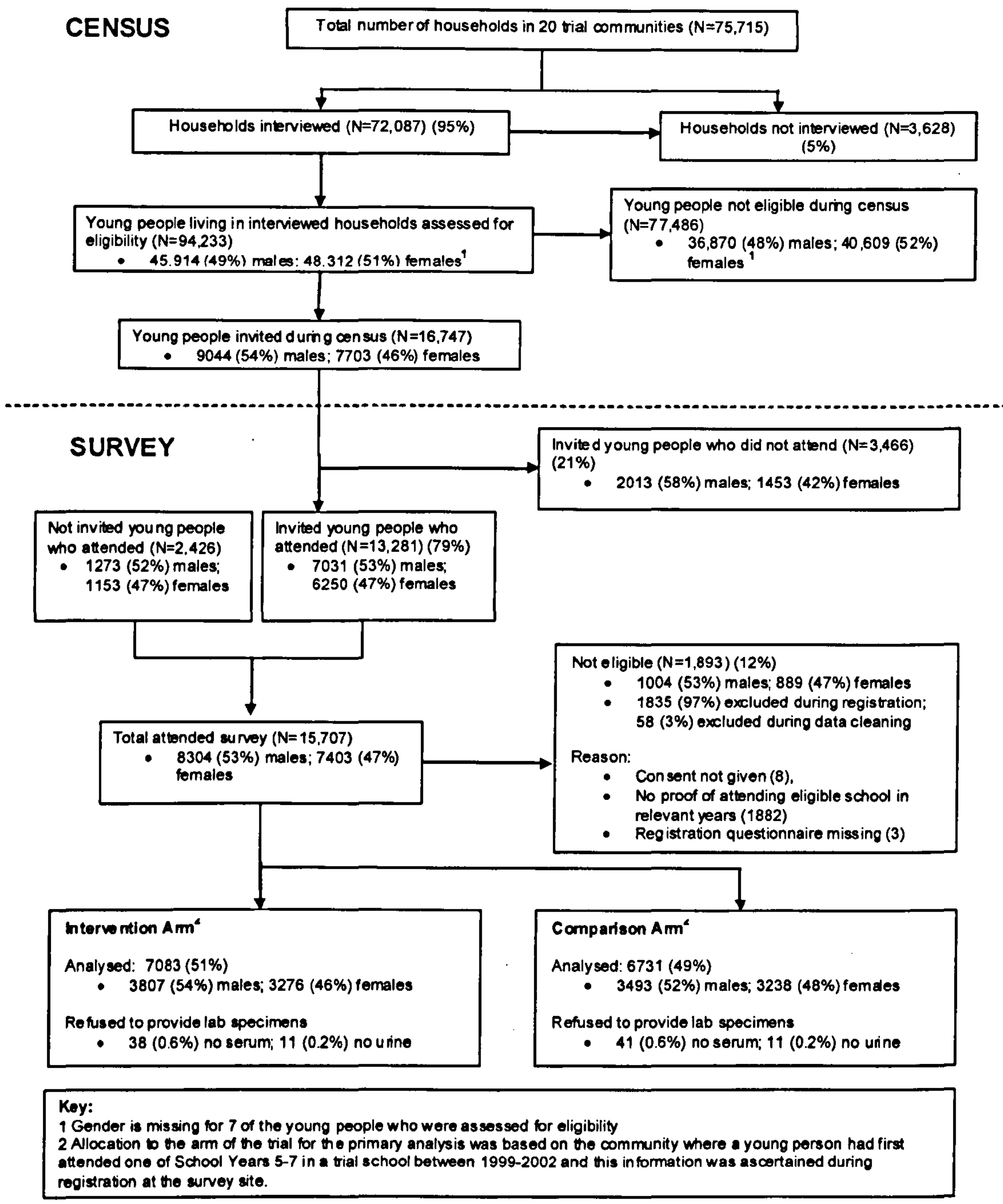
According to reports from ward and village leaders the total number of households in the 20 trial communities was **75,715** ***(Figure 4.1)*** with each community having an average of 3,786 households (range 2,296 to 7,272) ***(Appendix 7, Table A7.1)***. A total of **73,568** households were visited during the study census representing 97% of the estimated number of households. However, it was discovered that the estimates of the number of households in each village were not always accurate with both under and over estimates of the number of households ***(Table A7.1)***. These inaccuracies occurred for two main reasons: (i) Some newly built houses were not registered, (ii) Some registered houses no longer exist or are permanently vacant.

Of the households visited, **72,087** (98%) households were interviewed during the study census, representing 95% of the total estimated number of households in the census area ***(Figure 4.1)***. 82% of heads of the households were male. A small number of visited households (100-150, ~0.2%) refused to take part in the census and a number of households were absent despite repeat visits by census workers (1500-2000, 2-3%) ***(Table A7.1)***.

The total number of household members living in the interviewed households was reported to be **449,298** with **94,948** (21%) of these household members reported to be aged 15-30 years (only young people within this age range were assessed for potential eligibility for the survey). The potential eligibility of 94,233 of these young people (49% male, 51% female) was assessed either by direct interview with the young person (44%) or interview of the household head and/or other household members (56%).

16,747 (18%) of young people in the households were deemed potentially eligible on initial screening and were given an invitation to the survey. 54% of those invited were male ***(Figure 4.1)***. An average of 830 young people were invited per community (range 444 to 1056) ***(Table A7.2)***. **13,281** (80%) of the young people invited during the census attended the survey, and an additional 2,426 young people who had not been identified during the census also attended ***(Figure 4.1)***.

Figure 4.1. Long-term evaluation of the MEMA kwa Vijana intervention (MkV1FS), 2007/8



13,814 (88%) of the 15,707 survey attendees met the eligibility criteria for inclusion: 7,083 (51%) from intervention communities and 6,731 (49%) from comparison communities ***(Figure 4.1, Table A7.3)***. 11,482 (86%) of invited attendees were eligible and 2332 (96%) of the non-invited attendees were eligible. Reasons for non-eligibility were non-consent (8), no proof of attending an eligible school in relevant years (1882) and the registration questionnaire being missing (3) ***(Figure 4.1)***.

During repeat visits to the communities, field teams were encouraged to prioritise the tracing and interviewing of females and this is reflected in the high proportion of females interviewed at this time point of the study ***(Table 4.1)***. Of those eligible, 95% of males and 86% of females were interviewed during the survey teams' first visit to the trial community, 3% of males and 12% of females during the repeat visit to the community and 1% of males and 2% of females during visits to migration points. The proportion interviewed at each time point was similar within each sex by arm of the trial (males p=0.95, females p=0.55). Only 851 (6%) of participants were living outside their original trial community.

Table 4.1. Timing of survey interview for the 13,814 MkV1FS participants, by sex and trial arm

Timing of survey interview	Male						Female						Total	
	Intervention (N=3807)			Comparison (N=3493)			Intervention (N=3276)			Comparison (N=3238)				
	n	%	% of all males	n	%	% of all males	n	%	% of all females	n	%	% of all females	n	%
First visit to trial communities	3630	95.4	49.7	3332	95.4	45.6	2859	87.3	43.9	2769	85.5	42.5	12590	91.1
Repeat visit to trial communities	129	3.4	1.8	122	3.5	1.7	359	11.0	5.5	418	12.9	6.4	1028	7.4
Visits to Migration points	48	1.3	0.7	39	1.1	0.5	58	1.8	0.9	51	1.6	0.8	196	1.4
Total	3807	100	52.2	3493	100	47.8	3276	100	50.3	3238	100	49.7	13814	100

During the first visits to the communities, Team 1 interviewed 47% of eligible participants and Team 2 interviewed 53% of eligible participants. When compared to Team 2, Team 1 interviewed a relatively higher proportion of males (p=0.008) ***(Table 4.2)***.

Table 4.2. MkV1FS survey participants according to survey team, sex and trial arm

		Team 1		Team 2	
	Trial arm	**n**	**%**	**n**	**%**
Male	Intervention	1790	49.3	1840	50.7
	Comparison	1607	48.2	1725	51.8
	Total	**3397**	**48.8**	**3565**	**51.2**
Female	Intervention	1338	46.8	1521	53.2
	Comparison	1203	43.5	1566	56.6
	Total	**2541**	**45.2**	**3087**	**54.9**
Total	Intervention	3128	48.2	3361	51.8
	Comparison	2810	46.1	3291	53.9
	Total	**5938**	**47.2**	**6652**	**52.8**

75% of participants opted to know and therefore received their HIV result ***(Table 4.3)***.

Table 4.3. VCT uptake among MkV1FS participants, by sex and trial arm.

	Trial arm	**n**	**%**
Male	Intervention	2907	76.4
	Comparison	2627	75.2
	Total	**5534**	**75.8**
Female	Intervention	2421	73.9
	Comparison	2441	75.4
	Total	**4862**	**74.6**
Total	Intervention	5328	75.2
	Comparison	5068	75.3
	Total	**10396**	**75.3**

4.2 Characteristics of survey participants

4.2.1 Demographic

Participants' median age was 22 years among males and 21 years in females ***(Table 4.4)***. The age distribution ***(Table 4.4, Figure 4.2)*** shows a high proportion of females less than 21 years and males more evenly distributed across the different age groups.

Table 4.2. MkV1FS survey participants according to survey team, sex and trial arm

		Team 1		Team 2	
	Trial arm	**n**	**%**	**n**	**%**
Male	Intervention	1790	49.3	1840	50.7
	Comparison	1607	48.2	1725	51.8
	Total	**3397**	**48.8**	**3565**	**51.2**
Female	Intervention	1338	46.8	1521	53.2
	Comparison	1203	43.5	1566	56.6
	Total	**2541**	**45.2**	**3087**	**54.9**
Total	Intervention	3128	48.2	3361	51.8
	Comparison	2810	46.1	3291	53.9
	Total	**5938**	**47.2**	**6652**	**52.8**

75% of participants opted to know and therefore received their HIV result ***(Table 4.3)***.

Table 4.3. VCT uptake among MkV1FS participants, by sex and trial arm.

	Trial arm	**n**	**%**
Male	Intervention	2907	76.4
	Comparison	2627	75.2
	Total	**5534**	**75.8**
Female	Intervention	2421	73.9
	Comparison	2441	75.4
	Total	**4862**	**74.6**
Total	Intervention	5328	75.2
	Comparison	5068	75.3
	Total	**10396**	**75.3**

4.2 Characteristics of survey participants

4.2.1 Demographic

Participants' median age was 22 years among males and 21 years in females ***(Table 4.4)***. The age distribution ***(Table 4.4, Figure 4.2)*** shows a high proportion of females less than 21 years and males more evenly distributed across the different age groups.

Table 4.4. Characteristics of the 13,814 MkV1FS participants, by sex and trial arm.

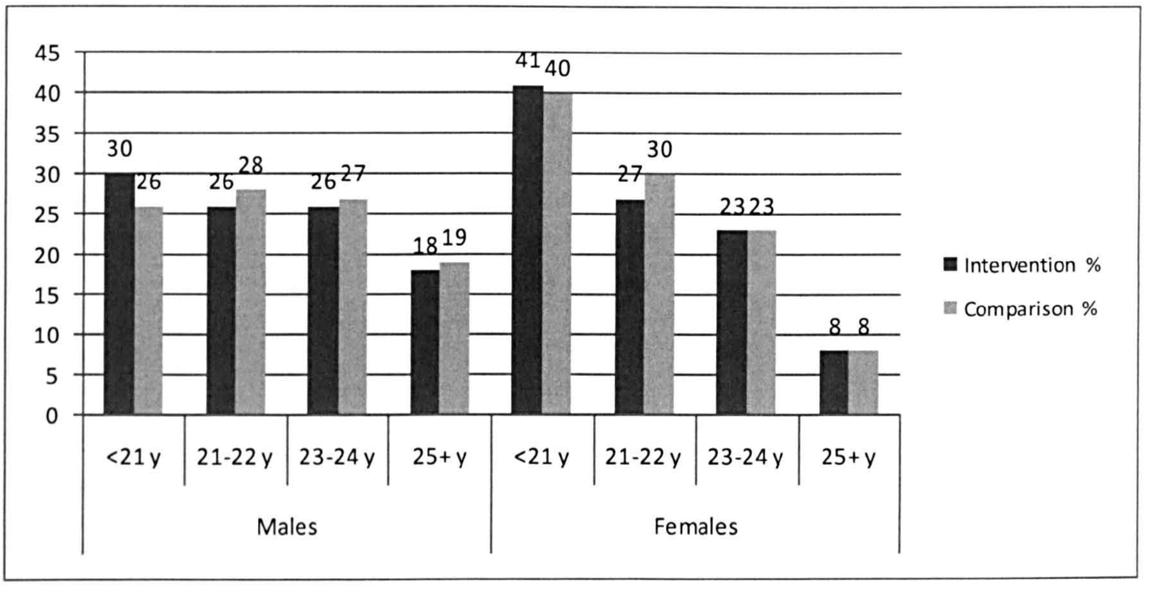
Characteristic	Male (n=7300)		Female (n=6514)	
	Intervention N=3807 (52%)	Comparison N=3493 (48%)	Intervention N=3276 (50%)	Comparison N=3238 (50%)
Age, n (%)				
<17 y	16 (0.4%)	5 (0.1%)	51 (2%)	40 (1%)
17-18 y	310 (8%)	220 (6%)	418 (13%)	375 (12%)
19-20 y	824 (22%)	671 (19%)	888 (27%)	869 (27%)
21-22 y	990 (26%)	987 (28%)	898 (27%)	966 (30%)
23-24 y	976 (26%)	938 (27%)	763 (23%)	735 (23%)
>=25 y	690 (18%)	672 (19%)	257 (8%)	252 (8%)
Median age and IQR, y	22 (20-24)	22 (20-24)	21 (19-23)	21 (20-23)
Sukuma ethnic group, n (%)	2882 (76%)	2834 (81%)	2549 (78%)	2747 (85%)
Religion, n (%)				
Christian	3099 (81%)	2784 (80%)	2860 (87%)	2905 (90%)
Muslim	143 (4%)	187 (5%)	142 (4%)	136 (4%)
Other religion	20 (0.5%)	38 (1%)	7 (0.2%)	2 (0.1%)
None	542 (14%)	476 (14%)	260 (8%)	187 (6%)
Currently married, n (%)	1242 (33%)	1202 (34%)	1806 (55%)	1858 (57%)
Ever married, n (%)	1346 (35%)	1327 (38%)	2121 (65%)	2168 (67%)
Highest level of education, n (%) Secondary school or higher	864 (23%)	678 (19%)	472 (14%)	411 (13%)
Currently at school/university, n (%)	989 (26%)	751 (22%)	460 (14%)	355 (11%)
Male circumcision (clinical examination), n (%)	1596 (43%)	1315 (38%)	NA	NA
Ever had sex[1], n (%)	3452 (91%)	3184 (91%)	3033 (93%)	3019 (93%)
Median age at sexual debut, y	18	17	17	17
Slept away from community in the last 4 weeks, n (%)	1040 (27%)	917 (26%)	387 (12%)	419 (13%)
Slept away from community in the last 12 months, n(%)	2634 (69%)	2319 (67%)	1603 (49%)	1504 (47%)
Blood transfusion in the previous 5 years, n (%)	30 (1%)	29 (1%)	82 (3%)	80 (3%)
Number of injections in the previous 12 months, n (%)				
0	2949(78%)	2700 (78%)	1821(56%)	1703(53%)
1	265(7%)	236(7%)	406(13%)	423 (13%)
2+	579(15%)	525(15%)	1008(31%)	1064 (33%)

1 Defined as answering 'yes' to the question 'Have you ever made love?' or reporting having made love to at least 1 man or woman in their lifetime

The great majority of participants (80%) were members of the Sukuma ethnic group ***(Table 4.4)***. 84% of participants were Christian, 4% Muslim, 0.5% had another religion and 11% reported no religion ***(Table 4.4)***. One third of males and half of females were currently married with a slightly higher proportion of each sex reporting having ever been married (37% males; 66% females) ***(Table 4.4)***. The majority of participants had obtained only primary education or less with only 21% of males and 14% of females having reached secondary school or higher.

24% of males and 13% of females reported that they were still at (secondary) school or university *(Table 4.4)*.

Figure 4.2. Age distribution of the MkV1FS participants, by sex and trial arm.



27% of male participants and 12% of female participants reported having slept away from their administrative ward in the previous 4 weeks *(Table 4.4)*. 68% of male participants and 48% of female participants reported having slept way from their ward in the previous year. Among those reporting having spent at least one night outside their ward in the past year, 17% of males and 14% of females report spending more than 3 months away and 15% of males and 18% of females report spending between 1 and 3 months away *(Table 4.5)*. Those interviewed during repeat visits to the trial communities were most likely to report having spent more than 3 months away in the previous year ($p<0.001$) *(Figure 4.3)*.

A priori, the trial outcome analysis was adjusted for age group, ethnic group and trial stratum as an imbalance in these covariates was seen at trial baseline.

Table 4.5: Length of time (nights) spent outside of community in the previous 12 months among those who reported having spent at least one night away from their community, by sex and trial arm.

(a) Males

	Intervention		Comparison		Total	
	n	%	n	%	n	%
Up to 1 week	1031	39.6	934	41.1	1965	40.3
1 week to 1 month	763	29.3	608	26.8	1371	28.1
1 month to 3 months	386	14.8	341	15	727	14.9
>3 months	423	16.3	389	17.1	812	16.7
Total	2603	100	2272	100	4875	100

(b) Females

	Intervention		Comparison		Total	
	n	%	n	%		%
Up to 1 week	616	38.7	555	37.2	1171	38.0
1 week to 1 month	484	30.4	462	31.0	946	30.7
1 month to 3 months	274	17.2	264	17.7	538	17.5
>3 months	217	13.6	210	14.1	427	13.9
Total	1591	99.9	1491	100	3082	100

4.2.2 Exposure to the Intervention

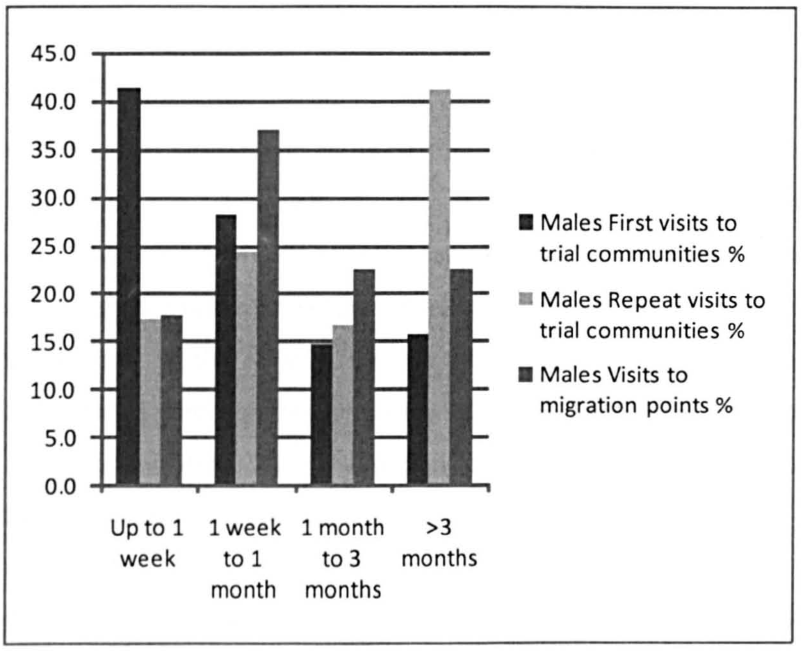
Two thirds of participants had had the opportunity to receive the full 3 years of the in-school intervention between 1999 and 2004 ***(Table 4.6)***. One third of participants received the full 3 years of the intervention during the years when the intervention implementation was most closely supervised (1999-2002).

Male participants had a mean age of 15 yrs and females a mean age of 14 yrs when they were first exposed to the in-school components of the interventions. The mean ages of participants during the three intervention years (standards 5, 6 and 7) were 15, 16 and 17 years for males and 14, 15 and 16 years for females, respectively.

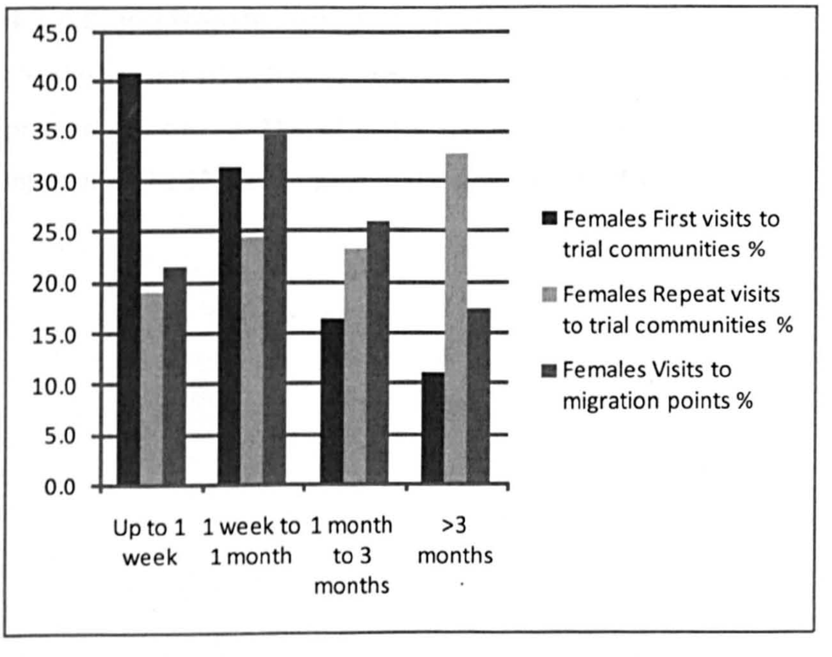
On average, participants had last been exposed to the in-school intervention (or equivalent years of school in comparison communities) 5.4 yrs prior to the survey ***(Table 4.6)***.

Figure 4.3: Length of time (nights) spent outside of community in the previous 12 months among those who reported having spent at least one night away from their community, by sex and timing of survey interview.

(a) Males



(b) Females



3808 (28%) of study participants were uniquely matched to a MkV1 cohort member using either their MkV1 identification number or a combination of their name, school attended, and the year that they attended year 7 of primary school ***(Table 4.6, Figure 4.4)***. This implies that 39% of the 9645 MkV1 cohort members were interviewed during MkV1FS. 3286 (47%) of the MkV1 cohort members interviewed in 2001/2 were also interviewed in 2007/8.

4.2.3 Circumcision

41% of males were found to be circumcised on clinician examination ***(Table 4.4)***. Males who were able to recall the age at which they were circumcised reported an average age of 16 years (range 1-28 yrs). 3% of males found to be circumcised on clinician examination had told the survey interviewer that they were not circumcised. Of those who were reported as 'not circumcised' by the clinician, 6% had told the survey interviewer that they were circumcised. 2% of males who reported that they were not circumcised were found to be circumcised on clinical examination. 9% of males who reported that they were circumcised were found not to be circumcised on clinical examination. Those from the Sukuma tribe had lower levels of circumcision when compared to members of other tribes (34% vs 63%, $p<0.0001$). Muslims (81%) were more likely to be circumcised than Christians (43%) and those with another or no religion (13%).

4.2.4 Blood transfusions and injections

1% of male and 3% of female participants report having had a blood transfusion in the 5 years prior to the survey. 21% of males and 45% of females reported having had at least one injection in the 12 months prior to the survey ***(Table 4.4)***.

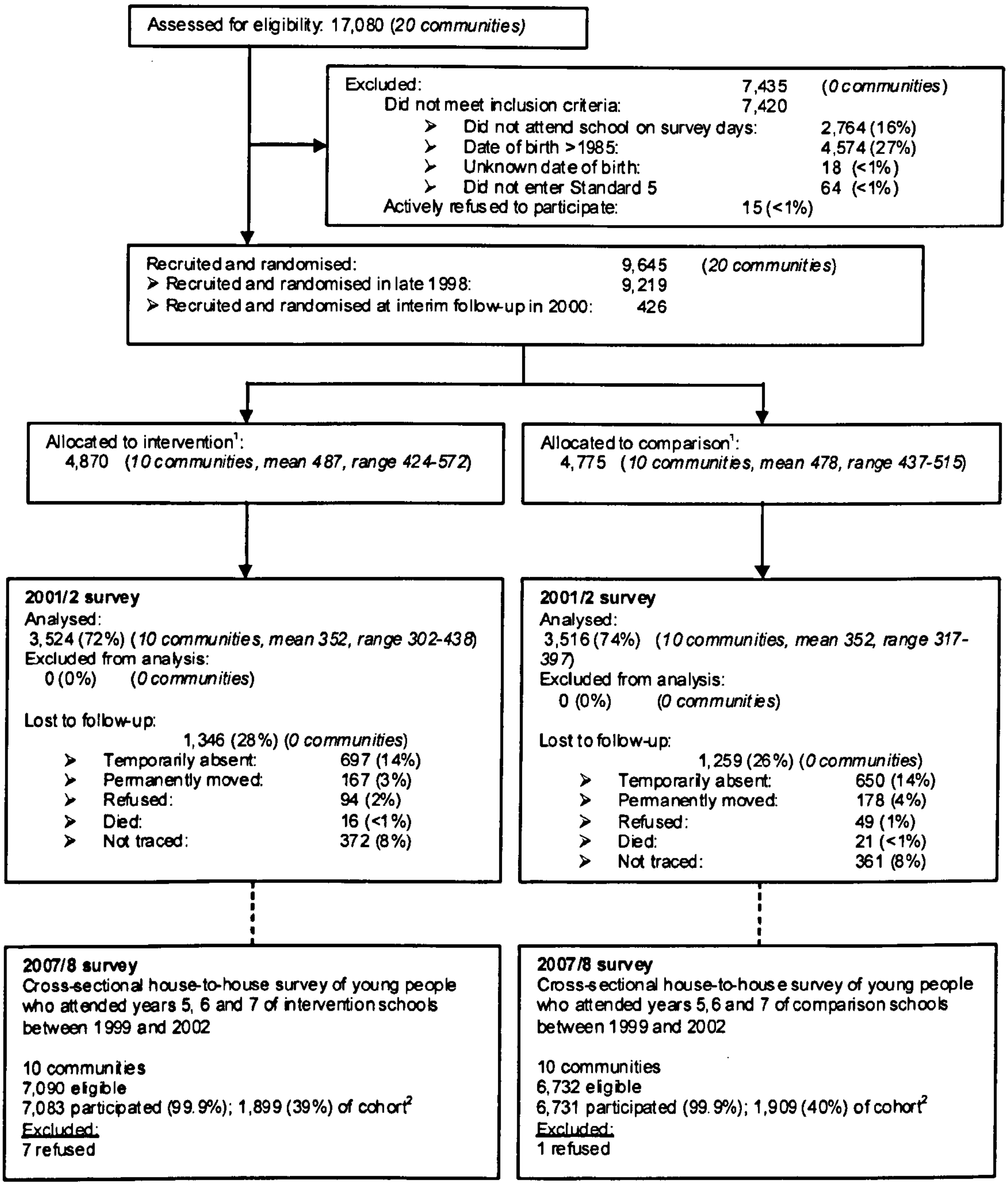
Table 4.6: Exposure of MkV1FS participants to the in-school component of the MEMA kwa Vijana intervention, by sex and trial arm.

	Male (n=7300)		Female (n=6514)	
	Intervention N=3807	Comparison N=3493	Intervention N=3276	Comparison N=3238
Years exposure to in-school component of MkV1 (or comparison), '99 - '04				
1 year	629 (17%)	576 (16%)	515 (16%)	517 (16%)
2 years	616 (16%)	647 (19%)	555 (17%)	518 (16%)
3 or more years	2562 (67%)	2270 (65%)	2206 (67%)	2203 (68%)
Years exposure to in-school component of MkV1 (or comparison), '99 - '02				
1 year	1358 (36%)	1136 (33%)	1156 (35%)	1157 (36%)
2 years	1241 (33%)	1159 (33%)	1065 (33%)	980 (30%)
3 or more years	1208 (32%)	1198 (34%)	1055 (32%)	1101 (34%)
Years since last exposure to in-school intervention (or comparison)				
3 yrs	711 (19%)	551 (16%)	604 (18%)	619 (19%)
4 yrs	715 (19%)	566 (16%)	604 (18%)	525 (16%)
5 yrs	623 (16%)	602 (17%)	521 (16%)	574 (18%)
6 yrs	622 (16%)	632 (18%)	576 (18%)	555 (17%)
7 yrs	543 (14%)	594 (17%)	489 (15%)	466 (14%)
8 yrs	593 (16%)	548 (16%)	482 (15%)	499 (15%)
Mean number of years	5.4	5.5	5.4	5.4
Mean age in Standard 5[1]	14.6 yrs	14.7 yrs	13.7 yrs	13.8 yrs
Mean age in Standard 6[1]	15.7 yrs	15.8 yrs	14.8 yrs	14.8 yrs
Mean age in Standard 7[1]	16.7 yrs	16.8 yrs	15.7 yrs	15.8 yrs
Mean age at first exposure to the in-school intervention (or comparison)[1]	15.1 yrs	15.2 yrs	14.2 yrs	14.2 yrs
First sex before exposure to the in-school intervention (or comparison)	1003 (26%)	1053 (30%)	570 (17%)	534 (16.5%)
Member of MkV1 trial cohort[2]	1114 (29%)	1131 (32%)	785 (24%)	778 (24%)

[1] mean age in school years based on year in each School Year (Std) and year of birth (or age and year of MkV1FS interview)

[2] Participants were defined as member of the MkV1 trial cohort if their cohort ID number (as presented during registration) could be matched uniquely with a cohort ID number of an individual using previous trial datasets. This may have resulted in an underestimate, as errors in transcription and/or omissions in the recording of the cohort ID number by the registration interviewer may have led to some cohort members not being identified.

Figure 4.4. The MEMA kwa Vijana Community Randomised Controlled Trial (1998-2008)



4.3 Main impact results

4.3.1 Impact on knowledge

Approximately two-thirds of participants had comprehensive knowledge on HIV acquisition. However, this also implies that one third of trial participants could not answer all three basic questions about HIV acquisition correctly ***(Table 4.7)***. Comprehensive knowledge of pregnancy prevention was also good and particularly high in males in the intervention communities ***(Table 4.7)***. Knowledge on the acquisition of sexually transmitted diseases (STD) was low particularly among females where only 38% of intervention and 30% of comparison community females could answer all 3 questions correctly ***(Table 4.7)***. For all three knowledge outcomes, correct knowledge was higher in the intervention communities and there was evidence of an association for each outcome (adjusted risk ratio (aPR) from 1.11-1.19 for males and 1.11-1.24 for females) ***(Table 4.7)***.

When the three HIV acquisition knowledge questions were looked at separately it was observed that almost all the participants knew that HIV could be caught by "making love" with someone ***(Table 4.8)***. About 90% knew that you cannot catch HIV by sharing a plate with a HIV positive person. A considerably lower proportion of young people knew that a person who looks strong and healthy can have HIV. The biggest difference between intervention and comparison communities was seen for this third question (aPR 1.06 (0.98, 1.15) for males and 1.09 (0.98, 1.20) for females) ***(Table 4.8)***.

When the three STD acquisition knowledge questions were looked at separately, a big difference in the level of knowledge between males and females was seen. The largest difference according to gender and also according to trial arm was seen for the question 'Can pus or abnormal fluids coming out of the private parts be caught by making love with someone?'. 84% of males and 72% of females in the intervention communities answered this question correctly with aPR of 1.07 (1.02, 1.13) for males and 1.17 (1.03, 1.32) for females ***(Table 4.8)***. The question 'Can schistosomiasis be caught by making love with someone?' had the least correct ("No") responses (71% intervention males; 64% intervention females) and there was weak evidence of a difference between trial arms. Preliminary work within earlier phases of the MEMA kwa Vijana trial had shown that schistosomiasis was widely thought to be sexually transmitted in Mwanza Region. The highest proportion of correct responses among both males and females was seen for the question 'Can an ulcer on the private parts be caught by making love with someone?' and there was strong evidence for a difference between trial arms for this question (aPR 1.05 (1.02,1.08) for males and 1.11 (1.05,1.17) for females) ***(Table***

4.8). The proportion of participants answering all of these three questions correctly was surprisingly low. Of the 40% of participants who answered only two questions correctly, 60% answered the question on schistosomiasis incorrectly (data not shown).

When the three pregnancy prevention knowledge questions were looked at separately, it was observed that over 80% of males and females in the intervention communities answered each question correctly ***(Table 4.8)***. The questions 'Is it possible for a person to prevent pregnancy by not making love at all?' and 'Is it possible for a person to prevent pregnancy by using a condom while making love?' were also answered well by those in the comparison communities and there was only weak evidence of a difference between trial arms. The poorest responses overall and the biggest difference between trial arms was for the question 'Is it possible for a girl to become pregnant the first time she makes love?' with aPR of 1.16 (1.12,1.20) for males and 1.15 (1.08,1.22) for females ***(Table 4.8)***.

4.3.2 Impact on reported attitudes to sexual risk

There was some evidence that reporting of desirable attitudes to sexual risk among males was higher in intervention communities than in comparison communities (aPR 1.31 95%CI:0.97-1.77) ***(Table 4.7)***. There was no evidence of a difference between trial arms among females (aPR 1.09 95%CI:0.67-1.77) ***(Table 4.7)***. When the responses to each of the 3 attitude questions were examined separately it was observed that a very low proportion (~25%) of women said that a woman can refuse to make love with a man if he is her lover ***(Table 4.8)***. The highest proportion of desired responses and the strongest evidence of a difference between trial arms was seen for the question 'If a young woman accepts a gift from a man, must she agree to make love with him?' with aPR of 1.12 (1.01,1.25) for males and 1.01 (0.98,1.24) for females ***(Table 4.8)***. Just over half of males and females gave the desired response to the question 'If a man wants to make love with a woman, can she refuse to make love with him if he is older than her?'. There was no evidence of a difference between trial arms for this question ***(Table 4.8)***.

Table 4.7. Impact of intervention on knowledge, reported attitudes, and reported behaviours by sex in 2007/8

Outcome	Male: Prevalence[1] Intervention (N=3807), n(%)	Male: Prevalence[1] Comparison (N=3493), n (%)	Male: Adjusted PR[2] (CI)	Female: Prevalence[1] Intervention (N=3276), n (%)	Female: Prevalence[1] Comparison (N=3238), n (%)	Female: Adjusted PR[2] (CI)
Knowledge (% with all 3 responses "correct")						
HIV acquisition	2773 (73%)	2295 (66%)	1.11 (0.99,1.23)	2233 (68%)	1952 (61%)	1.11 (1.00,1.24)
STD acquisition	2056 (54%)	1591 (46%)	1.18 (1.04,1.34)	1253 (38%)	974 (30%)	1.24 (0.97,1.58)
Pregnancy prevention	3133 (83%)	2410 (69%)	1.19 (1.12,1.26)	2304 (71%)	1934 (60%)	1.17 (1.06,1.30)
Reported Attitudes (% with all 3 responses "correct")						
Attitudes to sex	1053(28%)	759 (22%)	1.31 (0.97,1.77)	359 (11%)	332 (10%)	1.09 (0.67,1.77)
Reported Sexual Behaviour (% with outcome)						
Age at first sex <16y	954 (25%)	956 (28%)	0.91 (0.80,1.05)	903 (28%)	865 (27%)	1.01 (0.80,1.28)
>2 (female) or >4 (male) lifetime sexual partners	1412 (37%)	1531 (44%)	0.87 (0.78,0.97)	1096 (34%)	1191 (37%)	0.89 (0.75,1.05)
>1 partner in last 12 months	1542(41%)	1557 (45%)	0.92 (0.79,1.08)	333 (10%)	325 (10%)	0.97 (0.76,1.23)
Used condom at last sex in past 12m[3]	1021/2988 (34%)	795/2776 (29%)	1.19 (0.91,1.54)	541/2832 (19%)	407/2775 (15%)	1.27 (0.97,1.67)
Used condom at last sex in past 12m with non-regular partner[4]	903/1821 (50%)	760/1746 (44%)	1.15 (0.97,1.36)	189/427 (45%)	136/434 (31%)	1.34 (1.07,1.69)
Ever used modern contraceptive[5]	2232 (59%)	1911 (55%)	1.09 (0.94,1.26)	1561 (48%)	1371 (42%)	1.11 (0.95,1.30)
Used modern contraceptive at last sex[3,5]	1040 (35%)	803 (29%)	1.21 (0.92,1.58)	632/2841 (22%)	538/2796 (19%)	1.16 (0.91,1.47)
>1 partner in same time period in past 12m[6]	1087 (29%)	1132 (32%)	0.90 (0.76,1.06)	209 (6%)	219 (7%)	0.87 (0.63,1.20)
>1 partner in past 4 weeks	435 (11%)	464 (13%)	0.87 (0.65,1.15)	57 (2%)	53 (2%)	1.04 (0.66,1.66)
Went to health facility for most recent STI symptoms within past 12m[7]	192/401 (48%)	195/451 (43%)	1.19 (0.91,1.56)	102/216 (47%)	154/326 (47%)	1.02 (0.77,1.37)

1. Denominators vary depending on missing values & unless specified have the ranges: Male: Int 3786-3807; Comp 3473-3493; Female Int 3256-3276; Comp 3220-3238
2. Adjusted for: Age group (<21, 21-22, 23-24, ≥25y), stratum, ethnic group (Sukuma vs non-Sukuma)
3. Among those who reported having had sex in past 12m
4. Among those who reported having ever had sex with a non-regular partner in past 12m
5. Modern contraceptive = condom, oral contraceptive pill, injectable contraceptives
6. Based on reported start and end dates of last 3 sexual partnerships in the past 12m
7. Among those reporting STI symptoms (genital discharge or ulcer) within past 12m

Table 4.8. Impact of intervention on individual knowledge and reported attitudes questions by sex in 2007/8

Outcome	Male			Female		
	Prevalence[1]		Adjusted PR[2] (CI)	Prevalence[1]		Adjusted PR[2] (CI)
	Intervention (N=3807), n(%)	Comparison (N=3493), n(%)		Intervention (N=3276), n (%)	Comparison (N=3238), n (%)	
HIV acquisition (% with all 3 responses "correct")	2773 (73%)	2295 (66%)	1.11 (0.99,1.23)	2233 (68%)	1952 (61%)	1.11 (1.00,1.24)
Can HIV be caught by making love with someone? (Yes)	3767 (99%)	3424 (98%)	1.01 (1.00,1.02)	3241 (99%)	3169 (98%)	1.01 (1.00,1.02)
Can you catch HIV by sharing a plate of food with an HIV positive person? (No)	3538 (93%)	3098 (89%)	1.04 (1.01,1.08)	3001 (92%)	2859 (88%)	1.03 (1.00,1.06)
Can a person who looks strong and healthy have HIV? (Yes)	2960 (78%)	2554 (73%)	1.06 (0.98,1.15)	2385 (73%)	2147 (66%)	1.09 (0.98,1.20)
STD acquisition (% with all 3 responses "correct")	2056 (54%)	1591 (46%)	1.18 (1.04,1.34)	1253 (38%)	974 (30%)	1.24 (0.97,1.58)
Can pus or abnormal fluids coming out of the private parts be caught by making love with someone? (Yes)	3191 (84%)	2720 (78%)	1.07 (1.02,1.13)	2367 (72%)	1993 (62%)	1.17 (1.03,1.32)
Can schistosomiasis be caught by making love with someone? (No)	2697 (71%)	2347 (67%)	1.05 (0.95,1.16)	2096 (64%)	2079 (64%)	0.99 (0.90,1.08)
Can an ulcer on the private parts be caught by making love with someone? (Yes)	3388 (89%)	2952 (85%)	1.05 (1.02,1.08)	2588 (79%)	2279 (71%)	1.11 (1.05,1.17)
Pregnancy prevention (% with all 3 responses "correct")	3133 (83%)	2410 (69%)	1.19 (1.12,1.26)	2304 (71%)	1934 (60%)	1.17 (1.06,1.30)
Is it possible for a girl to become pregnant the first time she makes love? (Yes)	3393 (89%)	2673 (77%)	1.16 (1.12,1.20)	2710 (83%)	2324 (72%)	1.15 (1.08,1.22)
Is it possible for a person to prevent pregnancy by not making love at all? (Yes)	3582 (94%)	3174 (91%)	1.03 (1.00, 1.07)	3030 (93%)	2918 (90%)	1.02 (0.96,1.08)
Is it possible for a person to prevent pregnancy by using a condom while making love? (Yes)	3655 (96%)	3290 (94%)	1.02 (1.00,1.04)	2868 (88%)	2751 (85%)	1.03 (0.97,1.09)
Attitudes to sex (% with all 3 responses "correct")	1053(28%)	759 (22%)	1.31 (0.97,1.77)	359 (11%)	332 (10%)	1.09 (0.67,1.77)
Attitude 1 (If a man wants to make love with a woman, can she refuse to make love with him if he is older than her?) (Yes)	2237 (59%)	1960 (56%)	1.04 (0.94,1.15)	1712 (52%)	1633 (51%)	1.03 (0.92,1.14)
Attitude 2 (If a man wants to make love with a woman, can she refuse to make love with him if he is her lover?) (Yes)	1792 (47%)	1546 (44%)	1.08 (0.95,1.22)	803 (25%)	769 (24%)	1.04 (0.82,1.33)
Attitude 3 (If a young woman accepts a gift from a man, must she agree to make love with him?) (No)	2590 (68%)	2113 (61%)	1.12 (1.01,1.25)	2124 (65%)	1908 (59%)	1.01 (0.98,1.24)

1. Denominators vary depending on missing values and unless specified have the following ranges: Male Int: 3786-3807; Males Comp: 3473-3493; Female Int: 3256-3276; Females Comp:3220-3238

2. Adjusted for: Age group (<21, 21-22, 23-24, ≥25y), stratum, ethnic group (Sukuma vs non-Sukuma)

Table 4.9. Impact of intervention on clinical and biological outcomes by sex in 2007/8

Outcome	Male			Female		
	Prevalence[1]		Adjusted PR[2] (CI)	Prevalence[1]		Adjusted PR[2] (CI)
	Intervention (N=3807), n(%)	Comparison (N=3493), n(%)		Intervention (N=3276), n(%)	Comparison (N=3238), n(%)	
Reported clinical/biological outcomes						
Genital discharge prevalence (last 12mth)	288 (8%)	320 (9%)	0.83 (0.63,1.09)	122 (4%)	178 (6%)	0.70 (0.45,1.09)
among sexually active	277 (8%)	302 (9.5%)	0.84 (0.65, 1.09)	118 (4%)	176 (6%)	0.69 (0.44, 1.07)
Genital ulcer prevalence (last 12mth)	193 (5%)	245 (7%)	0.76 (0.59,0.99)	149 (5%)	216 (7%)	0.69 (0.47,1.01)
among sexually active	185 (5%)	240 (7.5%)	0.75 (0.57,0.99)	145 (5%)	213 (7%)	0.68 (0.46,1.01)
3+ reported pregnancies (lifetime)	207 (5%)	220 (6%)	0.95 (0.70,1.29)	587 (18%)	605 (19%)	0.96 (0.80,1.15)
Reported pregnancy while in primary school	113 (3%)	132 (4%)	0.84 (0.57, 1.23)	102 (3%)	91 (3%)	1.16 (0.68,1.97)
Reported ≥1 unplanned pregnancy	675 (39%)	782 (47%)	0.87 (0.69,1.10)	792 (25%)	759 (24%)	1.03 (0.83,1.26)
Primary biological outcomes						
HIV prevalence	74 (2.0%)	59 (1.7%)	0.91 (0.50,1.65)	126 (3.9%)	136 (4.2%)	1.07 (0.68,1.67)
HSV-2 prevalence	948 (25.0%)	928 (26.7%)	0.94 (0.77,1.15)	1313 (40.3%)	1369 (42.5%)	0.96 (0.87,1.06)
Secondary biological outcomes						
"Lifetime" syphilis exposure (TPPA+)	218 (5.8%)	183 (5.3%)	1.06 (0.74,1.52)	206 (6.3%)	241 (7.5%)	0.86 (0.62,1.21)
Active syphilis prevalence (TPPA+, RPR+)	144 (3.8%)	113 (3.3%)	1.11 (0.72,1.72)	147 (4.5%)	167 (5.2%)	0.91 (0.65,1.28)
Chlamydia prevalence	80 (2.1%)	73 (2.1%)	1.24 (0.66,2.33)	85 (2.6%)	69 (2.1%)	1.27 (0.87,1.86)
Gonorrhoea prevalence (16S PCR confirmed)	13 (0.3%)	15 (0.4%)	0.71 (0.21,2.41)	11 (0.3%)	12 (0.4%)	0.73 (0.20,2.63)

1. Denominators vary depending on missing values and unless specified have the following ranges: Male Int: 3786-3807; Males Comp: 3473-3493; Female Int: 3256-3276; Females Comp:3220-3238

2. Adjusted for: Age group (<21, 21-22, 23-24, ≥25y), stratum, ethnic group (Sukuma vs non-Sukuma)

4.3.3 Impact on reported sexual behaviour

91% of males and 93% of females reported ever having had sex. The median reported age at sexual debut in the intervention and comparison communities was 18 and 17 years in males, and 17 and 17 years in females, respectively ***(Table 4.4)***. 74% of males and 83% of females were first exposed to the intervention prior to the year that they reported first having sex.[f]

The distribution of lifetime partners by sex and trial arm is shown in ***Figure 4.5***. There was evidence of an impact of the intervention on number of lifetime sexual partners among males, with 37% of males in intervention communities reporting >4 lifetime sexual partners compared to 44% males in the comparison communities (aPR 0.87 95%CI:0.78-0.97). The prevalence of other measures of reported partner change and concurrency was similar between trial arms ***(Table 4.7)***. There was no evidence of an association between exposure to the intervention and period prevalence of reported concurrency of sexual partnerships (>1 partner in same time period in last 12 months; >1 partner in past 4 weeks) ***(Table 4.7)***.

The absolute proportions of respondents who reported using condoms at last sex within the past 12 months were relatively low in both intervention (males 34%, females 19%) and comparison communities (males 29%, females 15%) ***(Table 4.7)***. Reported use of condoms was higher at last sex with a non-regular partner, but was still only reported by 50% or less. There was some suggestion of an impact of the intervention on reported condom and modern contraceptive use in both sexes, however, there was strong evidence of intervention impact only for reported condom use with a non-regular partner among females (aPR 1.34, CI 1.07,1.60) ***(Table 4.7)***.

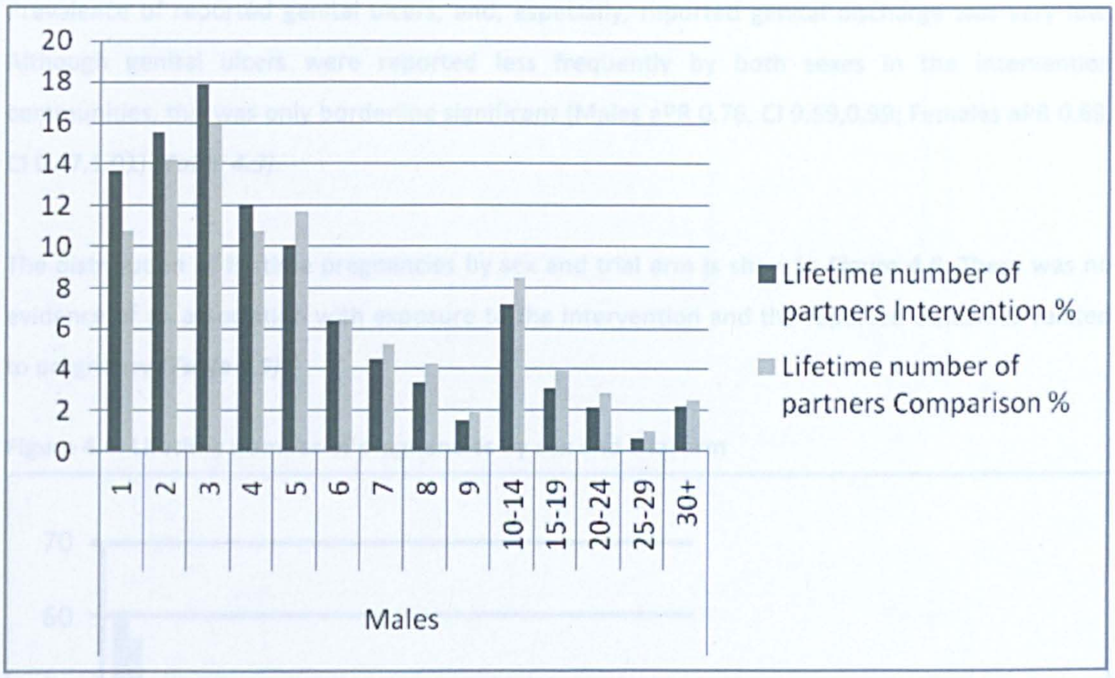
There was no evidence of an association between exposure to the intervention and reported use of health facilities for a respondent's most recent STI symptom among respondents who reported having STI symptoms within the last 12 months ***(Table 4.7)***.

---

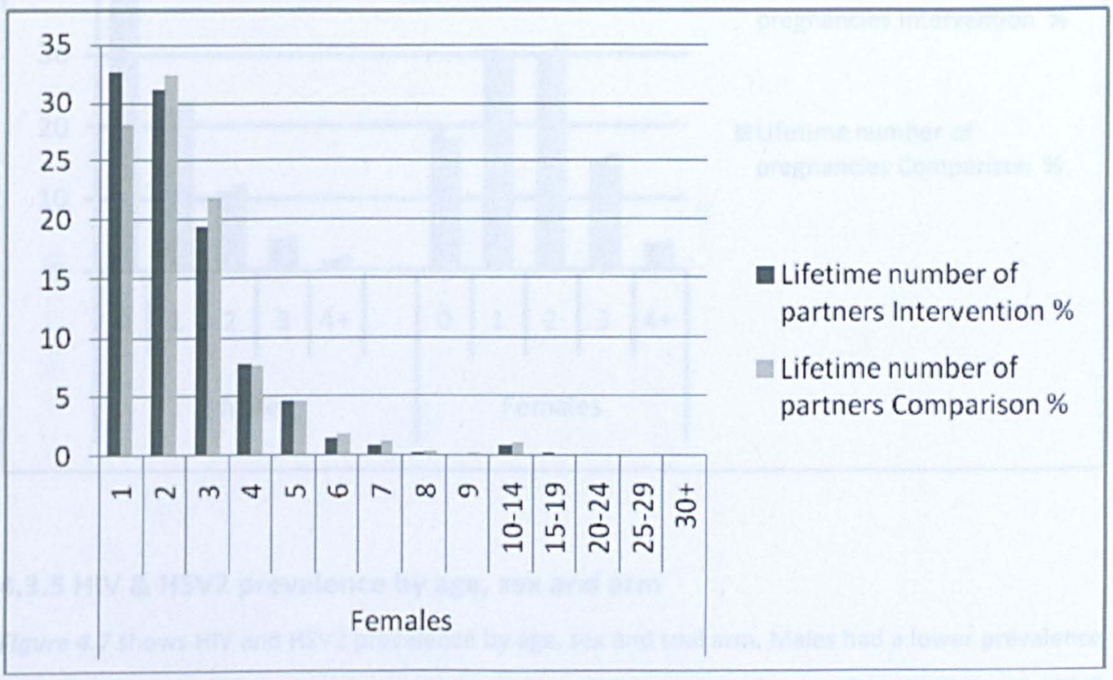
[f] The age when first exposed to the intervention was calculated using reported age or date of birth and reported years when attended standards 5-7 of primary school. This estimated age when first exposed to the intervention was then compared to the reported age at first sex.

Figure 4.5. Reported lifetime number of sexual partners by sex and trial arm

(a) Males



(b) Females

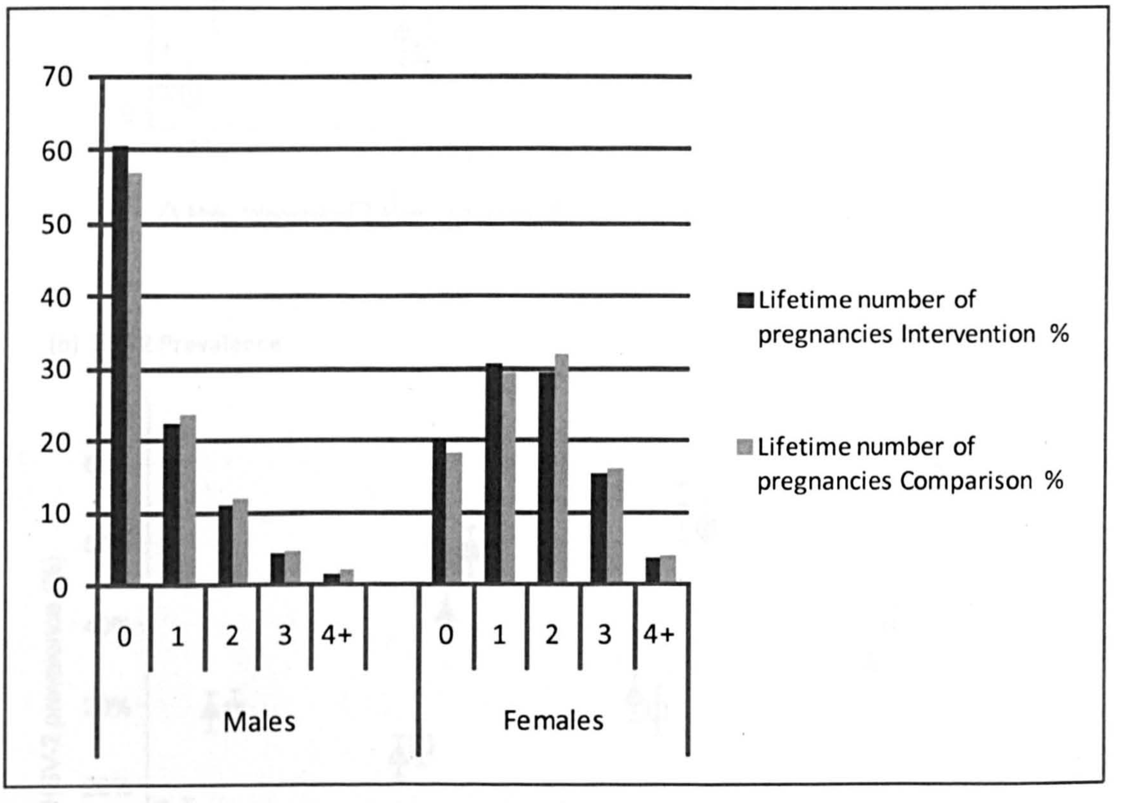


4.3.4 Impact on reported clinical and biological outcomes

Prevalence of reported genital ulcers, and, especially, reported genital discharge was very low. Although genital ulcers were reported less frequently by both sexes in the intervention communities, this was only borderline significant (Males aPR 0.76, CI 0.59,0.99; Females aPR 0.69, CI 0.47,1.01) ***(Table 4.9)***.

The distribution of lifetime pregnancies by sex and trial arm is show in ***Figure 4.6.*** There was no evidence of an association with exposure to the intervention and the reported outcomes related to pregnancy ***(Table 4.9)***.

Figure 4.6. Lifetime number of pregnancies by sex and trial arm

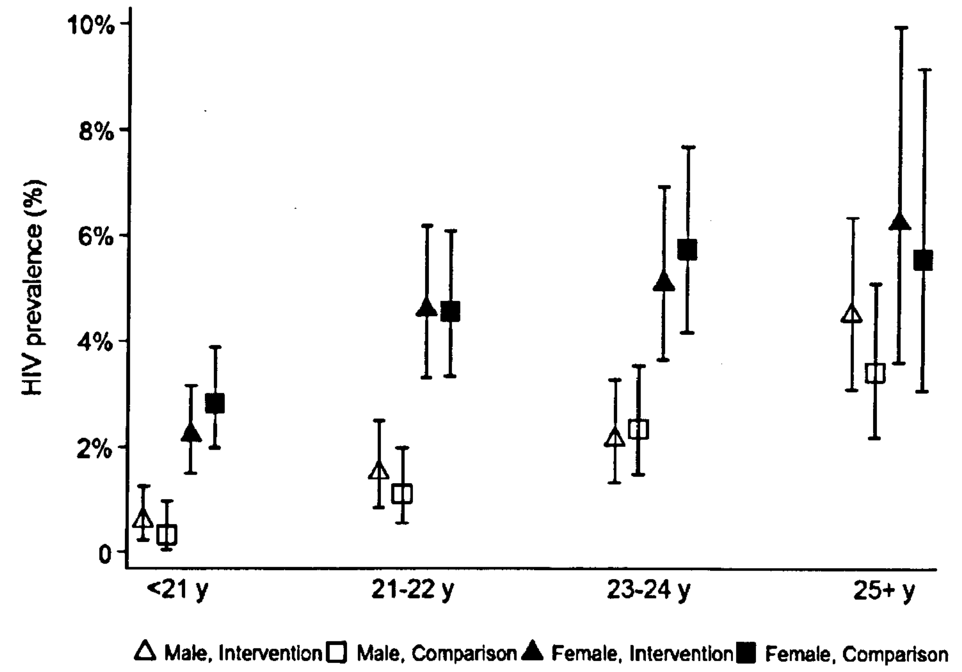


4.3.5 HIV & HSV2 prevalence by age, sex and arm

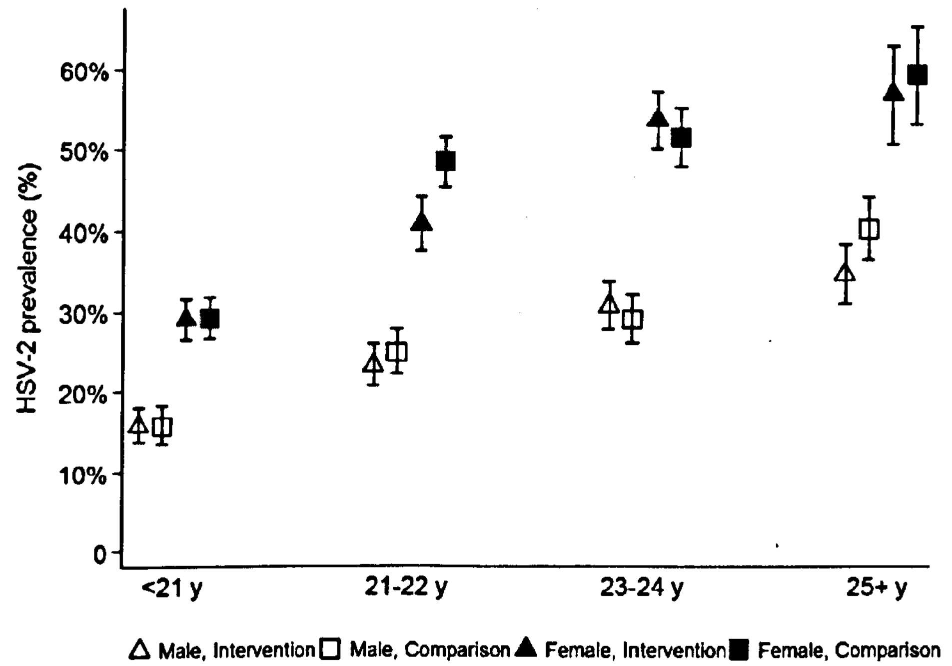
Figure 4.7 shows HIV and HSV2 prevalence by age, sex and trial arm. Males had a lower prevalence of both HIV and HSV2 prevalence compared to females. Prevalence of both HIV and HSV2 increased with age ***(Figure 4.7)***.

Figure 4.7. HIV and HSV2 prevalence and 95% confidence intervals, by sex, age group, and trial arm.

(a) HIV Prevalence



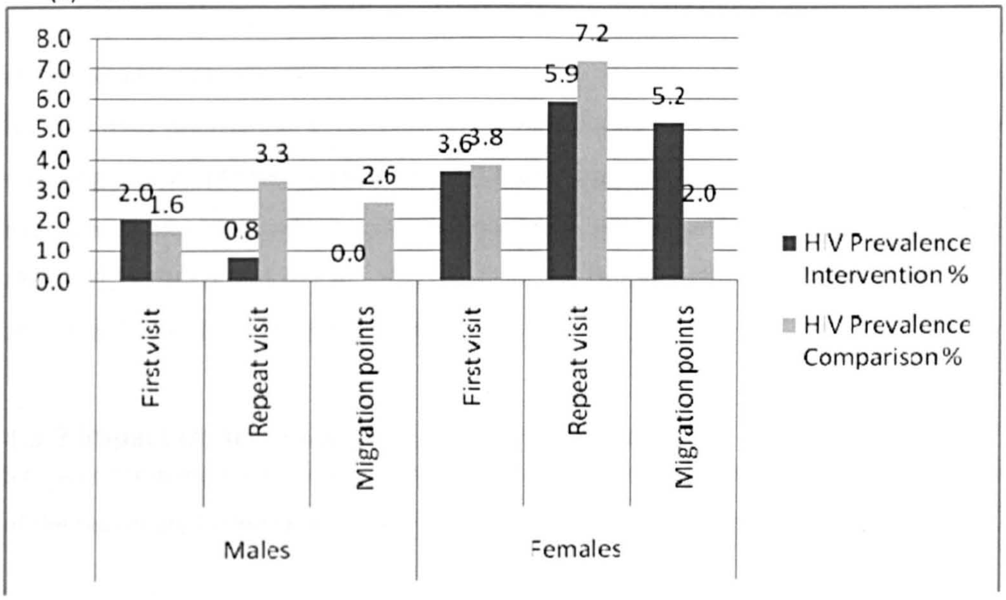
(b) HSV2 Prevalence



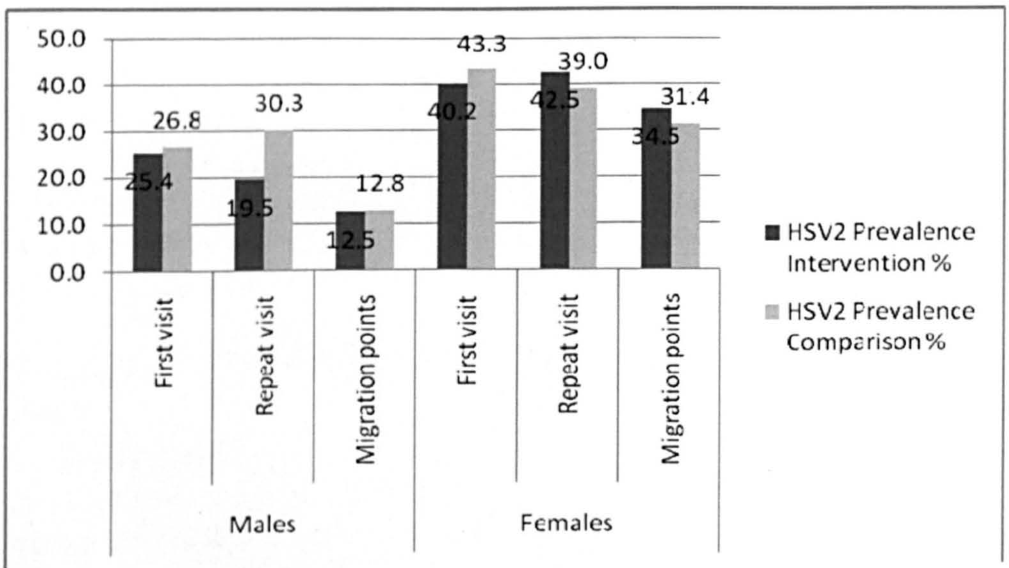
Young women interviewed during the repeat visits to the trial communities had a higher prevalence of HIV compared to those interviewed during the first visits to the communities and those interviewed at the migration points (p=0.0004) ***(Figure 4.8)***. Those interviewed at the migration points had the lowest level of HSV2 prevalence and the difference was particularly evident among males (females p=0.034, males p=0.0013) ***(Figure 4.8)***.

Figure 4.8. HIV and HSV2 prevalences by timing of interview, sex and trial arm.

(a) HIV



(b) HSV2



4.3.6 Impact on primary biological outcomes

The prevalence of the primary trial outcomes, HIV and HSV2, in the comparison communities were 1.7% and 26.7%, respectively, in males, and 4.2% and 42.5%, respectively, in females and were similar to the initial pre-survey estimates ***(Table 4.9)***. There was considerable variation in the prevalence of these outcomes between trial communities ***(Tables 4.10 and 4.11)***. Trial communities had been stratified as low, medium or high risk based on HIV prevalence in 15-19 year olds, as measured in the initial household survey in 1997, and on geographical characteristics of the communities e.g. remote rural villages were considered lower risk.[178] The stratum-specific HIV and HSV2 prevalences in 2007/8 suggest that these strata were not a good predictor of risk in the longer-term ***(Tables 4.10 and 4.11)***.There was no evidence of an association between exposure to the intervention and HIV prevalence (Males: aPR=0.91; 95%CI:0.50-1.65; Females: aPR=1.07, 95%CI:0.68-1.67) or HSV2 prevalence (Males: aPR=0.94, 95%CI:0.77-1.15; Females: aPR=0.96, 95%CI:0.87-1.06) ***(Tables 4.9-4.11)***.

4.3.7 Impact on secondary biological outcomes

Similarly, there were no evidence of an association between intervention exposure and prevalence of the secondary biological outcomes: syphilis, chlamydia or gonorrhoea ***(Table 4.9)***.

Table 4.10. HIV prevalence in 2007/8 according to trial arm, sex, community and strata

	HIV prevalence			
	Males		Females	
	Intervention	Comparison	Intervention	Comparison
HIV prevalence	74/3786 1.95	59/3473 1.70	126/3256 3.87	136/3220 4.22
Stratum 1 (LOW)	**1.10**	**1.84**	**4.07**	**4.11**
	0.32 (com 2)	2.33 (com 1)	4.04 (com 2)	3.21 (com 1)
	1.85 (com 9)	1.31 (com 4)	3.21 (com 9)	7.06 (com 4)
	1.01 (com 17)	1.95 (com 10)	4.64 (com 17)	1.69 (com 10)
Stratum 2 (MEDIUM)	**3.12**	**1.85**	**3.53**	**4.12**
	2.83 (com 3)	2.78 (com 6)	4.31 (com 3)	3.46 (com 6)
	3.78 (com 8)	1.26 (com 14)	3.08 (com 8)	1.58 (com 14)
	4.48 (com 12)	1.85 (com 16)	6.33 (com 12)	4.48 (com 16)
	1.52 (com 24)	1.74 (com 21)	3.02 (com 24)	6.46 (com 21)
Stratum 3 (HIGH)	**1.23**	**1.33**	**3.53**	**4.49**
	2.01 (com 5)	1.19 (com 13)	3.07 (com 5)	2.18 (com 13)
	0.23 (com 11)	1.23 (com 22)	2.76 (com 11)	6.11 (com 22)
	1.91 (com 18)	1.59 (com 23)	4.88 (com 18)	4.35 (com 23)
Geometric mean prevalence	**1.40%**	**1.70%**	**3.80%**	**3.60%**
Unadjusted PR	**0.87**		**1.06**	
95% CI	**0.47-1.62**		**0.67-1.68**	
Geometric mean O/E[1]	0.85	0.93	0.94	0.88
Adjusted PR	**0.91**		**1.07**	
95% CI	**0.50-1.65**		**0.68-1.67**	

[1] Expected numbers of HIV infections are calculated by logistic regression models fitted using data on individuals and including terms for sex, strata, age group (<21,21-22, 23-24,>=25) and tribe (Sukuma/non-Sukuma)

Table 4.11. HSV2 prevalence in 2007/8 according to trial arm, sex, community and strata

	HSV2 prevalence			
	Males		Females	
	Intervention	Comparison	Intervention	Comparison
HSV2 prevalence	948/3786 25.0	928/3473 26.7	1313/3256 40.3	1369/3220 42.5
Stratum 1 (LOW)	**25.2**	**28.3**	**40.9**	**45.8**
	16.8 (com 2)	29.7 (com 1)	39.8 (com 2)	48.2 (com 1)
	27.8 (com 9)	25.3 (com 4)	35.3 (com 9)	47.9 (com 4)
	28.5 (com 17)	30.3 (com 10)	45.4 (com 17)	41.4 (com 10)
Stratum 2 (MEDIUM)	**27.3**	**25.5**	**41.1**	**42.4**
	25.8 (com 3)	22.2 (com 6)	45.1 (com 3)	42.3 (com 6)
	33.3 (com 8)	24.7 (com 14)	37.5 (com 8)	38.6 (com 14)
	32.8 (com 12)	25.7 (com 16)	49.4 (com 12)	37.6 (com 16)
	17.7 (com 24)	28.7 (com 21)	35.2 (com 24)	51.4 (com 21)
Stratum 3 (HIGH)	**21.7**	**27.1**	**38.7**	**39.5**
	23.2 (com 5)	27.2 (com 13)	40.3 (com 5)	38.4 (com 13)
	16.7 (com 11)	29.6 (com 22)	35.6 (com 11)	42.8 (com 22)
	26.5 (com 18)	24.4 (com 23)	41.2 (com 18)	37.1 (com 23)
Geometric mean prevalence	**24.2%**	**26.7%**	**40.2%**	**42.3%**
Unadjusted PR	**0.91**		**0.95**	
95% CI	**0.74-1.11**		**0.85-1.07**	
Geometric mean O/E[1]	0.95	1.01	0.98	1.02
Adjusted PR	**0.94**		**0.96**	
95% CI	**0.77- 1.15**		**0.87-1.06**	

[1] Expected numbers of HIV infections are calculated by logistic regression models fitted using data on individuals and including terms for sex, strata, age group (<21,21-22, 23-24,>=25) and tribe (Sukuma/non-Sukuma)

4.3.8 Age difference between sexual partners

49% of the 6630 male participants who said they had ever had sex and who answered this question reported that their first sexual partner was younger than themselves ***(Table 4.12 (a))***. 64% of these younger partners were reported to be 2-4 years younger and 28% were 1 year or less than 1 year younger ***(Table 4.12 (b))***. Taking into account partners who were reported to be the same age or older, male participants reported that their first sexual partners were on average 1.0 years younger than themselves (median= 0 years, range -18, +15 years) ***(Table 4.13)***.

63% of the 6047 females who said that they had ever had sex and who answered this question reported that their first sexual partner was older in age ***(Table 4.14 (a))***. 58% of these younger partners were 2-4 years older, 15% were 1 year or less than 1 year older and 21% were 5-9 years older ***(Table 4.14 (b))***. Taking into account partners who were reported to be the same age or younger, female participants reported that their first sexual partners were on average 2.4 years older than themselves (median= 2 years, range -4, +26 years) ***(Table 4.13)***.

Table 4.12 Reported age difference between male participant & first sexual partner by trial arm.

(a) Age of first sexual partner relative to male participant's age[1]

	Intervention		Comparison		Total	
Age of first sexual partner relative to participant's age		%		%		%
Older	201	5.8	182	5.7	383	5.8
Younger	1671	48.5	1561	49.1	3232	48.8
Same age	1503	43.6	1371	43.1	2874	43.4
Not known	73	2.1	68	2.1	141	2.1
	3448		3182		6630	

[1] N=6 male participants where information on relative age of partner is not known or missing

(b) Number of years partner was reported to be younger than male participant[1]

	Intervention		Comparison		Total	
Number of years partner is younger than participant		%		%		%
1yr or less	473	29.1	417	27.5	890	28.4
2-4 yrs	1030	63.4	992	65.5	2022	64.4
5-9 yrs	114	7.0	101	6.7	215	6.9
10-14 yrs	4	0.3	1	0.1	5	0.2
15+ yrs	3	0.2	3	0.2	6	0.2
	1624		1514		3138	

[1] N=94 male participants where information on number of years younger is not known or missing

Table 4.13. Mean age difference (years) between participants and their first and most recent sexual partner according to partner type, sex and trial arm.

	Males (yrs)			Females (yrs)		
	Intervention	Comparison	Overall	Intervention	Comparison	Overall
First Sexual partner	**-1.0**	**-1.0**	**-1.0**	**2.4**	**2.4**	**2.4**
Most recent sexual partner in the last 12 months	**-2.3**	**-2.4**	**-2.4**	**4.0**	**4.0**	**4.0**
- Spouse	-3.3	-3.3	-3.4	4.5	4.5	4.5
- Other Regular Partner	-1.8	-2.0	-1.9	3.0	3.0	3.0
- Casual Partner	-1.5	-1.6	-1.5	2.6	2.8	2.7
		p<0.0001*			p<0.0001*	

*Association between partner type and age difference between participant
and partner type adjusted for community

The mean age difference between participants and their most recent sexual partner was reported to be 2 years younger by male participants and 4 years older by female participants. The age difference varied according to reported partner type, with casual partners being closest in age and the biggest age difference seen between participants and their spouses ***(Table 4.13)***.

Table 4.14. Age difference between female participant and their first partner by trial arm.

(a) Age of first sexual partner relative to female participants age[1]

	Intervention		Comparison		Total	
Age of first sexual partner relative to participants age		%		%		%
Older	1947	64.2	1880	62.3	3827	63.3
Younger	31	1.0	38	1.3	69	1.1
Same age	769	25.4	875	29.0	1644	27.2
Not known	284	9.4	223	7.4	507	8.4
	3031		3016		6047	

[1] N=5 female participants where information on relative age of partner is not known or missing

(b) Number of years partner is older than female participant[1]

	Intervention		Comparison		Total	
Number of years partner is older than participant		%		%		%
1yr or less	278	15.0	273	15.5	551	15.3
2-4 yrs	1102	59.6	998	56.8	2100	58.2
5-9 yrs	373	20.2	389	22.1	762	21.1
10-14 yrs	76	4.1	83	4.7	159	4.4
15+ yrs	20	1.1	14	0.8	34	0.9
	1849		1757		3606	

[1] N=221 male participants where information on number of years younger is not known or missing

4.4 Impact according to age group

4.4.1 Males

The impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence, was similar across all age groups ***(Table 4.15)***. Wide confidence intervals surround the estimates of relative risk for HIV prevalence and the variation seen in relative risk estimates across age groups is unlikely to indicate a real difference. Similarly, there was no evidence that the intervention impact on the secondary biological outcomes varied according to age group though some tendency towards increased risk of infection among younger participants in the intervention communities was observed.

The intervention impact on the 3 knowledge outcomes and the composite attitudes to sex outcome was similar across the age groups. There was strong evidence of intervention impact on the first individual attitude question (If a man wants to make love with a woman, can she refuse to make love with him if he is older than her?) decreasing with age (test for trend p-value 0.03) ***(Table 4.15)***.

Intervention impact on reported sexual behaviour was similar across age groups. Among the reported clinical and biological outcomes, evidence of a trend was seen only for the outcome 'Reported >= 1 unplanned pregnancy'. For this outcome the desired intervention impact was only seen in older age groups of males with males <21 years in intervention communities reporting higher numbers of unplanned pregnancies (test for trend p-value 0.02) ***(Table 4.15)***.

4.4.2 Females

In females, the impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence was similar across all age groups ***(Table 4.15)***. Similarly, there was no evidence that the intervention impact on the secondary biological outcomes varied according to age group though some tendency towards increased risk of Chlamydia infection among <21 year old females in the intervention communities was observed. Risk of Chlamydia infection was also higher among younger males in the intervention communities and weak evidence of a trend according to age group was seen when both sexes are combined (<21 yrs PR 1.74, 21-22 yrs PR 1.02, 23-24 yrs PR 0.81, 25+ yrs PR 1.02, test for trend p-value 0.07).

The intervention impact on the 3 knowledge outcomes and the composite attitudes to sex outcome was similar across the age groups. There was some evidence of intervention impact on the second and third individual attitude questions increasing with age (If a man wants to make love with a woman, can she refuse to make love with him if he is her lover? (test for trend p-value 0.06) and If a young woman accepts a gift from a man, must she agree to make love with him? (test for trend p-value 0.08)) ***(Table 4.15)***.

A trend in intervention impact according to age group was seen for a number of the reported sexual behaviour and clinical/biological outcomes. There was some evidence that the intervention led to a greater reduction in partners in the last 12 months among older females (test for trend p-value 0.06) and strong evidence of an increased use of condoms at last sex among the oldest females (test for trend p-value 0.005). Strong evidence of a trend in impact according to age group was seen for both of the concurrency measures: > 1 partner in the same time period in the last 12 months (test for trend p-value 0.04) and >1 partner in the past 4 weeks (test for trend p-value 0.03). Strong evidence of increased impact of the intervention among older ages was also seen for reported pregnancy while in primary school (test for trend p-value 0.0004) ***(Table 4.15)***.

Table 4.15: Impact of intervention on primary and secondary outcomes according to age group in 2007/8, Males and Females[1]

	Male					Female				
	Test for trend					Test for trend				
Outcome	**<21 yrs**	**21-22 yrs**	**23-24 yrs**	**25+ yrs**	**p-value**	**<21 yrs**	**21-22 yrs**	**23-24 yrs**	**25+ yrs**	**p-value**
Knowledge (% with all 3 responses "correct")										
HIV acquisition	1.12	1.11	1.07	1.13	0.8424	1.04	1.22	1.11	1.13	0.5654
STD acquisition	1.24	1.16	1.18	1.15	0.5064	1.14	1.42	1.22	1.23	0.9156
Pregnancy prevention	1.19	1.19	1.21	1.17	0.9722	1.14	1.19	1.20	1.23	0.2239
Reported Attitudes (% with all 3 responses "correct")										
Attitudes to sex[2]	1.24	1.23	1.32	1.23	0.8912	0.98	1.28	1.21	0.94	0.8813
Attitude 1	1.09	1.07	1.05	0.93	0.0339	1.02	1.04	1.03	0.97	0.7721
Attitude 2[2]	1.04	1.08	1.12	1.00	0.7990	0.93	1.03	1.19	1.46	0.0613
Attitude 3	1.10	1.13	1.12	1.21	0.2347	1.04	1.19	1.12	1.21	0.0848
Reported Sexual Behaviour (% with outcome)										
Age at first sex <16y	0.98	0.84	0.95	0.91	0.7695	0.99	0.99	1.06	1.18	0.4853
>2 (female) or >4 (male) lifetime sexual partners	0.86	0.80	0.88	0.91	0.4524	0.89	0.87	0.92	0.93	0.8930
>1 partner in last 12 months[2]	1.06	0.89	0.92	0.89	0.1773	1.05	0.93	0.93	0.66	0.0598
Used condom at last sex in past 12m[2,3]	1.21	1.12	1.23	1.12	0.7861	1.21	1.28	1.03	4.13	0.0051
Used condom at last sex in past 12m with non-regular partner[2,4]	1.19	1.10	1.16	1.08	0.5282	1.33	1.38	1.63	3.76	0.2098
Ever used modern contraceptive[5]	1.20	1.07	1.08	1.04	0.1339	1.09	1.12	1.05	1.42	0.3849
Used modern contraceptive at last sex[2,3,5]	1.21	1.11	1.24	1.20	0.8398	1.16	1.17	0.90	1.78	0.2627
>1 partner in same time period in past 12m[2]	1.05	0.82	0.93	0.89	0.4108	1.04	0.81	0.87	0.42	0.0381
>1 partner in past 4 weeks[2]	1.01	0.79	1.00	0.88	0.7824	1.50	0.93	0.81	0.09	0.0264
Went to health facility for most recent STI symptoms within past 12m[2,6]	1.09	1.17	1.41	1.05	0.8827	1.16	0.97	1.20	0.74	0.4180

(Key on next page)

Table 4.15 (CONTINUED): Impact of intervention on primary and secondary outcomes according to age group in 2007/8, Males and Females[1]

	Male					Female				
	Test for trend					Test for trend				
Outcome	<21 yrs	21-22 yrs	23-24 yrs	25+ yrs	p-value	<21 yrs	21-22 yrs	23-24 yrs	25+ yrs	p-value
Reported clinical/biological outcomes										
Genital discharge prevalence [6]	0.80	0.93	0.76	0.98	0.6591	0.72	0.79	0.50	0.82	0.9453
Genital ulcer prevalence [6]	0.88	0.85	0.62	0.81	0.5236	0.62	0.76	0.52	0.96	0.4000
>2 reported pregnancy (lifetime)[2]	0.24	1.04	1.01	0.91	0.1515	0.94	0.69	1.15	0.97	0.6249
Reported pregnancy while in primary school [2]	0.89	0.74	0.74	0.91	0.9148	2.53	0.93	0.95	0.66	0.0004
Reported ≥1 unplanned pregnancy	1.22	0.86	0.88	0.78	0.0207	1.01	0.97	1.13	1.03	0.8986
Primary biological outcomes										
HIV prevalence[2]	1.26 (0.20, 8.05)	1.18 (0.56, 2.50)	0.82 (0.47, 1.44)	1.43 (0.83, 2.46)	0.9276	0.86 (0.47, 1.55)	1.05 (0.56, 1.98)	0.98 (0.59, 1.62)	1.05 (0.55, 1.99)	0.5863
HSV-2 prevalence	1.04 (0.71, 1.52)	0.92 (0.70, 1.21)	1.01 (0.77, 1.32)	0.86 (0.72, 1.02)	0.3468	1.03 (0.83, 1.26)	0.84 (0.74, 0.96)	1.03 (0.95, 1.11)	1.02 (0.86, 1.20)	0.6799
Secondary biological outcomes										
"Lifetime" syphilis exposure (TPPA+)[2]	1.26	1.22	1.02	1.08	0.5420	0.85	0.83	0.89	0.85	0.9350
Active syphilis prevalence (TPPA+, RPR+)[2]	1.23	1.34	1.13	1.10	0.6962	0.78	0.92	0.88	0.90	0.7424
Chlamydia prevalence[2]	1.22	1.16	1.03	0.89	0.5238	2.19	0.88	0.57	2.38	0.8649
Gonorrhoea prevalence (Confirmed)[7]	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

1.Prevalence ratio adjusted for stratum and ethnic group (Sukuma vs non-Sukuma)

2. Analysis using arithmetic means

3. Among those who reported having had sex in past 12m

4. Among those who reported sex with a non-regular partner in past 12m

5. Modern contraceptive=condom, oral contraceptive pill, injectable contraceptive

6. Among those reporting STI symptom (genital discharge or ulcer) in past 12m

7. Subgroup analysis not done as too few cases ie less than 80 cases within each sex. The figure 80 is based on the number of subgroups ie 4 agegroups multiplied by the number of communities ie 20

4.5 Impact according to current marital status

4.5.1 Males

The impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence was similar for males who were currently married and not currently married ***(Table 4.16)***. Similarly, there was no evidence that the impact of the intervention on secondary biological outcomes varied according to current marital status

There was no evidence that intervention impact on the 3 knowledge outcomes and the composite attitudes to sex outcome varied according to current marital status. Strong evidence of greater intervention impact among males who were not currently married was seen for the first individual attitude question (Sex with older man, p-value 0.02). Some evidence of greater intervention impact among married men was seen for the third individual attitude question (Sex for gift, p-value 0.05) ***(Table 4.16)***.

Intervention impact on the reported sexual behaviour and reported clinical/biological outcomes was similar according to current marital status. Some evidence of greater impact of the intervention on lifetime number of pregnancies was seen among males who were not currently married (p-value 0.07) ***(Table 4.16)***.

4.5.2 Females

There was weak evidence that the intervention led to a reduction in HIV prevalence among females who were not currently married and an increase in HIV prevalence among married females (p-value 0.095). The intervention impact on HSV2 prevalence and the secondary biological outcomes was similar according to marital status ***(Table 4.16)***.

There was weak evidence that the intervention impact on the HIV acquisition knowledge score was greater among married females (p-value 0.08). There was no evidence that intervention impact on the other 2 knowledge outcomes and the composite attitudes to sex outcome varied according to current marital status. Strong evidence of greater intervention impact among currently married females was seen for the third individual attitude question (Sex for gift, p-value 0.009). When both sexes were combined there was strong evidence of greater impact of the intervention among those currently married on this third attitude question (married PR 1.17 (95% CI 1.08, 1.26), not married PR 1.07 (95% CI 0.99, 1.14), p-value 0.02) ***(Table 4.16)***.

There was some evidence of a greater impact on reduction in number of sexual partners among currently married females (p-value 0.04).There was also weak evidence that the intervention led to an increase in use of a health facility for the most recent STI symptoms among currently married females and a decrease in use among females who were not currently married (p-value 0.07) ***(Table 4.16)***.

Table 4.16: Impact of intervention on primary and secondary outcomes according to marital status in 2007-08, Males and Females [1]

Outcome	Male			Female		
	Currently married	Not currently married	T-test (p-value)	Currently married	Not currently married	T-test (p-value)
Knowledge (% with all 3 responses "correct")						
HIV acquisition	1.09 (0.94, 1.27)	1.12 (1.01, 1.24)	0.6262	1.14 (1.02, 1.29)	1.08 (0.98, 1.19)	0.0808
STD acquisition	1.11 (0.92, 1.33)	1.22 (1.05, 1.41)	0.3645	1.24 (0.91, 1.69)	1.24 (0.99, 1.54)	0.7341
Pregnancy prevention	1.21 (1.10, 1.33)	1.18 (1.10, 1.27)	0.6032	1.18 (1.04, 1.33)	1.17 (1.05, 1.29)	0.8138
Reported Attitudes (% with all 3 responses "correct")						
Attitudes to sex	1.44 (0.96, 2.16)	1.27 (0.95, 1.71)	0.5789	1.21 (0.66, 2.22)	0.99 (0.64, 1.54)	0.4425
Attitude 1 (Older)	0.96 (0.86, 1.07)	1.08 (0.96, 1.21)	0.0202	1.03 (0.90, 1.19)	1.00 (0.89, 1.12)	0.6520
Attitude 2 (Lover)	1.09 (0.91, 1.31)	1.08 (0.94, 1.23)	0.9839	1.09 (0.87, 1.36)	0.96 (0.72, 1.28)	0.1652
Attitude 3 (Gift)	1.20 (1.06, 1.37)	1.10 (0.98, 1.23)	0.0479	1.17 (1.00, 1.35)	1.03 (0.93, 1.15)	0.0091
Reported Sexual Behaviour (% with outcome)						
Age at first sex <16y	1.01 (0.77, 1.34)	0.88 (0.76, 1.02)	0.2976	0.97 (0.79, 1.18)	1.08 (0.74, 1.57)	0.1827
>2 (female) or >4 (male) lifetime sexual partners	0.89 (0.76, 1.03)	0.86 (0.76, 0.97)	0.5716	0.85 (0.72, 1.01)	0.97 (0.79, 1.18)	0.0405
>1 partner in last 12 m	0.91 (0.77, 1.08)	0.93 (0.77, 1.12)	0.6449	1.00 (0.63, 1.58)	0.98 (0.81, 1.19)	0.8319
Used condom at last sex in past 12m[3]	1.21 (0.81, 1.81)	1.18 (0.98, 1.43)	0.9388	1.03 (0.61, 1.73)	1.25 (0.99, 1.57)	0.8747
Used condom at last sex in past 12m with non-regular partner[2, 4]	1.08 (0.88, 1.32)	1.16 (0.98, 1.38)	0.4466	1.19 (0.65, 2.20)	1.36 (1.06, 1.74)	0.6240
Ever used modern contraceptive[5]	1.06 (0.89, 1.26)	1.12 (0.97, 1.30)	0.3661	1.06 (0.86, 1.31)	1.15 (1.01, 1.30)	0.3118
Used modern contraceptive at last sex[3,5]	1.29 (0.89, 1.86)	1.19 (0.97, 1.47)	0.7204	1.04 (0.75, 1.44)	1.16 (0.92, 1.47)	0.5244
>1 partner in same time period in past 12m	0.89 (0.75, 1.05)	0.91 (0.72, 1.16)	0.6756	0.89 (0.55, 1.46)	0.89 (0.66, 1.19)	0.8127
>1 partner in past 4 wk[2]	0.82 (0.63, 1.06)	0.98 (0.66, 1.45)	0.2541	1.12 (0.51, 2.46)	0.97 (0.53, 1.76)	0.7624
Went to health facility for most recent STI symptoms within past 12m[2,6]	1.25 (0.96, 1.62)	1.12 (0.83, 1.51)	0.4679	1.14 (0.79, 1.66)	0.75 (0.51, 1.11)	0.0731

Table 4.16 (CONTINUED): Impact of intervention on primary and secondary outcomes according to marital status in 2007-08, Males and Females [1]

Outcome	Male			Female		
	Currently married	Not currently married	T-test (p-value)	Currently married	Not currently married	T-test (p-value)
Reported clinical/biological outcomes						
Genital discharge prevalence	0.84 (0.59, 1.19)	0.89 (0.63, 1.24)	0.9374	0.7 (0.40, 1.20)	0.68 (0.39, 1.17)	0.4371
Genital ulcer prevalence	0.73 (0.58, 0.92)	0.79 (0.53, 1.17)	0.4086	0.74 (0.49, 1.12)	0.62 (0.41, 0.94)	0.2678
>2 reported pregnancy (lifetime)[2]	0.96 (0.76, 1.21)	0.65 (0.38, 1.12)	0.0676	0.99 (0.85, 1.16)	0.78 (0.56, 1.09)	0.1321
Reported pregnancy while in primary school[2]	0.73 (0.43, 1.24)	0.89 (0.54, 1.47)	0.5464	1.09 (0.62, 1.92)	1.35 (0.65, 2.77)	0.5717
Reported ≥1 unplanned pregnancy	0.81 (0.59, 1.10)	0.92 (0.76, 1.12)	0.2457	1.03 (0.75, 1.41)	1.04 (0.80, 1.34)	0.8745
Primary biological outcomes						
HIV prevalence[2]	1.18 (0.64, 2.15)	1.17 (0.66,2.08)	0.9941	1.16 (0.70, 1.93)	0.83 (0.54, 1.26)	0.0953
HSV-2 prevalence	0.96 (0.79, 1.16)	0.96 (0.77, 1.19)	0.9871	0.96 (0.87, 1.06)	1.00 (0.85, 1.18)	0.4030
Secondary biological outcomes						
"Lifetime" syphilis exposure (TPPA+)	0.89 (0.54, 1.47)	1.17 (0.80, 1.71)	0.2315	0.90 (0.63, 1.29)	0.81 (0.50, 1.30)	0.7723
Active syphilis prevalence (TPPA+, RPR+)	1.00 (0.64, 1.56)	1.23 (0.68, 2.22)	0.5971	0.95 (0.66, 1.36)	0.80 (0.47, 1.35)	0.7551
Chlamydia prevalence[2]	1.03 (0.49, 2.16)	1.04 (0.62, 1.75)	0.9720	1.17 (0.69, 1.97)	1.31 (0.83, 2.07)	0.6949
Gonorrhoea prevalence (confirmed)[7]	NA	NA	NA	NA	NA	NA

1.Prevalence ratio adjusted for age group, stratum and ethnic group (Sukuma vs non-Sukuma)
2. Analysis using arithmetic means
3. Among those who reported having had sex in past 12m
4. Among those who reported having ever had sex with a non-regular partner in past 12m
5. Modern contraceptive = condom, oral contraceptive pill, injectable contraceptives
6. Among those reporting STI symptoms (genital discharge or genital ulcer) within past 12m
7. Subgroup analysis not done as too few cases ie less than 40 cases within each sex.
The figure 40 is based on the number of subgroups ie 2 multiplied by the number of communities ie 20

4.6 Impact according to number of years of exposure to the in-school component of the intervention (1999-2004)

There was little difference in intervention impact according to the number of years of exposure (1999-2004) to the in-school component of the intervention. However, where there was evidence of a trend this was almost always in the expected direction i.e. greater beneficial impact among those with increased exposure to the intervention.

4.6.1 Males

In males, no increased or decreased impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence, was seen with increasing years exposure to the in-school intervention between 1999 and 2004. Similarly, there was no evidence that the impact of the intervention on secondary biological outcomes varied according to exposure to the intervention ***(Table 4.17)***.

There was no evidence that intervention impact on the 3 knowledge outcomes and the composite attitudes to sex outcome varied according to years of exposure to the intervention. There was strong evidence of increased intervention impact among those who had received either two or three years of the in-school intervention for the second individual attitude question (Sex with lover, p-value 0.03) ***(Table 4.17)***.

Intervention impact on almost all the reported sexual behaviour and reported clinical/biological outcomes was similar according to years of exposure to the intervention. There was weak evidence that increased years of exposure to the intervention led to a greater impact of the intervention on reported use of condom at last sex with a non-regular partner (test for trend p-value 0.10). Strong evidence of an increase in the impact of the intervention with increasing years exposure to the intervention was seen for reported use of a modern contraceptive (test for trend p-value 0.04) ***(Table 4.17)***.

4.6.2 Females

In females, no increased or decreased impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence, was seen with increasing years exposure to the in-school intervention. Similarly, there was no evidence that the impact of the intervention on secondary biological outcomes varied according to years of exposure to the intervention ***(Table 4.17)***.

Similarly, there was no evidence that intervention impact on the 3 knowledge outcomes varied according to years of exposure to the intervention. There was strong evidence of increased intervention impact among those who received either two or three years of the in-school intervention for the composite attitude outcome (test for trend, p-value 0.01) ***(Table 4.17)***. When both sexes were combined there was weak evidence of increasing impact of the intervention on the composite sexual attitudes score with increasing exposure to the intervention (1 yr aRR 1.04 (95% CI 0.73, 1.48); 2 yrs aRR 1.30 (95% CI 0.99, 1.70); 3 yrs aRR 1.27 (95% CI 0.97, 1.66), p-value 0.05). Intervention impact on almost all the reported sexual behaviour and reported clinical/biological outcomes was similar according to years of exposure to the intervention. The impact of the intervention on reported use of condom at last sex decreased as years of exposure to the intervention increased (test for trend, p-value 0.02) ***(Table 4.17)***.

Table 4.17: Impact of intervention on primary and secondary outcomes in 2007/8 according to number of years exposure to in-school intervention (1999-2004),Males and Females [1]

Outcome	Male				Female			
	Yrs of in-school intervention (99-04)				Yrs of in-school intervention (99-04)			
	1 yr	2 yrs	3+ yrs	Test for trend (p-value)	1 yr	2 yrs	3+ yrs	Test for trend (p-value)
Knowledge (% with all 3 responses "correct")								
HIV acquisition	1.08	1.14	1.11	0.7651	1.12	1.10	1.12	0.9934
STD acquisition	1.17	1.18	1.19	0.7610	1.18	1.33	1.24	0.5610
Pregnancy prevention	1.15	1.18	1.20	0.1876	1.13	1.19	1.18	0.3301
Reported Attitudes (% with all 3 responses "correct")								
Attitudes to sex[2]	1.11	1.34	1.30	0.1530	0.73	1.30	1.12	0.0139
Attitude 1 (Older)	0.98	1.04	1.06	0.2580	1.03	0.88	1.05	0.9196
Attitude 2 (Lover)	0.94	1.12	1.10	0.0286	0.97	1.31	0.99	0.5850
Attitude 3 (Gift)	1.15	1.19	1.10	0.7831	1.06	1.15	1.11	0.4097
Reported Sexual Behaviour (% with outcome)								
Age at first sex <16y	0.89	1.02	0.90	0.6492	1.06	1.05	1.01	0.7157
>2 (female) or >4 (male) lifetime sexual partners	0.91	0.89	0.83	0.2951	0.82	0.92	0.89	0.4050
>1 partner in last 12 months	0.94	0.86	0.93	0.8969	1.12	0.67	1.01	0.5662
Used condom at last sex in past 12m[2,3]	1.14	1.13	1.19	0.6959	1.66	1.43	1.17	0.0196
Used condom at last sex in past 12m with non-regular partner[2, 4]	1.00	1.08	1.20	0.0979	2.17	1.36	1.27	0.2651
Ever used modern contraceptive[5]	1.01	1.00	1.15	0.0411	1.06	1.13	1.10	0.8668
Used modern contraceptive at last sex[3,5]	1.23	1.21	1.21	0.8186	1.19	1.14	1.16	0.6149
>1 partner in same time period in past 12m[2]	0.90	0.89	0.92	0.8359	0.90	0.72	0.97	0.8236
>1 partner in past 4 weeks[2]	0.89	0.76	0.97	0.4806	0.49	0.59	1.42	0.1958
Went to health facility for most recent STI symptoms within past 12m[2,6]	1.04	1.17	1.19	0.4135	0.69	1.33	1.04	0.2046

(Key on next page)

Table 4.17 (CONTINUED): Impact of intervention on primary and secondary outcomes in 2007/8 according to number of years exposure to in-school intervention (1999-2004),Males and Females[1]

Outcome	Male: Yrs of in-school intervention (99-04) 1 yr	2 yrs	3+ yrs	Test for trend (p-value)	Female: Yrs of in-school intervention (99-04) 1 yr	2 yrs	3+ yrs	Test for trend (p-value)
Reported clinical/biological outcomes								
Genital discharge prevalence[2]	0.98	1.00	0.78	0.2759	0.66	0.56	0.73	0.6452
Genital ulcer prevalence[2]	0.70	0.81	0.79	0.6607	0.60	0.49	0.76	0.4343
>2 reported pregnancy (lifetime)	1.04	0.95	0.86	0.3635	1.04	0.94	0.86	0.2341
Reported pregnancy while in primary school[2]	0.85	0.91	0.71	0.5939	0.83	1.31	1.05	0.6527
Reported ≥1 unplanned pregnancy	0.87	0.87	0.88	0.4855	1.18	0.94	1.02	0.4268
Primary biological outcomes								
HIV prevalence[2]	1.27	1.13	1.03	0.4665	1.09	0.92	0.98	0.7355
HSV-2 prevalence	0.88	0.88	0.99	0.1278	0.95	0.95	0.97	0.6588
Secondary biological outcomes								
"Lifetime" syphilis exposure (TPPA+)[2]	1.03	1.01	1.22	0.4058	0.78	0.75	0.89	0.6635
Active syphilis prevalence (TPPA+, RPR+)[2]	1.31	0.96	1.23	0.8685	0.71	0.85	0.92	0.3810
Chlamydia prevalence[2]	1.35	0.62	1.00	0.2504	0.93	0.77	1.44	0.3957
Gonorrhoea prevalence (confirmed)[7]	NA	NA	NA	NA	NA	NA	NA	NA

1.Prevalence ratio adjusted for age group, stratum and ethnic group (Sukuma vs non-Sukuma)
2. Analysis using arithmetic means
3. Among those who reported having had sex in past 12m
4. Among those who reported having ever had sex with a non-regular partner in past 12m
5. Modern contraceptive = condom, oral contraceptive pill, injectable contraceptives
6. Among those reporting STI symptoms (genital discharge or genital ulcer) within past 12m
7. Subgroup analysis not done as too few cases ie less than 60 cases within each sex. The figure 60 is based on the number of subgroups ie 3 multiplied by the number of communities ie 20

4.7 Impact according to number of years of exposure to the in-school component of the intervention (1999-2002)

A further analysis was conducted of the relationship between intervention impact and the number of years of exposure to the in-school component of the intervention. This analysis was limited to intervention exposure during the period 1999-2002 when the interventions were most closely supervised and supported by the AMREF and District teams.

4.7.1 Males

In males, there is strong evidence that the impact of the intervention on HIV prevalence varied according to number of years of exposure to the intervention between 1999 and 2002 (test for trend p-value 0.02). However, it is important to note that although the aPRs ranged from 1.52 for 1 year of exposure during this period to 0.79 a similar trend was not seen for other biological outcomes ***(Table 4.18)***.

There is very strong evidence that the intervention impact on the pregnancy prevention knowledge score increased with increasing number of years of exposure to the in-school intervention (test for trend p-value 0.0001), though the intervention was associated with benefit at all levels of exposure. There was no evidence that intervention impact on the other 2 knowledge outcomes or on the composite attitudes to sex outcome varied according to years of exposure to the intervention. Weak evidence was seen of an increasing impact of the intervention with increasing years of exposure to the intervention on the second attitude question (Sex with lover, p-value 0.09) ***(Table 4.18)***.

Intervention impact on the reported sexual behaviour and reported clinical/biological outcomes was similar according to years of exposure to the intervention ***(Table 4.18)***.

4.7.2 Females

In females, no increased or decreased impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence, was seen with increasing years exposure to the in-school intervention. Similarly, there was no evidence that the impact of the intervention on secondary biological outcomes varied according to years of exposure to the intervention ***(Table 4.18)***.

As among males, there was strong evidence that the intervention impact on the pregnancy prevention knowledge score increased with increasing number of years of exposure to the in-school intervention (test for trend p-value 0.04). When both sexes were combined, the evidence of increasing impact of the intervention on pregnancy prevention knowledge according to years of exposure was very strong (test for trend p-value 0.0001). There was no evidence that intervention impact on the other 2 knowledge outcomes varied according to years of exposure to the intervention. There was strong evidence of increased impact of the intervention on the composite attitudes to sex outcome with increasing exposure to the intervention. When both sexes were combined, the evidence of increasing impact of the intervention on the composite attitudes to sex outcome according to years of exposure was very strong (test for trend p-value 0.0007). Weak evidence was seen of an increasing impact of the intervention with increasing years of exposure to the intervention on the third attitude question (Sex for gift, p-value 0.07) ***(Table 4.18)***.

Intervention impact on almost all the reported sexual behaviour and reported clinical/biological outcomes was similar according to years of exposure to the intervention. There is weak evidence that the impact of the intervention on the number of unplanned pregnancies varied according to years of exposure to the intervention with the intervention leading to the desired decrease in such pregnancies only in those who had received at least 3 years of the in-school intervention (test for trend p-value 0.05) ***(Table 4.18)***.

Table 4.18: Impact of intervention on primary and secondary outcomes in 2007/8 according to number of years exposure to in-school intervention (1999-2002),Males and Females[1]

Outcome	Male				Female			
	Yrs of in-school intervention (99-02)				Yrs of in-school intervention (99-02)			
	1 yr	2 yrs	3+ yrs	Test for trend (p-value)	1 yr	2 yrs	3+ yrs	Test for trend (p-value)
Knowledge (% with all 3 responses "correct")								
HIV acquisition	1.09	1.11	1.12	0.5092	1.11	1.11	1.12	0.9424
STD acquisition	1.19	1.20	1.16	0.7364	1.22	1.21	1.32	0.2948
Pregnancy prevention	1.13	1.19	1.25	0.0001	1.12	1.20	1.19	0.0338
Reported Attitudes (% with all 3 responses "correct")								
Attitudes to sex	1.24	1.32	1.38	0.1237	0.76	1.22	1.27	0.0061
Attitude 1 (Older)	1.02	1.08	1.04	0.8215	1.07	0.95	1.05	0.6886
Attitude 2 (Lover)	1.02	1.10	1.11	0.0884	0.92	1.12	1.10	0.2023
Attitude 3 (Gift)	1.12	1.10	1.14	0.5063	1.07	1.09	1.15	0.0695
Reported Sexual Behaviour (% with outcome)								
Age at first sex <16y	0.92	0.91	0.92	0.8472	1.04	1.04	0.97	0.2564
>2 (female) or >4 (male) lifetime sexual partners	0.88	0.92	0.81	0.3904	0.90	0.92	0.85	0.5622
>1 partner in last 12 months	0.94	0.92	0.90	0.7243	1.17	0.81	1.01	0.1064
Used condom at last sex in past 12m[3]	1.13	1.16	1.26	0.2130	1.25	1.08	1.52	0.1918
Used condom at last sex in past 12m with non-regular partner[2, 4]	1.07	1.13	1.21	0.1205	1.42	1.33	1.50	0.7888
Ever used modern contraceptive[5]	1.08	1.10	1.10	0.7850	1.09	1.10	1.14	0.3894
Used modern contraceptive at last sex[3,5]	1.18	1.18	1.28	0.2815	1.11	1.04	1.29	0.1363
>1 partner in same time period in past 12m	0.91	0.91	0.88	0.9925	1.03	0.72	0.87	0.1556
>1 partner in past 4 weeks[2]	0.88	0.84	0.95	0.6111	1.15	0.72	1.48	0.6142
Went to health facility for most recent STI symptoms within past 12m[2,6]	1.06	1.15	1.34	0.2223	1.01	0.99	0.94	0.5148

(Key on next page)

Table 4.18 (CONTINUED): Impact of intervention on primary and secondary outcomes in 2007/8 according to number of years exposure to in-school intervention (1999-2002),Males and Females[1]

Outcome	Male: Yrs of in-school intervention (99-02) 1 yr	2 yrs	3+ yrs	Test for trend (p-value)	Female: Yrs of in-school intervention (99-02) 1 yr	2 yrs	3+ yrs	Test for trend (p-value)
Reported clinical/biological outcomes								
Genital discharge prevalence[2]	0.93	0.94	0.73	0.3013	0.63	0.66	0.79	0.4118
Genital ulcer prevalence[2]	0.91	0.81	0.63	0.1871	0.61	0.63	0.80	0.3367
>2 reported pregnancy (lifetime)	1.00	1.00	0.91	0.5895	1.06	0.95	0.81	0.1099
Reported pregnancy while in primary school[2]	0.63	0.87	0.94	0.3625	1.17	1.39	0.84	0.3187
Reported ≥1 unplanned pregnancy	0.85	0.89	0.91	0.3383	1.13	1.04	0.94	0.0494
Primary biological outcomes								
HIV prevalence[2]	1.52	1.20	0.79	0.0214	0.92	0.93	1.08	0.5665
HSV-2 prevalence	0.94	0.93	0.95	0.9694	0.99	0.93	0.97	0.8192
Secondary biological outcomes								
"Lifetime" syphilis exposure (TPPA+)	0.94	1.17	1.04	0.7197	1.02	0.67	1.01	0.8417
Active syphilis prevalence (TPPA+, RPR+)[2]	1.42	1.07	1.09	0.3123	0.95	0.77	0.93	0.9568
Chlamydia prevalence[2]	1.25	0.82	1.09	0.6333	1.45	1.31	0.88	0.2014
Gonorrhoea prevalence (confirmed)[7]	NA	NA	NA	NA	NA	NA	NA	NA

1.Prevalence ratio adjusted for age group, stratum and ethnic group (Sukuma vs non-Sukuma)
2. Analysis using arithmetic means
3. Among those who reported having had sex in past 12m
4. Among those who reported having ever had sex with a non-regular partner in past 12m
5. Modern contraceptive = condom, oral contraceptive pill, injectable contraceptives
6. Among those reporting STI symptoms (genital discharge or genital ulcer) within past 12m
7. Subgroup analysis not done as too few cases ie less than 60 cases within each sex. The figure 60 is based on the number of subgroups ie 3 multiplied by the number of communities i.e. 20

4.8 Impact according to number of years since last exposure to the in-school component of the intervention

There was little evidence that intervention impact varied according to the number of years since last exposure to the in-school intervention. Where there was evidence of a trend, intervention impact was, in most cases, weakest among those who received the intervention most recently.

4.8.1 Males

In males, no increased or decreased impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence, was seen with length of time since last exposure to the in-school intervention ***(Table 4.19)***. There was a much higher risk to those from an intervention community both of lifetime exposure to syphilis and of active syphilis, in the sub-group who had last exposure to the intervention 3-4 years prior to the survey as compared to those with more distant exposure and the test for trend was significant for exposure to syphilis in their lifetime (test for trend p-value 0.04). There was no evidence that the impact of the intervention on Chlamydia varied according to years since last exposure to the intervention.

There was no evidence that intervention impact on the 3 knowledge outcomes or the composite attitudes to sex outcome varied according to years since last exposure to the intervention. Evidence of reduced intervention impact among those who received the in-school intervention more recently was seen for the third individual attitude question only (Sex for gift, test for trend p-value 0.04) ***(Table 4.19)***.

Intervention impact on almost all the reported sexual behaviour and reported clinical/biological outcomes was similar according to years since last exposure to the intervention. There is evidence that the impact of the intervention on use of modern contraceptives decreased with an increase in years since last exposure to the intervention (test for trend p-value 0.04). There is weak evidence that the impact of the intervention on reported pregnancies while in primary school decreased with an increase in years since last exposure to the intervention (test for trend p-value 0.09) ***(Table 4.19)***.

4.8.2 Females

Among females, no increased or decreased impact of the intervention on the primary biological outcomes, HIV and HSV2 prevalence, was seen with length of time since last exposure to the in-school intervention. There is strong evidence that increasing years since last exposure to the intervention was inversely associated with risk of chlamydia (test for trend p-value 0.03). There was no evidence that the impact of the intervention on syphilis varied according to years since last exposure to the intervention ***(Table 4.19)***.

There was no evidence that intervention impact on the 3 knowledge outcomes or the composite attitudes to sex outcome varied according to years since last exposure to the intervention. Strong evidence of reduced intervention impact among those who received the in-school intervention more recently was seen for the second individual attitude question (Sex with lover, test for trend p-value 0.03) ***(Table 4.19)***.

Intervention impact on almost all the reported sexual behaviour and reported clinical/biological outcomes was similar according to years since last exposure to the intervention. Very strong evidence of an increase in intervention impact with increasing time since last exposure to the intervention was seen for reported use of condom at last sex (test for trend p-value 0.006) ***(Table 4.19)***.

Table 4.19: Impact of intervention on primary and secondary outcomes according to number of years since last exposure to in-school intervention,Males and Females, in 2007/8 [1]

Outcome	Male: Yrs since last exposed to in-school intervention 3-4 yrs	5-6 yrs	7-8 yrs	Test for trend (p-value)	Female: Yrs since last exposed to in-school intervention 3-4 yrs	5-6 yrs	7-8 yrs	Test for trend (p-value)
Knowledge (% with all 3 responses "correct")								
HIV acquisition	1.12	1.12	1.11	0.9934	1.12	1.12	1.11	0.9219
STD acquisition	1.21	1.18	1.17	0.7726	1.17	1.32	1.26	0.4995
Pregnancy prevention	1.17	1.24	1.17	0.9667	1.17	1.19	1.16	0.7840
Reported Attitudes (% with all 3 responses "correct")								
Attitudes to sex	1.29	1.36	1.31	0.8302	0.98	1.22	0.90	0.9928
Attitude 1 (Older)	1.09	1.04	1.02	0.2634	1.05	1.04	0.98	0.3809
Attitude 2 (Lover)	1.10	1.10	1.04	0.3905	0.92	1.08	1.15	0.0254
Attitude 3 (Gift)	1.06	1.13	1.19	0.0382	1.08	1.14	1.10	0.7317
Reported Sexual Behaviour (% with outcome)								
Age at first sex <16y	0.89	0.96	0.91	0.9827	1.07	0.99	1.03	0.5492
>2 (female) or >4 (male) lifetime sexual partners	0.89	0.82	0.90	0.8626	0.99	0.85	0.87	0.1236
>1 partner in last 12 months	0.98	0.90	0.91	0.3668	1.05	1.02	0.95	0.8730
Used condom at last sex in past 12m[3]	1.12	1.25	1.19	0.5796	1.03	1.56	1.62	0.0059
Used condom at last sex in past 12m with non-regular partner[2, 4]	1.16	1.19	1.08	0.3953	1.18	1.62	1.48	0.2242
Ever used modern contraceptive[5]	1.19	1.10	1.03	0.0364	1.07	1.14	1.11	0.5833
Used modern contraceptive at last sex[3,5]	1.11	1.29	1.25	0.4017	1.04	1.30	1.13	0.5143
>1 partner in same time period in past 12m	0.95	0.88	0.91	0.8180	1.11	0.86	0.70	0.4096
>1 partner in past 4 weeks[2]	0.98	0.93	0.82	0.3412	1.36	1.27	0.58	0.1191
Went to health facility for most recent STI symptoms within past 12m[2,6]	1.06	1.27	1.22	0.3973	1.19	0.81	0.94	0.4980

(Key on next page)

Table 4.19 (CONTINUED): Impact of intervention on primary and secondary outcomes according to number of years since last exposure to in-school intervention,Males and Females, in 2007/8 [1]

Outcome	Male				Female			
	Yrs since last exposed to in-school intervention				Yrs since last exposed to in-school intervention			
	3-4 yrs	5-6 yrs	7-8 yrs	Test for trend (p-value)	3-4 yrs	5-6 yrs	7-8 yrs	Test for trend (p-value)
Reported clinical/biological outcomes								
Genital discharge prevalence[2]	0.88	0.69	1.01	0.4255	0.70	0.82	0.61	0.5324
Genital ulcer prevalence	1.18	0.58	0.77	0.1217	0.71	0.83	0.43	0.1578
>2 reported pregnancy (lifetime)[2]	0.87	0.80	1.00	0.6712	1.70	0.86	0.99	0.1371
Reported pregnancy while in primary school[2]	0.55	0.94	0.86	0.0890	1.72	0.86	0.97	0.1967
Reported ≥1 unplanned pregnancy	0.84	0.90	0.87	0.6180	1.16	0.91	1.07	0.3906
Primary biological outcomes								
HIV prevalence[2]	2.34	0.78	1.18	0.2558	0.92	1.13	0.99	0.8826
HSV-2 prevalence	1.05	0.94	0.90	0.2154	0.98	0.97	0.95	0.6900
Secondary biological outcomes								
"Lifetime" syphilis exposure (TPPA+)2	1.92	0.94	1.05	0.0369	0.98	0.90	0.77	0.4388
Active syphilis prevalence (TPPA+, RPR+)[2]	1.83	1.01	1.11	0.1282	1.06	0.92	0.79	0.4149
Chlamydia prevalence[2]	1.01	1.14	0.99	0.9610	2.56	0.85	0.94	0.0326
Gonorrhoea prevalence (confirmed)[7]	NA	NA	NA	NA	NA	NA	NA	NA

1.Prevalence ratio adjusted for age group, stratum and ethnic group (Sukuma vs non-Sukuma)
2. Analysis using arithmetic means
3. Among those who reported having had sex in past 12m
4. Among those who reported having ever had sex with a non-regular partner in past 12m
5. Modern contraceptive = condom, oral contraceptive pill, injectable contraceptives
6. Among those reporting STI symptoms (genital discharge or genital ulcer) within past 12m
7. Subgroup analysis not done as too few cases ie less than 60 cases within each sex. The threshold of 60 was chosen based on the number of subgroups (3) multiplied by the number of communities (20)

4.9 Comparison with 2001/2 impact evaluation results

The results of the impact evaluation of the intervention in 2001/2 and in 2007/8 are compared in *Table 4.20.*

4.9.1 Impact on Knowledge

In both 2001/2 and 2007/8 correct knowledge was higher in the intervention communities and there was evidence of an intervention impact ***(Table 4.20)***. Knowledge levels were higher in 2007/8, however the relative and absolute impact of the intervention on knowledge was greater in 2001/2. This was largely because knowledge had improved substantially among young people in the comparison communities, who had therefore largely caught up with their contemporaries from the intervention communities. Knowledge of HIV acquisition increased between 2001/2 and 2007/8 by ~ 20% in the intervention communities and ~ 50% in the comparison communities. Between 2001/2 and 2007/8 levels of STD acquisition knowledge increased by ~ 5% in the intervention communities and 15-20% in comparison communities. A slight, but nowhere near statistically significant decrease in pregnancy knowledge was seen in the intervention communities between 2001/2 and 2007/8 (males 84% to 83%; females 72% to 71%). By contrast, there was a 38% increase in knowledge of pregnancy prevention among males in the comparison communities and a 30% increase among females.

4.9.2 Impact on reported attitudes to sexual risk

In both 2001/2 and 2007/8 desired attitudes to sex were higher in the intervention communities and there was evidence of an association with exposure to the intervention for each outcome in 2001/2 and among males only in 2007/8 ***(Table 4.20)***. Desired attitudes to sex increased in relative terms by 27% among intervention males and 83% among comparison males between 2001/2 and 2007/8. However, desired attitudes to sex decreased by 59% among intervention females and 47% among comparison females.

4.9.3 Reported sexual behaviour

Early sexual debut was measured as 'Sexual debut during follow-up' in 2001/2 and 'Age at first sex < 16 years' in 2007/8. There was no evidence of intervention impact on either of these outcomes ***(Table 4.20)***. Between the two survey rounds, the proportion of males reporting multiple partners in the previous year increased from 19% to 41% in intervention and 28% to 45% in comparison communities. The proportion of females reporting multiple partners only increased slightly between the two surveys. In 2001/2 there was strong evidence that the intervention led to a reduction in the proportion of males who reported more than one sexual partner in the last 12 months, but this was no longer present in 2007/8. There was no evidence of a decrease in multiple partners among females either in 2001/2 or in 2007/8. Reported condom use was recorded at last sex in 2001/2 and at last sex in the previous 12 months in 2007/8. There was strong evidence of an impact of the intervention on reported condom use among males in 2001/2 and weak evidence of an impact on reported condom use among females in 2007-08. Reported condom use was higher in intervention communities among females in 2001/2 and males in 2007/8 but there was no evidence that these were real differences due to the intervention. Reported use of a health facility for the most recent STI symptom in the last 12 months increased between the two survey rounds in both intervention and comparison communities and in both sexes, however there was no evidence that the intervention led to an increase in health facility use in either survey. A number of outcomes related to pregnancy were measured in 2001/2 and also in 2007/8, however, none of these pregnancy outcomes were similar enough at both rounds to make useful comparisons. There was no evidence of intervention impact on any of the pregnancy outcomes in either survey.

4.9.4 Biological outcomes

HIV incidence and HIV prevalence were primary outcomes in 2001/2 and 2007/8 respectively. There was no evidence that the intervention had an impact on either of these outcomes ***(Table 4.20)***. There was also no evidence of intervention impact on the primary outcome HSV2 prevalence either in 2001/2 or in 2007/8. HSV2 prevalence increased by ~ 50% between 2001/2 and 2007/8 in both sexes and both trial arms, presumably because the participants were older in the latter survey. Lifetime syphilis exposure, a secondary biological outcome in both surveys, doubled in females between the 2 survey rounds and increased 4-fold in intervention males and 3-fold in comparison males. There was no evidence of an impact of the intervention on either lifetime syphilis (measured in both surveys) nor on active syphilis which was measured in 2007/8 only. There was weak evidence of the intervention leading to an increase in the prevalence of Chlamydia among females in 2001/2, however, there was no evidence of an impact of the intervention in either direction on this outcome in males in 2001/2 or in both sexes in 2007/8. In 2001/2 there was also weak evidence of an increase in the prevalence of Neisseria gonorrhoeae (NG) in females in the intervention communities compared to the comparison communities. This increase in prevalence was seen only among females who had the potential to receive one year of the in-school intervention.[186] There was no evidence of an impact of the intervention on NG prevalence among males in 2001/2 or among either sex in 2007/8 ***(Table 4.20)***.

Table 4.20: Impact of intervention on knowledge, reported attitudes and reported behaviours, by sex in 2001/2[186] vs. 2007/8

Outcome	Male						Female					
	2001/2			2007/8			2001/2			2007/8		
	I	C	Adjusted RR[1] (CI)	I	C	Adjusted PR[1] (CI)	I	C	Adjusted PR[1] (CI)	I	C	Adjusted PR[1] (CI)
Knowledge[2]												
HIV acquisition	65%	45%	1.44 (1.25,1.67)	73%	66%	1.11 (0.99,1.23)	58%	40%	1.41 (1.14,1.75)	68%	61%	1.11 (1.00,1.24)
STD acquisition	52%	40%	1.28 (1.07,0.54)	54%	46%	1.18 (1.04,1.34)	36%	25%	1.41 (1.06,1.88)	38%	30%	1.24 (0.97,1.58)
Pregnancy prevention	84%	50%	1.66 (1.55,1.78)	83%	69%	1.19 (1.12,1.26)	72%	46%	1.58 (1.26,1.99)	71%	60%	1.17 (1.06,1.30)
Reported Attitudes[2]												
Attitudes to sex	22%	12%	1.77 (1.42,2.22)	28%	22%	1.31 (0.97,1.77)	27%	19%	1.42 (1.11,1.81)	11%	10%	1.09 (0.67,1.77)
Reported Sexual Behaviour												
Sexual debut during follow-up[3]	60%	72%	0.84 (0.71,1.01)			-	68%	67%	1.03 (0.91,1.16)			-
Age at first sex <16y			-	25%	28%	0.91 (0.80,1.05)			-	28%	27%	1.01 (0.80,1.28)
>1 partner in last 12 months	19%	28%	0.69 (0.49,0.95)	41%	45%	0.92 (0.79,1.08)	9%	8%	1.04 (0.58,1.89)	10%	10%	0.97 (0.76,1.23)
Used condom at last sex[4]	29%	20%	1.47 (1.12,1.93)			-	27%	22%	1.12 (0.85,1.48)			-
Used condom at last sex in past 12m[5]			-	34%	29%	1.19 (0.91,1.54)			-	19%	15%	1.27 (0.97,1.67)
Went to health facility for most recent STI symptoms within past 12m[6]	29%	35%	0.84 (0.50,1.41)	48%	43%	1.19 (0.91,1.56)	36%	34%	1.02 (0.62,1.70)	47%	47%	1.02 (0.77,1.37)

(Key on next page)

Table 4.20: Impact of intervention on knowledge, reported attitudes and reported behaviours, by sex in 2001/2[186] vs 2007/8

Outcome	Male						Female					
	2001/2			2007/8			2001/2			2007/8		
	I	C	Adjusted RR[1] (CI)	I	C	Adjusted PR[1] (CI)	I	C	Adjusted PR[1] (CI)	I	C	Adjusted PR[1] (CI)
Primary biological outcomes												
HIV incidence (/1,000py)	0.43	0.3	NA			-	3.2	4.7	0.75 (0.34,1.66)			-
HIV prevalence			-	2.0%	1.7%	0.91 (0.50,1.65)			-	3.9%	4.2%	1.07 (0.68,1.67)
HSV-2 prevalence	11.3%	12.5%	0.92 (0.69,1.22)	25.0%	26.7%	0.94 (0.77,1.15)	21.3%	20.8%	1.05 (0.83,1.32)	40.3%	42.5%	0.96 (0.87,1.06)
Secondary biological outcomes												
"Lifetime" syphilis exposure (TPPA+)	1.40%	1.80%	0.78 (0.46,1.30)	5.8%	5.3%	1.06 (0.74,1.52)	3.3%	3.6%	0.99 (0.67,1.46)	6.3%	7.5%	0.86 (0.62,1.21)
Active syphilis prevalence (TPPA+, RPR+)			-	3.8%	3.3%	1.11 (0.72,1.72)			-	4.5%	5.2%	0.91 (0.65,1.28)
Chlamydia prevalence	0.50%	0.50%	1.14 (0.53,2.43)	2.1%	2.1%	1.24 (0.66,2.33)	4.9%	3.6%	1.37 (0.98,1.91)	2.6%	2.1%	1.27 (0.87,1.86)
Gonorrhoea prevalence (07-08 Amplicor PCR positives confirmed by 16S PCR; 01-02 based on Amplicor PCR results only)	0.40%	0.10%	NA	0.3%	0.4%	0.71 (0.21,2.41)	2.40%	1.20%	1.93 (1.01,3.71)	0.3%	0.4%	0.73 (0.20, 2.63)

1. Adjusted for: Age group (2001-2: (≤17, 18, ≥19y at 2001-2 survey; 2007-8: <21, 21-22, 23-24, ≥25y at 2007-8 survey), stratum, ethnic group (Sukuma vs non-Sukuma). 2001-2 also adjusted for number of lifetime partners at baseline (0, 1, 2, ≥3)

2. % with all 3 responses "correct"

3. Among those who reported never having had sex at recruitment in 1998

4. Among those who reported having had sex at the 2001-2 survey

5. Among those who reported having had sex in past 12m

6. .Among those reporting STI symptoms (genital discharge or genital ulcer) within past 12m

NA, Number of cases too small to justify comparison (<10 in each group); I, Intervention; C, comparison; -, not measured

Chapter 5 - Discussion

5.1 Key findings

5.1.1 Summary

The MkV1FS trial results demonstrate that the MEMA kwa Vijana intervention led to a sustained improvement in young people's sexual and reproductive health (SRH) knowledge and a reduction in some reported sexual risk behaviours. The lack of any significant impact on the prevalence of HIV and other STIs either after 3 years or after more than 8 years of the interventions being in place, indicates that skills-based, in-school education, linked to more youth-friendly health services and limited supportive community activities, while important in improving young people's knowledge of how to reduce their sexual risk, may not be sufficient to reduce HIV incidence and other biological outcomes among young people in this setting.

5.1.2 Knowledge

The intervention had a clear positive impact on HIV acquisition, STD acquisition and pregnancy prevention knowledge ***(Table 4.8)***. The magnitude of the intervention impact on these knowledge outcomes (10-20%), though statistically significant is not as strong as that observed in 2001/2 ***(Table 4.20)***. An increase in knowledge was observed in both trial arms between 2001/2 and 2007/8. Improvements in knowledge in the young people in the comparison communities will have decreased the chances of finding differences in knowledge by trial arm, making it even more impressive that such differences were still observed an average of 5.4 years after the young people had left primary school. Knowledge is a reliable measure and should not have been subject to reporting bias.

The fact that HIV acquisition and pregnancy prevention knowledge were also high in the comparison communities suggests that other sources of health education are important to young people e.g. relatives/friends, radio, newspapers, government health services, in-school education, non-governmental organisations. For example, improvements in HIV knowledge in the comparison communities may have resulted from exposure to national media campaigns, including recent campaigns encouraging VCT, exposure to HIV information at antenatal care or marriage preparation, and the roll out of antiretroviral treatment. National survey data show that knowledge about HIV has gradually increased in Tanzania since 1999.[6] The increases in knowledge about pregnancy prevention and STIs may be due to the older age of the respondents and their personal experiences with pregnancy and/or STIs.

Of the three HIV acquisition knowledge questions, the question 'Can a person who looks strong and healthy have HIV?' was most frequently answered incorrectly and intervention impact was greatest for this question. Intervention impact on this question is highly plausible as one of the key intervention messages was that someone who is healthy and fit can have HIV. While knowledge on HIV acquisition was encouragingly high in both intervention and comparison communities (61-73%), it is important to note that comprehensive knowledge was not universal. Further efforts will be needed to ensure that all young people know the basic facts about HIV transmission.

Individual STD acquisition knowledge questions were answered reasonably well with at least two thirds of respondents having some knowledge of STD acquisition. Among both males and females, the intervention appears to have been more successful at increasing the proportion that had a more comprehensive knowledge (correct response to each of the three STD acquisition knowledge questions) as opposed to increasing the proportion with the correct response to one or other of the individual questions. Nevertheless, it is concerning that comprehensive knowledge of STD acquisition remained low (38%) among females in the intervention communities. One possible explanation for limited intervention impact on STD acquisition knowledge is that teaching on STIs was weak though the process evaluation did not report any specific problems with the quality or intensity of teaching of this subject.[105] It is also possible that the information on STIs was more complex or perceived as less important and hence poorly absorbed by the students.

In terms of the three pregnancy prevention knowledge questions, the lowest proportion of correct responses in both trial arms was seen for the question 'Is it possible for a girl to become pregnant the first time she makes love?' Intervention impact on the overall pregnancy prevention knowledge score in both sexes was due almost exclusively to an impact on this question. Again, this observed effect is highly plausible given that one of the key intervention messages was that having sexual intercourse 'even one time' was enough to become pregnant. The sub-group analysis revealed evidence of a trend of increasing pregnancy knowledge with increased number of years of exposure to the intervention during the most intensive years (1999-2002). This finding suggests that the intervention was most successful when implemented in its entirety i.e. the full 3 years. If this is the case then it is puzzling that a similar trend was not seen for the other knowledge outcomes. Perhaps, it was not the length of the teaching but the specific topics that were covered in each of the three years that were important in improving knowledge.

In both 2001/2 and 2007/8 the strongest intervention impact on knowledge was seen for pregnancy prevention knowledge. Qualitative research in Mwanza has shown that many young people feel more at risk of becoming pregnant than of contracting HIV[183, 316] and this may have influenced their absorption and retention of pregnancy related knowledge. It is also possible that teachers focused more on topics related to pregnancy and/or the curriculum was more effective at imparting knowledge on this subject. On all knowledge scores, including pregnancy prevention knowledge, males performed better than females. This difference may be due to pedagogy or family expectations favouring boys at school.

5.1.3 Reported Attitudes

In males, there was weak evidence of an intervention impact on the composite 'attitudes to sex' score, however, in females there was no evidence of intervention impact on this outcome ***(Table 4.8)***. These results are disappointing given the strong evidence of intervention impact on this outcome that was observed in 2001/2 ***(Table 4.20)***. Among females, reporting of desirable attitudes to sex decreased between 2001/2 and 2007/8 in both trial arms. The reason for a decrease among females and not among males is not immediately clear. Poorer recall of the desirable responses among females is unlikely given that levels of correct knowledge were similar among females at both time periods. Those interviewed in 2007/8 were older and more likely to be married than those interviewed in 2001/2. It is likely that the attitudes of this older, married population have been influenced by what they have personally experienced since exposure to the intervention. Perhaps, the females interviewed in 2007/8 had more realistic expectations of what behaviour is feasible for girls and women within their social context. It is important to note that in both surveys, the proportion of young people answering all 3 attitudinal questions desirably was <30% in both sexes and both trial arms ***(Table 4.20)***. These questions focused mainly on gender norms and the results suggest that the intervention did not have a major impact on such norms.

Looking at the individual attitude questions, by far the lowest proportion of desirable responses, among both sexes but especially among females, was seen for the question 'If a man wants to make love with a woman, can she refuse to make love with him if he is her lover?'. There was no evidence of the intervention having a desirable impact on this attitude among females and only very weak evidence of an impact among males ***(Table 4.8)***. This result suggests that the intervention had little success in changing the gender norms within relationships which dictate that the man has the greatest authority in the household.[104] The highest proportion of desirable responses among both sexes and within both trial arms, and the strongest intervention impact among men, was seen for the question 'If a young woman accepts a gift from a man, must she agree to make love with him?'. This is encouraging and suggests that the intervention was able to impact on this aspect of sexual relationships. However, the term 'gift' is very general and it is possible that the young people answering 'No' were merely agreeing that sex need not be offered if the 'gift' was inappropriate or too small. It is also possible that these questions suffered from social desirability bias though material exchange for sex is not necessarily considered an undesirable behaviour in the study communities.[104]

There was evidence of a dose-response effect of the intervention on the composite attitude score, especially among females ***(Tables 4.17-4.18)***. There is also some evidence that the intervention had a desirable impact on the attitude question 'If a man wants to make love with a woman, can she refuse to make love to him if he is older than her?' among the youngest men and among unmarried men ***(Tables 4.15-4.16)***. For the other two attitude questions (refuse if lover, refuse if gift), there is some evidence that intervention impact was greatest among those who were married and among those who were exposed to the intervention 7-8 years ago ***(Tables 4.16, 4.19)***. It is possible that those who were more empowered due to their older age and/or married status were in a better position to state an attitude that goes against traditional sexual behaviour norms. However, it would be unwise, to over-interpret the results of the sub-group analysis as a large number of outcomes were tested and we would, therefore, expect that some of them might be significant.

5.1.4 Reported sexual behaviour, and reported clinical and biological outcomes

It is useful to discuss the intervention impact on reported sexual behaviour in relation to the key behavioural objectives of the intervention ***(Section 1.4.2)***. The first of these objectives was to delay sexual debut among youth who were not already sexually active. In 2007/8, 25-30% of the young people interviewed reported having had sex before the age of 16 years and there was no evidence of intervention impact on this outcome ***(Table 4.7)***. This is in contrast to the results of the 2001/2 evaluation where there was weak evidence of a reduction in the intervention communities of males who had sexual debut during the 3 year follow-up ***(Table 4.20)***. There was no evidence of an impact on this outcome among population sub-groups

(Tables 4.15-4.19). The mean age of potential exposure to the in-school component of the intervention was 15 years for males and 14 years for females. By comparing reported age, year potentially first exposed to the in-school component of the intervention and reported age at first sex it is estimated that 74% of males and 83% of females were first exposed to the intervention prior to the year that they reported first having sex. It is surprising that a higher proportion of males than females had sex before being exposed to the intervention and suggests that males and/or females provide inaccurate reports of their age at first sex. Qualitative research in Tanzania has observed that there are differing interpretations of what constitutes 'sex'[451] and it is possible that experimentation and 'playing sex' were described by some respondents as 'making love'. Also, the HALIRA qualitative research found that most young people reported being sexually active by the age of 15 so there may be some misreporting of age at first sex.[452]

The second objective was to reduce the number of sexual partners among those already sexually active. Of the two outcomes measuring the number of sexual partners, strong evidence of intervention impact was only seen on the reported number of lifetime sexual partners among males *(Table 4.7)*. Taking the results of the 2001/2 and 2007/8 evaluations together we could conclude that the intervention led to a transient short-term reduction in the number of sexual partners among men and this has been translated into a reduced number of lifetime partners. If this is the case then the initial success of the intervention may have been due to the young age of the participants and/or the fact that the intervention was more intense or more recent. While the intervention obviously had some positive impact on reported number of sexual partners it is important to keep in mind that the proportion of males who reported more than one sexual partner in the 12 months prior to the 2007/8 survey was high in the intervention communities and almost double the proportion who reported this outcome in 2001/2 *(Table 4.20)*. The proportions of both male (~ 40%) and female (~10%) MkV1FS participants reporting >1 partner in the past 12 months are high compared to similar figures from the 2007/8 national survey in Tanzania (18% males and 3% of females aged 20-24 years).[6] Among females, while overall there was no impact on the reported number of sexual partners, there did appear to be evidence of a reduction in the number of lifetime sexual partners among married women in the intervention communities *(Table 4.16)*. There is no obvious explanation for this apparent intervention impact only in married women and it could have been a chance finding. All of these outcomes that relate to reported number of partners are highly likely to suffer from recall and, more importantly, social desirability bias.

The third objective was to promote the correct and consistent use of condoms among those who were sexually active. Among both males and females, there was weak evidence of an increase in reported use of condoms at last sex in the 12 months prior to the 2007/8 survey and among females there was strong evidence of an increase in reported condom use at last sex with last non-regular partner during the same time period ***(Table 4.7)***. This stronger evidence of intervention impact on reported condom use among females is in contrast to the 2001/2 evaluation where strong evidence of increased reported condom use was seen only among males ***(Table 4.20)***. It is interesting to note that while reported use of condom at last sex has increased over time among males it has actually decreased over time among females. Presumably, this reflects the fact that the majority of females are now married and last sex is likely to have been with their husbands with whom condom use would be less likely. The point estimates of intervention impact suggest that the impact on reported condom use was greatest among females who were not married, however, there is no evidence of a real difference in impact according to marital status ***(Table 4.16)***. The results of the other subgroup analysis suggest that the impact on reported condom use at last sex among women was greatest among the oldest women, those who received only one year of the intervention and those who received the intervention between 5-8 years ago ***(Tables 4.15, 4.17, 4.19)***. This group of women are likely to have made up a large proportion of the trial cohort ***(Figure 3.1)*** and, perhaps, this finding reflects a higher intensity and fidelity of intervention delivery during the first few years of intervention implementation.

Condom use data are often subject to reporting biases and qualitative research carried out in Mwanza (1999-2002) suggests that young people may have over-reported condom use in earlier MkV1 surveys.[183] However, higher reports of condom use with non-regular partners and low reported use among a largely married female population suggests that the reporting may have been reasonably accurate. Despite the clear intervention impact on reported condom use it is concerning that less than 50% of respondents reported using a condom with their last non-regular partner. National data on reported levels of condom use at last sex with non-marital, non-cohabiting partner are similar with 49% of men and 46% of women aged 15-24 years reporting use of a condom.[6] Reasons given for non-use of condoms in Mwanza included association of the method with infection or promiscuity, reduced male sexual pleasure, and cultural understandings of meaningful sex.[183] Plummer and colleagues suggest that future interventions should address the trade-off between possible short- and long-term consequences of condom use, especially for men.[183]

The final objective was to increase the uptake of family planning and STI services. There was no evidence that the intervention led to an increase in reported lifetime use of modern contraceptives or reported use of modern contraceptives at last sex in the 12 months prior to the 2007/8 survey ***(Table 4.7).*** Neither was there evidence that the intervention led to a decrease in reported lifetime number of pregnancies, reported pregnancies while the respondent or their partner were in primary school, or reported unplanned pregnancies ***(Table 4.9)***. Results from the 3 year evaluation and this longer-term evaluation show that the MkV1 intervention did not lead to an increase in the use of family planning methods. Evidence from the recent qualitative research with MkV1FS participants suggests that one reason for non-use of modern contraceptives might be fear of side-effects and more effort is needed to improve knowledge of and access to appropriate family planning methods.[316]

There was weak evidence that the intervention led to a reduction in reported genital ulcers in the 12 months prior to the 2007/8 survey among both males and females. There was no evidence that the intervention led to an increase in reported use of health facilities among those who reported either abnormal genital discharge or a genital ulcer in the previous 12 months either in 2001/2 or 2007/8 ***(Table 4.20).*** However, between 1998 and 2001, a significant increase in the numbers attending for STIs in both intervention and comparison health facilities was seen with some evidence that the increase was greater in intervention community health facilities.[187]

Overall, the intervention appears to have had less impact on reported sexual behaviour in the 2007/8 survey than in the 2001/2 survey. One potential explanation may be that the length of time since exposure to the in-school intervention led to an attenuation of intervention effect. Another is that when young people are older and/or have left primary school their sexual behaviour is more influenced by community norms. Alternatively, as the young people interviewed in 2007/8 were older and exposed to the intervention many years previously, responses may have been more honest and less subject to differential reporting bias by trial arm.

5.1.5 Prevalence of STIs

In 2001/2 the point estimate of the adjusted relative risk among females was 0.75 ***(Table 4.20)*** and while the study at that time was underpowered to find an effect of this size, this result provided hope that in the longer-term there would be evidence of an impact on HIV. The absence of evidence of an impact on the primary outcomes, HIV prevalence and HSV2 prevalence, and on the secondary biological outcomes *(Table 4.9)*, is hugely disappointing from a public health perspective. An impact on STIs might have been more likely if a larger and more consistent impact on reported number of sexual partners and reported condom use had been seen. However, this would only have been the case if reported behaviour reflected actual behaviour. Furthermore, the relationship between, for example, condom use and STI prevention, is not straightforward and the disease-specific infectivity, the number of exposures to an infected partner and the correct and consistent use of condoms are all important factors.[453, 454] This lack of impact, in either direction, on biological outcomes an average of 8.9 years after the start of the intervention tends to contradict the frequently held belief that positive changes in knowledge, reported attitudes and reported behaviours will eventually lead to a reduction in HIV, STIs and unwanted pregnancies. A direct comparison between overall prevalences in the various survey rounds is not appropriate because the ages of the young people included differed, the median ages in the 1998, 2001/2 and 2007/8 surveys being 15 years, 18 years and 22 years, respectively.

5.1.6 Sub-group analysis

As highlighted in the summary of the results above, a number of sub-group analyses were carried out. Such analyses are important as there could have been differential intervention effects within sub-groups of the target population. There is some suggestion that the intervention had a more beneficial impact on attitudes and reported risk behaviours among females who were married, older in age, and who had received the intervention in the more distant past. Despite some evidence of differential intervention impact on some outcomes the results are not consistent and, importantly, no sub-group emerges as clearly having had greater benefit from the intervention.

A dose-response relationship is one of the Bradford-Hill criteria for evidence of causation.[455] The in-school component of the MkV1 intervention was designed to be implemented over a 3-year period. As such, the 2007/8 survey was designed to maximise the proportion of participants who had the potential to be exposed to the full 3 years of this component of the intervention. In 2001/2, the results suggested a dose-response effect of the intervention with strong evidence of greater impact among those receiving 2 or 3 years of the in-school component on pregnancy prevention knowledge among both sexes and on the following outcomes among males: HIV acquisition knowledge, STI acquisition knowledge, attitudes to sex and number of sexual partners in the previous 12 months. In 2007/8, a dose-response effect on attitudes to sex was seen for both sexes with improved attitudes among those who had received 2 or 3 years of the intervention between 1999 and 2004 ***(Table 4.17).*** Interestingly, when 'dose' of the intervention was considered only during the years when the intervention was most intensively supported and supervised i.e. 1999-2002, a stronger dose-response effect was seen for attitudes to sex and a dose-response effect was also seen for knowledge of pregnancy prevention in both sexes ***(Table 4.18).*** The greater evidence of trend, based on 'dose' of exposure between 1999 and 2002, suggests that implementation of the intervention may have been weaker in some schools between 2002 and 2004. *Apriori*, it was in fact suspected that that the fidelity and intensity of the intervention may have been weaker when the teacher training and supervision visits were led by District staff. Because of this only those with potential exposure to at least one year of the in-school intervention between 1999 and 2002 were deemed eligible to participate in MkV1FS. Could a decrease in intensity or quality of the in-school component of the intervention between 2002 and 2004 have attenuated the impact of the intervention on the primary outcomes? While this is possible, it seems unlikely, as among females there was no evidence of a trend of intervention impact on either HIV or HSV2 according to years of exposure to the intervention between 1999 and 2002 ***(Table 4.18)***. Among males, there was a significant trend in intervention impact on HIV prevalence with an intervention impact being seen only in the sub-group who had at least 3 years of exposure to the intervention between 1999 and 2002. However, this is likely to be a chance finding as prevalence in males was low (~2%) and the prevalence ratio estimates from the sub-group analysis have wide confidence intervals that all contain the value 1 i.e. no increased or decreased risk (data not shown).

Table 4.19 shows that for 5 of the 6 outcomes that had evidence of a trend in intervention impact according to years since last exposure to the intervention, intervention impact was decreased or was negative in the sub-group of young people who were exposed to the in-school intervention in the 3-4 years prior to the 2007/8 survey. The differences may have occurred by chance. If these differences really exist then they could suggest that levels of risk have changed in recent years in the intervention communities due perhaps to higher relative increases in mobility or poverty. Another explanation might be that the intervention had been less effective in more recent years due to reduced intensity and/or quality of the intervention. It would be hard to argue that the latter is the case, however, given that there is no evidence of the intervention having an overall impact on these outcomes.

5.1.7 Comparison of 3-year and 9-year impact evaluation results

In the above sections the results of the 3 year and the 9 year evaluations have been compared. In summary, the intervention impact on reported sexual behaviours appears to have diminished over time. In 2001/2, among men, there was weak evidence of an intervention impact on delaying sexual debut and good evidence of an intervention impact on reported number of partners in the previous 12 months and condom use at last sex. In 2007/8, an impact was seen on lifetime number of sexual partners among men and reported condom use with last non-regular partner among females. These results suggest that there may be some lasting intervention impact, especially on condom use. As I will discuss later in this chapter, the reported behaviour results of both the 2001/2 and 2007/8 surveys are likely, to some extent, to have been biased by poor recall and/or differential reporting bias.

The intervention impact on knowledge and on reported attitudes to sex (only significant among males) also appears to have diminished though this may have been primarily due to a larger relative increase in knowledge/reported attitudes in the comparison communities (i.e. the comparison communities have 'caught up' with the intervention communities). There is no evidence to suggest that knowledge decreased in the intervention communities between 2001/2 and 2007/8 ***(Table 4.20)***. The decrease over time in intervention impact on reported attitudes to sex suggests that the influence of community and social norms was stronger than memories of the intervention messages.

In the intervention communities, between 2001/2 and 2007/8, reported desirable attitudes to sex decreased over time among females and reported number of partners in the previous 12 months increased among males suggesting that there may have been some degree of 'intervention decay' ***(Table 4.20).*** In contrast, levels of knowledge and reported use of health facilities for most recent STI symptoms increased in the intervention communities between these two time points. 'Intervention decay' has been identified as an important problem[228] and the extent of this problem in the longer term is rarely measured. The findings of the 2007/8 survey are, therefore, of great importance in shedding light on this problem.

5.2 Did the study address the research hypothesis?

The primary hypothesis of this study was that in the longer-term the MkV1 intervention would lead to an improvement in SRH and a reduction in HIV and other STIs among young people exposed to the intervention. Through the measurement of HIV and HSV2 prevalence among young people in the trial communities approximately 9 years after the start of the intervention, this study was able to assess whether in the long-term, young people exposed to the MkV1 intervention had improved sexual health. This study also measured the intervention impact on additional biological and reported clinical and biological outcomes and on the more 'upstream' outcomes of knowledge, attitudes and reported sexual behaviours.

It was hypothesised that a change in social norms and an increase in the number of young women's older male sexual partners who had been exposed to the intervention would lead to the long-term positive impact of the intervention ***(Section 1.4.8)***. In MkV1FS no attempt was made to directly measure 'social norms', however, the proportion of study participants in the intervention communities who reported desirable attitudes to sex was low and the improvement in reporting of desirable attitudes among intervention males was relatively small. Furthermore, persisting low levels of reported condom use and high numbers of reported sexual partners among males suggest that social norms in relation to sexual behaviour have not changed significantly. In 2001/2, over 90% of female participants were in the age range 14-16 years and 90% of male participants in the age range 14-17 years.[186] It is likely, therefore, that a considerable proportion of the male sexual partners of young females had not been exposed to the intervention ***(Table 4.14)***. Given that the age ranges of participants was much wider in the 2007/8 survey (15-28 years for females; 16-30 years for males[8]), it is likely that, as predicted, a higher proportion of the male partners of female participants were also exposed to the intervention.

It is important to point out that, as in the 2001/2 survey, the intervention was evaluated only among young people who had attended at least one of the last 3 years of primary school and no attempt was made to evaluate the impact of the intervention on other community members. This was, therefore, primarily an evaluation of the in-school component of the intervention with participating young people also having had potential exposure to the other components of the intervention.

5.3 Were there any alternative explanations for the findings?

It is important to consider whether there are other explanations for the observed effect and lack of effect of the intervention. There was no evidence of intervention impact on the primary

[8] The overall age range was 13-31 years for females and 15-34 years for males. However, 99.9% of females were in the age range 15-28 years and 99.9% of males were in the age range 16-30 years. Collecting information on exact age is challenging in rural Mwanza and it was suspected that the outlying very high and very low ages may have been a result of reporting or recording errors.

outcomes of HIV and HSV2 prevalence. If there was an imbalance in risk or protective factors for HIV between trial arms then this could have impacted on the ability to detect an impact of the intervention. However, this was a RCT with an adequate number of clusters and imbalances would have been unlikely also, minor differences in the baseline characteristics of participants in each trial arm were adjusted for in the analysis. The assumption was made that the young people who took part in the 2007/8 survey would have been infected with HIV through heterosexual intercourse with an infected individual. Other possible sources of HIV infection include mother-to-child transmission, transfusion with unscreened blood, unsafe injections (including illegal drug use) and homosexual intercourse. Respondents were asked about their history of blood transfusion in the previous 5 years and injections in the previous year and no differences were observed between trial arms *(Table 4.4)*. No attempt was made to collect information on illicit drug use though the abuse of intravenous drugs in rural Tanzania is likely to be very rare or non-existent[111] and, therefore, is unlikely to have biased the results. The study participants are unlikely to have been infected through their mothers as the vast majority were born prior to the extensive spread of the HIV epidemic in Tanzania. Participants were not asked about same-sex behaviours and while research suggests the widespread existence of men who have sex with men across Africa,[456] the prevalence of such behaviour in rural Mwanza is unknown and levels are likely to have been similar in each trial arm. Other factors that have a strong association with HIV acquisition include the prevalence of other STIs and the prevalence of circumcision. Both of these were measured and no major differences between trial arms were observed *(Tables 4.4, 4.9)*.

An alternative explanation for the observed intervention impact on knowledge could be that the young people in the intervention communities had a greater exposure to educational information from other sources. Qualitative data collected on NGO and CSO activities in the trial communities during 1999-2001 and 2007/8 indicated that there were few groups working in these areas and there was no evidence that the intervention communities had a relatively higher exposure to these activities. Though not formally measured, it is not believed that intervention communities had a relatively higher level of access to radio, television, newspapers or the internet.

5.4 Strengths and limitations of the study design

The design of the long-term impact evaluation survey had a number of strengths. The cluster randomised trial design meant that significant differences in the outcomes between trial arms were likely to be due to the intervention effects. This study was unique in having such a long follow-up period and as such should have been able to detect change in behaviours resulting from exposure of consecutive cohorts of young people to the intervention, such as changes within age-mixed relationships. One of the major strengths was the inclusion of objective biological outcomes in addition to reported behaviour, reported attitude and knowledge outcomes. These biological outcomes were not subject to any of the reporting and recall biases that are associated with reported behaviour outcomes.

The study also had an increase in power, when compared to the 2001/2 evaluation survey, to detect an impact on the primary outcomes HIV and HSV2 prevalence. In 2001/2, the trial was powered to detect a 50% decrease in HIV. It was clear, following that survey, that the incidence of HIV in the comparison communities was considerably lower than predicted. Furthermore, as expected, there had been considerable loss to follow-up with only 73% of the trial cohort interviewed at the 3-year evaluation in 2001/2. It was recognised that there were many obstacles to achieving a substantial reduction in HIV prevalence through a sustainable youth intervention and that a 50% reduction might not be realistic. In order to increase the power of the long-term evaluation survey and to ensure a more representative sample of young people, a cross-sectional design was selected. This cross-sectional design allowed the inclusion of additional younger groups of young people who had been exposed to the intervention (or comparison) more recently. The 2007/8 study was designed to have the power to detect a 35% reduction in HIV among females and a 50% reduction among males. Even a relatively modest impact would have the potential to save millions of lives and a 35% reduction was expected to be of substantial public health importance while being measurable in a study of reasonable size.

The study population was likely to have been, on average, at lower risk of HIV and other STIs compared to other rural populations for two main reasons. Firstly, it was restricted to young people who had reached at least year five of primary school. A preliminary, population-based survey in the trial communities showed that HIV was more prevalent in 15-19y-olds who had never been to school or who had left school before School Year 5.[10] On the other hand, the study population might have been more amenable to behaviour change because of their better education. Secondly, survey participants were initially identified through a house-to-house census. In this way an effort was made to identify all of those who were potentially eligible to participate in the survey. A census is a good method of identifying the 'middle group' but may be a poor method of identifying some sub-groups of the population. Despite repeat visits to the trial communities and tracing of young people to major migration points and local secondary schools, it is likely that many of those attending secondary school outside the trial communities, those who migrated outside the study area for employment or marriage, and mobile groups such as fishermen, miners or traders were missed. Studies in Mwanza Region have shown that mobile young people often have higher risk sexual behaviours and are at increased risk of HIV and other STI.[145, 457] Contrary to initial expectations, those interviewed at the major migration points did not have a higher prevalence of HIV or HSV2 ***(Figure 4.8)***. In fact, there is some evidence that these participants were at lower risk of HSV2. The teams were only able to trace young people where information on location was available from other community members and this fact alone may have led to the tracing of lower risk young people. Given the limited time that the study teams had for tracing at the migration points, it is likely that they were more successful at finding those on whom detailed and accurate tracing information was available (potentially the less mobile migrants). This possibility is supported by the fact that those interviewed at the migration points report only moderate mobility ***(Figure 4.3)***. Among those still living in the trial communities, those who personally had or whose family members had poor recall of the years and standards that they attended primary school were less likely to be invited during the census to attend the survey. Furthermore, those who had poor recall of school years and standards and/or who had had multiple names were less likely to be determined eligible to participate in MKV1FS. These groups were likely to be similar in both trial arms. However, the retention of MkV1 trial ID cards, which facilitated confirmation of identity, may have been higher among those in the intervention arm. In both the trial communities and at the migration points, not all invitees attended and those who did not attend the survey may have been at higher risk (e.g. had a high-risk profession, knew that they were HIV+ etc.).

Initial estimations were that an average of 365 males and 365 females would be interviewed in each trial community. HIV and HSV2 prevalence was higher in young females when compared with young males and the study, therefore, had greater power to detect a difference in the primary outcomes among females. Following the first visits to the trial communities it was noted that only 82% of the target recruitment had been reached and that participation was particularly low among females ***(Table 4.1)***. The study teams were instructed, therefore, to prioritise the tracing of females during the repeat visits to the study communities and also during the visits to migration points. This strategy was largely successful and females made up 47% of the final study sample, with an average of 326 females per trial community. It is important to note that this strategy of targeting females was used in both trial arms and that the proportion of females interviewed in each arm and at each time point was similar ***(Table***

4.1). This strategy will not, therefore, have biased the results as they were presented separately for each sex. It could be argued that, because of this strategy, the female participants were more representative of all potentially eligible females. In particular, it is possible that this strategy led to an increase in participation of more mobile and potentially higher risk females when compared to males. For example, HIV prevalence was higher among those interviewed during the repeat visits to the communities and, among females, there was strong evidence to suggest that this difference was not due to chance ***(Figure 4.8)***. However, the factors influencing survey attendance may be very different for males and females and it is unclear as to whether potentially eligible males who were not interviewed were at higher risk. Interestingly, the ratio of males to females in the original trial cohort was 1.22, at 2001/2 follow-up 1.38 and in 2007/8 1.13. These data highlight the fact that, in these communities, the follow-up of young females is a challenge. The more balanced sex ratio obtained in the recent survey is likely to reflect the strategy of prioritising the tracing of females during the second visits to the trial communities and at the migration points.

The study inclusion criteria prioritised exposure to the in-school component of the intervention and current residence in a trial community was not essential. This had the advantage of allowing the inclusion of certain groups of interest who may have left their original community of residence such as married women who were more likely to migrate. However, when a young person out-migrated they would no longer be exposed to the community component of the intervention or to any change in community norms. Only 6% of participants were interviewed outside of their original trial communities and so a dilution of intervention effect through the inclusion of out-migrants is unlikely.

As expected, there was considerable loss to follow-up among the original trial cohort with only 40% of the cohort interviewed in 2007/8, down from the 73% that were interviewed in 2001/2 ***(Figure 4.4)***. It was thought that loss to follow-up might increase with the age of the young person and the original trial cohort were the oldest of the young people who were eligible to participate in this study. It was predicted that a large number of young people would not be traceable and this was factored into the sample size calculation. It is important to note that follow-up was similar in both trial arms and so while this may affect the generalisabilty of the results of MkV1FS it will not have biased the measurement of impact of the intervention, unless there was differential impact among those who were and were not followed-up in 2007/8.

It is also important to consider the balance in the numbers recruited in the intervention and comparison arms. In 2001/2 the males and females that were interviewed were equally distributed between the two trial arms. In 2007/8, it appears that slightly more males were interviewed in the intervention arm when compared to the comparison arm ***(Table 4.4)***. There also appears to be a higher proportion of intervention community males who are currently studying and it is possible that a higher number of males attending secondary school were recruited in the intervention communities. Alternatively, perhaps those in the intervention arm were more interested in participating due to their previous positive experiences with MkV1 or perhaps they were more likely to have retained their MkV1 ID cards which allowed easier confirmation of their eligibility. It is not clear what impact, if any, this apparent imbalance between arms had on the results of the study. If anything improved participation of males in intervention communities might mean that a greater number of more mobile and potentially higher risk males were interviewed in that trial arm and this would decrease the possibility of seeing a positive intervention impact. However, the absolute sizes of the differences by arm were small so any effect of this imbalance was also likely to have been small.

Another major strength of the 2007/8 survey design was that the participants had higher levels of exposure to the intervention. In 2001/2 only 26% of participants had had the potential to receive the full 3 years of the in-school component of the intervention. In 2007/8, almost two thirds of participants had the potential to receive the full 'dose' of the intervention. This greatly increased the chances of finding evidence of intervention impact if it did exist.

One of the main limitations of cross-sectional surveys is that there is usually no possibility of assessing the temporality of events. For example, did reported condom use among females increase prior to or following their exposure to the intervention? In this study we had the advantage of having baseline data on young people from the trial communities and this allowed us to adjust our analysis for those factors that were, at a community level, imbalanced between trial arms at baseline. Therefore, any difference seen between trial arms in 2007/8 can be assumed to be due to the effect of the intervention.

The lack of individual level baseline data for several of the school year-groups included in the 2007/8 survey prevented the exploration of within-individual change in outcomes over time and meant that HIV and HSV2 prevalence and not incidence were the primary outcomes. The use of prevalence could be seen as a weakness of this survey when compared to the 2001/2 evaluation survey. However, for non-curable STI, including HIV, the prevalence may be similar to cumulative incidence. Virtually all of the 2007/8 participants would have been HIV negative prior to receiving the intervention (or not) as the prevalence of HIV was very low in both males and females in the 1998 cohort recruitment survey.[198] HIV prevalence is influenced by deaths among those who are HIV positive. The exact death rate due to HIV among young people in this setting is not known but it is likely to be low given their young age and the fact that few, if any, will have been infected before the age of 15 years.[458, 459] In summary, there is quite strong evidence to suggest that the prevalence of non-curable STIs, especially HIV, will be similar to cumulative incidence.

Participating young people were allocated to intervention or comparison arm of the trial based on the location of the first primary school that they attended and 'Intention to treat' analysis was conducted. This kind of analysis maintains the benefits of the initial randomisation thus reducing the chances of the introduction of any bias into the results. Intention to treat analysis, is recommended for analysis of RCT though some argue that this type of analysis can lead to false conclusions if, for example, there was poor delivery of the intervention.[181] We cannot rule out the possibility of poor delivery of the intervention by some teachers in some schools. However, process evaluation data from 1999-2002 suggested that teaching was generally good.[105] The requirement of at least one year of exposure to the intervention between 1999 and 2002 ensured that all participants had at least one year of high quality teaching. Had a large number of young people moved between intervention and comparison communities during the trial then this analysis might also have led to false conclusions, however, only a handful of study participants had lived in both an intervention and comparison community. On balance this choice of analysis method was the best option not only from the methodological point of view but also because accurate measurement of intervention exposure was not feasible.

The rural communities included in the trial were geographically separated from each other. Migration in the area is usually to larger towns, often to seek work, or to neighbouring villages, such as when a woman gets married. It was, therefore, unlikely that there was significant spill-over of the intervention into the comparison communities. Qualitative data collected in 1999-2002 and more recently in 2007/8 suggest that there was little SRH intervention activity by other government or non-governmental organisations (NGOs) in the trial communities. Similarly, between 1999 and 2005 there was only a minimal amount of SRH education included in the national curriculum for primary schools in the comparison communities.[171] It is unlikely that the introduction of interventions into primary schools and health facilities in comparison communities between 2005 and 2007 had any important effect on the sexual and reproductive health of survey respondents who had all left primary school by that time.

In summary, this study successfully identified and interviewed the target number of eligible young people. Recruitment was likely to have been biased towards less mobile and potentially lower risk young people. Some important populations such as fishermen and married women who out-migrated may have been missed. In terms of generalisability, this study provides data on a representative sample of young people who had attended primary school until at least year 5 and who were still living within their original communities, or who had out-migrated to major migration points and kept in touch with their families in their original trial communities. Those who never attended school, an estimated 15% of young people (15-30 years) in the census households, were not eligible for inclusion and may have a higher risk than those who attended school.

5.5 Quality of the data collected

Data on the majority of the study outcomes were collected using a face-to-face questionnaire. Interpretation of the study findings depends on the extent to which the data collected are considered to be valid, reliable and unbiased. Of all the outcomes, the knowledge outcomes were likely to have been the most valid, reliable and unbiased. Response bias was unlikely as less than 1% of respondents answered 'don't know' to the knowledge and attitude questions. The questionnaire was designed to minimise response order bias and for the knowledge and attitude questions the correct answer varied between 'yes' and 'no'. The possibility that the reported attitudes to sex outcome suffered from differential reporting bias cannot be ruled out as it is possible that, for example, males in the intervention communities responded with what they remembered to be the 'correct' responses.

The reported behaviour outcomes may have been subject to differential reporting bias and recall bias. However, given the lack of intervention impact on most of the reported behaviour outcomes, it is unlikely that differential reporting bias was a major problem in the 2007/8 survey. The reliability of the reported sexual behaviour data is unclear. A number of key questions such as 'number of sexual partners in the previous year', were asked in more than one way and while there were some inconsistencies, the majority of respondents (>98%) answered these repeated questions consistently. The validity of the reported behaviour data is more difficult to ascertain but based on previous detailed research in this area[133] we can assume that at least the more sensitive data are likely to be of questionable validity. The age at which the respondent first had sex is likely to have suffered from recall bias though there is no reason to believe that this bias would differ between trial arms. The number of partner outcomes may also have been subject to recall bias. Previous research in Mwanza Region found that males were more likely to exaggerate and females more likely to underestimate their number of previous sexual partners.[314] Reported condom use outcomes are also often associated with differential reporting bias. The lack of strong evidence on most of the reported condom use outcomes suggests that this kind of bias was not prevalent. It is possible, however, that participants in both trial arms exaggerated their use of condoms as the promotion of the use of condoms is not unique to the MkV1 intervention. That said, the level of reported condom use was low (<20% at last sex among females), and higher levels would be expected if the respondents were providing the responses that they thought the interviewer wanted to hear. The condom and contraceptive use at last sex outcomes were based on use with the most recent sexual partner. For married participants, the most recent partner is likely to have been their spouse and condom use may have been higher with 'casual' and 'other regular' partners. Further analysis (post PhD) will look at the reported behaviour using data on the last 3 partners.

The reported clinical and biological outcomes may also have been subject to differential reporting bias, though, again the absence of evidence of intervention impact on these outcomes suggests that this bias was not widespread if it did exist. The validity and reliability of the sensitive questions relating to pregnancy in primary school and to unplanned pregnancies is unclear and it would be interesting to include further exploration of these outcome measures in any future studies among this population.

Two different teams collected data in 2007/8 and while every attempt was made to ensure that team members followed the same procedures, there may have been some bias associated with either an interviewer or a team as a whole. However, each team covered an equal number of intervention and comparison communities so any biases should not have been differential between the trial arms.

5.6 Sensitivity and specificity of the laboratory analysis

The choice of tests used to detect HIV and other STIs is important as different types of tests have varying levels of sensitivity and specificity.[325] The specificity of a test is of particular importance in intervention evaluation research as low specificity can lead to an underestimation of intervention impact. This problem is particularly important where the prevalence of the outcome, such as HIV, is low and/or the study has a small sample size.[325] Furthermore, evidence from studies in African settings, including Mwanza, show that serological tests for HIV and HSV2 may perform differently in different populations.[460-462]

The HIV testing algorithm that was used in this study was developed based on the experience of previous trials in the Mwanza Region and is thought to have both high sensitivity and specificity. Third generation HIV ELISA (Murex and Uniform) were chosen as the specificity of fourth generation Murex ELISA in this population is thought to be affected by endemic infections such as schistosomiasis.[463] Overall the HIV status of 1.4% of samples remained indeterminate (unknown) and these participants were deemed negative for HIV.

The test used to detect HSV2, KALON HSV Type 2 IgG (KALON Biological, Guildford, UK) has been shown to be suitable for African populations and one evaluation study on East African sera found the Kalon test to have a sensitivity of 92.3% (95% CI 88.6%-96.0%) and a specificity of 97.7% (82.3%-100%).[461] However, there is some evidence that specificity was lower among those who were HIV positive and this may partly explain the lower specificities for the Kalon test (79-92%) that were observed in a number of more recent evaluations.[462, 464, 465] In MkV1FS, the HIV prevalence was similar in each trial arm and any decreased specificity of the Kalon test among those who are HIV+ is unlikely to have biased the trial results. Also, the Kalon test has a long seroconversion window which means that some young people who had been newly infected with HSV2 may have tested negative. Despite repeat testing, nine samples remained indeterminate for HSV2.

The syphilis testing algorithm had a very high sensitivity and specificity as it included both a treponemal test (TPPA), which had high sensitivity and specificity but could not distinguish between current or past infection, and a non-treponemal test (RPR), which had lower specificity but which allowed the identification of active syphilis infections.[466]

Both chlamydia and gonorrhoea were tested for using the Amplicor PCR test. All positive and equivocal samples were retested up to twice and an internal control plate was used to detect inhibition. Evidence, mostly from developed countries, suggests that PCR has good sensitivity and high specificity for the detection of both CT and NG.[467] However, a number of studies have shown that the specificity of Amplicor to detect NG might be suboptimal as Amplicor primers cross-react with DNA of other *Neisseria* species [468] and also with DNA of *Lactobaccilus spp.*[469]

The confirmation of all NG positives with a 16S rDNA PCR ensured high specificity for NG, however, the relatively low prevalence of NG suggests that this may have reduced the sensitivity of the NG testing algorithm. Every effort was made to maximise the specificity and sensitivity of the HIV and STI testing algorithms, nevertheless, any misclassification is likely to have been differential and would have led to an underestimate of intervention impact.

5.7 Limitations of the intervention

One explanation for the lack of impact could have been weaknesses in the design or implementation of the intervention.

5.7.1 Intervention Design

This was a well thought out intervention that was developed following formative research. External evaluations of the intervention design and materials concluded that it was theoretically sound and of high quality. Nevertheless, while the intervention appears to have been successful at addressing knowledge of risks and benefits of behaviours it was less successful at changing other cognitions such as susceptibility to risk.[105] This is supported by more recent qualitative research among trial participants which found that young people had low perceived susceptibility to risk.[316] The fact that adolescents do not always recognise their vulnerability to risk has also been noted in reviews of other adolescent health promotion studies such as smoking, recreational use of drugs.[360] At an individual level, the intervention messages were appropriate though, as with many ASRH interventions, the focus was on the negative (e.g. importance of avoiding pregnancy, dangers of sex) rather than on the positive (e.g. safer sex is enjoyable, staying in education is good). Sexual exploration and some risk taking are to be expected and the promotion of harm minimisation is likely to be more successful than the promotion of abstinence.

The intervention design had a number of constraints due to the Tanzanian context and because the intervention had to be sustainable and easily scaled-up through government services.[179] For example, the Tanzanian Ministry of Education limited ASRH to last 3 years of primary school though some argue that interventions might be more successful if they are started at a younger age.[94] The ban on condom demonstrations in the classroom[179] is also likely to have diminished the intervention's ability to encourage correct use of condoms. The inherent conservatism of the education system (e.g. didactic teaching styles) further constrained the design of the in-school component of the intervention and may have had a negative impact on the coverage and delivery of the intervention. Gender imbalances including a low proportion of female teachers and girls' traditional inhibition in participating in mixed group discussions and dramas may have meant that girls experienced the intervention differently to boys.

A significant limitation of the intervention related to the intensity of the community component. Preparatory research had highlighted five key environmental influences ***(Section 1.4.2)***, including community resistance to the discussion of adolescent sexual behaviour and the importance of sex as a source of income for girls, and intervention efforts at addressing these influences were probably insufficient. Furthermore, as highlighted above, the absence of appropriate role models and strong community norms in relation to sexual behaviour, made it difficult for young people to practise the MkV1 teachings. In addition, these interventions had very limited reach to out-of-school youth, who were potentially a higher risk group and who may have shared the same sexual networks as the in-school youth.

The obvious way to try to bring about community-wide education and behaviour change would be larger-scale community-wide programmes. However, the feasibility and sustainability of such programmes in resource-poor countries, such as Tanzania, is debatable. For example, a large-scale out-of-school youth programme would have been expensive as a large number of suitable community outreach staff would have had to have been identified, recruited, trained, paid and supervised. [179] An income generation programme for girls was not included, presumably, as this would also have been resource intensive. Traditional healers are commonly used for STI treatment but the careful development of an appropriate intervention with them was beyond the scope of MkV1.[179] Mass media, radio and other national or region-wide approaches were not included as these would have compromised the trial design.[186]

In summary, those who designed the intervention were not unaware of the environmental influences on young people's sexual risk behaviours and they did make both direct and indirect attempts to address these. However, many of these influences appear to be very strong and as such the intervention could only go some way to reaching its objectives. In reality, it was perhaps not feasible to expect a short intervention among young people to change long-standing gender and age power hierarchies.[179, 316]

5.7.2 Intervention implementation

The main component of the intervention was a teacher-led in-school education and one of the most important questions to ask is 'Was the intervention correctly delivered by the teachers?'

Internal and external process evaluations carried out between 1999 and 2002 demonstrated that the interventions were delivered to a high standard and that coverage was high ***(Section 1.4.3.1)***. However, a number of limitations were noted which are likely to have led to sub-optimal implementation of the intervention (e.g. some teachers had difficulty with the new teaching style, the class peer educators (CPE) had limited ability as informal educators and behavioural models).[105]

Detailed process evaluation data is not available for 2003 and 2004 and it is possible that implementation quantity and quality decreased during this time, especially as refresher training for teachers did not take place and there was no training provided for new teachers who had replaced trained teachers who had left the trial schools due to transfers, retirement, or death. Process evaluation, however, was carried out during the scale-up of the intervention (2005-2007) when there was also a lower level of supervision and support for the programme. Researchers found that, while the teaching quality remained high, the coverage of sessions waned especially for the final sessions in each school year (i.e. the more life-skills based sessions such as planning your life, resisting temptations, and condom use). Furthermore, even after teacher training, a number of the teachers still believed that teaching ASRH encouraged sexual activity.[205] Given the high turnover of teachers and lack of refresher training, it is reasonable to assume that the quality and quantity of in-school teaching decreased during 2003 and 2004.

The health facility component of the intervention also appears to have been well implemented including the visits to schools by a health worker and visits of classes to the local health facility.[105] The small simulated patient study revealed some improvements in the 'youth-friendliness' of health services in the intervention communities, however, privacy for consultations was largely lacking and condom demonstrations may not have been carried out as frequently as might be desired.[187] No refresher or replacement training for intervention health workers was carried out in 2001 and, given the reported high turnover of staff,[187] this is likely to have reduced the successful implementation of the intervention in some health facilities during 2001.

The condom promotion and distribution component of the intervention was not as successful as anticipated ***(Section 1.4.3.3)*** and this component was dropped in the middle of 2002 as there was no obvious mechanism whereby this could be sustained by a government-run programme. It is possible that improved access to condoms would have led to an increase in condom use but the qualitative research suggests that limited demand was the primary reason for low levels of condom use.[183] The community component of the intervention was limited and there were limitations in the coverage of the community activities with many community members remaining unaware of MkV1 activities ***(Section 1.4.3.4)***.[179]

In summary, there were some limitations to the intervention implementation though major limitations were restricted to the condom promotion and distribution component. Interventions that strongly rely on the performance of individuals, as opposed to, for example, the performance of a drug, are unlikely to be perfectly implemented. An intervention such as MkV1, which was designed to be sustainable and delivered through government structures, was always going to be more likely to have less than perfect implementation as it was relying on staff not directly paid by the project. It is clear that contextual factors inhibited the perfect implementation of the intervention and also prevented young people from putting into practice the teachings of the intervention. The following key structural barriers to the implementation of teacher-led programmes in Mwanza have been identified: too few teachers, teacher absenteeism, low paid and poorly motivated teachers, turnover of trained teachers, lack of supervision, low priority of reproductive health topics and a paucity of female teachers.[28, 105, 470] Also, several official and unofficial school practices have serious implications for teacher-pupil relationships and contribute to pupils' secretiveness about their sexual activity (e.g. mandatory pregnancy examinations, corporal punishment and sexual abuse of schoolgirls by teachers).[28] The fact that teachers and also CPE may have been practising behaviours that went against the teachings of the intervention would have prevented them from being good role models.[105] Young people and especially young females are exposed to powerful and contradictory sexual norms and expectations[104] and some pupils reported that the teachings were unrealistic and irrelevant.[105] Modelling behaviour and self-efficacy are integral to Social Learning Theory, the theory on which the intervention was based, and if the intervention failed to modify these cognitions/concepts then desired behaviour change among young people would not be likely.

Despite all these weaknesses, the quality of implementation was likely to have been strong relative to what one would expect in a routine programme as training was done to a high standard and supervision and support was provided every quarter.

5.8 Comparison with the findings of other similar research

5.8.1 Systematic review

The systematic review of evidence (1990-2008) on the effectiveness of interventions in sub-Saharan Africa to reduce risky sexual behaviours and pregnancy, HIV and other STIs among youth ***(Section 2.4)*** found that, despite 19 years of research, there was still insufficient evidence to recommend wide scale implementation of the majority of the types of interventions that had been considered ***(Chapter 2)***. That said, the volume of evidence is increasing and 22 relevant studies which had been completed in recent years (2005-2008) were identified. Sufficient evidence existed to recommend wide scale large-scale implementation (***Go!***) of in-school interventions that are adult-led and curriculum-based, based on their impact on knowledge, attitudes and reported sexual behaviour. Evidence also existed to suggest that the following interventions were effective, but large scale implementation of these types of interventions should be accompanied by further careful monitoring and evaluation (***Ready***):

- Interventions in health facilities that train service providers and take actions to make the facility more youth-friendly, coupled with activities in the community with or without involvement of other sectors to link or refer young people to health services
- Community interventions targeting youth and creating own system and structure for delivery
- Community interventions targeting the whole community and delivered through traditional networks.

In-school interventions that were peer-led and/or non-curriculum based, health facility interventions that do not also involve actions in the clinic and in the community, and community interventions that target youth using existing organisations and that target the whole community using community-wide activities were recommended for more research and development (***Steady***).

It is important to note that multi-component interventions that were conducted in more than one setting, for example, in schools, health facilities and geographically-defined communities were considered under more than one setting in the review. Had the decision been made to classify the interventions according to one of the settings only (e.g. selected arbitrarily or by the component that cost the most), then less interventions would have been under consideration in each setting. If intervention impact was due primarily to one component of the intervention, for example, the in-school component, then inclusion of the intervention in another category such as health facility, would have artificially increased or decreased the effectiveness of such health facility interventions. However, given that insufficient data were available to determine which component was the most effective, the inclusion of multi-component interventions under a number of settings is justified. Recommendations were made based on the ability of specific intervention types to impact on reported risk behaviours. Therefore, for example, in-school teacher-led interventions such as MEMA kwa Vijana are given a 'Go' recommendation despite the fact that there is no evidence to suggest that these kinds of interventions will lead to a reduction in HIV, one of the main UNGASS goals.

Also, an intervention was considered as having an effect (positive or negative) if one or more significant results were found from among all of the relevant outcomes measured. This decision meant that many interventions appeared more successful in reaching their objectives than they really were. For example, Study L, the 'I choose life' intervention in Kenya ***(Table 2.1-2.2)*** encouraged primary or secondary abstinence, faithfulness and condom use yet a positive intervention impact was seen only on the condom use outcomes. This suggests that the intervention only met one of its three main objectives, however, in the review this intervention is categorised as having an overall positive impact. A similar pattern is seen for other interventions with few of the more rigorously designed evaluations finding a positive impact on more than one or two of their reported behaviour outcomes ***(Table 2.2)***. From a policy and programming point of view, this 'glass half full' approach is appropriate as even small reductions in risk behaviour could have an important impact on the health of young people. In the absence of a 'perfect' intervention (i.e. one that reduces all types of sexual risk behaviour), it will be important to advocate the scale-up of interventions that lead to a reduction in some sexual risk behaviours. However, it should also be a priority to further explore the reasons for the failure of an intervention to achieve all of its objectives. In particular, the appropriateness of the chosen theory of behaviour change should be considered if an impact is seen on behaviour but not on the hypothesised antecedents to behaviour change or vice versa.

5.8.2 Qualitative sub-study findings

One of the key questions that cannot be answered through a quantitative questionnaire is 'Why was there an apparent gap between knowledge and biological outcomes among those exposed to the MEMA kwa Vijana intervention?' The HALIRA work had highlighted that young people were situated in norms where they alone could not change behaviour patterns.[104] Follow-on qualitative work in 2009 involved the re-interviewing of 23 young people who had participated in MkV1FS and who had also participated in in-depth interviews and participant observations during the HALIRA project (1999-2002). This recent study further demonstrated the lack of agency for young people in rural Mwanza to shape their own sexual histories and behaviours and the importance of the social context.[316] The authors conclude that *'More distal influences, such as cultural norms and expectations, are likely to have also been very important and could have been major counter forces to the application of the knowledge acquired through the MEMA kwa Vijana SRH intervention'.*[316] In this study, the earlier HALIRA qualitative research and the more recent formative research conducted with MkV2, a number of themes emerged including the centrality of the family context, especially parenting, in influencing either negatively or positively the sexual behaviour of rural youth.[104, 316, 471] Factors associated with abstinence among females included fear of getting pregnant while at school, no need to have sex to get money and gifts as they received most of their material needs from their parents, and living with both parents before getting married.[316] The individuals interviewed had a low perception of 'self-risk' which research has shown to be associated with higher risk behaviours.[147] One male student suggested that MkV1 should emphasise even more that risky sexual activity could prevent them from achieving their future goals and aspirations (such as pursuing further education).[316] The authors suggest that *'the focus of sexual health interventions targeting young people in rural Mwanza should broaden from a narrow focus on psychological models of behaviour change which have tended to centre on individuals and individual decision-making. They should instead give more prominence to factors influencing the wider social, economic and cultural environment within which the young people are living and playing out their sexual lives.'*

The extensive body of qualitative research that has now been carried out among young people in rural areas of Mwanza Region strongly suggests that it is important to explore interventions that will attempt to change the social and sexual norms within the wider community.

5.8.3 Other studies

Three other African studies have measured the impact of ASRH interventions on biological outcomes and generally their findings have not been promising. [289, 384, 420] This present study is a valuable complement to these three studies. A direct comparison between these studies is difficult given the differing contexts and the differences in interventions, nevertheless, some important observations can be made.

The Regai Dzive Shiri (RDS) Trial in Zimbabwe ***(Study A, Table 2.2)*** is probably the closest to MEMA kwa Vijana (MkV1) in terms of intervention design and target population.[420, 472] Both MkV1 and RDS included in-school education, though this was led by older young people in RDS, and both included efforts to make health facilities more 'youth-friendly'. Importantly, the RDS intervention included a more intensive community component with 22 3-hour sessions for parents and other community members delivered by a trained community facilitator. Also, in the fourth year of the RDS intervention a 24-session out-of-youth programme was implemented though this may have been too late to have much impact on, for example, HIV prevalence at the end of year 4. It is possible that MkV1 failed to change behaviour because the intervention did not focus sufficiently on the broader community and on out-of-school youth. If this is the case then the RDS results are particularly discouraging. However, the RDS trial suffered from excessive out migration and any intervention impact is likely to have been diluted by low levels of exposure to the intervention for many young people in the intervention arm.[420]

The Stepping Stones intervention ***(Study B, Table 2.2)*** was associated with a 33% reduction in the incidence of HSV2 over the two years of follow-up and was the only of these interventions to show an impact on a biological outcome. Among males, the intervention was also associated with a reduction in reported intimate partner violence over 2 years of follow-up and a decrease in reported transactional sex and problem drinking at 12 months. The authors suggest that the success of this intervention may have been associated with the fact that the intervention had been more extensively tested and adapted when compared to other similar interventions.[384] The Stepping Stones intervention involved training sessions for school-going youth after school hours and the impact of the intervention was evaluated in groups of self-selected volunteers, who were therefore likely to be motivated to learn about and perhaps change their HIV risk behaviour. As originally designed, the Stepping Stones intervention also involved working with older men and women in each community as well as young people and suggested that peer groups be encouraged to continue to meet after the end of the workshops. Had these two aspects been included in the South African Stepping Stones intervention then perhaps the intervention would have been associated with an impact on some of the other outcomes including reported sexual risk behaviours and HIV incidence. Interestingly, qualitative research associated with this trial found that women were sometimes able to change their behaviour with younger male partners but not with older male partners. The prevalence of HSV2 is much higher in young men than the prevalence of HIV and the authors suggest that this may explain why a reduction was seen in HSV2 and not HIV prevalence.[384]

The IMAGE intervention ***(Study W, Table 2.2)***, also in South Africa, was a mixed structural and health education intervention. The latter involved women (who happened to be in a microfinance programme) receiving fairly standard behaviour change education.[289] An impressive 55% reduction in reported intimate-partner violence was seen among the women who directly participated in the intervention but there was no impact on the rate of unprotected sex with a non-spousal partner either among household members nor in the broader community. It was thought that HIV infection rates in the wider community might decrease as a result of this intervention through diffusion from those receiving the intervention. The authors admit that the 2-3 year follow-up may have been too short to see such an impact.[289] Additional analysis on females aged 14-35 years who participated directly in the intervention revealed some similarities with the MkV1FS results. In particular, the intervention led to an increase in reported condom use at last sex with a non-spousal partner in the previous 12 mths but the intervention was not associated with a reduction in number of sexual partners during the same time period. The intervention was also associated with an increase in reported communication about sex or HIV within participants' homes. Qualitative data suggested that the women had enhanced bargaining power and increased confidence in negotiating safer sex.[290] Perhaps, the MkV1 intervention was associated with an increase in reported condom use because women exposed to MkV1 also had increased confidence in negotiating safer sex.

One other African study is worth mentioning as it also attempted to measure the impact of a behavioural intervention on HIV infection, albeit using a non-randomised, observational, cross-sectional design. The LoveLife programme is a national HIV prevention programme for youth in South Africa ***(Study D, Table 2.2)*** which combines a sustained multi-media education and awareness campaign and a nationwide programme of youth-friendly health clinics. A cross-sectional survey carried out almost 4 years after the start of the programme found that sexually experienced youth who reported participating in the LoveLife programme were significantly less likely to be HIV infected. [385]However, exposure to the intervention was defined quite crudely as 'participated in one of the LoveLife programmes' and it is possible that those who participated in LoveLife were a lower risk group. The possibility that the observed differences in HIV prevalence related to exposure to the LoveLife programme were not causal but due to confounding cannot be excluded. Pettifor and colleagues subsequently wrote an interesting paper highlighting the challenges faced when trying to assess the impact of such a multi-faceted national prevention programme e.g. lack of control group, no clear way to measure overall exposure to the various components of the programme and multiple other programmes simultaneously being implemented. [220]

In the UK, two cluster randomised trials of sex education programmes for young people also failed to find an impact on biological outcomes. The SHARE trial compared a participatory teacher-led in-school sex education programme for 13-15 year olds with the standard teacher-led sex education programme for this age group in Scotland. The trial did not find a difference in the primary outcomes of clinically recorded conceptions and terminations by age 20.[433] A strong association between rates of conceptions and socio-economic status was observed and the authors suggest that future interventions should address *'fundamental socioeconomic divisions in society'*. They also suggest involving parents as parenting factors have been shown to influence sexual behaviour.[433, 473] The RIPPLE trial in England evaluated the impact of a much shorter peer-led in-school intervention compared to an equivalent number of classes taught by teachers. This trial was important as it also used linkage to routine data to objectively measure rates of abortions and live births among study participants and it had a long period of follow-up (7 years).[432] While the peer-led approach was more popular with students, the rates of abortion and live births were similar in each trial arm.[432] These two trials opened again the debate over peer-led vs teacher-led in-school interventions. [246] However, while on paper peer-led approaches may appear better, in practice the evidence on their effectiveness, certainly in SSA, is weak ***(Table 2.4)*** and they are more difficult to implement in terms of feasibility and cost. Importantly, both of these UK interventions, like the MkV1 intervention, led to significant improvements in sexual health knowledge. The lessons learnt from these UK trials are similar to those that can be learnt from trials in SSA, for example, the importance of rigorous study design, the inclusion of objective biological outcomes, the fact that interventions may not reach their objectives in the longer-term and the potential need for additional interventions to address broader social norms.

One key question for researchers is whether intervention effects will be sustained over time. It is, therefore, very encouraging that both the MkV1 and the RDS intervention have found that knowledge of HIV, other STIs and Pregnancy was sustained in the long-term. In South Africa, the Stepping Stones intervention was associated with decreases in some reported risk behaviours at 12 months but these reductions were not observed at 24 months.[384] Conversely, this study also found an impact on reported incidence of intimate-partner violence that was greater at 24 months than at 12 months. The authors suggest that this may be because people have had a chance over time to reflect on their behaviour or for the environment to reinforce behaviours. If this is true, however, it is not clear why a similar longer-term impact was not seen on other targeted behaviours. DiClemente and colleagues argue that a broader, ecological perspective may be needed to amplify and extend the efficacy of sexual risk reduction interventions.[147]

One general observation, which is supported by other studies,[226, 347, 422, 429] is that interventions appear to more frequently have an impact on reported condom use than on a reduction in reported numbers of sexual partners ***(Table 2.2)***. However, it is unclear whether this is due to reporting biases, a relatively greater emphasis on condoms in intervention curricula or because changing behaviour in relation to condom use is easier than avoiding sexual relationships. It is likely that in the past there has been insufficient attention paid to encouraging a reduction in sexual partners. In recent years there have been increased efforts to try to understand the kinds of partners and partnerships that put people most at risk of HIV e.g. the type and age of partners, concurrency and gaps between partners, etc.[474-477] Further exploration of risk associated with different partners and partnerships using MkV1FS data is beyond the scope of this thesis but will be explored during a post-doc fellowship. Future interventions might be more effective if the choice of intervention messages and target groups is informed by the levels of risk associated with different types of partnerships and partners.

5.9 Conclusions

It is important to highlight the context in which the research question of the long-term evaluation was conceived. Despite evidence to suggest that HIV incidence was falling among some groups in some parts of sub-Saharan Africa, HIV remained an important public health problem. Incidence rates are highest in the late teens and early twenties and good evidence suggests that it is easier to influence behaviours before they are well-established, so preventing HIV in young people was considered a top priority. It was unlikely that an effective vaccine or microbicide would become available in the near future and behavioural interventions were therefore the best hope for prevention in the short to medium term.

The 2001/2 impact evaluation survey had shown a positive intervention impact on upstream knowledge, attitudes and reported behaviour outcomes and a point estimate of the adjusted rate ratio for HIV incidence of 0.75 among females. The widely held belief at the time was that reported behaviour change would lead to an impact on biological outcomes, if not in the short-term, then in the longer-term. On the one hand the results of the 2001/2 evaluation survey did not necessarily contradict this belief though on the other hand no impact on biological outcomes was observed.

The 2007/8 impact evaluation survey made three important additional contributions, though some have questioned the added value. Firstly, the study demonstrated that in the long-term (9 years of implementation) this intervention, in this context, did not lead to a reduction in HIV, HSV2, other STIs or reported pregnancy. Secondly, exposure to the MEMA kwa Vijana intervention did not increase risk-taking among youth, however, the study highlighted a reduction in intervention impact over time on reported attitudes to sex among females and reported behavioural outcomes but a sustained impact on reported attitudes among males. Thirdly, significant differences in ASRH knowledge persisted in the 2007/8 survey when the young people had last been exposed to the in-school intervention an average of 5.4 years previously.

The results of this trial show that such skills-based sexual health education interventions and youth-friendly health services can make a valuable contribution towards the UN General Assembly Special Session on HIV/AIDS goal of increasing young people's access to the information, skills and services they need to reduce their vulnerability to HIV. However, there was no evidence that the MkV1 intervention had any impact on HIV, HSV2 or other STIs in the long-term.

These findings are an important addition to the knowledge gained from the 2001/2 evaluation. Following the 2001/2 results the narrative in relation to this intervention in terms of reduction of HIV, other STIs and unplanned pregnancies, in this context, was 'it might work' whereas following the 2007/8 results the narrative is 'it probably doesn't work'. Furthermore, an extensive review of the literature linked to the MkV1FS suggested that the results of the MEMA kwa Vijana trial reflected a more general inability of existing behavioural interventions to reduce rates of HIV, other STIs and unplanned pregnancies among youth, not only in SSA but globally.

The first generation of behavioural interventions that have largely focused on young people through the use of individual behavioural change theories have been unsuccessful and efforts to design, implement, and rigorously evaluate behaviour change interventions among adults as well as young people, with strong support from political leaders, are urgently needed.

Chapter 6 - Conclusion & Recommendations

6.1 Summary of main findings

The MEMA kwa Vijana trial has shown that a local African NGO and existing government health and education staff can successfully implement an intensive, innovative adolescent sexual health programme on a large scale. The MEMA kwa Vijana Trial Further Survey (MKV1FS) investigated whether the absence of any significant beneficial impact of the intervention on the key biological outcomes after 3-years of implementation (2001/2) was because the intervention needed more time to work. The results showed that, even when the intervention had been implemented for over 8 years, and 67% of the young people surveyed had received 3 years of the in-school intervention, there was no significant impact on either of the primary outcomes, HIV or HSV2, nor a consistent impact on other STIs or on reported pregnancy rates. However, significant benefits in knowledge were still present among a group of young people who had, on average, last had exposure to the in-school intervention, 5.4 years prior to the survey.

The findings of MkV1FS are an important contribution to the field of HIV prevention as this was the first study in sub-Saharan Africa (SSA) that showed that improvements in SRH knowledge can be sustained for such a long period of time after exposure to an in-school intervention and confirmed that such interventions can make a valuable contribution to the UNGASS goal of increasing young people's knowledge of how to protect themselves from HIV. However, it also provided evidence that, contrary to popular opinion, an impact on upstream outcomes such as knowledge, attitudes and reported behaviours will not necessarily lead to a reduction in HIV and other objectively measured SRH outcomes in at least the medium term.

The systematic review of the evidence on the effectiveness of behavioural ASRH interventions to reduce sexual risk behaviours and rates of HIV, other STIs and pregnancies revealed that, while there is strong evidence to show that some types of interventions can impact on some of the more upstream outcomes such as knowledge or attitudes to sexual risk, there was no evidence that any of the types of interventions considered had led to a reduction in HIV and only one intervention had led to a reduction in an STI (HSV2). Qualitative research conducted among young people in the same communities that were involved in the MEMA kwa Vijana trial revealed important and deeply-entrenched social norms among the general population that mitigated against young people's ability to avoid sexual risk. These included gender and age-related power imbalances, pronatalist norms, reluctance to use condoms, and the acceptance of transactional sex among unmarried people. [104, 183]

Taken together, the findings from the long-term impact evaluation survey, the systematic review and the accompanying qualitative research strongly support the suggestion that future interventions should be accompanied by more intensive efforts to change population norms.

6.2 Implications of findings for policy makers

The results of MkV1FS and those of the impact evaluation of the Regai Dzive Shiri (RDS) Trial in Zimbabwe ***(Study A, Table 2.1-2.2)*** led to the formulation of two key messages for policy makers. The first message related to the impact of the interventions on knowledge and the second related to the failure of these interventions to reduce the rate of HIV and other STIs.

Knowledge and skills are essential for young people who want to reduce their risk of HIV or other STI and interventions can have a sustained impact on knowledge

Accurate knowledge and skills are essential for young people who want to change their behaviour, and access to them is a human right. The sustained impact on knowledge that was demonstrated in the MkV1 and RDS studies was an important achievement. Such skills-based sexual health education interventions and youth-friendly health services can make a valuable contribution towards the UN General Assembly Special Session on HIV/AIDS goal of increasing young people's access to the information and skills they need to reduce their vulnerability to HIV.

Current interventions have not led to a reduction in rates of HIV and other approaches need to be developed, implemented and evaluated

The two trials' results imply that such interventions on their own will not be sufficient to reduce HIV and other STIs among young people in SSA. This suggests that, in order to reduce HIV incidence among young people in SSA, additional efforts are needed to:

a. Increase young people's access to effective HIV prevention interventions including condoms, male circumcision, early STI treatment, and clean injecting services for IV drug users

b. Design, implement, and rigorously evaluate interventions to change population norms related to sexual risk behaviours among adults as well as young people, with support from strong political leadership

c. Address structural (societal) issues, such as gender inequality, that are drivers of the HIV epidemic

A number of challenges to the response to HIV/AIDS in Tanzania have been identified ***(Section 1.3.6)*** such as inadequate and uncoordinated advocacy efforts, and addressing these challenges will facilitate increased access to existing effective interventions. This must be a priority, as recent data from Tanzania suggests low use of health facilities for STI treatment, low levels of condom and contraceptive use, low levels of circumcision and low uptake of PMTCT. Furthermore, while MkV1FS revealed high levels of HIV acquisition knowledge in both trial arms, the correct responses to the three basic questions that comprised the knowledge score were not universally known. Further efforts are needed to ensure that all young people have the knowledge that they need to protect themselves from HIV, other STIs and unplanned pregnancies.

It will be important to base policy decisions on evidence from research studies and other evaluations of interventions. Planning for evaluation early in the intervention development and implementation process, with an emphasis on the use of high quality evaluation design, should be encouraged. Funding for intervention development, including evaluation, should be provided. This is particularly important as high quality HIV prevention studies are expensive as they often require large sample sizes to see modest but important reductions in HIV.

In terms of the development of interventions to change population norms, one of the key areas to address will be stigma as this can prevent people accessing both prevention and treatment services and can hamper efforts to increase communication on sexual health.[80] Communities, families, young people and the media should all be involved in prevention as intervention efforts among young people may be most effective when they are reinforced by other sectors of society.[92] Achieving the other global goals of reduction of poverty and gender imbalances, improvement of employment opportunities and protection of human rights could reduce young people's vulnerability to HIV/AIDS.[291] However, any efforts to address community norms and broader societal issues must be accompanied by the commitment of political and religious leaders. An examination of the context of the behaviour change programmes in Uganda and Mbeya, Tanzania revealed that political support was important to their success.[92] It is important that neither politics nor ideology prevent policy being based on evidence and best practice. Dickinson and Buse suggest that analysis which identifies the political obstacles to and opportunities for evidence-informed policy should constitute a core feature of every national HIV response.[478]

6.3 Recommendations for researchers

Three important recommendations for researchers come out of the results of this research.

- Firstly, the high rates of HIV and other STIs, high levels of reported sexual risk behaviour and low levels of knowledge of STI acquisition and pregnancy prevention that were observed in this population of young people imply that intervention development and evaluation should be given a high priority.

- Secondly, given the lack of correlation between the various behavioural and biological outcomes, objective biological outcomes should be used in future studies, wherever possible.

- Thirdly, efforts must be made to improve existing interventions and to develop alternative interventions so that population norms can be changed and societal factors that impact on young people's vulnerability to adverse SRH outcomes can be addressed.

In the following sections some of the key methodological challenges that will need to be addressed by researchers developing and evaluating interventions in the future are highlighted. Some potential ways that current interventions can be modified and possible alternative interventions that might complement interventions such as MEMA kwa Vijana in rural Mwanza are then suggested.

6.3.1 Challenges faced in the rigorous evaluation of structural and community-based interventions

Research to date has mainly focused on the relatively easy approach to HIV prevention; individual theory-based interventions in a controlled setting, usually schools. The targeted pathways were relatively short and clearly defined. With the shift towards structural and community-based interventions new methodological challenges are emerging that relate to both the evaluation study design and the measurement of outcomes such as social drivers and empowerment. [75, 208, 284, 291, 479, 480] For example, randomised controlled trials may not be suitable for the evaluation of mass media interventions due to problems with contamination of control areas and alternative designs may be more appropriate.[268] Similarly, where the intervention is likely to bring about other important benefits such as income generation, then a control group might be considered unethical.[480] Where it is possible to have a control group, it will become increasingly difficult, ethically, to define what the control group should receive.[340, 481] Future interventions are likely to face challenges similar to those faced by the team who evaluated the nationwide LoveLife campaign in South Africa, such as difficulty in measuring exposure to the interventions, and to multiple other programmes being implemented simultaneously.[220] Further research on the most appropriate way to rigorously evaluate structural and community-level interventions is recommended. Linked to this is the need for appropriate exposure and outcome measures and the appropriate use of multi-level analytical methods.

6.3.2 Study context and generalisability

Preparation for future community and structural level interventions will require careful mapping of the social, political, economic and environmental factors influencing both vulnerability and risk.[291] Such preparatory work will represent a large investment in terms of time and resources; however, this is preferable to the implementation and evaluation of interventions that are inappropriate to the target population and context. One important question will be to what extent behavioural or structural interventions that have been shown to be effective in one context will be effective in another. A thorough understanding of the context in which the intervention has been implemented will go some way to improving our understanding of whether an intervention might work in another context. However, such knowledge is unlikely to negate the need to modify the intervention to make it culturally appropriate and to evaluate the intervention's impact in the new context. It will be important to consider what kind of study design will be required for evaluating an 'effective' intervention in a new setting. Traditionally, when sufficient evidence of impact was available from systematic review of the scientific literature, then an intervention was recommended for wide-scale implementation. However, if we believe that the success of behavioural interventions among young people is context-dependant then this approach to making recommendations has its limitations. Mathematical modelling is likely to be increasingly utilised for the prediction of potential intervention impact in other settings[482] though the success of this approach will depend on how well the pathways through which the intervention act are understood.

6.3.3 Understanding the 'how' and 'why' of intervention success and failure

Qualitative research has long played a key role in the development of interventions and in helping to interpret the impact of the interventions. As was shown in the case of MEMA kwa Vijana, large-scale and longtitudinal qualitative research can help to explain the how and why of intervention success and failure and should accompany any quantitative intervention evaluation. Many of the most successful interventions that have been developed are multi-component and there are a number of questions outstanding as to how they work. Operational research should focus on attempting to explain in more detail the content of the intervention and its mechanism of action. Efforts should be made to disentangle the various components of an intervention and their relative importance, in order to inform future programming decisions related to what aspects of the interventions are essential and the most cost-effective. Given that the mechanisms through which multilevel interventions act are complex, care must be taken during the development stage as such interventions may be more prone to having unintended consequences. For example, in the SHAZ! microcredit and lifeskills training and mentorship programme in Zimbabwe the personal safety of some of the girls involved was threatened as a result of their travel to trade in unfamiliar places where they did not have safe accommodation.[483]

6.3.4 The importance of intervention evaluation outcomes

Positive changes in knowledge, attitudes and reported behaviours do not always lead to a positive impact on HIV, STDs and unplanned pregnancies. Care, therefore, should be taken when interpreting the results of evaluations that only report self-reported sexual behaviour. Future evaluations of HIV prevention interventions should, wherever possible, include biological outcomes as this will allow direct objective measurement of intervention impact on rates of HIV. In deciding on appropriate outcomes, the advantages and disadvantages of the use of biological outcomes should be weighed up. For example, if the prevalence of HIV or another target STI is very low then laboratory tests may yield a high proportion of false positives and/or the study may not have the power to detect a difference in such rare outcomes. The expense and logistical effort required to collect and analyse biological samples should also be considered. The fact that reported sexual behaviours are not necessarily a good proxy for biological outcomes, and that one STI is not necessarily a good proxy for another STI has been well described[302, 323, 324, 327, 484] and suggests that it is advantageous to measure both behavioural and biological outcomes. Linked to this is the need to improve the measurement of sexual behaviour to reduce the possibility of biases and to develop ways to measure more abstract outcomes such as empowerment and vulnerability. Impact evaluation of structural interventions will be complicated by the fact that interventions that target such distal determinants may take longer to impact on e.g. HIV incidence, and longer-term commitment from funders will be needed. One key question is whether, with a clear theoretical construct for understanding causality, it will be sufficient to measure the impact of an intervention on a distal determinant of HIV or whether an impact on HIV is necessary.[485]

6.3.5 Looking forward: scale-up, sustainability and cost

In addition to the evaluation of new interventions it will be important to scale-up existing effective interventions and to evaluate the impact of the scaled-up interventions.[50, 138] In generalised epidemics, the ultimate aim will usually be to scale up interventions on a large-scale e.g. nationwide. It is essential to ensure that such scale-up does not lead to an effective intervention becoming ineffective e.g. due to poor implementation or because of intervention modification. It will be important for future interventions to consider the possibility of booster sessions.[316] This may be especially important where interventions are delivered to young people prior to their sexual debut as messages and skills acquisition may need to be reinforced as they mature and their relationships change.[486] Sustainability is an issue for both structural and community-based interventions and youth and community ownership of the programme and strong links with the government and/or NGOs are recommended.[267] Sustaining the quality and intensity of community-based interventions may pose a particular challenge as there is often no clear structure through which training, monitoring and supervision can take place. Not only must interventions be sustainable and suitable for scale-up, they must also be cost-effective. Cost and cost-effectiveness data are lacking in most intervention evaluations and it is imperative that such data should be collected wherever possible, as they are essential for guiding programming, particularly in resource-poor settings.

6.3.6 Improvement of existing interventions and development of alternative interventions

There is broad consensus that in addition to individual (micro-) and community (meso-) level interventions, research should address the structural and social factors (macro-level), the 'drivers' of the epidemic, that increase young people's vulnerability to HIV infection.[26, 279] The main 'drivers' are believed to be economic underdevelopment and poverty, migration/mobility and gender inequalities[74] and Kim and Watts argue that major transitions in these 'drivers' are essential preconditions to change.[487] Many have discussed the need to create a 'safe and supportive environment' [27, 361] where young people are safe from harm, cared for equally and treated with respect. In such an environment sexual violence, exploitation and abuse would be condemned and there would be equality between the sexes.[27]

Income generation

In Tanzania, there is evidence to suggest that reported sexual risk behaviours are lower and access to VCT higher among young people who are wealthier, better educated and who live in urban areas.[6] There is also some evidence to suggest that HIV prevalence has decreased in recent years among those who are wealthier but has increased among the poorest women.[137] One approach worth exploring in Mwanza is the use of income generation to reduce young girls vulnerability and to reduce the need for transactional and age-disparate sex.[105] In some settings, microfinance programmes have been effective in empowering women and have led to a reduction in gender inequity and in intimate partner violence.[289] However, there is no evidence to suggest that such programmes that address gender inequality can, in the longer-term, lead to a reduction in HIV incidence.[75] The feasibility of the introduction of an income generation project in rural Mwanza should be explored and the relative merits of micro-credit vs microcredit with livelihood training vs livelihood training on its own considered.

Education

Another approach that could reduce poverty and encourage equality between the genders would be an improvement in the level of general education among girls. Analysis of data on the young people who participated in MkV1FS revealed that those who were currently in education had a lower risk of HIV.[488] The protective effect of education among girls has also been observed in South Africa and other parts of Africa.[489, 490] A number of different attempts have been made to try to remove the structural barriers to education e.g. alternative forms of financial support such as the payment of school fees, the provision of school uniforms and conditional cash transfers for education.[376, 491] Some of these kinds of interventions might be effective in increasing school attendance by girls in rural Mwanza and should be considered.

Migration and mobility

It is likely to be much more difficult to develop interventions to reduce the high levels of migration and mobility in rural Tanzania. Economic development in rural areas might encourage more young people to stay at home though migration of females for marriage and of young people of both sexes for education would most likely continue as would mobility due to seasonal farming and fishing activities. It may, however, be feasible to reduce risk among young people who are mobile and also among their partners who stay at home. Educating community members on the higher risks involved with sexual relations when they or their partner are away from home may lead to safer sexual behaviour though the ability of education alone to change behaviours is uncertain. One idea that has been proposed is that partners travel together which could potentially reduce the risk for both partners though this might not be feasible where e.g. the man is travelling to work in a mine or where he plans to share a room with relatives, or the partner has a job that is not movable, such as farming the family's land.[145] An intensive prevention programme at migration points might be a feasible option. This idea is not new and such a 'Hot spot' approach which moves the focus from high-risk populations to high-risk places has previously been proposed.[207, 492, 493]

Changing community norms

The results of MkV1FS suggest that the MkV1 intervention was not effective at changing gender norms and future interventions should focus on gender norms and find ways to increase a woman's ability to make decisions within a relationship. Qualitative research in Mwanza identified a lack of community-based communication channels for ASRH information, a lack of collective efficacy, poor communication between parents and schools/committees, contradictory social norms regarding ASRH, a lack of coordination from village authorities, risky leisure and recreational activities, poverty, and unequal power and gender relations.[106, 135] Additional efforts to reduce gender inequalities, stigma and poverty and change population norms related to sexual risk behaviours should, therefore, involve the whole community and aim to provide information, stimulate discussion, develop skills, and build collective efficacy. Interventions that specifically target those members of the community who have the greatest influence on young people e.g. parents, are also recommended. Development of such interventions might benefit from the lessons learnt from African countries where a reduction in HIV incidence has been possible e.g. Uganda, Zimbabwe and Ethiopia. In Uganda, increased communication about HIV through social networks and the involvement of high-level political and community leaders is thought to have been important in facilitating behaviour change.[60]

Working with parents

Family support, parental monitoring, positive parental attitudes and increased parental communication have all been associated with a reduction in sexual risk behaviours among young people[147] In Mwanza, key factors influencing young people's sexual and reproductive health (SRH) include low parental monitoring, low parental provision, low levels of SRH knowledge (both youth and parents) and prior beliefs about ASRH.[106] Some studies in SSA have shown that parents were among the most utilised source for sexual and reproductive health information [494, 495] and are also considered by adults to be the preferred source of such information.[496] However, other studies have shown that parents were judgmental and that young people were uncomfortable sharing sex-related information with them.[90] Interventions may be able to improve communication between parents and their children and also improve parenting skills. For example, the IMAGE study in South Africa found that the female participants exposed to the intervention reported higher levels and also higher quality of communication with their children about sex.[497] Some interventions have already made efforts to include parents e.g. RDS in Zimbabwe, LoveLife in South Africa, and the MEMA kwa Jamii pilot programme in Mwanza and more work in this area is recommended.

Important sub-groups that should be targeted

Other intervention target groups that should be considered are younger young people, young people who are HIV+, married couples and older men. MkV1 attempted to target young people prior to their sexual debut i.e. before risk-taking patterns are established. Nevertheless, it is estimated that 26% of male and 17% of female MkV1FS participants were first exposed to the MkV1 intervention after they reported that they first had sex. These estimations may be subject to reporting bias but they do highlight the potential need to extend interventions to a younger age group e.g. 12-13 year olds or Years 3 and 4 of primary school. Different stages of adolescence have been identified and interventions should be tailored to the particular developmental stage of the young people who are targeted.

A large proportion of the young men and, especially, the young women who participated in MkV1FS were married or in cohabiting relationships. In generalised epidemics, it is likely that a large majority of new infections will take place within these more regular relationships as sex can be more frequent and condom use is low and often inconsistent.[78] If one of the partners in the long-term relationship has a concurrent partner then this will increase the risk. Intervention messages need to be developed specifically for married and cohabiting couples as the standard 'abstinence' and 'condom use' messages are not feasible especially when the couple wants to have children. One option might be the promotion of monogamous relationships and for consistent and universal condom use with any external partners but such a strategy would only work if both partners in the 'monogamous' relationship were to follow those two rules. Interventions that are targeted at the couple should be explored as such interventions transfer responsibility for STI protective behaviours from the individual to the dyad and may be particularly important for females in the rural Tanzanian context.[147] There is some evidence that sexual dissatisfaction or sexual dysfunction may lead to the decision to have a concurrent partner and interventions with couples should try to improve communication on these issues.

As the epidemic matures, an increasing number of young people will be infected with HIV either as a result of unprotected sex or because they were infected through their mothers. Specific risk reduction messages should be tailored to these young people to encourage them to access health services and to adopt safer behaviours so that they can protect themselves and their partners. As discussed above, interventions may be most effective when targeted at the couple and interventions will need to address the specific issues that discordant couples face. Children who have been orphaned by AIDS have been identified as being particularly vulnerable to HIV infection themselves and they will also be an important sub-group to target. There are strong arguments for targeting interventions specifically at women and young girls, however, the males should not be forgotten as they often have greater power to reduce the risk of infection within a relationship. Leclerc-Madlala suggests that new culturally recognized markers of manhood are required and that males should be encouraged to take on the role of protecting and supporting women.[86] The targeting of older men is recommended in order to encourage them to stop engaging in potentially exploitative relationships and to recognise that they are abusing their power and status by forming relationships with young girls.[86] Community-wide interventions that aim to generate community disapproval for such age-disparate relationships have been tried in Tanzania[498] and may be a successful way of changing the behaviour of men.

What kinds of interventions?

I have highlighted some potential target groups within the community, however, the question remains as to how exactly to engage these groups and more importantly to change their behaviour. In addition to in-school education and youth-friendly health services, both of which were incorporated in MkV1, UNAIDS have proposed peer-education and outreach using existing youth services, youth clubs, workplace programmes, campaigns for social change to address age-disparate and transactional sex, VCT, the removal of legal barriers to access prevention and care services including condoms, mass media and the social mobilisation of young people.[499] All of these are valid suggestions though, as always, the key question relates to the effectiveness, feasibility and sustainability of such interventions in resource-poor settings. Very few of these interventions have rigorous evidence on their effectiveness. Before thinking about developing new interventions it will be important to look at the design and success of existing small-scale interventions e.g. implemented by NGOs and community groups, as these 'ground-up' approaches may be the most effective[92] and might warrant more formal and rigorous evaluation.

Peer educators and role models

In rural Mwanza, a new parenting intervention, MEMA kwa Jamii, is being pilot tested which uses local opinion leaders to promote collective efficacy and to act as a resource for parents and caregivers. This is a promising approach, though, interventions led by peer educators and popular opinion leaders have had mixed, and seemingly context-specific, success. The use of school-going young people to act as peers was not very successful during MkV1 though it might be worth exploring the RDS model of using older young people who may be in a better position to positively influence young people. Qualitative research carried out in Mwanza suggests that there may be an absence of appropriate role models for young people with both peer educators and teachers often engaging in the exact behaviours that they tell young people to avoid. Changing community norms will require strong leadership not only from the peers of young people but also from adult opinion leaders at all levels of society. This is essential as National, Regional and local leaders are often seen to have multiple partners which can hamper the effectiveness of HIV prevention messages.

Mass media

Mass media or 'Edutainment' may be one of the most cost-effective means of increasing awareness, stimulating public debate, reducing stigma and promoting gender equality and is currently being used in many countries e.g. LoveLife and Soul City in South Africa, Femina HIP in Tanzania. In rural Mwanza, the most appropriate mass medium is likely to be radio as many of the population are illiterate and not many people have access to a television. One recent national campaign in Tanzania used radio spots and outdoor banners in an attempt to create a taboo against age-disparate sex, to provide a language of opposition to this and to model and encourage appropriate behaviours for community members. This campaign seems to have had some success though the implementers stress that such media interventions require a long-term strategy, adequate funding and must be complimented by community mobilisation.[498] Novel delivery methods should be explored.[283] For example, most people, even in the remotest parts of rural Mwanza, have access to mobile phones (often through their relatives/friends) and interventions may be able to harness this mode of communication[90] e.g. the LoveLife intervention in South Africa have pilot tested a mobile-phone based social network dedicated to youth empowerment & HIV prevention.[500]. In rural Mwanza, the use of the internet is not very widespread, however, internet cafes are present in the larger towns and access is likely to increase in future. Internet-based interventions in urban areas could, therefore, be an important component in a multiple delivery method approach, though internet interventions are unlikely to be feasible in rural areas of Mwanza where electricity is scarce.

Offering opportunities

Economic development, youth development programmes, continued school enrolment, community-group participation and church involvement may all enhance the social connectedness of young people and provide them with a sense of opportunity and a reason to stay safe.[501] Bearinger and colleagues support the idea of youth development programmes that could connect young people with supportive adults and with educational and economic opportunities.[11] Harrison, in a reflection on the gap between knowledge and behaviour change among young people in South Africa suggests that *'changing perceptions of opportunity should be central to behavioural interventions'*.[502] In developed countries, researchers are also realising the importance of opportunity and teenage pregnancy prevention programmes have incorporated career development and work experience components in an attempt to raise aspirations.[434] Furthermore, improving leisure and recreation facilities for young people may act as a 'positive diversion' that will discourage young people from engaging in sexual relations at an early age.[503] Sport, especially football, has been used in many countries in SSA to e.g. challenge stereotypes[504] and to promote HIV/AIDS education for at-risk youths.[505] Participation in sport may also lead to the development of lifeskills, promote a sense of social inclusion, act as a point of access to health services, and sportspeople and coaches can act as role models.[503] The capacity of sport to address HIV/AIDS is uncertain,[503] however, participation in sport is likely to offer other benefits to young people, such as promoting physical fitness, building self-esteem and self-confidence and reducing stress and depression, and the possibility of using sport as an intervention in rural Mwanza should be explored.[504]

Communication

Irrespective of their chosen format or medium, future interventions may be more successful if they place a stronger emphasis on the development of life skills, especially communication and negotiation skills. Such efforts should include the encouragement of high quality communication on sexual and reproductive health topics between young people and their parents, other adult family members, their teachers and their sexual partners. More frequent communication with sexual partners and greater communication with parents have both been associated with a reduction in risk behaviour.[147] An increase in communication may also lead to increased access to health services.

Perception of risk

Future interventions should pay particular attention to helping young people and other community members to understand the risk associated with their behaviour. In particular, the potentially higher risks associated with transactional sex and age-disparate sex should be highlighted. There is some evidence that a change in perception of risk is associated with a change in risk behaviour,[147, 486] However, other studies have found that exposing young people to population-based data about STI risk did not always translate into increased personal vulnerability[506] and that individual self-perception of risk may even be associated with HIV acquisition.[507] Interventions among girls to increase their perception of risk associated with age-disparate relationships have been tried in Kenya[440] and might be successful in the Tanzanian context. Games illustrating the transmission of infections and visits by HIV-infected individuals may also help in this regard.[105] Interventions that include a focus on perception of risk will continue to be important as there is a danger that the introduction of future biomedical interventions e.g. vaccines, microbicides, will be accompanied by an increase in risky behaviour.[508] Harrison and colleagues suggest that the issue may not be a lack of perception of risk but more a tolerance of risk and that the structural factors that predispose to high risk tolerance need to be targeted.[485]

A fresh look at risk communication

There is an increasing recognition that sexual and reproductive health interventions need to focus more on the positive aspects of sexual health and acknowledge that many young people choose to have multiple partners in order to satisfy their sexual desires.[475] The most effective HIV prevention programmes are likely to provide an alternative pleasurable option to young people e.g. a lower risk behaviour as opposed to abstinence. [440] Interventions to improve knowledge should be more comprehensive and include information on ART, PMTCT, the relative risk associated with different kinds of partners, the relative risk associated with different stages of the disease e.g. link between HIV viral load and infectiousness, and the protective role of circumcision.[86, 509] One of the major challenges to HIV prevention efforts is the stigma associated with condom use, especially within a stable relationship and interventions should attempt to reduce this stigma. However, given the challenges associated with condom use e.g. potential for decreased pleasure, need to interrupt love making to put on a condom; it is unlikely that 100% condom use will ever be attained. Interventions to encourage a reduction in high risk relationships are, therefore, even more important.

Health services

Data from MkV1FS have revealed that less than 50% of young people reported having used a health facility for their most recent STI symptoms. Less than half of females reported having ever used a modern contraceptive and the qualitative research suggests that low levels of contraceptive use might be due to fear of side-effects. Efforts to improve access by e.g. making health facilities more 'youth-friendly' have not been completely successful in rural Mwanza and further work is needed. A continuation of the national 'youth-friendly' training for health facility staff is essential. Health facilities should be provided with adequate condom supplies and such condoms should be distributed free of charge, proactively and indiscriminately to any member of the community. Further education on contraceptives is needed for all community members and any rumours about side-effects should be addressed. Integration of HIV/STI prevention and treatment, family planning, PMTCT and circumcision services is essential. Young people interviewed during both the 2001/2 and 2007/8 MkV1 surveys cited 'unfamiliarity with services' as one of the reasons for non-use of health facilities. Further efforts should be made to make young people more aware of the services that are on offer. One idea that has been proposed is a '12-year-old check-in' for girls[85] which would have both health and social components and would have the additional advantage of increasing awareness of what services are on offer at health facilities. Even with additional efforts, it might not be possible to convince all young people to access government health facilities and a mechanism should be developed to involve traditional healers in a comprehensive SRH programme in rural Tanzania. Private health facilities, which exist primarily in urban Mwanza, should also be included.

6.4 Concluding remarks

The results of the long-term evaluation of the MEMA kwa Vijana intervention have brought considerable clarity to the situation regarding the impact of the intervention. The inconvenient finding that the young people who participated in the research were wiser but unfortunately not safer is disappointing. There are however many valuable lessons that can be learnt from this research. Most importantly, the results show that skills-based sexual health education interventions and youth-friendly health services can make a valuable and sustained contribution towards the UN General Assembly Special Session on HIV/AIDS goal of increasing young people's access to the information, skills and services they need to reduce their vulnerability to HIV. However, these results imply that such interventions, on their own, will not be sufficient to reduce HIV and other STIs among young people in Sub-Saharan Africa. It is imperative that additional efforts address the broader sexual norms and expectations that make it difficult for young people to change their behaviour. There are many challenges associated with changing the structural and community-level determinants of health but it is important that attempts to address these challenges should not be made at the expense of quality and rigour of intervention development and evaluation. Future interventions and their evaluation will be complex but the ultimate goal of reducing the mortality and morbidity that is associated with preventable diseases and unplanned pregnancies among young people remains clear.

References

1. UN. Political declaration on HIV/AIDS. Resolution adopted by the General Assembly.A/RES/60/262.; 2006.
2. UNAIDS, World Health Organization. AIDS epidemic update: November 2009. Geneva; 2009
3. UNAIDS. Report on the global HIV/AIDS epidemic: 4th Global Report. Geneva; 2004 June 2004. Report No.: UNAIDS/04.16E.
4. World Population Prospects: The 2008 Revision Population Database [database on the Internet]. United Nations Population Division. 2008 [cited 09/02/2010]. Available from: http://esa.un.org/unpp/p2k0data.asp.
5. WHO. More positive living: strengthening the health sector response to young people living with HIV. Geneva; 2008.
6. Tanzanian Commission for AIDS (TACAIDS), Zanzibar AIDS Comission (ZAC), National Bureau of Statistics (NBS), Office of the Chief Government Statistician (OCGS), Inc. MI. Tanzania HIV/AIDS and Malaria Indicator Survey 2007-08. Dar es Salaam, Tanzania: TACAIDS, ZAC, NBS, OCGS, Macro International Inc.; 2008.
7. Weiss HA, Halperin D, Bailey RC, Hayes RJ, Schmid G, Hankins CA. Male circumcision for HIV prevention: from evidence to action? AIDS. 2008 Mar 12;22(5):567-74.
8. Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. Cochrane Database Syst Rev. 2002;2:CD003255.
9. Gouws E, Stanecki KA, Lyerla R, Ghys PD. The epidemiology of HIV infection among young people aged 15-24 years in southern Africa. AIDS. 2008 Dec;22 Suppl 4:S5-16.
10. Obasi AI, Balira R, Todd J, Ross DA, Changalucha J, Mosha F, et al. Prevalence of HIV and Chlamydia trachomatis infection in 15--19-year olds in rural Tanzania. Trop Med Int Health. 2001 Jul;6(7):517-25.
11. Bearinger LH, Sieving RE, Ferguson J, Sharma V. Global perspectives on the sexual and reproductive health of adolescents: patterns, prevention, and potential. Lancet. 2007 Apr 7;369(9568):1220-31.
12. Dehne KL, Riedner G, Berer Me. Sexually transmitted infections among adolescents: the need for adequate health services. Geneva: WHO,GTZ; 2005.
13. Save the Children. State of the World's Mothers: Children having children: Save the Children,; 2004.
14. Monasch R, Mahy M. Young people: the centre of the HIV epidemic. World Health Organ Tech Rep Ser. 2006;938:15-41; discussion 317-41.
15. WHO. Steady....ready.... go! The Talloires consultation to review the evidence for policies and programmes to achieve the global goals on young people and HIV/AIDS. Geneva; 2004 28/05/2004.
16. Piot P, Bartos M, Larson H, Zewdie D, Mane P. Coming to terms with complexity: a call to action for HIV prevention. Lancet. 2008 Sep 6;372(9641):845-59.
17. Dick B, Ferguson J, Ross DA. Introduction and rationale. In: Ross DA, Dick B, Ferguson J, editors. Prevening HIV/AIDS in young people: a systematic review of the evidence from developing countries: UNAIDS interagency task team on HIV and young people. Geneva: World Health Organization; 2006. p. 1-14.
18. Dixon-Mueller R. How young is "too young"? Comparative perspectives on adolescent sexual, marital, and reproductive transitions. Stud Fam Plann. 2008 Dec;39(4):247-62.
19. Lloyd CB. Growing up Global: The Changing Transitions to Adulthood in Developing Countries.": Executive Summary. Washington, D.C.; 2005.
20. WHO. Sexually Transmitted Diseases amongst adolescents in the developing world: a review of published data. Geneva; 1993.

21. Berman SM, Hein K. Adolescents and STDs. In: Holmes KK, Mardh PA, Lemon SM, Stamm WE, Piot P, Wasserheit JN, editors. Sexually Transmitted Diseases. New York: McGraw-Hill; 1999. p. 129-39.
22. Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect. 1999 Feb;75(1):3-17.
23. Temmerman M. Sexually transmitted diseases and reproductive health. Sex Transm Dis. 1994 Mar-Apr;21(2 Suppl):S55-8.
24. UNAIDS, WHO. AIDS epidemic update:2004: UNAIDS; 2004 Dec 2004. Report No.: UNAIDS/04.45E.
25. Lloyd CB, Mensch BS. Marriage and childbirth as factors in dropping out from school: an analysis of DHS data from sub-Saharan Africa. Popul Stud (Camb). 2008 Mar;62(1):1-13.
26. UNAIDS. Practical Guidelines for Intensifying HIV Prevention: Towards Universal Access; 2007. Report No.: UNAIDS/07.07E/JC1274E.
27. UNICEF U, WHO. Young people and HIV/AIDS: Opportunity in crisis; 2002 01/06/2002.
28. Plummer ML, Wight D, Wamoyi J, Nyalali K, Ingal T, Mshana G, et al. Are schools a good setting for adolescent sexual health promotion in rural Africa? A qualitative assessment from Tanzania. Health Education Research. [Article]. 2007 Aug;22(4):483-99.
29. Merson MH, Dayton JM, O'Reilly K. Effectiveness of HIV prevention interventions in developing countries. AIDS. 2000 Sep;14 Suppl 2:S68-84.
30. UNFPA. Programme of action of the International Conference on Population and Development. Cairo; 1994.
31. UNAIDS, WHO. Consultation on STD interventions for preventing HIV: what is the evidence? Geneva; 2001 (English original May 2000). Report No.: UNAIDS/01.81E-WHO/HSI/2000.02.
32. UN. Resolution adopted by the General Assembly. Key actions for the further implementation of the Programme of Action of the International Conference on Population and Development. A/RES/S-21/2: UN; 1999 8 Nov.
33. UNAIDS. United Nations General Special Session on HIV/AIDS: Declaration of Committment on HIV/AIDS. Geneva: United Nations; 2001.
34. Global HIV Prevention Working Group. Global Mobilization for HIV Prevention: A blueprint for action: In Kaiser Family Foundation; 2002.
35. UN. United Nations Millennium Declaration. Resolution adopted by the General Assembly A/RES/55/2: UN; 2000 September.
36. UN Millenium Project. Combating AIDS in the developing World: Task Force on HIV/AIDS, Malaria, TB, and Access to essential Medicines. Working group on HIV/AIDS.; 2005.
37. Organisation of African Unity (OAU). Abuja Declaration on HIV/AIDS, Tuberculosis and other related infectious diseases. . Abuja, Nigeria: Organisation of African Unity; 2001.
38. UN. A world fit for children. Resolution adopted at the Special Session of the General Assembly on Children. A/RES/S-27/2; 2002.
39. UN. UNGASS Goals. Declaration of commitment on HIV/AIDS.; 2001.
40. UNFPA. ICPD at Ten. The World Reaffirms Cairo. Official outcomes of the ICPD at Ten Review.; 2005.
41. AU. Abuja call for accelerated action towards universal access to HIV and AIDS, Tuberculosis and Malaria services in Africa. Abuja; 2006.
42. UN. The Millenium Development Goals Report. New York; 2009.
43. Jha P, Vaz LME, Plummer F. 'The evidence base of interventions to prevent HIV infection in low and middle income countries' Working paper. Commission on Macroeconomics and Health. Working Group 5.; 2001.
44. Bertozzi SM, Laga M, Bautista-Arredondo S, Coutinho A. Making HIV prevention programmes work. Lancet. 2008 Sep 6;372(9641):831-44.
45. UNAIDS. Intensifying HIV prevention: a UNAIDS policy position paper.; 2005.

46. UNAIDS. HIV Prevention-Fact Sheet. Journal [serial on the Internet]. Date: Available from: http://data.unaids.org/Publications/Fact-Sheets04/FS_Prevention_en.pdf.

47. UNAIDS. Joint action for results: UNAIDS outcome framework, 2009-2011; 2009.

48. Horton R, Das P. Putting prevention at the forefront of HIV/AIDS. Lancet. 2008 Aug 9;372(9637):421-2.

49. Stover J, Bertozzi S, Gutierrez JP, Walker N, Stanecki KA, Greener R, et al. The Global Impact of Scaling-Up HIV/AIDS Prevention Programs in Low- and Middle-Income Countries. Science. 2006 Feb 2.

50. Manhart LE, Holmes KK. Randomized controlled trials of individual-level, population-level, and multilevel interventions for preventing sexually transmitted infections: What has worked? Journal of Infectious Diseases. [Editorial Material]. 2005 Feb;191:S7-S24.

51. Kirby D, Laris BA, Rolleri LA. The impact of Sex and HIV Education Programs in Schools and Communities on Sexual Behaviors Among Young Adults. Research Triangle Park, NC: Family Health International; 2006.

52. Kamali A, Carpenter LM, Whitworth JA, Pool R, Ruberantwari A, Ojwiya A. Seven-year trends in HIV-1 infection rates, and changes in sexual behaviour, among adults in rural Uganda. Aids. 2000 Mar 10;14(4):427-34.

53. Asiimwe-Okiror G, Opio AA, Musinguzi J, Madraa E, Tembo G, Carael M. Change in sexual behaviour and decline in HIV infection among young pregnant women in urban Uganda. Aids. 1997 Nov 15;11(14):1757-63.

54. Stoneburner RL, Low-Beer D. Population-level HIV declines and behavioral risk avoidance in Uganda. Science. 2004 Apr 30;304(5671):714-8.

55. Gregson S, Garnett GP, Nyamukapa CA, Hallett TB, Lewis JJ, Mason PR, et al. HIV Decline Associated with Behavior Change in Eastern Zimbabwe. Science. 2006 Feb 3;311(5761):664-6.

56. Nelson KE, Celentano DD, Eiumtrakol S, Hoover DR, Beyrer C, Suprasert S, et al. Changes in sexual behavior and a decline in HIV infection among young men in Thailand. N Engl J Med. 1996 Aug 1;335(5):297-303.

57. UNAIDS. Report on the global HIV/AIDS epidemic 2008. Geneva; 2008. Report No.: UNAIDS/08.25E/JC1510E.

58. Hallett TB, Aberle-Grasse J, Bello G, Boulos LM, Cayemittes MP, Cheluget B, et al. Declines in HIV prevalence can be associated with changing sexual behaviour in Uganda, urban Kenya, Zimbabwe, and urban Haiti. Sex Transm Infect. 2006 Apr;82 Suppl 1:i1-8.

59. Zaba B, Pisani E, Slaymaker E, Boerma JT. Age at first sex: understanding recent trends in African demographic surveys. Sex Transm Infect. 2004 Dec;80 Suppl 2:ii28-ii35.

60. Green EC, Halperin DT, Nantulya V, Hogle JA. Uganda's HIV prevention success: the role of sexual behavior change and the national response. AIDS Behav. 2006 Jul;10(4):335-46; discussion 47-50.

61. Auerbach JD, Hayes RJ, Kandathil S. Overview of effective and promising interventions to prevent HIV infection. In: Ross DA, Dick B, Ferguson J, editors. Preventing HIV/AIDS in young people: a systematic review of the evidence from developing countries: UNAIDS interagency task team on HIV and young people. Geneva: World Health Organization; 2006. p. 43-78.

62. Weinhardt LS, Carey MP, Johnson BT, Bickham NL. Effects of HIV counselling and testing on sexual risk behavior: a meta-analytic review of published research. Am J Public Health. 1999;89:1397-405.

63. Khumalo-Sakutukwa G, Morin SF, Fritz K, Charlebois ED, Rooyen H, Chingono A, et al. Project Accept (HPTN 043): A Community-Based Intervention to Reduce HIV Incidence in Populations at Risk for HIV in Sub-Saharan Africa and Thailand. Jaids-Journal of Acquired Immune Deficiency Syndromes. 2008;49(4):422-31.

64. Padian NS, Buve A, Balkus J, Serwadda D, Cates W, Jr. Biomedical interventions to prevent HIV infection: evidence, challenges, and way forward. Lancet. 2008 Aug 16;372(9638):585-99.

65. Siegfried N, Muller M, Deeks JJ, Volmink J. Male circumcision for prevention of heterosexual acquisition of HIV in men. Cochrane Database Syst Rev. 2009(2):CD003362.
66. Grosskurth H, Mosha F, Todd J, Mwijarubi E, Klokke A, Senkoro K, et al. Impact of improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomised controlled trial. Lancet. 1995 Aug 26;346(8974):530-6.
67. Mayaud P, Mosha F, Todd J, Balira R, Mgara J, West B, et al. Improved treatment services significantly reduce the prevalence of sexually transmitted diseases in rural Tanzania: results of a randomized controlled trial. Aids. 1997 Dec;11(15):1873-80.
68. Wawer MJ, Sewankambo NK, Serwadda D, Quinn TC, Paxton LA, Kiwanuka N, et al. Control of sexually transmitted diseases for AIDS prevention in Uganda: a randomised community trial. Rakai Project Study Group. Lancet. 1999 Feb 13;353(9152):525-35.
69. Kamali A, Quigley M, Nakiyingi J, Kinsman J, Kengeya-Kayondo J, Gopal R, et al. Syndromic management of sexually-transmitted infections and behaviour change interventions on transmission of HIV-1 in rural Uganda: a community randomised trial. Lancet. 2003 Feb 22;361(9358):645-52.
70. Orroth KK, Korenromp EL, White RG, Gavyole A, Gray RH, Muhangi L, et al. Higher risk behaviour and rates of sexually transmitted diseases in Mwanza compared to Uganda may help explain HIV prevention trial outcomes. Aids. 2003;17(18):2653-60.
71. Sangani P, Rutherford G, Wilkinson D. Population-based interventions for reducing sexually transmitted infections, including HIV infection. Cochrane Database Syst Rev. 2004(2):CD001220.
72. White RG, Orroth KK, Glynn JR, Freeman EE, Bakker R, Habbema JDF, et al. Treating curable sexually transmitted infections to prevent HIV in Africa - Still an effective control strategy? Jaids-Journal of Acquired Immune Deficiency Syndromes. 2008;47(3):346-53.
73. Sumartojo E. Structural factors in HIV prevention: concepts, examples, and implications for research. Aids. 2000 Jun;14 Suppl 1:S3-10.
74. Parker RG, Easton D, Klein CH. Structural barriers and facilitators in HIV prevention: a review of international research. AIDS. 2000 Jun;14 Suppl 1:S22-32.
75. Auerbach JD, Parkhurst J, Caceres CF, Keller CC. Addressing Social Drivers of HIV/AIDS: Some Conceptual, Methodological, and Evidentiary Considerations. New York: Clark University ICRW; 2009 August 2009.
76. Pequegnat W, Stover E. Behavioral prevention is today's AIDS vaccine! AIDS. 2000 Sep;14 Suppl 2:S1-7.
77. WHO. Global Consultation on Adolescent friendly Health services : A consensus statement. Geneva: Department of Child and Asolescent Health and Development; 2002 7-9 March 2001.
78. Wellings K, Collumbien M, Slaymaker E, Singh S, Hodges Z, Patel D, et al. Sexual behaviour in context: a global perspective. Lancet. 2006 Nov 11;368(9548):1706-28.
79. Cleland J, Watkins SC. The key lesson of family planning programmes for HIV/AIDS control. AIDS. 2006 Jan 2;20(1):1-3.
80. Piot P, Kazatchkine M, Dybul M, Lob-Levyt J. AIDS: lessons learnt and myths dispelled. Lancet. 2009 Jul 18;374(9685):260-3.
81. Glynn JR, Carael M, Auvert B, Kahindo M, Chege J, Musonda R, et al. Why do young women have a much higher prevalence of HIV than young men? A study in Kisumu, Kenya and Ndola, Zambia. Aids. 2001 Aug;15 Suppl 4:S51-60.
82. Laga M, Schwartlander B, Pisani E, Sow PS, Carael M. To stem HIV in Africa, prevent transmission to young women. Aids. 2001 May 4;15(7):931-4.
83. Stirling M, Rees H, Kasedde S, Hankins C. Introduction: Addressing the vulnerability of young women and girls to stop the HIV epidemic in southern Africa. AIDS. 2008 Dec;22 Suppl 4:S1-3.
84. Levine R, Lloyd CB, Greene ME, Grown C. Girls Count: A Global Investment and Action Agenda. Washington D.C.: Center for Global Development; 2008.

85. Temin M, Levine R. Start with a Girl: A New Agenda for Global Health. Washington D.C.: Centre for Global Development; 2009.
86. Leclerc-Madlala S. Age-disparate and intergenerational sex in southern Africa: the dynamics of hypervulnerability. AIDS. 2008 Dec;22 Suppl 4:S17-25.
87. Clark S, Bruce J, Dude A. Protecting young women from HIV / AIDS: the case against child and adolescent marriage. International Family Planning Perspectives. 2006 Jun;32(2):79-88.
88. Clark S. Early marriage and HIV risks in sub-Saharan Africa. Stud Fam Plann. 2004 Sep;35(3):149-60.
89. Cleland J, Ali MM. Sexual abstinence, contraception, and condom use by young African women: a secondary analysis of survey data. Lancet. 2006 18;368(9549):1788-93.
90. Biddlecom AE, Hessburg L, Singh S, Bankole A, Darabi L. Protecting the next generation in Sub-Saharan Africa: Learning from adolescents to prevent HIV and unintended pregnancy. New York, Guttmacher Institute, 2007.; 2007.
91. Crepaz N, Lyles CM, Wolitski RJ, Passin WF, Rama SM, Herbst JH, et al. Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials. AIDS. 2006 Jan 9;20(2):143-57.
92. Coates TJ, Richter L, Caceres C. Behavioural strategies to reduce HIV transmission: how to make them work better. Lancet. 2008 Aug 23;372(9639):669-84.
93. Bonell C, Bennett R, Oakley A. Sexual health interventions should be subject to experimental evaluation. In: Stephenson JM, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in experimental evaluation. Oxford, UK: Oxford University Press; 2003. p. 3-16.
94. Gallant M, Maticka-Tyndale E. School-based HIV prevention programmes for African youth. Soc Sci Med. 2004 Apr;58(7):1337-51.
95. Ross DA, Wight D, Dowsett G, Buve A, Obasi AI. The weight of evidence: a method for assessing the strength of evidence on the effectiveness of HIV prevention interventions among young people. World Health Organ Tech Rep Ser. 2006;938:79-102; discussion 317-41.
96. Global HIV Prevention Working Group. Behavior Change and HIV Prevention: (Re)Considerations for the 21st Century; 2008.
97. UNESCO. UNESCO Country Programming Document for the United Republic of Tanzania: 2008-2010; 2007.
98. Government of the United Republic of Tanzania. Accessed 09/02/10 [updated Accessed 09/02/10; cited 09/02/2010]; Available from: http://www.tanzania.go.tz/healthf.html.
99. Population Council. The Adolescent Experience In-Depth: Using Data to Identify and Reach the Most Vulnerable Young People: Tanzania 2004." New York: Population Council; 2009.
100. Policy Forum. Growth in Tanzania: Is it reducing poverty? Dar es Salaam, Tanzania; 2008.
101. Changalucha J, Gavyole A, Grosskurth H, Hayes R, Mabey D. STD/HIV intervention and research programme Mwanza Region, NW Tanzania. Sex Transm Infect. 2002 Apr;78 Suppl 1:i91-6.
102. Grosskurth H, Mosha F, Todd J, Senkoro K, Newell J, Klokke A, et al. A community trial of the impact of improved sexually transmitted disease treatment on the HIV epidemic in rural Tanzania: 2. Baseline survey results. Aids. 1995 Aug;9(8):927-34.
103. National Bureau of Statistics [Tanzania], Macro O. Tanzania Demographic and Health Survey 2004-2005. Dar es Salaam: National Bureau of Statistics
ORC Macro; 2005.
104. Wight D, Plummer ML, Mshana G, Wamoyi J, Shigongo ZS, Ross DA. Contradictory sexual norms and expectations for young people in rural Northern Tanzania. Soc Sci Med. 2006 Feb;62(4):987-97.

105. Plummer ML, Wight D, Obasi AIN, Wamoyi J, Mshana G, Todd J, et al. A process evaluation of a school-based adolescent sexual health intervention in rural Tanzania: the MEMA kwa Vijana programme. Health Education Research. [Article]. 2007 Aug;22(4):500-12.
106. Remes P, Renju J, Nyalali K, Medard L, Kimaryo M, Changalucha J, et al. Dusty discos and dangerous desires: community perceptions of adolescent sexual and reproductive health risks and vulnerability and the potential role of parents in rural Mwanza, Tanzania. Cult Health Sex. 2009 Nov 25:1.
107. TACAIDS TcfA, (NBS) NBoS, Macro O. Tanzania HIV/AIDS Indicator Survey 2003-04. Calverton, Maryland, USA: TACAIDS, NBS, ORC Macro; 2005.
108. National Bureau of Statistics [Tanzania], Ministry of Health and Social Welfare [Tanzania], Inc. MI. Tanzania Service Provision Assessment Survey 2006: Key findings on Family Planning, Maternal and Child Health, and Malaria. Dar es Salaam: National Bureau of Statistics Macro International Inc.; 2006.
109. Nnko S, Washija R, Urassa M, Boerma JT. Dynamics of male circumcision practices in northwest Tanzania. Sex Transm Dis. 2001 Apr;28(4):214-8.
110. Weiss HA, Plummer ML, Changalucha J, Mshana G, Shigongo ZS, Todd J, et al. Circumcision among adolescent boys in rural northwestern Tanzania. Trop Med Int Health. 2008 Jun 18.
111. UNAIDS, World Bank (ASAP). The HIV epidemic in Tanzania Mainland: Where have we come from, where is it going, and how are we responding? Final Report: AIDS Strategy and Action Plan, UNAIDS, World Bank; 2008.
112. Hallett TB, Stover J, Mishra V, Ghys PD, Gregson S, Boerma T. Estimates of HIV incidence from household-based prevalence surveys. AIDS. Jan 2;24(1):147-52.
113. Wambura M, Urassa M, Isingo R, Ndege M, Marston M, Slaymaker E, et al. HIV prevalence and incidence in rural Tanzania: Results from 10 years of follow-up in an open-cohort study. Journal of Acquired Immune Deficiency Syndromes. 2007 Dec;46(5):616-23.
114. Urassa M, Kumogola Y, Isingo R, Mwaluko G, Makelemo B, Mugeye K, et al. HIV prevalence and sexual behaviour changes measured in an antenatal clinic setting in northern Tanzania. Sexually Transmitted Infections. 2006 Aug;82(4):301-6.
115. Kumogola Y, Slaymaker E, Zaba B, Mngara J, Isingo R, Changalucha J, et al. Trends in HIV & syphilis prevalence and correlates of HIV infection: results from cross-sectional surveys among women attending ante-natal clinics in Northern Tanzania. unpublished:10.
116. Todd J, Balira R, Grosskurth H, Mayaud P, Mosha F, ka-Gina G, et al. HIV-associated adult mortality in a rural Tanzanian population. Aids. 1997 May;11(6):801-7.
117. Corey L, Wald A. Genital Herpes. In: Holmes KK, Mardh PA, Sparling PF, Lemon SM, Stamm WE, Poit P, et al., editors. Sexually Transmitted Diseases- third edition. New York: McGraw-Hill; 1999. p. 285-312.
118. Obasi A, Mosha F, Quigley M, Sekirassa Z, Gibbs T, Munguti K, et al. Antibody to herpes simplex virus type 2 as a marker of sexual risk behavior in rural Tanzania. J Infect Dis. 1999 Jan;179(1):16-24.
119. Freeman EE, Weiss HA, Glynn JR, Cross PL, Whitworth JA, Hayes RJ. Herpes simplex virus 2 infection increases HIV acquisition in men and women: systematic review and meta-analysis of longitudinal studies. Aids. 2006 Jan 2;20(1):73-83.
120. del Mar Pujades Rodriguez M, Obasi A, Mosha F, Todd J, Brown D, Changalucha J, et al. Herpes simplex virus type 2 infection increases HIV incidence: a prospective study in rural Tanzania. AIDS. 2002 Feb 15;16(3):451-62.
121. Nilsen A, Mwakagile D, Marsden H, Langeland N, Matre R, Haarr L. Prevalence of, and risk factors for, HSV-2 antibodies in sexually transmitted disease patients, healthy pregnant females, blood donors and medical students in Tanzania and Norway. Epidemiol Infect. 2005 Oct;133(5):915-25.

122. Msuya SE, Mbizvo E, Hussain A, Sam NE, Jeansson S, Stray-Pedersen B. Seroprevalence and correlates of herpes simplex virus type 2 among urban Tanzanian women. Sex Transm Dis. 2003 Jul;30(7):588-92.
123. Kasubi MJ, Nilsen A, Marsden HS, Bergstrom T, Langeland N, Haarr L. Prevalence of antibodies against herpes simplex virus types 1 and 2 in children and young people in an urban region in Tanzania. J Clin Microbiol. 2006 Aug;44(8):2801-7.
124. Riedner G, Rusizoka M, Hoffmann O, Nichombe F, Lyamuya E, Mmbando D, et al. Baseline survey of sexually transmitted infections in a cohort of female bar workers in Mbeya Region, Tanzania. Sex Transm Infect. 2003 Oct;79(5):382-7.
125. Watson-Jones D, Weiss HA, Rusizoka M, Baisley K, Mugeye K, Changalucha J, et al. Risk factors for herpes simplex virus type 2 and HIV among women at high risk in northwestern Tanzania: preparing for an HSV-2 intervention trial. J Acquir Immune Defic Syndr. 2007 Dec 15;46(5):631-42.
126. Kapiga SH, Sam NE, Shao JF, Masenga EJ, Renjifo B, Kiwelu IE, et al. Herpes simplex virus type 2 infection among bar and hotel workers in northern Tanzania: prevalence and risk factors. Sex Transm Dis. 2003 Mar;30(3):187-92.
127. Radolf JD, Sanchez PJ, Schulz KF, Murphy FK. Congenital syphilis. In: Holmes KK, Mardh PA, Sparling PF, Lemon SM, Stamm WE, Poit P, et al., editors. Sexually Transmitted Diseases-third edition. New York: McGraw-Hill; 1999. p. 1165-89.
128. Todd J, Munguti K, Grosskurth H, Mngara J, Changalucha J, Mayaud P, et al. Risk factors for active syphilis and TPHA seroconversion in a rural African population. Sex Transm Infect. 2001 Feb;77(1):37-45.
129. Orroth KK, Korenromp EL, White RG, Changalucha J, de Vlas SJ, Gray RH, et al. Comparison of STD prevalences in the Mwanza, Rakai, and Masaka trial populations: the role of selection bias and diagnostic errors. Sex Transm Infect. 2003 Apr;79(2):98-105.
130. Klepp KI, Ndeki SS, Seha AM, Hannan P, Lyimo BA, Msuya MH, et al. AIDS education for primary school children in Tanzania: an evaluation study. Aids. 1994 Aug;8(8):1157-62.
131. Marston C, King E. Factors that shape young people's sexual behaviour: a systematic review. Lancet. 2006 Nov 4;368(9547):1581-6.
132. Hindin MJ, Fatusi AO. Adolescent sexual and reproductive health in developing countries: an overview of trends and interventions. Int Perspect Sex Reprod Health. 2009 Jun;35(2):58-62.
133. Plummer ML, Ross DA, Wight D, Changalucha J, Mshana G, Wamoyi J, et al. "A bit more truthful": the validity of adolescent sexual behaviour data collected in rural northern Tanzania using five methods. Sex Transm Infect. 2004 Dec;80 Suppl 2:ii49-ii56.
134. Silberschmidt M, Rasch V. Adolescent girls, illegal abortions and "sugar-daddies" in Dar es Salaam: vulnerable victims and active social agents. Soc Sci Med. 2001 Jun;52(12):1815-26.
135. MEMA kwa Vijana. Designing and Developing Community Interventions. Technical Briefing Paper No. 4 Mwanza, Tanzania; 2008 [updated 2008; cited 18/02/10]; Available from: http://www.memakwavijana.org/images/stories/Documents/developingcommunityinterventions.pdf.
136. Gillespie S, Kadiyala S, Greener R. Is poverty or wealth driving HIV transmission? Aids. 2007;21(Supplement.7):S5-S16.
137. Parkhurst JO. Understanding the correlations between wealth, poverty and human immunodeficiency virus infection in African countries. Bull World Health Organ. 2010:17.
138. Piot P, Greener R, Russell S. Squaring the circle: AIDS, poverty, and human development. PLoS Med. 2007 Oct;4(10):1571-5.
139. Mishra V, Assche SB, Greener R, Vaessen M, Hong R, Ghys PD, et al. HIV infection does not disproportionately affect the poorer in sub-Saharan Africa. AIDS. 2007 Nov;21 Suppl 7:S17-28.

140. Msisha WM, Kapiga SH, Earls F, Subramanian SV. Socioeconomic status and HIV seroprevalence in Tanzania: A counterintuitive relationship. International Journal of Epidemiology. 2008;37(6):1297-303.
141. Hargreaves JR, Bonell CP, Boler T, Boccia D, Birdthistle I, Fletcher A, et al. Systematic review exploring time trends in the association between educational attainment and risk of HIV infection in sub-Saharan Africa. Aids. 2008 Jan 30;22(3):403-14.
142. Mundandi C, Vissers D, Voeten H, Habbema D, Gregson S. No difference in HIV incidence and sexual behaviour between out-migrants and residents in rural Manicaland, Zimbabwe. Tropical Medicine & International Health. 2006 May;11(5):705-11.
143. Coffee M, Lurie MN, Garnett GP. Modelling the impact of migration on the HIV epidemic in South Africa. AIDS. 2007 Jan 30;21(3):343-50.
144. Erasmus M. The role of mobility in the spread and control of STD and HIV; Implications for decision making-Annexes. Rotterdam: ERASMUS MC University Medical Center Rotterdam
LSHTM
TANESA Project, NIMR, Tanzania
Manicaland HIV Prevention Project, Zimbabwe; 2005 April.
145. Kishamawe C, Vissers DC, Urassa M, Isingo R, Mwaluko G, Borsboom GJ, et al. Mobility and HIV in Tanzanian couples: both mobile persons and their partners show increased risk. Aids. 2006 Feb 28;20(4):601-8.
146. Blum R, Mmari K. Risk and protective factors affecting adolescent reproductive health in developing countries: an analysis of adolescent sexual and reproductive health literature from around the world: summary. Geneva: World Health Organization; 2004.
147. DiClemente RJ, Salazar LF, Crosby RA. A review of STD/HIV preventive interventions for adolescents: sustaining effects using an ecological approach. J Pediatr Psychol. 2007 Sep;32(8):888-906.
148. UNAIDS, UNICEF, USAID. Children on the Brink 2004- A joint report of New Orphan Estimates and a Framework for Action. New York: UNAIDS, UNICEF, USAID; 2004.
149. Gregson S, Nyamukapa CA, Garnett GP, Wambe M, Lewis JJC, Mason PR, et al. HIV infection and reproductive health in teenage women orphaned and made vulnerable by AIDS in Zimbabwe. AIDS Care. 2005 Oct;17(7):785-94.
150. Birdthistle IJ, Floyd S, Machingura A, Mudziwapasi N, Gregson S, Glynn JR. From affected to infected? Orphanhood and HIV risk among female adolescents in urban Zimbabwe. AIDS. 2008 Mar 30;22(6):759-66.
151. Fisher JD, Fisher WA. Theoretical Approaches to Individual-Level Change in HIV Risk Behavior. In: Peterson JL, DiClemente D, editors. Handbook of HIV Prevention. New York: Kluwer Academic/ Plenum Publishers; 2000. p. 3-56.
152. National Bureau of Statistics [Tanzania], Inc. MI. Tanzania Reproductive and Child Health Survey 1999. Calverton, Maryland: National Bureau of Statistics
Macro International Inc.; 2000.
153. Wight D. Theoretical bases for teacher- and peer-delivered sexual health promotion. Health Education. 2008;108(1):18.
154. Pettifor AE, van der Straten A, Dunbar MS, Shiboski SC, Padian NS. Early age of first sex: a risk factor for HIV infection among women in Zimbabwe. Aids. 2004;18(10):1435-42.
155. Bongaarts J, Cohen B. Adolescent reproductive behavior in the developing world. Introduction and review. Stud Fam Plann. 1998 Jun;29(2):99-105.
156. Matasha E, Ntembelea T, Mayaud P, Saidi W, Todd J, Mujaya B, et al. Sexual and reproductive health among primary and secondary school pupils in Mwanza, Tanzania: need for intervention. AIDS Care. 1998 Oct;10(5):571-82.
157. Zaba B, Isingo R, Wringe A, Marston M, Slaymaker E, Urassa M. Influence of timing of sexual debut and first marriage on sexual behaviour in later life: findings from four survey rounds in the Kisesa cohort in northern Tanzania. Sex Transm Infect. 2009 Apr;85 Suppl 1:i20-6.

158. WHO. Married adolescents: no place of safety. Geneva: World Health Organization; 2005.
159. Khan S, Mishra V. Youth reproductive and sexual health; 2008.
160. Bongaarts J. Late marriage and the HIV epidemic in sub-Saharan Africa. Popul Stud (Camb). 2007 Mar;61(1):73-83.
161. Green EC, Mah TL, Ruark A, Hearst N. A framework of sexual partnerships: risks and implications for HIV prevention in Africa. Stud Fam Plann. 2009 Mar;40(1):63-70.
162. Luke N. Confronting the 'sugar daddy' stereotype: age and economic asymmetries and risky sexual behavior in urban Kenya. Int Fam Plan Perspect. 2005 Mar;31(1):6-14.
163. Hearst N, Chen S. Condoms for AIDS prevention in the developing world: a review of the scientific literature. Geneva: UNAIDS; 2003.
164. Marston C, King E, Ingham R. Young people and condom use: findings from qualitative research. In: Ingham R, Aggleton P, editors. Promoting young people's sexual health: international perspectives. Oxon: Routledge; 2006. p. 27-40.
165. Tanzanian Commission for AIDS (TACAIDS). UNGASS Country Progress Report: Tanzania Mainland. Dar es Salaam; 2008.
166. Abdool Karim Q, Abdool Karim SS, Preston-Whyte E. Teenagers seeking condoms at family planning services. Part II. A provider's perspective. S Afr Med J. 1992 Nov;82(5):360-2.
167. Langhaug LF, Cowan FM, Nyamurera T, Power R. Improving young people's access to reproductive health care in rural Zimbabwe. AIDS Care. 2003 Apr;15(2):147-57.
168. UNAIDS. Towards universal access to prevention, treatment and care: experiences and challenges from the Mbeya Region in Tanzania- a case study. Geneva; 2007. Report No.: UNAIDS/07.11E/JC1291E.
169. Tanzania PMo. National Policy on HIV/AIDS. Dar es Salaam: Prime Minister's Office, The United Republic of Tanzania; 2001 November, 2001.
170. Klepp KI, Ndeki SS, Leshabari MT, Hannan PJ, Lyimo BA. AIDS education in Tanzania: promoting risk reduction among primary school children. Am J Public Health. 1997 Dec;87(12):1931-6.
171. Makokha M. What MEMA kwa Vijana has to offer the education sector AIDS response in Tanzania: A comparative review. : National Institute for Medical Research, Medical Research Council. Liverpool School of Tropical Medicine; 2008.
172. MOEC. Sexual and Reproductive Health, Family Life Education for Schools and Teachers' Training Colleges. Dar es Salaam: Ministry of Education and Culture, Tanzania; 2001.
173. Tanzania Commission for HIV/AIDS (TACAIDS). National Multi-Sectoral Strategic Framework on HIV/AIDS: 2003-2007. Dar es Salaam; 2003.
174. USAID, UNAIDS, WHO, UNICEF, The Policy Project. Coverage of Selected services for HIV/AIDS Prevention, Care and Support in Low and Middle Income countries in 2003. Washington D.C.: Futures Group; 2004.
175. Munguti K, Grosskurth H, Newell J, Senkoro K, Mosha F, Todd J, et al. Patterns of sexual behaviour in a rural population in north-western Tanzania. Soc Sci Med. 1997 May;44(10):1553-61.
176. Barongo LR, Borgdorff MW, Mosha FF, Nicoll A, Grosskurth H, Senkoro KP, et al. The epidemiology of HIV-1 infection in urban areas, roadside settlements and rural villages in Mwanza Region, Tanzania. Aids. 1992 Dec;6(12):1521-8.
177. Obasi A, Cleophas-Frisch B, Chima KL, Mataba S, Mmassy G, Balira R, et al., editors. Health Worker and head teacher attitude to the provision of reproductive health education and services to adolescents in rural Mwanza region, Tanzania. XIII International AIDS Conference; 2000 9-14 July, 2000; Durban, South Africa. hand; no.
178. Hayes RJ, Changalucha J, Ross DA, Gavyole A, Todd J, Obasi AIN, et al. The MEMA kwa Vijana project: design of a community randomised trial of an innovative adolescent sexual health intervention in rural Tanzania. Contemporary Clinical Trials. 2005 Aug;26(4):430-42.

179. Obasi AI, Cleophas B, Ross DA, Chima KL, Mmassy G, Gavyole A, et al. Rationale and design of the MEMA kwa Vijana adolescent sexual and reproductive health intervention in Mwanza Region, Tanzania. AIDS Care. 2006 May;18(4):311-22.

180. Terris-Prestholt F, Kumaranayake L, Obasi AIN, Cleophas-Mazige B, Makokha M, Todd J, et al. From trial intervention to scale-up: costs of an adolescent sexual health program in Mwanza, Tanzania. Sexually Transmitted Diseases. 2006 Oct;33(10 Suppl):S133-9.

181. Wight D, Obasi A. Unpacking the black box: The importance of process data to explain outcomes. In: Stephenson J, Imrie J, Bonnell C, editors. Effective sexual health interventions:Issues in experimental evaluation. London: Oxford University Press; 2003. p. 151-66.

182. Wamoyi J, Wight D, Plummer M, Mshana G, Ross D. Exchanging sex for gifts or money among young people in rural northern Tanzania. submitted to Soc Sci Med. unpublished last draft dec 2003.

183. Plummer ML, Wight D, Wamoyi J, Mshana G, Hayes RJ, Ross DA. Farming with your hoe in a sack: condom attitudes, access, and use in rural Tanzania. Studies in Family Planning. 2006 Mar;37(1):29-40.

184. Cleophas-Frisch B, Obasi AIN, Manchester T, Rwakatare M, Alex R, Charles J, et al. Pilot Study of a Village-based Condom Social Marketing Initiative in Rural Mwanza, Tanzania (abstract no. ThPeC5356). XII International AIDS Conference; 2000; Durban. 2000.

185. Cleophas-Frisch B, Obasi A, Mshana G, Wamoyi J, Plummer M, Rwakatare M, et al., editors. Evaluation of the youth-friendliness of reproductive health services in rural Tanzania using simulated patients. AIDS; 2002. hand; no.

186. Ross DA, Changalucha J, Obasi AI, Todd J, Plummer ML, Cleophas-Mazige B, et al. Biological and behavioural impact of an adolescent sexual health intervention in Tanzania: a community-randomized trial. AIDS. 2007 Sep 12;21(14):1943-55.

187. Larke N, Cleophas- Mazige B, Plummer ML, Obasi AIN, Rwakatare M, Todd J, et al. Impact of the MEMA kwa Vijana adolescent sexual and reproductive health interventions on use of health services by young people in rural Mwanza, Tanzania: results of a cluster randomised trial. J Adolesc Health. In press.

188. Kirby D. Sex and HIV/AIDS education in schools. Bmj. 1995 Aug 12;311(7002):403.

189. Plummer M. Process Evaluation Report: MEMA kwa Vijana Community and Class Peer Educator Training; 1999.

190. Guyon A, Lugoe WL, Ferguson J. Evaluation report of HIV/AIDS peer education in the MEMA kwa Vijana project, Mwanza, Tanzania.: AMREF, NIMR and LSHTM Collaborative research projects.; 2000.

191. Kirby D. The Mema Kwa Vijana Curriculum: A Review. Santa Cruz, California: ETR Associates; 2001 May 19, 2001.

192. Lugoe WL. Evaluation of Teacher-training sessions for MkV teacher led component. Dar es Salaam: Health promotion, Faculty of Education, University of Dar es Salaam; 2001.

193. Plummer ML, Wight D, Ross DA, Balira R, Anemona A, Todd J, et al. Asking semi-literate adolescents about sexual behaviour: the validity of assisted self-completion questionnaire (ASCQ) data in rural Tanzania. Trop Med Int Health. 2004 Jun;9(6):737-54.

194. Chima K, Obasi A, Cleophas-Frisch B, Makokha M, Ross D, Gavyole A, et al., editors. Participatory reproductive health education for Primary school: Lessons learned during the first 3 years of an intervention in Mwanza, Tanzania. AIDS; 2002. hand; no.

195. Todd J, Obasi A, Cleophas BF, Plummer M, Mosha FF, Masanja J, et al., editors. Monitoring attitudes towards adolescent sexual health among programme implementers in Tanzania. The XIV International AIDS Conference, 2002; 2002 July 8; Barcelona, Spain. yes.

196. Guyon A, editor. Evaluation of HIV/AIDS peer education in primary schools in Mwanza. XIII International AIDS conference; 2000; Durban. hand; no.

197. Ross DA, Wight D. The role of randomized controlled trials in assessing sexual health interventions. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 35-50.
198. Todd J, Changalucha J, Ross DA, Mosha F, Obasi AI, Plummer M, et al. The sexual health of pupils in years 4 to 6 of primary schools in rural Tanzania. Sex Transm Infect. 2004 Feb;80(1):35-42.
199. MEMA kwa Vijana. Results of the MEMA kwa Vijana Standard 7 Exam for Year 2002. Mwanza, Tanzania: National Institute for Medical Research,
London School of Hygiene & Tropical Medicine, AMREF,; 2002.
200. Stanton BF, Li X, Kahihuata J, Fitzgerald AM, Neumbo S, Kanduuombe G, et al. Increased protected sex and abstinence among Namibian youth following a HIV risk-reduction intervention: a randomized, longitudinal study. Aids. 1998 Dec 24;12(18):2473-80.
201. MEMA kwa Vijana. MEMA kwa Vijana: The Whole Picture, Technical Briefing Paper No. 1. Mwanza: National Institute for Medical Research,; 2008 [updated 2008; cited 18/02/10]; 2]. Available from:
http://www.memakwavijana.org/images/stories/Documents/mkvoverview.pdf.
202. MEMA kwa Vijana. MEMA kwa Vijana 2- Proposal Summary. Technical Briefing Paper No. 2. Mwanza, Tanzania: National Institute for Medical Research; 2008 [updated 2008; cited 18/02/10]; Available from:
http://www.memakwavijana.org/images/stories/Documents/mkv2proposalsummary.pdf.
203. Andrew B, Renju J, Kishamawe C, Obasi AIN. Impact of MEMA kwa Vijana, phase 2 on knowledge, attitudes and reported behaviour among primary school pupils in Mwanza Region. Mwanza, Tanzania: National Institute for Medical Research,
Liverpool School of Tropical Medicine,; 2008.
204. Renju J, Makokha M, Kato C, Kimaryo M, Kishamawe C, Remes P, et al. Partnering to proceed: scaling up adolescent sexual reproductive health programmes with a novel partnerships between a non governmental organisation and local government authorities- A detailed process evaluation of the factors that influenced the uptake and implementation of the programme at the district level. In preparation.
205. Renju J. Can an ASRH intervention be scaled up through existing government systems? What affects the coverage? In preparation.
206. Rogers E. Diffusion of Innovations. 5th ed. New York: Free Press; 2003.
207. Boerma JT, Urassa M, Nnko S, Ng'weshemi J, Isingo R, Zaba B, et al. Sociodemographic context of the AIDS epidemic in a rural area in Tanzania with a focus on people's mobility and marriage. Sex Transm Infect. 2002 Apr;78 Suppl 1:i97-105.
208. Beeker C, Guenther-Grey C, Raj A. Community empowerment paradigm drift and the primary prevention of HIV/AIDS. Soc Sci Med. 1998 Apr;46(7):831-42.
209. Kirby D, Short L, J C. School based programmes to decrease sexual risk behaviours: a review of effectiveness. Publ Health Rep. 1994;109:339 60.
210. Kelly JA, St Lawrence JS, Stevenson LY, Hauth AC, Kalichman SC, Diaz YE, et al. Community AIDS/HIV risk reduction: the effects of endorsements by popular people in three cities. Am J Public Health. 1992 Nov;82(11):1483-9.
211. Kelly JA, Murphy DA, Sikkema KJ, McAuliffe TL, Roffman RA, Solomon LJ, et al. Randomised, controlled, community-level HIV-prevention intervention for sexual-risk behaviour among homosexual men in US cities. Community HIV Prevention Research Collaborative. Lancet. 1997 Nov 22;350(9090):1500-5.
212. Campbell R, Starkey F, Holliday J, Audrey S, Bloor M, Parry-Langdon N, et al. An informal school-based peer-led intervention for smoking prevention in adolescence (ASSIST): a cluster randomised trial. Lancet. 2008 May 10;371(9624):1595-602.
213. Sutton SR. Using theories of behaviour change to develop and evaluate sexual health interventions. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 16.

214. Janz NK, Becker MH. The Health Belief Model: a decade later. Health Educ Q. 1984 Spring;11(1):1-47.
215. Rosenstock IM, Stretcher VJ, Becker MH. The health belief model and HIV risk behavior change. In: DiClemente D, Peterson JL, editors. Preventing AIDS: Theories and methods of Behavioural Interventions. New York: Plenum Press; 1994. p. 5-25.
216. Fishbein M, Middlestadt S, Hitchcock P. Using information to change sexually transmitted disease-related behaviors. In: DiClemente D, Peterson JL, editors. Preventing AIDs: Theories and Methods of Behavioral Interventions. New York: Plenum Press; 1994. p. 61-78.
217. Bandura A. Social cognitive theory and exercise control of HIV infection. In: DiClemente D, Peterson JL, editors. Preventing AIDS: Theories and Methods of Behavioral Interventions. New York: Plenum Press; 1994. p. 25-59.
218. Catania JA, Kegeles SM, Coates TJ. Towards an understanding of risk behavior: an AIDS risk reduction model (ARRM). Health Educ Q. 1990 Spring;17(1):53-72.
219. Waldo CR, Coates TJ. Multiple levels of analysis and intervention in HIV prevention science: exemplars and directions for new research. Aids. 2000 Sep;14 Suppl 2:S18-26.
220. Pettifor AE, MacPhail C, Bertozzi S, Rees HV. Challenge of evaluating a national HIV prevention programme: the case of loveLife, South Africa. Sexually Transmitted Infections. 2007 Aug;83 Suppl 1:i70-4.
221. Fishbein M. The role of theory in HIV prevention. AIDS Care. 2000 Jun;12(3):273-8.
222. Kamb ML, Fishbein M, Douglas JM, Jr., Rhodes F, Rogers J, Bolan G, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: a randomized controlled trial. Project RESPECT Study Group. Jama. 1998 Oct 7;280(13):1161-7.
223. Community-level HIV intervention in 5 cities: final outcome data from the CDC AIDS Community Demonstration Projects. Am J Public Health. 1999 Mar;89(3):336-45.
224. Kirby D. School-based interventions to prevent unprotected sex and HIV among adolescents. In: Peterson J, DiClemente R, editors. Handbook of HIV prevention. New York: Plenum; 2000. p. 83-101.
225. Kirby D, Laris BA, Rolleri LA. Impact of Sex and HIV Education Programs on Sexual Behaviors of Youth in Developing and Developed Countries. Washington, DC: Family Health International; 2005 2005. Report No.: WP05-03.
226. Kim N, Stanton B, Li X, Dickersin K, Galbraith J. Effectiveness of the 40 adolescent AIDS-risk reduction interventions: a quantitative review. J Adolesc Health. 1997 Mar;20(3):204-15.
227. Maticka-Tyndale E, Brouillard-Coyle C. The effectiveness of community interventions targeting HIV and AIDS prevention at young people in developing countries. In: Ross DA, Dick B, Ferguson A, editors. Preventing HIV/AIDS in Young People A systematic review of the evidence from developing countries. Geneva: World Health Organisation; 2006. p. 42.
228. Fitzgerald A, BF S, N T. Use of Western-based HIV risk-reduction interventions targeting adolescents in an African setting. J Adolesc Health. 1999;25:52-6.
229. Aggleton P, O'Reilly K, Slutkin G, Davies P. Risking everything? Risk behavior, behavior change, and AIDS. Science. 1994 Jul 15;265(5170):341-5.
230. Grunseit A. Impact of HIV and sexual health education on the sexual behaviour of young people: A review update. Geneva: UNAIDS; 1997.
231. Choi KH, Coates TJ. Prevention of HIV infection. Aids. 1994 Oct;8(10):1371-89.
232. Boler T, Aggleton P. Life Skills Education for HIV prevention: a critical analysis. London: Save the Children, Action Aid International; 2005.
233. Okonofua FE, Coplan P, Collins S, Oronsaye F, Ogunsakin D, Ogonor JT, et al. Impact of an intervention to improve treatment-seeking behavior and prevention of sexually transmitted diseases among Nigerian youth. Int J Infect Dis. 2003;7:61-73.
234. Kinsman J, Nakiyingi J, Kamali A, Carpenter LM, Quigley M, Pool R, et al. Evaluation of a comprehensive school-based AIDs education programme in rural Masaka, Uganda. Health Educ res- Theory and Practice. 2001;16(1):85-100.

235. Kirby D, Obasi A, Laris BA. The effectiveness of sex education and HIV education interventions in schools in developing countries. In: Ross DA, Dick B, Ferguson J, editors. Preventing HIV/AIDS in Young People: a systematic review of the evidence from developing countries: UNAIDS interagency task team on HIV and young people. Geneva: World Health Organization; 2006. p. 103-50.
236. Bennett SE, Assefi NP. School-based teenage pregnancy prevention programs: a systematic review of randomized controlled trials. J Adolesc Health. 2005;36(1):72-81.
237. Underhill K, Montgomery P, Operario D. Abstinence-plus programs for HIV infection prevention in high-income countries. Cochrane Database of Systematic Reviews. [Review]. 2008(1).
238. Barnett E, de Konig K, Francis B. Health and HIV/AIDS education in primary and secondary schools in Africa and Asia. Liverpool, England: Oversease Development Administration, Education Resource Group; 1995.
239. UNESCO. Education for All Global Monitoring Report: Is the world on track?: UNESCO; 2002.
240. Kaaya S, Mukoma G, Flisher AJ, Klepp KI. School-based sexual health initiatives in sub-saharan Africa: A review. Social Dynamics. 2002;28:64-88.
241. Speizer IS, Magnani RJ, Colvin CE. The effectiveness of adolescent reproductive health interventions in developing countries: a review of the evidence. J Adolesc Health. 2003 Nov;33(5):324-48.
242. WHO. Skill for Health. Skill-based health education including life skills: An important component of a Child-Friendly/Health-Promoting School. Geneva: WHO; 2003.
243. WHO. Key Issues in the Implementation of Programmes for Adolescent Sexual and Reproductive Health. Geneva: World Health Organisation; 2004.
244. James-Traore T, Magnani R, Murray N, Senderowitz J, Speizer IS, Stewart L. Intervention Strategies that Work for Youth: Summary of the FOCUS on Young Adults End of Program Report. Arlington, VA: Family Health International; 2002.
245. Boler T, Adoss R, Ibrahim A, Shaw M. The Sound of Silence: difficulties in communicating on HIV/AIDS in schools. London: Action Aid; 2003 2003.
246. Ross DA. Approaches to sex education: peer-led or teacher-led? PLoS Med. 2008 Nov 25;5(11):e229.
247. IATT I-ATToHaYP. Global Guidance Brief on HIV Interventions for Young People in the Education Sector. New York: UNFPA; 2008.
248. UNESCO. EDUCAIDS Technical Briefs. Paris: UNESCO; 2008.
249. UNESCO, IBE. Manual for integrating HIV and AIDS education in school curricula. Geneva: International Bureau of Education, UNESCO; 2006.
250. Stover J, Walker N, Garnett GP, Salomon JA, Stanecki KA, Ghys PD, et al. Can we reverse the HIV/AIDS pandemic with an expanded response? Lancet. 2002 Jul 6;360(9326):73-7.
251. WHO, UNFPA, UNICEF. Programming for adolescent health and development: report of a WHO/UNFPA/UNICEF study group on programming for adolescent health. Geneva; 1999.
252. WHO. Protecting Young People from HIV and AIDS. The Role of Health Services. Geneva: WHO; 2004.
253. IATT I-ATToHaYP. Global Guidance Brief on HIV Interventions for Young People in the Health Sector. New York: UNFPA; 2008.
254. Dick B, Ferguson J, Chandra-Mouli V, Brabin L, Chatterjee S, Ross DA. Review of the evidence for interventions to increase young people's use of health services in developing countries. In: Ross DA, Dick B, Ferguson J, editors. Preventing HIV/AIDS in Young People: A systematic review of the evidence from developing countries: UNAIDS interagency task team on HIV and young people; 2006. p. 151-204.

255. Senderowitz J, Hainsworth G, Solter C. A Rapid Assessment of Youth Friendly Reproductive Health Services. Technical Guidance Series. Waterstown, MA: Pathfinder International; 2003 September.
256. Focus. Advancing Young Adult Reproductive Health: Actions for the next decade (end of program report). Washington DC: Focus on Young Adults; 2001.
257. WHO. Adolescent Friendly Health Services. An agenda for change. Geneva: WHO; 2002. Report No.: WHO/FCH/CAH/02.14.
258. WHO. Global consultation on the health services response to the prevention and care of HIV/AIDS among young people : achieving the global goals : access to services : technical report of a WHO consultation, Montreux, Switzerland, 17-21 March 2003. Geneva: World Health Organization; 2004.
259. Nelson K, Maclaren L, Magnani R. Assessing and Planning for Health Services for Youth. Washington DC: Focus on Young Adults Program Pathfinder International; 2000.
260. Senderowitz J. Making Reproductive Health Services Youth Friendly. Washington, D.C.: FOCUS on Young Adults; 1999.
261. Murray N, Toledo V, Luengo X. An Evaluation of an integrated Adolescent Development Program for Urban Teenagers in Santiago, Chile: FOCUS on young adults; 2000.
262. MOH MoH. Standards for Adolescent Friendly Reproductive Health Services. Dar es Salaam: Tanzanian MoH, Reproductive and Child Health section, Directorate of Preventive Services.; 2004.
263. Dickson-Tetteh K, Pettifor A, Moleko W. Working with public sector clinics to provide adolescent-friendly services in South Africa. Reprod Health Matters. 2001;19:160-8.
264. WHO. Guidelines for Adaption of the WHO Orientation Programme on Adolescent Health for Health Care Providers in Europe and Central Asia. Geneva: World Health Organization; 2006.
265. Maclean A. Community involvement in youth reproductive health: a two-part review and analysis of the literature. . Arlington, VA: Family Health International; 2006.
266. CSDH. Closing the gap in a generation: health equity through action on the social determinants of health. Final Report of the Commission on Social Determinants of Health. Geneva: WHO; 2008.
267. Maticka-Tyndale E, Barnett JP. Peer-led interventions to reduce HIV risk of youth: A review. Eval Program Plann. 2009 available online Jul 31 as In Press (corrected proof).
268. Bertrand JT, Anhang R. The effectiveness of mass media in changing HIV / AIDS-related behaviour among young people in developing countries. Preventing HIV / AIDS in young people A systematic review of the evidence from developing countries UNAIDS Inter-agency Task Team on Young People, edited by David A Ross, Bruce Dick and Jane Ferguson: Geneva, Switzerland, World Health Organization [WHO], 2006.; 2006. p. 205-41.
269. Bertrand JT, O'Reilly K, Denison J, Anhang R, Sweat M. Systematic review of the effectiveness of mass communication programs to change HIV/AIDS-related behaviors in developing countries. Health Education Research. 2006;21(4):567-97.
270. Adamchak SE, Kiragu K, Watson C, Muhwezi M, Sapiano TN, Akia-Fiedler A, et al. "Helping youth prevent HIV: An evaluation of the Straight Talk program in Uganda," Horizons Research Summary. Washington, DC: Population Council; 2008.
271. Marum E, Morgan G, Hightower A, Ngare C, Taegtmeyer M. Using mass media campaigns to promote voluntary counseling and HIV-testing services in Kenya. AIDS. 2008 Oct 1;22(15):2019-24.
272. IATT I-ATToHaYP. Global Guidance Brief on HIV Interventions for Young People in the Workplace. New York: UNFPA; 2008.
273. Celentano DD, Nelson KE, Lyles CM, Beyrer C, Eiumtrakul S, Go VF, et al. Decreasing incidence of HIV and sexually transmitted diseases in young Thai men: evidence for success of the HIV/AIDS control and prevention program. AIDS. 1998 Mar 26;12(5):F29-36.

274. Bhave G, Lindan CP, Hudes ES, Desai S, Wagle U, Tripathi SP, et al. Impact of an intervention on HIV, sexually transmitted diseases, and condom use among sex workers in Bombay, India. Aids. 1995 Jul;9 Suppl 1:S21-30.
275. Impact of an Adolescent Reproductive Health Intervention Undertaken in Garment Factories in Cambodia. Boston, MA: Pathfinder International, FOCUS/CARE International—Cambodia.; 2000.
276. Cash K, Anasuchatkul B, Busayawong W. Experimental educational interventions for AIDS prevention among northern Thai single migratory factory workers.. Washington DC: IRCW 1995.
277. Erulkar A, Beksinka M, Cebekhulu Q. An Assessment of Youth Centres in South Africa: USAID, Henry J Kaiser Foundation, DFID; 2001.
278. Hoffman O, Boler T, Dick B. Achieving the global goals on HIV among young people most at risk in developing countries: young sex workers, injecting drug users and men who have sex with men. In: Ross DA, Dick B, Ferguson J, editors. Preventing HIV/AIDS in young people: a systematic review of the evidence from developing countries: UNAIDS interagency task team on HIV and young people. Geneva: World Health Organization; 2006. p. 287-316.
279. Sumartojo E, Doll L, Holtgrave D, Gayle H, Merson M. Enriching the mix: incorporating structural factors into HIV prevention. AIDS. 2000 Jun;14 Suppl 1:S1-2.
280. Des Jarlais DC. Structural interventions to reduce HIV transmission among injecting drug users. AIDS. 2000 June;14 Supplement 1:S41-S6.
281. Phoolcharoen W. HIV/AIDS prevention in Thailand: success and challenges. Science. 1998 Jun 19;280(5371):1873-4.
282. WHO. Effectiveness of sterile needle and syringe programming in reducing HIV/AIDS among injecting drug users. Geneva: World Health Organization; 2004.
283. Rotheram-Borus MJ. Expanding the range of interventions to reduce HIV among adolescents. Aids. 2000 Jun;14 Suppl 1:S33-40.
284. Kim J, Pronyk P, Barnett T, Watts C. Exploring the role of economic empowerment in HIV prevention. Aids. [Review]. 2008 Dec;22:S57-S71.
285. Amin S. Enhancing the Benefits of Girls' Livelihood Initiatives. New York: The Population Council; 2008.
286. Hall J, Dondo A, Sebstad J. Tap and Reposition Youth (TRY) Program: Providing Social Support, Savings, and Microcredit Opportunities to Adolescent Girls at Risk for HIV/AIDS in Kenya. New York: Population Council; 2006.
287. Erulkar AS, Chong E. Evaluation of a Savings & Micro-Credit Program for Vulnerable Young Women in Nairobi. New York: Population Council; 2005.
288. Katz E. Programs Promoting Young Women's Employment: What works?: World Bank; 2008.
289. Pronyk PM, Hargreaves JR, Kim JC, Morison LA, Phetla G, Watts C, et al. Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial. Lancet. 2006 Dec 2;368(9551):1973-83.
290. Pronyk PM, Kim JC, Abramsky T, Phetla G, Hargreaves JR, Morison LA, et al. A combined microfinance and training intervention can reduce HIV risk behaviour in young female participants. AIDS. 2008 Aug 20;22(13):1659-65.
291. Gupta GR, Parkhurst JO, Ogden JA, Aggleton P, Mahal A. Structural approaches to HIV prevention. Lancet. 2008 Aug 30;372(9640):764-75.
292. Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. Int J Epidemiol. 1999 Feb;28(1):10-8.
293. Kirkwood BR, Cousens SN, Victora CG, de Zoysa I. Issues in the design and interpretation of studies to evaluate the impact of community-based interventions. Trop Med Int Health. 1997 Nov;2(11):1022-9.

294. Stephenson J, Imrie J. Why do we need randomised controlled trials to assess behavioural interventions? Bmj. 1998 Feb 21;316(7131):611-3.
295. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. Bmj. 2000 Sep 16;321(7262):694-6.
296. Hallett TB, White PJ, Garnett GP. Appropriate evaluation of HIV prevention interventions: from experiment to full-scale implementation. Sex Transm Infect. 2007 August 1, 2007;83(suppl_1):i55-60.
297. Fisher AA, Foreit JR. Designing HIV/AIDS intervention studies: An operations research handbook. New York: Population Council; 2002.
298. Rychetnik L, Frommer M, Hawe P, Shiell A. Criteria for evaluating evidence on public health interventions. J Epidemiol Community Health. 2002 Feb;56(2):119-27.
299. Kippax S. Sexual health interventions are unsuitable for experimental evaluation. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health: Issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 17-34.
300. Victora CG, Habicht JP, Bryce J. Evidence-based public health: moving beyond randomized trials. Am J Public Health. 2004 Mar;94(3):400-5.
301. Guyatt GH, DiCenso A, Farewell V, Willan A, Griffith L. Randomized trials versus observational studies in adolescent pregnancy prevention. J Clin Epidemiol. 2000 Feb;53(2):167-74.
302. Aral SO, Peterman TA. Measuring outcomes of behavioural interventions for STD/HIV prevention. Int J STD AIDS. 1996;7 Suppl 2:30-8.
303. Oakley A, Fullerton D, Holland J, Arnold S, France-Dawson M, Kelley P, et al. Sexual health education interventions for young people: a methodological review. Bmj. 1995 Jan 21;310(6973):158-62.
304. WHO. National AIDS programmes: a guide to indicators for monitoring and evaluating national HIV/AIDS prevention programmes for young people. Geneva: WHO; 2004. Report No.: ISBN 92 4 159257 5.
305. MacNeil JM, Hogle J. Applying social, behavioral and evaluation research to developing country HIV prevention programs. Aids. 1998;12 Suppl 2:S99-108.
306. Power R, Langhaug LF, Nyamurera T, Wilson D, Bassett MT, Cowan FM. Developing complex interventions for rigorous evaluation--a case study from rural Zimbabwe. Health Educ Res. 2004 Oct;19(5):570-5.
307. Morrow RH, Smith PG. Field trials of health interventions in developing countries: a toolbox. London: Macmillan; 1996.
308. Cowan F, Plummer F. Biological, behavioural and psychological outcome measures. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 111-36.
309. Dare O, Cleland J. Reliability and validity of survey data on sexual behaviour. Health Transition Review. 1994;4:93-110.
310. Catania JA, Gibson DR, Chitwood DD, Coates TJ. Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. Psychol Bull. 1990 Nov;108(3):339-62.
311. Weinhardt LS, Forsyth AD, Carey MP, Jaworski BC, Durant LE. Reliability and validity of self-report measures of HIV-related sexual behavior: progress since 1990 and recommendations for research and practice. Arch Sex Behav. 1998 Apr;27(2):155-80.
312. Gregson S, Zhuwau T, Ndlovu J, Nyamukapa C. Methods to reduce social desirability bias in sex surveys in low-development settings: experience in Zimbabwe. Sex Transm Dis. 2002;29:568-75.
313. Buve A, Lagarde E, Carael M, Rutenberg N, Ferry B, Glynn JR, et al. Interpreting sexual behaviour data: validity issues in the multicentre study on factors determining the differential spread of HIV in four African cities. Aids. 2001 Aug;15 Suppl 4:S117-26.

314. Nnko S, Boerma JT, Urassa M, Mwaluko G, Zaba B. Secretive females or swaggering males? An assessment of the quality of sexual partnership reporting in rural Tanzania. Soc Sci Med. 2004 Jul;59(2):299-310.

315. Bersamin MM, Fisher DA, Walker S, Hill DL, Grube JW. Defining virginity and abstinence: adolescents' interpretations of sexual behaviors. J Adolesc Health. 2007 Aug;41(2):182-8.

316. Wamoyi J, Mshana G. What sticks in the mind? Rural Tanzanian Young People's Memories of the MEMA kwa Vijana In-school Sexual and Reproductive Health Intervention 7-9 Years Later. London: London School of Hygiene & Tropical Medicine
National Institute for Medical Research, Mwanza, Tanzania; 2010 Version of 5 March 2010.

317. Mensch BS, Hewett PC, Gregory R, Helleringer S. Sexual behavior and STI/HIV status among adolescents in rural Malawi: an evaluation of the effect of interview mode on reporting. Studies in Family Planning. 2008 Dec;39(4):321-34.

318. Minnis AM, Muchini A, Shiboski S, Mwale M, Morrison C, Chipato T, et al. Audio computer-assisted self-interviewing in reproductive health research: reliability assessment among women in Harare, Zimbabwe. Contraception. [Article]. 2007 Jan;75(1):59-65.

319. Hewett PC, Mensch BS, Ribeiro MC, Jones HE, Lippman SA, Montgomery MR, et al. Using sexually transmitted infection biomarkers to validate reporting of sexual behavior within a randomized, experimental evaluation of interviewing methods. Am J Epidemiol. 2008 Jul 15;168(2):202-11.

320. Gregson S, Mushati P, White PJ, Mlilo M, Mundandi C, Nyamukapa C. Informal confidential voting interview methods and temporal changes in reported sexual risk behaviour for HIV transmission in sub-Saharan Africa. Sex Transm Infect. 2004 Dec;80 Suppl 2:ii36-42.

321. Power R, Langhaug L, Cowan F. "But there are no snakes in the wood": risk mapping as an outcome measure in evaluating complex interventions. Sexually Transmitted Infections. 2007 Jun;83(3):232-6.

322. Cowan FM, Langhaug LF, Mashungupa GP, Nyamurera T, Hargrove J, Jaffar S, et al. School based HIV prevention in Zimbabwe: feasibility and acceptability of evaluation trials using biological outcomes. Aids. 2002 Aug 16;16(12):1673-8.

323. Fishbein M, Pequegnat W. Evaluating AIDS prevention interventions using behavioral and biological outcome measures. Sex Transm Dis. 2000 Feb;27(2):101-10.

324. Pequegnat W, Fishbein M, Celentano D, Ehrhardt A, Garnett G, Holtgrave D, et al. NIMH/APPC workgroup on behavioral and biological outcomes in HIV/STD prevention studies: a position statement. Sex Transm Dis. 2000 Mar;27(3):127-32.

325. Schachter J, Chow JM. The fallibility of diagnostic tests for sexually transmitted diseases: the impact of behavioral and epidemiologic studies. Sex Transm Dis. 1995 May-Jun;22(3):191-6.

326. Shain RN, Perdue ST, Piper JM, Holden AE, Champion JD, Newton ER. Developing and validating complex behavioural outcome measures. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 137-50.

327. Peterman TA, Lin LS, Newman DR, Kamb ML, Bolan G, Zenilman J, et al. Does measured behavior reflect STD risk? An analysis of data from a randomized controlled behavioral intervention study. Project RESPECT Study Group. Sex Transm Dis. 2000 Sep;27(8):446-51.

328. Slaymaker E, Zaba B. Measurement of condom use as a risk factor for HIV infection. Reprod Health Matters. 2003 Nov;11(22):174-84.

329. Lagarde E, Auvert B, Chege J, Sukwa T, Glynn JR, Weiss HA, et al. Condom use and its association with HIV/sexually transmitted diseases in four urban communities of sub-Saharan Africa. Aids. 2001 Aug;15 Suppl 4:S71-8.

330. Schachter J. Biologic versus behavioral endpoints--the duet continues. Sex Transm Dis. 2000 Sep;27(8):456-7.

331. Pinkerton SD, Layde PM, DiFranceisco W, Chesson HW. All STDs are not created equal: an analysis of the differential effects of sexual behaviour changes on different STDs. Int J STD AIDS. 2003 May;14(5):320-8.
332. Ferry B, Carael M, Buve A, Auvert B, Laourou M, Kanhonou L, et al. Comparison of key parameters of sexual behaviour in four African urban populations with different levels of HIV infection. AIDS. 2001 Aug;15 Suppl 4:S41-50.
333. Buve A, Carael M, Hayes RJ, Auvert B, Ferry B, Robinson NJ, et al. The multicentre study on factors determining the differential spread of HIV in four African cities: summary and conclusions. Aids. 2001 Aug;15 Suppl 4:S127-31.
334. UNAIDS. National AIDS Programmes. A guide to monitoring and evaluation. Geneva: UNAIDS; 2000 June.
335. Wegbreit J, Bertozzi S, DeMaria LM, Padian NS. Effectiveness of HIV prevention strategies in resource-poor countries: tailoring the intervention to the context. AIDS. 2006 Jun 12;20(9):1217-35.
336. Pawson R, Tilley N. Realistic Evaluation. London: Sage; 1997.
337. Ingham R. The importance of context in understanding and seeking to promote sexual health. In: Ingham R, Aggleton P, editors. Promoting young people's sexual health: international perspectives. Oxon: Routledge; 2006. p. 41-60.
338. Flowers P, Hart GJ, Williamson LM, Frankis JS, Der GJ. Does bar-based, peer-led sexual health promotion have a community-level effect amongst gay men in Scotland? Int J STD AIDS. 2002 Feb;13(2):102-8.
339. Elford J, Bolding G, Sherr L. Peer education has no significant impact on HIV risk behaviours among gay men in London. AIDS. 2001 Mar 9;15(4):535-8.
340. Results of the NIMH Collaborative HIV/Sexually Transmitted Disease Prevention Trial of a Community Popular Opinion Leader Intervention. J Acquir Immune Defic Syndr. Mar 27.
341. Elford J, Sherr L, Bolding G, Serle F, Maguire M. Peer-led HIV prevention among gay men in London: process evaluation. AIDS Care. 2002 Jun;14(3):351-60.
342. Hart G, Elford J. The limits of generalizability: community-based sexual health interventions among gay men. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 191-200.
343. DiClemente RJ, Milhausen R, Sales JM, Salazar LF, Crosby RA. A programmatic and methodologic review and synthesis of clinic-based risk-reduction interventions for sexually transmitted infections: research and practice implications. Semin Pediatr Infect Dis. 2005 Jul;16(3):199-218.
344. Kirby D. Effective approaches to reducing adolescent unprotected sex, pregnancy, and childbearing. J Sex Res. 2002 Feb;39(1):51-7.
345. Kirby D, Coyle K. School-based programs to reduce sexual risk-taking behavior. Children and Youth Services Review. 1997;19:415-36.
346. DiCenso A, Guyatt G, Willan A, Griffith L. Interventions to reduce unintended pregnancies among adolescents: systematic review of randomised controlled trials. BMJ. 2002 Jun 15;324(7351):1426.
347. Robin L, Dittus P, Whitaker D, Crosby R, Ethier K, Mezoff J, et al. Behavioral interventions to reduce incidence of HIV, STD, and pregnancy among adolescents: a decade in review. J Adolesc Health. 2004 Jan;34(1):3-26.
348. Magnussen L, Ehiri JE, Ejere HO, Jolly PE. Interventions to prevent HIV/AIDS among adolescents in less developed countries: are they effective? Int J Adolesc Med Health. 2004 Oct-Dec;16(4):303-23.
349. Downing J, Jones L, Cook PA, Bellis MA. Prevention of Sexually Transmitted Infections (STIs): A review of reviews into the effectiveness of non-clinical interventions. Evidence briefing update. Liverpool: John Moores University; 2006.

350. Ellis S, Grey A. Prevention of Sexually Transmitted Infections (STIs): A review of reviews into the effectiveness of non-clinical interventions. London: Health Development Agency; 2004.
351. Ward DJ, Rowe B, Pattison H, Taylor RS, Radcliffe KW. Reducing the risk of sexually transmitted infections in genitourinary medicine clinic patients: a systematic review and meta-analysis of behavioural interventions. Sex Transm Infect. 2005 Oct;81(5):386-93.
352. Grunseit A, Kippax S, Aggleton P, Baldo M, Slutkin G. Sexuality education and young people's sexual behavior: a review of studies. J Adolesc Res. 1997 Oct;12(4):421-53.
353. Pedlow CT, Carey MP. HIV sexual risk-reduction interventions for youth: a review and methodological critique of randomized controlled trials: Behav Modif. 2003 Apr;27(2):135-90.
354. Yankah E, Aggleton P. Effects and Effectiveness of Life Skills Education for Hiv Prevention in Young People. Aids Education and Prevention. [Article]. 2008 Dec;20(6):465-85.
355. Kim C, Free C. Recent evaluations of the peer-led approach in adolescent sexual health education: A systematic review. International Family Planning Perspectives. 2008;34(2):89-96.
356. Kaaya SF, Flisher AJ, Mbwambo JK, Schaalma H, Aaro LE, Klepp KI. A review of studies of sexual behaviour of school students in sub-Saharan Africa. Scand J Public Health. 2002;30(2):148-60.
357. Paul-Ebhohimhen VA, Poobalan A, van Teijlingen ER. A systematic review of school-based sexual health interventions to prevent STI/HIV in sub-Saharan Africa. BMC Public Health. 2008;8:4.
358. Mukoma W, Flisher AJ. A Systematic Review of School-Based HIV/AIDS Prevention Programmes in South Africa. In: Klepp KI, Flisher AJ, Kaaya S, editors. Promoting Adolescent Sexual and Reproductive Health in East and Southern Africa. Cape Town, South Africa: HSRC Press; 2008. p. 267-87.
359. Ross DA, Dick B, Ferguson J. Preventing HIV/AIDS in young people: a systematic review of the evidence from developing countries. UNAIDS Inter-agency Task Team on Young People. Geneva: World Health Organization; 2006.
360. Johnson BT, Carey MP, Marsh KL, Levin KD, Scott-Sheldon LAJ. Interventions to Reduce Sexual Risk for the Human Immunodeficiency Virus in Adolescents, 1985-2000: A Research Synthesis. Arch Pediatr Adolesc Med. 2003 April 1, 2003;157(4):381-8.
361. Adults FoY. Advancing Young Adult Reproductive Health: Actions for the Next Decade. Washington, DC: FOCUS on Young Adults; 2001.
362. Mbizvo MT, Kasule J, Gupta V. Effects of a randomized health education intervention on aspect of reproductive health knowledge and reported behaviour among adolescents in Zimbabwe. Soc Sci Med. 1997;44:573-7.
363. Fawole IO, Asuzu MC, Oduntan SO, Brieger WR. A school-based AIDS education programme for secondary school students in Nigeria: a review of effectiveness. Health Educ Res. 1999 Oct;14(5):675-83.
364. Harvey B, Stuart J, Swan T. Evaluation of a drama-in-education programme to increase AIDS awareness in South African high schools: a randomized community intervention trial. Int J STD AIDS. 2000 Feb;11(2):105-11.
365. Moyo I, Bond K, Williams T. Reproductive Health Antecedents, Attitudes, and Practices among Youth in Gweru, Zimbabwe. Arlington, VA.: John Snow International, SEATS project.; 2000 June.
366. Nelson K, Magnani R. The effects of Youth Friendly Service Projects on Service Utilization among youth in Lusaka, Zambia. Final Report for the FOCUS on Young Adults Program. Washington, D.C.: FOCUS on Young Adults Progam; 2000 July.
367. Speizer IS, Oleko Tambashe B, Tegang SP. An Evaluation of the "Entre Nous Jeunes" Peereducation Program for Adolescents in Cameroon. Stud Fam Plann. 2001;32(4):339-51.
368. Speizer IS, Heller G, Breiger WR. Survey Findings from the West African Youth Initiative Project: Final Evaluation of Peer Educator Intervention: Report prepared for Rockefeller Foundation; 2000.

369. Brieger WR, Delano GE, Lane CG, Oladepo O, Oyediran KA. West African Youth Initiative: outcome of a reproductive health education program. J Adolesc Health. 2001 Dec;29(6):436-46.
370. Agha S, Van Rossem R. Impact of a school-based peer sexual health intervention on normative beliefs, risk perceptions, and sexual behavior of Zambian adolescents. J Adolesc Health. 2004 May;34(5):441-52.
371. Erulkar AS, Ettyang LI, Onoka C, Nyagah FK, Muyonga A. Behavior change evaluation of a culturally consistent reproductive health program for young Kenyans. Int Fam Plan Perspect. 2004 Jun;30(2):58-67.
372. Reddy P, James S, McCauley A. Programming for HIV Prevention in South African Schools. Horizons Research Summary. Washington. D.C.: Population Council; 2003.
373. Maticka-Tyndale E, Brouillard-Coyle C, Gallant M, Holland D, Metcalfe K. Primary School Action for Better Health: 12-18 Month Evaluation- Final Report on PSABH Evaluation in Nyanza and Rift Valley. Windsor: University of Windsor; 2004.
374. Cowan F, Pascoe S, Langhaug L. The Regai Dzive Shiri Project: the results of a cluster randomised trial of a multi-component HIV prevention intervention for young people in rural Zimbabwe. Submitted to PloSMed. unpub.
375. Dente MG, Fabiani M, Okwey R, Conesta N, Opira C. Impact of voluntary counselling and testing and health education on HIV prevention among secondary school students in northern Uganda. Health Policy and Development. 2005;3(1):1-11.
376. Duflo E, Dupas P, Kremer M, Sinei S. Education and HIV / AIDS prevention: evidence from a randomized evaluation in western Kenya: Cambridge, Massachusetts, Massachusetts Institute of Technology [MIT], Abdul Latif Jameel Poverty Action Lab, 2006 Jun.; 2006.
377. James S, Reddy P, Ruiter RAC, McCauley A, van den Borne B. The Impact of an HIV and AIDS Life Skills Program on Secondary School Students in KwaZulu-Natal, South Africa. AIDS Education & Prevention. 2006 Aug;18(4):281-94.
378. Karnell AP, Cupp PK, Zimmerman RS, Feist-Price S, Bennie T. Efficacy of an American alcohol and HIV prevention curriculum adapted for use in South Africa: results of a pilot study in five township schools. AIDS Education & Prevention. 2006 Aug;18(4):295-310.
379. Magnani R, Macintyre K, Karim AM, Brown L, Hutchinson P, Kaufman C, et al. The impact of life skills education on adolescent sexual risk behaviors in KwaZulu-Natal, South Africa. Journal of Adolescent Health. 2005 Apr;36(4):289-304.
380. Maticka-Tyndale E, Wildish J, Gichuru M. Quasi-experimental evaluation of a national primary school HIV intervention in Kenya. Evaluation & Program Planning. 2007 May;30(2):172-86.
381. Miller AN, Mutungi M, Facchini E, Barasa B, Ondieki W, Warria C. An outcome assessment of an ABC-based HIV peer education intervention among Kenyan university students. Journal of Health Communication. 2008 Jun;13(4):345-56.
382. Smith EA, Palen LA, Caldwell LL, Flisher AJ, Graham JW, Mathews C, et al. Substance use and sexual risk prevention in Cape Town, South Africa: an evaluation of the healthwise program. Prevention Science. 2008;9(4):311-21.
383. Visser MJ. HIV/AIDS prevention through peer education and support in secondary schools in South Africa. SAHARA J: Journal of Social Aspects of HIV/AIDS Research Alliance. 2007 Nov;4(3):678-94.
384. Jewkes R, Nduna M, Levin J, Jama N, Dunkle K, Puren A, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial.[see comment]. BMJ. 2008;337:a506.
385. Pettifor AE, Rees HV, Kleinschmidt I, Steffenson AE, MacPhail C, Hlongwa-Madikizela L, et al. Young people's sexual health in South Africa: HIV prevalence and sexual behaviors from a nationally representative household survey.[see comment]. AIDS. 2005 Sep 23;19(14):1525-34.

386. Evaluation of the African Youth Alliance program in Ghana. Impact on sexual and reproductive health behavior among young people. Rosslyn, Virginia: JSI Research and Training Institute, 2007.; 2007.
387. Evaluation of the African Youth Alliance program in Tanzania. Impact on sexual and reproductive health behavior among young people. Rosslyn, Virginia: JSI Research and Training Institute, 2007.; 2007.
388. Evaluation of the African Youth Alliance program in Uganda. Impact on sexual and reproductive health behavior among young people. Rosslyn, Virginia: JSI Research and Training Institute, 2007.; 2007.
389. AYA. Youth-friendly services: Botswana end of program evaluation report. Watertown, MA: Pathfinder International; 2005.
390. Madagascar (2006): HIV / AIDS TRaC study evaluating abstinence among youth (15-24 years). Second round. Antananarivo, Madagascar. Washington, D.C., PSI, 2007.; 2007.
391. Plautz A, Meekers D. Evaluation of the reach and impact of the 100% Jeune youth social marketing program in Cameroon: Findings from three cross-sectional surveys. Reproductive Health. 2007 Feb 26;4(1):1.
392. Fonseca-Becker F, Bakadi G, Sow A. Mobilizing communities for behavior change: HIV / AIDS and pregnancy prevention among youth in upper Guinea. Baltimore, Maryland, Johns Hopkins Bloomberg School of Public Health, Center for Communication Programs, 2005 May.; 2005.
393. Kajubi P, Kamya MR, Kamya S, Chen S, McFarland W, Hearst N. Increasing condom use without reducing HIV risk: results of a controlled community trial in Uganda. Journal of Acquired Immune Deficiency Syndromes: JAIDS. 2005 Sep 1;40(1):77-82.
394. Svenson G, Burke H, Johnson L. Impact of Youth Peer Education Programs: Final Results from an FHI/YouthNet Study in Zambia. . Research Triangle Park: Family Health International; 2008.
395. Mmari KN, Magnani RJ. Does making clinic-based reproductive health services more youth-friendly increase service use by adolescents? Evidence from Lusaka, Zambia. J Adolesc Health. 2003 Oct;33(4):259-70.
396. Mboyne AK. Disease and health-seeking patterns among adolescents in Uganda. Int J Adolesc Med Health. 2003;15:105-12.
397. Kim YS, Kols A, Nyakauru R, Marangwanda C, Chibatamoto P. Promoting sexual responsibility among young people in Zimbabwe. Int Fam Plann Persp. 2001;27:11-9.
398. Diop NJ, Bathidja H, Touré ID, Dieng T, Mané B, RamaRao S, et al. Improving the Reproductive Health of Adolescents in Senegal: USAID; 2004.
399. Hainsworth G. Providing sexual reproductive health and STI/HIV information and services to this generation: insights from the Geracao Biz experience. . Maputo: Pathfinder International; 2002.
400. Solo J, Pollard F, Mugambi M. Enjoy your youth, be wise: an evaluation of the Innovate project in Ghana. London: International Planned Parenthood Federation; 2001.
401. LoveLife. Lovelife 2004:report on activities and progress. Cape Town, Parklands: Lovelife; 2004.
402. Neukom J, Ashford DA. Changing youth behaviour through social marketing: program experiences and research findings from Cameroon, Madagascar, and Rwanda. Washington, D.C.: Population Services International Population Reference bureau; 2003.
403. AYA. Youth-friendly services: Tanzania end of program evaluation report. Watertown, Massachusetts: Pathfinder International; 2005.
404. AYA. Youth-friendly services: Ghana end of program evaluation report. Watertown, MA: Pathfinder Intervnational; 2005.
405. AYA. Youth-friendly services: Uganda end of program evaluation report. Watertown, MA: Pathfinder International; 2005.

406. Esu-Williams E, Schenk K, Motsepe J, Gelbel S, Zulu A. Involving Young People in the Care and Support of People Living with HIV and AIDS in Zambia (Horizons final report). Washington DC: Population Council; 2004.
407. IRESCO. Peer Education as a Strategy to Increase Contraceptive Prevalence and Reduce the Rate of STIs/HIV Among Adolescents in Cameroon (Frontiers Final Report). Washington D.C.: Population Council; 2002.
408. Muyinda H, Kengeya J, Pool R, Whitworth J. Traditional sex counselling and STI/HIV among young women in rural Uganda. Cult Health Sex. 2001;3:353-61.
409. Kagimu M, Marum E, Wabwire-Mangen F, Nakyanjo N, Walakira Y, Hogle J. Evaluation of the effectiveness of AIDS health education interventions in the Muslim community in Uganda. AIDS Educ Prev. 1998;10(3):215-28.
410. Reijer P, Chalimba M, Nakwagala A. Malawi goes to scale with anti-AIDS clubs and popular media. Evaluation and Program Planning. 2002;25:357-63.
411. CEDPA. Using Peer Educators to Improve Adolescent Reproductive Health in Ghana (CEDPA). Washington DC: CEDPA; 2000.
412. Hughes-d'Aeth A. Evaluation of HIV/AIDS peer education projects in Zambia. Evaluation and Program Planning. 2002;25:397-407.
413. Ghana U-. Evaluation of HIV/AIDS prevention through peer education, counselling, healthcare, training and urban refuges in Ghana. Evaluation and Program Planning. 2002;25:409-20.
414. Bagamoyo CoA, Centre TT, Mabala R, Allen K. Participatory action research on HIV/AIDS through a popular theatre approach in Tanzania. Evaluation and Program Planning. 2002;25:333-9.
415. UNFPA. Rapport evaluation thematique du projet UNFPA: mobilisation communautaire, participation et renforcement de l'autonomie des adolescent(e)s [Thematic evaluation report of UNFPA project: community mobilization, participation and empowerment of adolescents]. Burkina Faso: UNFPA; 2004.
416. Brady M, Khan A. Letting Girls Play: The Mathare Youth Sports Association's Football Program for Girls (Population Council). New York: Population Council; 2002.
417. Muyinda H, Nakuya R, Pool R, Whitworth J. Harnessing the senga institution of adolescent sex education for the control of HIV and STDs in rural Uganda. AIDS Care. 2003 167;15(2):159.
418. Khan JH, Marseille E, Kramer S. Assessment of the Potential Economic Impact of South Africa's loveLife National HIV Prevention Program. South Africa: loveLife Trust 2005.
419. Pettifor AE, Kleinschmidt I, Levin J, Rees HV, MacPhail C, Madikizela-Hlongwa L, et al. A community-based study to examine the effect of a youth HIV prevention intervention on young people aged 15-24 in South Africa: results of the baseline survey. Tropical Medicine & International Health. 2005 Oct;10(10):971-80.
420. Cowan F, Woelk G, Chidiya S, Regai Dzive Shiri Trial Team. Results and policy implications of two major adolescent sexual and reproductive health trials in Africa: The MEMA kwa Vijana Trial in Tanzania and the Regai Dzive Shiri Trial in Zimbabwe. Satellite Meeting, ICASA; 2008 5 Dec 2008; Dakar, Senegal. 2008.
421. Ross DA, White R, editors. Surrogate outcomes for HIV: Handle with care! XVII International AIDS Conference; 2008; Mexico City, Mexico.
422. Kirby DB, Laris BA, Rolleri LA. Sex and HIV education programs: Their impact on sexual behaviors of young people throughout the world. Journal of Adolescent Health. [Review]. 2007 Mar;40(3):206-17.
423. Walker D, Gutierrez JP, Torres P, Bertozzi SM. HIV prevention in Mexican schools: prospective randomised evaluation of intervention. Bmj. 2006 May 20;332(7551):1189-94.
424. McCauley A. Programming for HIV prevention in Mexican schools. Washington, DC: Population Council; 2004.

425. Pick De Weiss S, Givaudan M, Givaudan S. Planeando Tu Vida: sex and family life education: fundamentals of development, implementation, and evaluation. Int J Adolesc Med Health. 1993 Jul-Dec;6(3-4):211-24.
426. Antunes MC, Stall RD, Paiva V, Peres CA, Paul J, Hudes M, et al. Evaluating an AIDS sexual risk reduction program for young adults in public night schools in Sao Paulo, Brazil. Aids. 1997 Sep;11 Suppl 1:S121-7.
427. Magnani RJ, Gaffikin L, Leao de Aquino EM, Seiber E, Almeida M, Lipovsek V. Impact of an integrated adolescent reproductive health program in Brazil. Stud Fam Plann. 2001;32:230-43.
428. Cabezon C, Vigil P, Rojas I, Leiva ME, Riquelme R, Aranda W, et al. Adolescent pregnancy prevention: An abstinence-centered randomized controlled intervention in a Chilean public high school. J Adolesc Health. 2005 Jan;36(1):64-9.
429. Shain RN, Piper JM, Newton ER, Perdue ST, Ramos R, Champion JD, et al. A randomized, controlled trial of a behavioral intervention to prevent sexually transmitted disease among minority women. N Engl J Med. 1999 Jan 14;340(2):93-100.
430. Koblin B, Chesney M, Coates T. Effects of a behavioural intervention to reduce acquisition of HIV infection among men who have sex with men: the EXPLORE randomised controlled study. Lancet. 2004 Jul 3-9;364(9428):41-50.
431. Baker SA, Beadnell B, Stoner S, Morrison DM, Gordon J, Collier C, et al. Skills training versus health education to prevent STDs/HIV in heterosexual women: a randomized controlled trial utilizing biological outcomes. AIDS Educ Prev. 2003 Feb;15(1):1-14.
432. Stephenson J, Strange V, Allen E, Copas A, Johnson A, Bonell C, et al. The long-term effects of a peer-led sex education programme (RIPPLE): a cluster randomised trial in schools in England. PLoS Med. 2008 Nov 25;5(11):e224; discussion e.
433. Henderson M, Wight D, Raab GM, Abraham C, Parkes A, Scott S, et al. Impact of a theoretically based sex education programme (SHARE) delivered by teachers on NHS registered conceptions and terminations: final results of cluster randomised trial. BMJ. 2007 Jan 20;334(7585):133.
434. Harden A, Brunton G, Fletcher A, Oakley A. Teenage pregnancy and social disadvantage: systematic review integrating controlled trials and qualitative studies. BMJ. 2009;339:b4254.
435. Hallett TB, Singh K, Smith JA, White RG, Abu-Raddad LJ, Garnett GP. Understanding the impact of male circumcision interventions on the spread of HIV in southern Africa. PLoS ONE. 2008;3(5):e2212.
436. White RG, Freeman EE, Orroth KK, Bakker R, Weiss HA, O'Farrell N, et al. Population-level effect of HSV-2 therapy on the incidence of HIV in sub-Saharan Africa. Sexually Transmitted Infections. 2008;84:II12-II8.
437. Hallett TB, Garnett GP, Mupamberiyi Z, Gregson S. Measuring effectiveness in community randomized trials of HIV prevention. Int J Epidemiol. 2008 February 1, 2008;37(1):77-87.
438. White RG, Orroth KK, Korenromp EL, Bakker R, Wambura M, Sewankambo NK, et al. Can population differences explain the contrasting results of the Mwanza, Rakai, and Masaka HIV/sexually transmitted disease intervention trials?: A modeling study. J Acquir Immune Defic Syndr. 2004 Dec 1;37(4):1500-13.
439. Chapman R, White RG, Shafer LA, Pettifor A, Mugurungi O, Ross D, et al. Do behavioural differences help to explain variations in HIV prevalence in adolescents in sub-Saharan Africa? Trop Med Int Health. May;15(5):554-66.
440. Dupas P. Relative Risks and the Market for Sex: Teenagers, Sugar Daddies and HIV in Kenya. Paris: EHESS-PSE; 2005.
441. Stephenson J. Challenges for future sexual health intervention trials. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in experimental evaluation. Oxford: Oxford University Press; 2003. p. 217-22.

442. Stewart H, McCauley AP, Baker S, Givaudan M, James S, Leenen I, et al. Reducing HIV Infection Among Youth: What Can Schools Do? Key Baseline Findings from Mexico, South Africa, and Thailand: Horizons; ICRW;IMIFAP;MRC;PATH;Population Council; 2001 2001.
443. Hayes RJ, Bennett S. Simple sample size calculation for cluster-randomized trials. Int J Epidemiol. 1999 Apr;28(2):319-26.
444. Todd J, Carpenter L, Li X, Nakiyingi J, Gray R, Hayes R. The effects of alternative study designs on the power of community randomized trials: evidence from three studies of human immunodeficiency virus prevention in East Africa. Int J Epidemiol. 2003 Oct;32(5):755-62.
445. Cleland J, Boerma JT, Carael M, Weir SS. Monitoring sexual behaviour in general populations: a synthesis of lessons of the past decade. Sex Transm Infect. 2004 December 1, 2004;80(suppl_2):ii1-7.
446. Rossau R, Heyndrickx L, Van Heuverswyn H. Nucleotide sequence of a 16S ribosomal RNA gene from Neisseria gonorrhoeae. Nucleic Acids Res. 1988 Jul 11;16(13):6227.
447. Roymans R, Onland G, Jansz A, Quint W, Boel E. Evaluation of an in-house polymerase chain reaction for detection of Neisseria gonorrhoeae in urogenital samples. J Clin Pathol. 1999 Jun;52(6):411-4.
448. Hayes R, Moulton LH. Cluster Randomised Trials. Morgan BJT, Keiding N, Van der Heijden P, Speed T, editors.: CRC Pr I Llc; 2008.
449. Cheung YB, Jeffries D, Thomson A, Milligan P. A simple approach to test for interaction between intervention and an individual-level variable in community randomized trials. Tropical Medicine & International Health. [Article]. 2008 Feb;13(2):247-55.
450. Doyle AM, Ross DA, Maganja K, Baisley K, Masesa C, Andreasen A, et al. Long-term biological and behavioural impact of an adolescent sexual health intervention in tanzania: follow-up survey of the community-based MEMA kwa Vijana Trial. PLoS Med. 2010;7(6):e1000287.
451. Van den Bergh G. To Risk or not To Risk? Is It a Question? Sexual Debut, Poverty and Vulnerability in Times of HIV: A Case from Kigoma Region, Tanzania. In: Klepp KI, Flisher AJ, Kaaya S, editors. Promoting Adolescent Sexual and Reproductive Health in East & Southern Africa. Cape Town: HSRC Press; 2008. p. 162-82.
452. Plummer ML, Wamoyi J, Nyalali K, Mshana G, Shigongo ZS, Ross DA, et al. Aborting and Suspending Pregnancy in Rural Tanzania: An Ethnography of Young People's Beliefs and Practices. Studies in Family Planning. [Article]. 2008 Dec;39(4):281-92.
453. Mann JR, Stine CC, Vessey J. The role of disease-specific infectivity and number of disease exposures on long-term effectiveness of the latex condom. Sex Transm Dis. 2002 Jun;29(6):344-9.
454. Cates W, Jr. The condom forgiveness factor: the positive spin. Sex Transm Dis. 2002 Jun;29(6):350-2.
455. Hill AB. THE ENVIRONMENT AND DISEASE: ASSOCIATION OR CAUSATION? Proc R Soc Med. 1965 May;58:295-300.
456. Smith AD, Tapsoba P, Peshu N, Sanders EJ, Jaffe HW. Men who have sex with men and HIV/AIDS in sub-Saharan Africa. Lancet. 2009 Aug 1;374(9687):416-22.
457. Zaba B, Marston M, Isingo R, Urassa M, Ghys PD, editors. How well do cross-sectional population surveys measure HIV prevalence? Exploring the effects of non-participation (LbOrC23). XVth International AIDS Conference, 11–16 July 2004; 2004; Bangkok, Thailand.
458. Isingo R, Zaba B, Marston M, Ndege M, Mngara J, Mwita W, et al. Survival after HIV infection in the pre-antiretroviral therapy era in a rural Tanzanian cohort. Aids. [Article]. 2007 Nov;21:S5-S13.
459. Porter K, Zaba B. The empirical evidence for the impact of HIV on adult mortality in the developing world: data from serological studies. Aids. 2004 Jun;18 Suppl 2:S9-S17.
460. Everett DB, Weiss HA, Changalucha J, Anemona A, Chirwa T, Ross DA, et al. Low specificity of the Murex fourth-generation HIV enzyme immunoassay in Tanzanian adolescents. Tropical Medicine & International Health. [Article]. 2007 Nov;12(11):1323-6.

461. van Dyck E, Buve A, Weiss HA, Glynn JR, Brown DW, De Deken B, et al. Performance of commercially available enzyme immunoassays for detection of antibodies against herpes simplex virus type 2 in African populations. J Clin Microbiol. 2004 Jul;42(7):2961-5.
462. Smith JS, Bailey RC, Westreich DJ, Maclean I, Agot K, Ndinya-Achola JO, et al. Herpes simplex virus type 2 antibody detection performance in Kisumu, Kenya, using the Herpeselect ELISA, Kalon ELISA, Western blot and inhibition testing. Sex Transm Infect. 2009 Apr;85(2):92-6.
463. Everett DB, Baisely KJ, McNerney R, Hambleton I, Chirwa T, Ross DA, et al. Association of schistosomiasis with false positive HIV test results in an African adolescent population. J Clin Microbiol. Feb 24.
464. Gamiel JL, Tobian AA, Laeyendecker OB, Reynolds SJ, Morrow RA, Serwadda D, et al. Improved performance of enzyme-linked immunosorbent assays and the effect of human immunodeficiency virus coinfection on the serologic detection of herpes simplex virus type 2 in Rakai, Uganda. Clin Vaccine Immunol. 2008 May;15(5):888-90.
465. Delany-Moretlwe S, Jentsch U, Weiss H, Moyes J, Ashley-Morrow R, Stevens W, et al. Comparison of focus HerpesSelect and Kalon HSV-2 gG2 ELISA serological assays to detect herpes simplex virus type 2 antibodies in a South African population. Sex Transm Infect. 2010 Feb;86(1):46-50.
466. Peeling RW, Ye H. Diagnostic tools for preventing and managing maternal and congenital syphilis: an overview. Bull World Health Organ. 2004 Jun;82(6):439-46.
467. Cook RL, Hutchison SL, Ostergaard L, Braithwaite RS, Ness RB. Systematic review: noninvasive testing for Chlamydia trachomatis and Neisseria gonorrhoeae. Ann Intern Med. 2005 Jun 7;142(11):914-25.
468. Farrell DJ. Evaluation of AMPLICOR Neisseria gonorrhoeae PCR using cppB nested PCR and 16S rRNA PCR. J Clin Microbiol. 1999 Feb;37(2):386-90.
469. van Doornum GJ, Schouls LM, Pijl A, Cairo I, Buimer M, Bruisten S. Comparison between the LCx Probe system and the COBAS AMPLICOR system for detection of Chlamydia trachomatis and Neisseria gonorrhoeae infections in patients attending a clinic for treatment of sexually transmitted diseases in Amsterdam, The Netherlands. J Clin Microbiol. 2001 Mar;39(3):829-35.
470. Renju J, Nyalali K. Scaling up ASRH education through widespread teacher training: training evaluation report: National Institute for Medical Research, Mwanza, Tanzania. Liverpool School of Tropical Medicine, UK; 2008.
471. Wamoyi J. Family context and the complexity of parenting: A focus on the influence on young people's sexual behaviour in rural Tanzania: Southampton University, UK; 2008.
472. Cowan FM, Pascoe SJS, Langhaug LF, Dirawo J, Chidiya S, Jaffar S, et al. The Regai Dzive Shiri Project: a cluster randomised controlled trial to determine the effectiveness of a multi-component community-based HIV prevention intervention for rural youth in Zimbabwe--study design and baseline results. Tropical Medicine & International Health. 2008 Oct;13(10):1235-44.
473. Wight D, Williamson L, Henderson M. Parental influences on young people's sexual behaviour: a longitudinal analysis. J Adolesc. 2006 Aug;29(4):473-94.
474. Todd J, Cremin I, McGrath N, Bwanika JB, Wringe A, Marston M, et al. Reported number of sexual partners: comparison of data from four African longitudinal studies. Sex Transm Infect. 2009 Apr;85 Suppl 1:i72-80.
475. Rweyemamu D, Fuglesang M. Multiple and concurrent sexual partnerships among youth in Tanzania. A research study commissioned by Femina HIP in preparation for a regional youth MCP campaign. Dar es Salaam; 2008.
476. Halperin DT, Epstein H. Concurrent sexual partnerships help to explain Africa's high HIV prevalence: implications for prevention. Lancet. 2004 Jul 3;364(9428):4-6.
477. Lurie M, Rosenthal S, Williams B. Concurrency driving the African HIV epidemics: where is the evidence? Lancet. 2009 Oct 24;374(9699):1420; author reply -1.

478. Dickinson C, Buse K. Understanding the politics of national HIV policies: the roles of institutions, interests and ideas: HSLP Institute, HEARD, University of KwaZulu Natal, South Africa; 2008.
479. Blankenship KM, Friedman SR, Dworkin S, Mantell JE. Structural interventions: concepts, challenges and opportunities for research. J Urban Health. 2006 Jan;83(1):59-72.
480. Bonell C, Hargreaves J, Strange V, Pronyk P, Porter J. Should structural interventions be evaluated using RCTs? The case of HIV prevention. Soc Sci Med. 2006 Sep;63(5):1135-42.
481. Auerbach JD, Coates TJ. HIV prevention research: accomplishments and challenges for the third decade of AIDS. Am J Public Health. 2000 Jul;90(7):1029-32.
482. Grosskurth H, Kumaranayake L, Bonell C. Generalizability of trials and implementation of research into practice. In: Stephenson J, Imrie J, Bonell C, editors. Effective Sexual Health Interventions: Issues in Experimental Evaluation. Oxford: Oxford University Press; 2003. p. 169-90.
483. Dunbar MS, Maternowska MC, Kang MS, Laver SM, Mudekunye-Mahaka I, Padian NS. Findings from SHAZ!: a feasibility study of a microcredit and life-skills HIV prevention intervention to reduce risk among adolescent female orphans in Zimbabwe. J Prev Interv Community. Apr;38(2):147-61.
484. Fishbein M, Jarvis B. Failure to find a behavioral surrogate for STD incidence--what does it really mean? Sex Transm Dis. 2000 Sep;27(8):452-5.
485. Dick B, Hargreaves J, Harrison DB, Ng'wanansabi D. HIV Prevention among young people in sub-Saharan Africa: what more? Background paper for the meeting on 'HIV Prevention among young people in Sub-Saharan Africa: the Way Forward". 2009; Dar es Salaam. 2009. p. 28.
486. Pedlow CT, Carey MP. Developmentally appropriate sexual risk reduction interventions for adolescents: rationale, review of interventions, and recommendations for research and practice. Ann Behav Med. 2004 Jun;27(3):172-84.
487. Kim JC, Watts CH. Gaining a foothold: tackling poverty, gender inequality, and HIV in Africa. Bmj. 2005 Oct 1;331(7519):769-72.
488. Lemme F, Doyle AM, Changalucha J, Weiss HA, Baisley K, Maganja RK, et al. HIV infection among young people in northwestern Tanzania: the role of biological, behavioural and socio-demographic risk factors In preparation.
489. Pettifor AE, Levandowski BA, Macphail C, Padian NS, Cohen MS, Rees HV. Keep them in school: The importance of education as a protective factor against HIV infection among young South African women. International Journal of Epidemiology. 2008;37(6):1266-73.
490. Jukes M, Simmons S, Bundy D. Education and vulnerability: The role of schools in protecting young women and girls from HIV in southern Africa. Aids. [Review]. 2008 December;22(SUPPL. 4):S41-S56.
491. Making it Pay to Stay in School. Washington, D.C.: Centre for Global Development; 2005.
492. Tanser F, Barnighausen T, Cooke GS, Newell ML. Localized spatial clustering of HIV infections in a widely disseminated rural South African epidemic. Int J Epidemiol. 2009 Aug;38(4):1008-16.
493. Weir SS, Pailman C, Mahlalela X, Coetzee N, Meidany F, Boerma JT. From people to places: focusing AIDS prevention efforts where it matters most. AIDS. 2003 Apr 11;17(6):895-903.
494. Ybarra ML, Emenyonu N, Nansera D, Kiwanuka J, Bangsberg DR. Health information seeking among Mbararan adolescents: results from the Uganda Media and You survey. Health Educ Res. 2008 Apr;23(2):249-58.
495. Nwagwu WE. The Internet as a source of reproductive health information among adolescent girls in an urban city in Nigeria. BMC Public Health. 2007 Dec 20;7(354):[31].

496. Mbonile L, Kayombo EJ. Assessing acceptability of parents / guardians of adolescents towards introduction of sex and reproductive health education in schools at Kinondoni Municipal in Dar es Salaam city. East African Journal of Public Health. 2008 Apr;5(1):26-31.

497. Phetla G, Busza J, Hargreaves JR, Pronyk PM, Kim JC, Morison LA, et al. "They have opened our mouths": increasing women's skills and motivation for sexual communication with young people in rural South Africa. AIDS Education and Prevention. 2008;20(6):504-18.

498. Ng'wanansabi D. Engaging Tanzanian Families and Communities in Prevention of Cross Generational Sex. HIV Implementer's Conference; 2009; Windhoek, Namibia. 2009.

499. UNAIDS practical guidelines for intensifying HIV prevention: Towards universal access. Geneva, Switzerland, UNAIDS, 2007.; 2007.

500. Fazekas K, Moffett J. Communicating with Youth: Using the Internet and Mobile Phones in Reproductive Health Programs (No.28). Research Triangle Park, NC, USA: FHI; 2009 May 2009.

501. Harrison A, Cleland J, Frohlich J. Young People's Sexual Partnerships in KwaZulu-Natal, South Africa: Patterns, Contextual Influences, and HIV Risk. Studies in Family Planning. [Article]. 2008 Dec;39(4):295-308.

502. Harrison DB. HIV prevention needs to confront the elephant on the road. S Afr Med J. 2008 Oct;98(10):786-7.

503. Mwaanga O. Sport for addressing HIV/AIDS: Explaining our convictions. LSA Newsletter. 2010:7.

504. UNFPA. Generation of Change: Young People and Culture. New York: UNFPA; 2008.

505. Maro CN, Roberts GC, Sorensen M. Using sport to promote HIV/AIDS education for at-risk youths: an intervention using peer coaches in football. Scand J Med Sci Sports. 2009 Feb;19(1):129-41.

506. Awasthi S, Nichter M, Pande V. Developing an interactive STD-prevention programme for youth: Lessons from a North Indian slum. Stud Fam Plann. 2000;31(2):138-50.

507. Kagaayi J, Gray RH, Ssetuba A, Nabukenya D, Makumbi F, Kiwanuka N, et al., editors. Individual Self Perception of HIV Risk is associated with HIV acquisition. International AIDS Society; 2009; Cape Town.

508. Cassell MM, Halperin DT, Shelton JD, Stanton D. Risk compensation: the Achilles' heel of innovations in HIV prevention? Bmj. 2006 Mar 11;332(7541):605-7.

509. Olsen R. Achieving MDG 6. Target 7: to halt and begin to reverse the spread of HIV and AIDS by 2015 by reducing the risk and vulnerability of Adolescent Girls in Eastern and Southern Africa Region (ESAR) (Working Draft- November 2007 version). Johannesburg: UNICEF Regional Office for Eastern and Southern Africa (ESARO); 2007.

Appendix 1. Study Chronology

Dates	Activities	Location of the Candidate
November 2004-September 2006	-Literature review -Proposal Development -PhD Upgrading (June 2005) -Grant applications -Development of data collection tools -Development of alternative PhD study proposal and conducting literature review for this study	London, UK (initial 2 week visit to Mwanza in Feb '05)
October 2006-April 2007	-Start of DFID/IA £1.6 million grant for MkV1FS (Oct 06) -Preparations for survey in Mwanza (staff recruitment and training, procurement, pre-testing of procedures)	Mwanza, Tanzania
May 2007	-Pilot Study	Mwanza, Tanzania
June 2007-May 2008	-Main Survey -Data entry & laboratory analysis	Mwanza, Tanzania
June-July 2008	-Mop-up Survey -STI treatment -Data entry & laboratory analysis	Mwanza, Tanzania
August-October 2008	-Data cleaning -Closure of project in Mwanza	Mwanza, Tanzania
November – December 2008	-Data analysis -Presentation of main results to stakeholders in Tanzania and at ICASA, Senegal	London, UK (attended dissemination meetings)
January-March 2009	-Sub-group analysis -Preparation and submission of main results paper -Systematic review	London, UK
April- September 2009	-Maternity leave -Systematic review -Qualitative sub-study	*Maternity Leave*
October 2009-May 2010	-Systematic review -End of DFID/IA Project Grant (Dec '09) -PhD write-up	London, UK

Appendix 2. Results of the 2001/2 MEMA kwa Vijana intervention impact evaluation[1]

Outcome	Young men			Young women		
	Frequency[1]			Frequency[1]		
	Intervention (N=2076) n (%)	Comparison (N=2024) n (%)	Adjusted RR[2] (CI)	Intervention (N=1448) n (%)	Comparison (N=1492) n (%)	Adjusted RR[2] (CI)
Knowledge (% with all 3 responses "correct")						
HIV acquisition	1356 (65%)	908 (45%)	1.44 (1.25,1.67)	832 (58%)	601 (40%)	1.41 (1.14,1.75)
STD acquisition	1074 (52%)	807 (40%)	1.28 (1.07, 0.54)	522(36%)	376 (25%)	1.41 (1.06,1.88)
Pregnancy prevention	1746 (84%)	1018 (50%)	1.66 (1.55,1.78)	1047 (72%)	688 (46%)	1.58 (1.26,1.99)
Reported Attitudes (% with all 3 responses "correct")						
Attitudes to sex	454 (22%)	247 (12%)	1.77 (1.42,2.22)	383 (27%)	283 (19%)	1.42 (1.11,1.81)
Reported Sexual Behaviour (% with outcome)						
Sexual debut during follow-up[3]	638 (60%)	677 (72%)	0.84 (0.71,1.01)	801 (68%)	763 (67%)	1.03 (0.91,1.16)
More than 1 partner in last 12 months	394 (19%)	556 (28%)	0.69 (0.49,0.95)	123 (9%)	116 (8%)	1.04 (0.58,1.89)
First used condom during follow-up[4]	548 (39%)	427 (28%)	1.41 (1.15,1.73)	387 (38%)	297 (28%)	1.30 (1.03,1.63)
Used condom at last sex[5]	431 (29%)	326 (20%)	1.47 (1.12,1.93)	284 (27%)	238 (22%)	1.12 (0.85,1.48)
Went to health facility for most recent STI symptoms within the last 12 months[6]	26/91 (29%)	52/150 (35%)	0.84 (0.50,1.41)	33/93 (36%)	54/160 (34%)	1.02 (0.62,1.70)
Primary biological outcomes						
HIV incidence (/1,000person- years)	3 (0.43)	2 (0.30)	NA	16 (3.18)	24 (4.73)	0.75 (0.34,1.66)
HSV-2 prevalence	234 (11.3%)	251 (12.5%)	0.92 (0.69,1.22)	305 (21.3%)	309 (20.8%)	1.05 (0.83,1.32)
Secondary biological outcomes						
Syphilis prevalence	28 (1.4%)	37 (1.8%)	0.78 (0.46,1.30)	47 (3.3%)	54 (3.6%)	0.99 (0.67,1.46)
Chlamydia prevalence	11 (0.5%)	11 (0.5%)	1.14 (0.53,2.43)	71 (4.9%)	54 (3.6%)	1.37 (0.98,1.91)
Gonorrhoea prevalence	8 (0.4%)	2 (0.1%)	NA	35 (2.4%)	18 (1.2%)	1.93 (1.01,3.71)
Trichomonas prevalence[7]				413 (28.6%)	383 (25.8%)	1.13 (0.92,1.37)
Pregnancy (test) prevalence[7]				277 (19.2%)	268 (18.0%)	1.09 (0.85,1.40)
Reported pregnancy during follow-up[7,8]				489 (46.9%)	489 (45.5%)	1.03 (0.89,1.20)

CI, 95% Confidence interval; HSV2, herpes simplex virus 2; NA, number of cases too small to justify comparison (< 10 in each group); RR, rate ratio (prevalence, risk or rate ratio); STD, sexually transmitted disease; STI, sexually transmitted infection.

[1]Prevalence, risk or rate depending on outcome [2]Adjusted for: age group(≤17, 18, ≥19 years at final survey), stratum, tribe (Sukuma versus non-Sukuma), number of lifetime partners at baseline (0,1,2,≥3). [3]Among those who reported never having had sex at recruitment [4]Among those who reported having had sex at the final round, who had not reported ever using a condom at recruitment; [5]Among those who reported having had sex at the final round; [6]Among those reporting STI symptoms within the past 12 months; [7]Young women only; [8]Among those who reported never having been pregnant at recruitment

Appendix 3. Recommendations from the first Steady, Ready, Go! (SRG) review.

Table A3.1. Threshold of evidence for the different types of school-based interventions in sub-Saharan Africa(SSA) [2]

	Attributes of the intervention							
Intervention type	**Feasible**	**Low cost**	**Low risk of adverse outcomes**	**Acceptable**	**Large potential size of effect**	**Other health or social benefits**	**Overall threshold**	**Comments**
Curriculum-based	++	++	+	+	+++	+	low	Curriculum-based programmes provide guidance,and have little potential for adverse outcomes and greater potential effect size.
Not curriculum-based	+++	++	-	+	+++	+	low	Non curriculum-based interventions may be easier to implement and require less class time or less training.
Adult-led	++	++	-	+	++	+	Low	Teachers have to be trained, but can then implement intervention at relatively little cost.
Older peer-led	+	+	+	++	++	+	Low	Older peers require considerable training, though potentially less than same-age peers. New peers will have to be trained as others get older, and resources are required to allow them to travel to schools and implement interventions. Peers themselves may learn important skills as peer educators.
Peer-led	+	+	+	+	++	++	Low	Peers require considerable training, and new peers will have to be trained as others get older. Peers themselves may learn important skills as peer educators.
With characteristics of effective interventions	+	+	++	+	+++	+	Low	Characteristics of effective interventions require focus on HIV/STIs, pregnancy, and on the behaviours affecting them. These characteristics might make the intervention more difficult to implement and less acceptable, but will increase the potential effect size.
Without characteristics of effective interventions	++	++	++	++	+	+	Low	Interventions without these characteristics may be easier to implement and more acceptable, but with a smaller potential effect size.

Degree of desirability is indicated with a maximum of 3 '+' signs. Degree of undesireability is indicated with a maximum of 3 '-' signs.

Table A3.2 Summary of evidence on effectiveness of interventions in schools, in SSA only in the first SRG review[2]

Evaluation design	Reported behaviour: Positive effect	No significant effect	Negative effect	Strength of evidence	SRG recommendation
Curriculum-based interventions					
» With Characteristics of Effective Programs					
Adult-led				**Very strong**	**Go**
RCT	7	1	-		
Quasi-experimental	4	1	-		
Peer-led				**Weak**	**Steady**
Quasi-experimental	1	-	-		
» Without Characteristics of Effective Programs					
Adult-led				**Weak**	**Steady**
Quasi-experimental	1	1	-		
Peer-led				**Weak**	**Steady**
RCT	-	1	-		
Non curriculum-based interventions					
» Without Characteristics of Effective Programs					
Adult-led				**Weak**	**Steady**
RCT	-	2	-		
Quasi-experimental	2	-	-		
Peer-led				**Equivocal**	**Steady**
Quasi-experimental	1*	-	1*		

* There was only one study of a non-curriculum-based peer-led only program. It had a statistically significant negative impact on initiation of sex and statistically significant positive effects on numbers of sexual partners, condom use and contraceptive use. Thus it is counted twice in the table, both as having a negative impact and a positive impact.

Table A3.3 Threshold of evidence for different types of health facility-based interventions in sub-Saharan Africa[3]

	Attributes of the intervention							
Intervention type	**Feasible**	**Low cost**	**Low risk of adverse outcomes**	**Acceptable**	**Large potential size of effect**	**Other health or social benefits**	**Overall threshold**	**Comments**
Type 1a (training service providers, with interventions in the community)	+++	++	++	++	+	+	Low	Likely to be easiest and most acceptable type to implement but least impact.
Type 1b (training service providers and involvement of other sectors)	+	++	+	+	+	++	Moderate	The addition of other sectors make problems of acceptability more likely. Likely to be wider debate in the community, having both positive and negative implications.
Type 1c (training service providers, with interventions in the community and involvment of other sectors)	+	+	+	+	++	++	Moderate	Involving community and other sectors is likely more difficult but may also have greater impact and other health and social benefits.
Type 2a (training service providers and actions in the clinic, with interventions in the community)	++	+	++	++	++	+	Low	Including improvement of facilities will likely increase impact without significantly impacting feasibility or decreasing acceptability
Type 2b (training service providers and actions in the clinic and involvment of other sectors)	+	+	+	++	++	++	Moderate	As per Type 1b
Type 2c (training service providers and actions in the clinic, with interventions in the community and involvment of other sectors)	+	+	+	++	+++	++	Moderate	As per Type 1c

Degree of desirability is indicated with a maximum of 3 '+' signs. Degree of undesirability is indicated with a maximum of 3 '-' signs.

Table A3.4 Summary of evidence on effectiveness of interventions in health services, in SSA only in the first SRG review[3]

Evaluation Design	Positive Effect		No Effect		Strength of evidence	SRG recommendation
	Statistically Significant	Statistical Significance Not Known	Statistically Significant	Statistical Significance Not Known		
Type 1a (training service providers with interventions the community)					**Equivocal**	**Steady (or do not go)**
Quasi-experimental (≥1 comparison group)	-	-	-	1		
Type 1b (training service providers and involvement of other sectors)					**Weak**	**Steady (or do not go)**
Quasi-experimental (≥1 comparison group)	-	-	-	1		
Type 1c (training service providers, with interventions in the community and involving other sectors)					**Equivocal**	**Steady (or do not go)**
Quasi-experimental (≥1 comparison group)	1	-				
RCT	-	-	1			
Type 2a (training service provider and actions in the clinic, with interventions in the community)					**Equivocal**	**Ready**
Qualitative Only	-	1	-	-		
Cross-sectional (no comparison group)	1	-	-	-		
Quasi-experimental (≥1 comparison group)	2	-	-	-		
Type 2b (training service providers and actions in the clinic, and involvment of other sectors) No Type 2b						
Type 2c (training service providers and actions in the clinic,with interventions in the community and involvment of other sectors)					**Weak**	**Ready**
Qualitative Only	-	3	-	-		
Before-After (no comparison group)	-	1	-	-		
Quasi-experimental (≥1 comparison group)	1	1	-	1		
RCT	1	-	-	-		

Table A3.5 Threshold of evidence for the different types of community-based interventions in sub-Saharan Africa[4]

Attributes of the intervention								
Intervention type	**Feasible**	**Low cost**	**Low risk of adverse outcomes**	**Acceptable**	**Large potential size of effect**	**Other health or social benefits**	**Overall threshold**	**Comments**
Type 1 (targeting youth and delivered using existing organisations or events)	+++	++	--	+++	++	++	Moderate	Requires an existing organisation that is accepted by community, with infrastructure to support programme; effect size depends on reach of the organisation or centre.
Type 2 (targeting youth and creating own system and structure for delivery)	+	+	-	+	+	+	High	Must create a system of delivery acceptable to community, and that penetrates target population.
Type 3 (community-wide intervention delivered through traditional networks)	++	++	-	++	+	+++	Moderate	Must address social norms associated with communicating about sexual matters within the identified networks.
Type 4 (community-wide intervention delivered through community-wide activities)	+++	+	-	++	++	++	Moderate	Community activities provide wide reach if approach is acceptable and meaningful to community; little or no attention paid to the individual.

Degree of desirability is indicated with a maximum of 3 '+' signs. Degree of undesireability is indicated with a maximum of 3 '-' signs.

Table A3.6 Summary of evidence on the effectiveness of interventions in geographically-bounded communities, in SSA only, in the first SRG review[4]

Evaluation Design	Positive Effect: Statistically Significant	Positive Effect: Statistical Significance Not Known	No significant Effect	Negative Effect: Statistically Significant	Negative Effect: Statistical Significance Not Known	Strength of evidence	SRG recommendation
Type 1 (targeting youth and delivered using existing organisations or events)						**Equivocal**	**Ready**
Anecdotal	-	1	-	-	-		
Qualitative Only	-	2	-	-	-		
Before-After (no comparison group)	2	-	-	1	-		
Quasi-experimental (≥1 comparison group)	3	-	3	-	-		
RCT (≥6 clusters)	2	-	2	-	-		
Type 2 (targeting youth and creating own system and structure for delivery)						**Weak**	**Steady (or do not go)**
Anecdotal	-	1	-	-	-		
Qualitative Only	-	3	-	-	-		
Before-After (no comparison group)	1	-	-	-	-		
Quasi-experimental (≥1 comparison group)	1	-	-	-	-		
Type 3 (community-wide intervention delivered through traditional networks)						**Weak**	**Steady**
Anecdotal	-	-	-	-	-		
Qualitative Only	-	1	-	-	-		
Quasi-experimental (≥1 comparison group)	2	-	1	-	-		
Type 4 (community-wide intervention delivered through community-wide activities)						**Weak**	**Steady**
Qualitative Only	-	1	-	-	-		

Appendix 4. Estimation of sample size

Table A4.1: Estimated number of survey participants

Population (per community)	Students in 6 school year groups
Number in school registers assuming equal numbers of students in each school year and equal numbers of males and females per school year [1]	858 males 858 females
Number who actually attended school at this time assume 84%[2]	720 males 720 females
Number in eligible age range: 17 – 25 years assume 90%[4]	648 males 648 females
Number of those eligible that we expect to detect during the census ie still living in the community assume 70%	454 males 454 females
Number of eligible individuals identified during the census that will participate in survey assume 80%	**363 males** **363 females**

[1]MkV1 trial: 17,080 were on the school registers in the 20 trial communities during the cohort recruitment survey in late 1998[1]

[2]MkV1 trial: 3,441 excluded [1]

- 2764 (16%) did not attend on survey days

- 18 (<1%) unknown date of birth

- 64 (<1%) did not enter standard 5

- 15 (<1%) actively refused to participate.

[3] MkV1 trial comparison communities: 14% temporarily absent, 4% permanently moved, 1% refused, <1% died, 8% not traced [1]

[4] Estimate 90% of males and females in the survey school year groups will be aged 17-25 years at the end of 2006 based on an extrapolation of the average age distribution of standards 4-6 observed during MkV1 Enrolment survey in 1998.

Table A4.2: Age-weighted estimate of HIV prevalence

Males					Females				
Age (yrs)	%	Prevalence of HIV (%) [a]	Incidence of HIV (/yr) [a]	% with age* prevalence	Age (yrs)	%	Prevalence of HIV (%) [a]	Incidence of HIV (/yr) [a]	% with age* prevalence
16	0.14	0		0.00	16	0.33	0.71	0.5	0.23
17	0.84	0.04	0.1	0.03	17	1.79	1.21	0.5	2.17
18	3.08	0.14	0.1	0.43	18	6.05	1.71	0.5	10.35
19	7.1	0.24	0.1	1.70	19	11.19	2.21	0.5	24.73
20	11.63	0.84	0.6	9.77	20	14.89	3.11	0.9	46.31
21	14.26	1.44	0.6	20.53	21	16.21	4.01	0.9	65.00
22	15.53	2.04	0.6	31.68	22	16.26	4.91	0.9	79.84
23	15.57	2.64	0.6	41.10	23	14.88	5.81	0.9	86.45
24	13.58	3.24	0.6	44.00	24	10.62	6.71	0.9	71.26
25	9.56	3.84	0.6	36.71	25	5.47	7.61	0.9	41.63
26	5.04				26	1.77			
27	2.4				27	0.45			
28	0.99				28	0.08			
29	0.25				29	0			
Average age-weighted HIV prevalence (%)				**1.86**	Average age-weighted HIV prevalence (%)				**4.28**

[a] HIV prevalence was estimated using the following data: HIV prevalence in 17-19 year olds in 2001/02 survey was 1.71% for females and 0.14% for males.[1] HIV incidence for 15-24 yr olds in HIV/STD trial was 0.6%/yr for males and 1.1%/yr for females.[5] HIV incidence for 15-19 yr olds during MkV initial survey was estimated as 0.2%/yr for males and 0.9%/yr for females.[6]

Table A4.3: Age-weighted estimate of HSV2 prevalence

Males					Females				
Age (yrs)	%	Prevalence of HSV2 (%) [a]	Incidence of HSV2 (%/yr)	% with age* prevalence	Age (yrs)	%	Prevalence of HSV2 (%) [a]	Incidence of HSV2 (%/yr)	% with age* prevalence
16	0.14	1.1	5.7	0.15	16	0.33	0.8	10	0.26
17	0.84	6.8	5.7	5.71	17	1.79	10.8	10	19.33
18	3.08	12.5	5.7	38.50	18	6.05	20.8	10	125.84
19	7.1	18.2	5.7	129.22	19	11.19	30.8	10	344.65
20	11.63	24.15	5.95	280.86	20	14.89	37.3	6.5	555.40
21	14.26	30.1	5.95	429.23	21	16.21	43.8	6.5	710.00
22	15.53	36.05	5.95	559.86	22	16.26	50.3	6.5	817.88
23	15.57	42	5.95	653.94	23	14.88	56.8	6.5	845.18
24	13.58	47.95	5.95	651.16	24	10.62	63.3	6.5	672.25
25	9.56				25	5.47			
26	5.04				26	1.77			
27	2.4				27	0.45			
28	0.99				28	0.08			
29	0.25				29	0			
Average age-weighted HSV2 prevalence (%)				**27.49**	Average age-weighted HSV2 prevalence (%)				**40.91**

[a] HSV2 prevalence was estimated using the following data: HSV2 prevalence in 17-19 year olds in 2001/02 survey was 20.8% for females and 12.5% for males.[1] HSV2 seroincidence over 2 years of the HIV/STD trial was 11.4%/yr for males aged 15-19 yrs and 11.9% for males aged 20-24 yrs; 20.3% for females aged 15-19 years and 13.3% for females aged 20-24 yrs.[7]

Place Stiker Here	
If Eligible:	*FS_____* Sticker_numbera
Non Eligible:	*XFS_____*

Appendix 5. MkV1FS Main Questionnaire

SECTION A: 1. Respondent's ID			(completed by REGISTRATION INTERVIEWER)
01.01	Date of interview		/ /200 q0101_day q0101_month q0101_year
01.02	Ward *(record ward code number)*	ward name: --------q0102------------------	
01.03	Village *(record village code number)*	village name: --------q0103---------------	
01.04	Registration Interviewer's staff code	q0104	
01.05	Sex of respondent *(do not ask respondent)*	*(circle one)* q0105	Male 1 Female 2
01.06	Do you have MkV1 FS Invitation letter with you?	*(circle one)* q0106	Yes 1 No, but received 2 Never received 3
01.07	Identification: name of attendee on list A? *Find name of attendee on census list (list A).*	*(circle one)* q0107	Yes 1 No 2
01.08	Census ID No. ***If invitation is produced or name on census list then enter census id number*** ***If no invitation and not on census list then enter 88 88 88 88***		⊗ ⊗ q0108a q0108b q0108c
01.09	What is your date of birth? 99/99/1999=NK If full date of birth **NOT KNOWN** then ask How old are you? **Use calendar of events to assist young person to remember his/her age in completed years**		/ /19 **If full date of birth known → 01.10** q0109a1 q0109a2 q0109a3 age in years 99= Not known q0109b

01.10	Proof of date of birth (Circle only <u>one</u> option) q0110	Birth certificate	1
		Clinic/ MCH card	2
		Baptismal cert	3
		Health survey ID card	4
		School leaving card	5
		Voters ID	6
		Other documentation	7
		No documentation	8

01.11	What was the highest standard that you <u>completed</u> in primary school? *(circle one)* q0111	Std 1-4	4 →*end interview*
	If attendee did not reach std 5 in primary school then not eligible to continue- thank and end interview.	Std 5	5
		Std 6	6
		Std 7	7
	If don't know or can't remember then continue.	Did not attend primary school	8 →*end interview*
		Don't know / don't remember	9

01.12 What primary school(s) did you attend?

Check name(s) of primary school(s) with list of primary schools in the community and enter school name and school code. ***999 = school not on list .***

Name of school: ____________________ q0112a School Code:

Name of school: ____________________ q0112b School Code:

Name of school: ____________________ q0112c School Code:

If did not attend eligible primary school then thank and end interview

01.13 Which primary school and standard were you attending in (...year...)?

Ask first about 2004 then 2003 etc

If not in primary school then enter school code=888 and standard=8.

<u>School codes</u>
enter school code from 01.12 above
(888=not in primary school)
(999=school not on list)

<u>Standard codes</u>
enter standard code
e.g. std 1 = '1'
not in school = '8'

Year	School code	Standard
2004	q0113a1	q0113a2
2003	q0113b1	q0113b2
2002	q0113c1	q0113c2
2001	q0113d1	q0113d2
2000	q0113e1	q0113e2
1999	q0113f1	q0113f2
1998	q0113g1	q0113g2

01.14	Have you previously taken part in a health survey where specimens (urine and/or blood) were collected? q0114 **If no then proceed to q01.18**	**(circle one)**	Yes No	1 2 →*01.18*
01.15	Which survey? **If did not take part in MkV1 then proceed to q01.18** q0115	**(circle one)**	MkV1 Other	1 2 →*01.18*
01.16	Ask if man/woman has MkV1 ID card. • If card seen then indicate colour of card. • If do not have MkV1 ID card then look on list of MkV1 participants to see if on list. **If 4=not on list then proceed to q01.18**	q0116	MkV1 White card MkV1 Blue card Name on MkV1 list Not on list	1 2 3 4 →*01.18*
01.17	MkV1 ID number ***(write number from ID card or MkV1 list)***	q0117a q0117b q0117c q0117d q0117e q0117f ⊗ ⊗ ⊗ ⊗ ⊗ ***This person is eligible. Please proceed to q01.19***		
01.18	Look at Q 01.13 to see what year were they in Std 7 OR what year would they have been in Std 7 if had reached Std 7. <u>Take list D.</u> Find name of attendee OR if left before std 7 must name 2 classmates who reached Std 7	q0118a Std 7 year q0118b	Std 7 list (list D) Std 7 list (list D) – classmates Neither of the above	1 → *eligible* 2 → *eligible* 3 → *NOT eligible*
01.19	ELIGIBLE?	*(circle one)*	q0119 Yes No	1 2
	PLEASE ASSESS IF ELIGIBLE PERSON IS ABLE TO GIVE INFORMED CONSENT AND IF SO ASK THEM TO SIGN CONSENT FORM			
01.20	Has the participant signed the consent form? **If refuse or not able to give informed consent then not eligible to continue. Thank and end interview.**	*(circle one)*	q0120 Yes No- refused Not able to give informed consent	1 2 3
01.21	If the laboratory tests in Mwanza show that you have a sexually transmitted infection (Syphlis, CT, NG) would you like us to return to treat you?	*(circle one)*	q0121 Yes No	1 2

Sticker_numberb

Place Sticker here

FS_ _ _ _ _ _

SECTION B: 2. Demographic Information			(completed by MAIN INTERVIEWER)
02.01	Main Interviewer's staff code	q0201	
02.02	I am going to ask you some questions. This will take about half an hour. I can ask the questions in either Swahili or Sukuma, depending on which language you would prefer. Would you like me to ask the questions in Swahili or Sukuma? ***Say "Remember that I can also use the other language at any point if you think you will understand better. Just tell me."***	q0202 *(circle one)*	Swahili 1 Sukuma 2
02.03	What is your tribe?	*(circle only one)* q0203	Sukuma 1 Jita 2 Zinza 3 Kara 4 Kerewe 5 Sumbwa 6 Rongo 7 Other 8
02.04	What is your religion?	*(circle only one)* q0204	Catholic 1 Other Christian 2 Moslem 3 Other religion (including traditional) 4 No religion 5
02.05	What is the highest education level you have attained?	*(circle only one)* q0205	Did not complete primary school 1 Completed primary school 2 Incomplete secondary 3 Secondary school 4 Advanced Secondary school 5 Vocational training 6 College (e.g. Teachers' Training College, Police college, etc) 7 University 8 Other studies (Islamic College: theological college) 9

02.06	What are the main kinds of work/activities (shughuli or kazi) you do or have done over the last 12 months? *Do Not prompt the respondent, but after each answer ask him/her to mention as many as possible* *(TICK ALL THAT APPLY)*	
	Mine employee professional (*engineer, accountant, geologist, surveyor etc*)	q0206a
	Mine employee non professional (labourer, workman, watchman, driver etc)	q0206b
	Professional (*eg teacher/nurse/accountant/police*)	q0206c
	Other manual (*eg carpenter / tailor*)	q0206d
	Business (e.g. duka owner, garage owner, Bar & Guest owner, commercial farming)	q0206e
	Petty Trade (e.g. produce at market, or sell peanuts in evening, food vendor, alcohol brewer)	q0206f
	Bar worker / guest house worker / hotel worker	q0206g
	Truck Driver	q0206h
	Turn boy	q0206i
	Fisherman	q0206j
	Farmer	q0206k
	Housewife	q0206l
	House girl / domestic worker	q0206m
	At School/university	q0206n
	None	q0206o
	Other	q0206p
	Other (specify: ____________ q0206q [string] ______________________________)	
02.07	In the past 4 <u>weeks</u>, have you slept away from your ward? q0207 If yes, → for how many night(s) If no, put "00" **If yes, circle 1 to Q02.08 and ask how many times did you sleep at least 1 night away in the past 12 months?**	
02.08	In the past <u>12 months</u>, have you sept away from your ward? q0208a *(circle one)* Yes 1 / No 2 / don't know 9 *If NO or don't know→skip to section 3*	
	If YES: How many times did you sleep at least 1 night away?	q0208b
	If YES: What was the total length of time you slept away in the past 12 months?	q0208c N N N
	Enter as respondent chooses to answer: Indicate unit (D,W,M) in the last box e.g. '003M' = 3 months; '060D' = 60 days; '012W' = 12 weeks; '999X' = NK	q0208d unit U

SECTION C: 3. SEXUAL and REPRODUCTIVE HEALTH KNOWLEDGE AND ATTITUDES				
**** *Interviewer: Read the explanatory sheet now* ****			(completed by MAIN INTERVIEWER)	
I'm now going to ask you some questions about reproductive health knowledge, diseases and making love. Always when I mention the word making love I am talking about having penetrative sex with somebody. This will include sexual intercourse where one of the two has not agreed (one part forced). We know that some young people like you are already having sex and some are not. We are only interested in hearing the truth about young peoples' sexual experience even if you have not ever had sex yet. This discussion is very confidential between you and me, so I hope that you will be free to tell me about your life sexual experience.				
03.01	Can pus or abnormal fluids coming out of the private parts be caught by making love with someone?	q0301	(Circle one)	Yes 1 No 2 NK 9
03.02	Can schistosomiasis be caught by making love with someone?	q0302	(Circle one)	Yes 1 No 2 NK 9
03.03	Can an ulcer on the private parts be caught by making love with someone?	q0303	(Circle one)	Yes 1 No 2 NK 9
03.04	Can HIV be caught by making love with someone?	q0304	(Circle one)	Yes 1 No 2 NK 9
03.05	Can you catch HIV by sharing a plate of food with an HIV positive person?	q0305	(Circle one)	Yes 1 No 2 NK 9
3.06	Can a person who looks strong and healthy have HIV?	q0306	(Circle one)	Yes 1 No 2 NK 9
03.07	If a man wants to make love with a woman, can she refuse to make love with him if he is older than her?	q0307	(Circle one)	Yes 1 No 2 NK 9
03.08	If a man wants to make love with a woman, can she refuse to make love with him if he is her lover?	q0308	(Circle one)	Yes 1 No 2 NK 9
03.09	If a young woman accepts a gift from a man, must she agree to make love with him?	q0309	(Circle one)	Yes 1 No 2 NK 9
I'm now going to ask you some questions about pregnancy				
03.10	Is it possible for a girl to become pregnant the first time she makes love?		q0310 (Circle one)	Yes 1 No 2 NK 9

03.11	Is it possible for a person to prevent pregnancy by not making love at all?	q0311 (Circle one)	Yes 1 No 2 NK 9
03.12	Is it possible for a person to prevent pregnancy by using a condom while making love?	q0312 (Circle one)	Yes 1 No 2 NK 9
I'm now *going* to ask you questions about condoms			
03.13	Do you know what a condom is? **If answer is No → skip to q04.01**	q0313 (Circle one)	Yes 1 No 2 →section 4
03.14	Has anyone ever shown you how to use a condom?	q0314 (Circle one)	Yes 1 No 2 NK 9
03.15	Do some male condoms have HIV in them before they are used?	q0315 (Circle one)	Yes 1 No 2 NK 9
03.16	Does using a male condom when making love prevent the man/woman being infected with HIV?	q0316 (Circle one)	Yes 1 No 2 NK 9
03.17	Where could you get condoms in your village if you needed them? **Do NOT prompt the respondent, but after each answer ask, "Thank you. Anywhere else?"** **(TICK ALL THAT ARE MENTIONED)**	Store / kiosk / pharmacy Health facility Non-governmental organisation representative Other private person Other (specify): ______ Don't know	q0317a q0317b q0317c q0317d q0317e q0317f
03.18	Where could you get condoms <u>for free</u> in your village if you needed them? **Do NOT prompt the respondent, but after each answer ask, "Thank you. Anywhere else?"** **(TICK ALL THAT ARE MENTIONED)**	Store / kiosk / pharmacy Health facility Non-governmental organisation representative Other private person Other (specify): ______ q0318f (string) ______ Don't know	q0318a q0318b q0318c q0318d q0318e q0318g

4. SEXUAL BEHAVIOUR

(completed by MAIN INTERVIEWER)

I'm now going to ask you some questions about making love. Always when I mention the word making love I am talking about having penetrative sex with somebody. This will include sexual intercourse where one of the two has not agreed (one part forced). We know that some young people like you are already having sex and some are not. It is not important whether you have or have not had sex, as we are only interested in hearing the truth about young peoples' sexual experience. This discussion is very confidential between you and me, so I hope that you will be free to tell me about your life sexual experience. Some of these questions are about long periods of months and years. It may be difficult to quickly recall experiences over such a long period of time. What is most important is that you answer such questions as fully and accurately as possible. So please, take as much time as you need to think about them when answering.

04.01	Have you ever made love? *(Circle one)* q0401 **If "No", Check by asking: "Have I understood you correctly, that you have never made love throughout your whole life?" If still says that (s)he has never made love: Circle 2 = No**	Yes 1 No 2

If still says that (s)he has never made love, skip to section 8

04.02	Have you ever used a male condom? q0402	Yes 1 No 2 NK 9
04.03	I now want you to think of the first time you made love with someone. How old were you when you first made love with someone? **(Please try to help respondent to remember the actual age at first sex, e.g which std were you in primary school etc.)** ***Enter age at first sex*** years q0403a ***If exact age not known estimate (tick)*** 12yrs or less 44 13-14yrs 55 15-17yrs 66 18yrs or more 77 NK 99 q0403b	
04.04	I now want you to think of the first person that you made love with. Was that person older, younger, or the same age as you? q0404 ***If 'same age' or 'not known' then skip to q04.06***	Older 1 Younger 2 Same age 3 →q 04.06 Not known 9 →q 04.06
04.05	How many years older/younger? ***If not known estimate (tick)*** 1yr or less 44 2-4yrs 55 5-9yrs 66 10-14yrs 77 15yrs or more 88 NK 99 q0405a	***Enter Years*** q0405
04.06	I now want you to think of all the people you have made love with in the past four weeks. How many people have you made love with in the past four weeks? q0406	**Enter number (two digits)**
04.07	I would now like you to think about where you were a year ago at this time. That would be xx month (mention the current month) last year till today, and / or xx season eg.raining season, harvesting season etc last year till today. Do you remember? Can you now recall how many people you made love with since that time? Again please take your time as you think about this. **NB Check that this number include partners in the last 4 weeks.**	**Enter number (two digits)** *unknown = 99* q0407

04.08	How many of these partners were new to you? (ie made love for the first time in the last 12 months)	q0408	**Enter number (two digits)** *not applicable = 88* *unknown = 99*

If says that (s)he has not made love in past 12 months, skip to section 6

5. SEXUAL PARTNERS IN LAST 12 MONTHS

(completed by MAIN INTERVIEWER)

****** *Fill in one column for each partner, starting with the most recent* ******

			Most recent	2nd most recent	3rd most recent
05.01	Think about the last / second last / third last person that you made love with in the past twelve months. These do not need to be new partners. Do you have them in mind? ***NO:*** ***Try to make him / her recall by specifying the period e.g. since last Christmas*** Do you have them in mind? ***YES - continue*** Was this your wife/husband, another regular partner, a casual partner, or a CSW?		q0501a	q0501b	q0501c
		Spouse	1	1	1
	(circle one for each partner)	Other regular partner	2	2	2
		Casual partner	3	3	3
		Commercial Sex Worker	4	4	4
05.02	Do you live with this person? ***(circle one for each partner)***	Yes	1 q0502a	1 q0502b	1 q0502c
		No	2	2	2
05.03	Is this person older, younger or the same age as you?	Older	1 q0503a	1 q0503b	1 q0503c
	(circle one for each partner)	Younger	2	2	2
		Same age→Q05.05	3	3	3
		Don't know→Q05.05	9	9	9
05.04	How many years older/younger? **enter exact years, if not known enter 99**		q0504a NN	q0504b NN	q0504c NN
05.05	Did this person go to primary school in this ward?	Yes	1	1	1
		No	2 q0505a	2 q0505b	2 q0505c
		Don't know	9	9	9
05.06	What was the highest standard that this person reached in primary school? ***(circle one for each partner)***		q0506a	q0506b	q0506c
		Std 1-4	4	4	4
		Std 5	5	5	5
		Std 6	6	6	6
		Std 7	7	7	7
		Did not attend primary school	8	8	8
		Don't know / don't remember	9	9	9

		Partner a	Partner b	Partner c
05.07	What are the main kinds of work/activities (shughuli or kazi) this partner does / has done over the last 12 months? *Do Not prompt the respondent, but after each answer ask him/her to mention as many as possible* ***(for each partner tick ALL that apply)***			
	Mine employee professional (*engineer, accountant, geologist, surveyor etc*)	q0507a01	q0507b01	q0507c01
	Mine employee non professional (labourer, workman, watchman, driver etc)	q0507a02	q0507b02	q0507c02
	Professional (eg teacher / nurse / accountant / police)	q0507a03	q0507b03	q0507c03
	Other manual (eg carpenter / tailor)	q0507a04	q0507b04	q0507c04
	Business (e.g. duka owner, garage owner, Bar & Guest owner, commercial farming)	q0507a05	q0507b05	q0507c05
	Petty Trade (e.g. produce at market, sell peanuts in evening, food vendor, alcohol brewer)	q0507a06	q0507b06	q0507c06
	Bar worker / guest house worker / hotel worker	q0507a07	q0507b07	q0507c07
	Truck driver	q0507a08	q0507b08	q0507c08
	Turn boy	q0507a09	q0507b09	q0507c09
	Fisherman	q0507a10	q0507b10	q0507c10
	Farmer	q0507a11	q0507b11	q0507c11
	Housewife	q0507a12	q0507b12	q0507c12
	House girl/domestic worker	q0507a13	q0507b13	q0507c13
	At School/ University	q0507a14	q0507b14	q0507c14
	None	q0507a15	q0507b15	q0507c15
	Don't know	q0507a16	q0507b16	q0507c16
	Other (specify): partner 1: ____________________ partner 2: ____________________ partner 3: ____________________	q0507a17	q0507b17	q0507c17
05.08	How long ago was the <u>first time</u> you made love with this person? **Enter as respondent chooses to answer: Indicate unit (D,W,M, Y) in the last box** **e.g. '002Y' = 2 years ago; '003M' = 3 months ago; '999X' = DK**	q0508a1 N N N unit q0508a2	q0508b1 N N N unit q0508b2	q0508c1 N N N unit q0508c2
05.09	How long ago was the <u>last time</u> you made love with this person? **Enter as respondent chooses to answer: Indicate unit (D,W,M) in the last box** **e.g.'003M' = 3 months ago; '999X' = NK**	q0509a1 N N N unit q0509a2	q0509b1 N N N unit q0509b2	q0509c1 N N N unit q0509c2
05.10	How many times did you make love with this person in the last four weeks? (Enter number- two digit) OR 99=NK	NN q0510a	NN q0510b	NN q0510c
05.11	What is your current sexual relationship status with this person?	q0511a	q0511b	q0511c
	We are still in a relationship and will make love again	1	1	1
	Our relationship is not continuing but we might make love again	2	2	2
	Our relationship has completely ended	3	3	3
	Don't know	9	9	9

05.12	Did you use any family planning method to prevent pregnancy the <u>last time</u> you made love with this partner? *(Circle one)*		q0511a0	q0511b0	q0511c0
		Yes	1	1	1
		No	2	2	2
	If YES: What did you use to prevent pregnancy? *(tick ALL that apply)*				
		Condom	q0512a1	q0512b1	q0512c1
		Oral contraceptive pills	q0512a2	q0512b2	q0512c2
		Injectable contraceptives	q0512a3	q0512b3	q0512c3
		Rhythm method	q0512a4	q0512b4	q0512c4
		Traditional medicines	q0512a5	q0512b5	q0512c5
		Withdrawal method	q0512a6	q0512b6	q0512c6
		Douching after sex	q0512a7	q0512b7	q0512c7
		Don't know	q0512a8	q0512b8	q0512c8
	Other (specify): partner 1: ____________ partner 2: ____________ partner 3: ____________		q0512a9	q0512b9	q0512c9
05.13	Did you use a condom <u>the last time</u> you made love with this person? *If yes* Did you use the condom throughout making love this last time? ***Using a condom throughout making love means <u>start AND end</u> making love using condom.***		q0513a	q0513b	q0513c
	(circle one for each partner)	Yes, throughout making love→q05.15	1	1	1
		Yes, but not throughout→q05.14	2	2	2
		No→q05.14	3	3	3
	If answer in 05.13 is NO, DID NOT USE A CONDOM or YES, BUT NOT THROUGHTOUT ask q05.14 below. Otherwise skip to q05.15.				
05.14	Why didn't you and your partner use a condom that time? or Why didn't you and your partner use a condom throughout making love that time?	*(tick ALL that apply)*			
		Not available/ Don't know where to get them	q0514a01	q0514b01	q0514c01
		Too expensive	q0514a02	q0514b02	q0514c02
	Do NOT prompt the respondent, but after each answer ask, "Thank you. Anything else?"	Partner objected	q0514a03	q0514b03	q0514c03
		Don't like them	q0514a04	q0514b04	q0514c04
		Don't know how to use them	q0514a05	q0514b05	q0514c05
		Morally wrong / against religion	q0514a06	q0514b06	q0514c06
		Used other contraceptive	q0514a07	q0514b07	q0514c07
		Don't have many partners	q0514a08	q0514b08	q0514c08
		Trust partner	q0514a09	q0514b09	q0514c09
		Didn't think of it / forgot	q0514a10	q0514b10	q0514c10
		Did not want to prevent pregnancy	q0514a11	q0514b11	q0514c11
		Condom broke	q0514a12	q0514b12	q0514c12
		Don't know	q0514a13	q0514b13	q0514c13
	Other (specify): partner 1: ____________ partner 2: ____________		q0514a14	q0514b14	q0514c14

	partner 3: ______			
05.15	Has there been an occasion when you did not want to make love with this partner?	q0515a0	q0515b0	q0515c0
	Yes	1	1	1
	No	2	2	2
	Don't remember	9	9	9
	If YES: What did you do the <u>last time</u> that this happened?	q0515a1	q0515b1	q0515c1
	Refused and did not have sex	1	1	1
	Refused but still had sex	2	2	2
	Did not refuse	3	3	3
	Don't remember	9	9	9

6. CONTRACEPTION

(completed by MAIN INTERVIEWER)

06.01 Throughout your whole life up to now, how many different men / women have you made love with? (Including current partners, past partners, spouse and all other kinds of partner) Again please take as much time as you need to remember this accurately.

If participant cannot remember the exact number please ask them to give an approximate number

q0601 — Enter number (two digits)

06.02 – 06.04 FEMALES ONLY (skip to q06.05 for MALES)

06.02 < Females > How many times have you been pregnant?

q0602 — Enter number (two digits)
not known = 99

06.03 <Females> In what year in school did you first get pregnant?

q0603

Not in school / left school	2
Std 3	3
Std 4	4
Std 5	5
Std 6	6
Std 7	7
Not applicable	8
Don't know / don't remember	9

06.04 < Females > Sometimes a girl or young woman becomes pregnant when she does not plan to (not a good time to become pregnant).

Have you ever become pregnant when you did not plan to (when it was not a good time)?

q0604

Yes	1
No	2
NK	9

06.05 – 06.07 MALES ONLY (skip to q06.08 for FEMALES)

06.05 < Males > How many times have you made girls pregnant?

If the answer is NO, enter 00 then→go to 06.08

q0605 — Enter number (two digits)
not known = 99

06.06 <Males> In what year in school did you first make a girl pregnant?

q0606

Not in school / left school	2
Std 3	3
Std 4	4
Std 5	5
Std 6	6
Std 7	7
Not applicable	8
Don't know / don't remember	9

06.07 < Males > Sometimes a girl or young woman becomes pregnant when she does not plan to (not a good time to become pregnant).

Have you ever got a girl pregnant when you did not plan to (when it was not a good time)?

q0607

Yes	1
No	2
NK	9

06.08	Did you <u>ever</u> use any contraceptive methods to prevent pregnancy while you were making love?	q0608	Yes	1
			No	2→q 07.01
			NK	9→q 07.01
	If YES: Which contraceptive methods did you <u>ever</u> use to prevent pregnancy	q0608a1	Condom	
	Do not prompt the respondent, but after each answer ask "Thank you. Anything else?"	q0608b1	Oral contraceptive pills	
		q0608c1	Injectable contraceptives	
	(TICK ALL THAT ARE MENTIONED)	q0608d1	Rhythm method	
		q0608e1	Traditional medicines	
		q0608f1	Withdrawal method	
		q0608g1	Douching after sex	
		q0608h1	Other (specify): ________________	

7. MARRIAGE			(completed by MAIN INTERVIEWER)
I'm now going to ask you some questions about marriage experience "marital status". Always when I mention the word marriage I am talking about living with somebody as wife/husband. This will include unofficial marriage (in Swahili "Kimada/ Nyumba ndogo") or living with somebody as wife/husband without any initiation ceremony. We know that some young people like you have been married once, others have been married more than once and some have never been married. We are only interested in hearing the truth about young peoples' marriage experiences. This discussion is very confidential between you and me, so I hope that you will be free to tell me about your life marriage experience.			
07.01	In total, how many times have you been married OR lived with man / woman as married? **Enter '00' if never married or lived as married and skip to question 07.08**		**Enter number (two digits)** *not known = 99* q0701
07.02	How old were you when you first married OR lived with a man / woman as married? ***Enter age at first marriage*** years q0702 ***If exact age not known estimate (tick)*** 12yrs or less 44 13-14 55 15-17yrs 66 18yrs or more 77 NK 88 q0702a		
07.03	<Males> Are you currently married or living with woman as married?	*(Circle one)* q0703	Yes 1 No 2 → q07.08
07.04	<Females> Are you currently married or living with man as married?	*(Circle one)* q0704	Yes 1 No 2 → q07.08
07.05	<Males> How many wives currently do you stay/live with?	q0705	**Enter number (two digits)** *not known = 99*
07.06	<Females> How many wives, including you, does your husband have now?	q0706	**Enter number (two digits)** *not known = 99*
07.07	Do you live with (any of) your spouse(s)?	*(Circle one)* q0707	Yes 1 → q08.01 No 2
07.08	Do you live with a lover(s)?	*(Circle one)* q0708	Yes 1 No 2

8. EXPERIENCE OF SEXUALLY TRANSMITTED DISEASES

(completed by MAIN INTERVIEWER)

08.01	Have you ever had pus or abnormal fluids coming out of your private parts (vagina/penis) in the past 12 months? q0801	*(Circle one)*	Yes 1 No 2 Don't know 9
08.02	Have you had ulcers or blisters on your private parts in the past 12 months? q0802	*(Circle one)*	Yes 1 No 2 Don't know 9

If both 08.01 and 08.02 are answered No or Don't know, skip to question 08.06

08.03 Did you do any of the following the last time (i.e. the most recent time) you had a genital ulcer/blister or pus/abnormal fluids coming out of your private parts?

READ ANSWER OPTIONS ALOUD, then tick all that apply .

q0803a	Self- treatment (traditional medicine at home)	
q0803b	Self- treatment (western / modern medicine at home)	
q0803c	Sought advice / medicine from a government hospital or health facility	→q08.05
q0803d	Sought advice / medicine from a private hospital or health facility	→q08.05
q0803e	Sought advice / medicine from a traditional healer	
q0803f	None of the above	

08.04 What are the reasons, why you did not go to a hospital/health facility?

Do not prompt the respondent, but after each answer ask "Thank you. Anything else?"

(TICK ALL THAT ARE MENTIONED)

q0804a	Unfamiliarity with services	→08.06
q0804b	Too far	→ 08.06
q0804c	High cost	→ 08.06
q0804d	Poor treatment	→ 08.06
q0804e	Lack of confidentiality	→ 08.06
q0804f	Unfriendly staff	→ 08.06
q0804g	Embarrassment/Shyness	→ 08.06
q0804h	Other (specify): ___q0804i (string) __	→ 08.06

8.05	How long after first experiencing symptoms did you go to a hospital [health facility]? *(Circle one)* q0805	Immediately (1 to 2 days)	1
		3 to 6 days	2
		One week and above	3
		Not applicable	8
		Don't know	9

8.06	Have you had a blood transfusion in the last 5 years?	*(Circle one)* q0806	Yes No Don't know	1 2 9
8.07	How many injections have you had in the last 12 months?	q0807	Enter number (two digits) *not known = 99*	
8.08	We are aware that some men / women in this area are circumcised. Are you circumcised? ***If answer is 2 or 9 skip to section 9***	*(Circle one)* q0808	Yes No Don't know	1 2 → q09.01 9 → q09.01
8.09	If yes, how old were you when this was done?	q0809	years Enter age (two digits) *not known = 99*	
9. SCHOOL LESSONS & MEMA KWA VIJANA INTERVENTION			(completed by MAIN INTERVIEWER)	
I'm now going to ask you questions about health and some diseases				
09.01	Did you ever attend a MkV session when you were in primary school?	*(Circle one)* q0901	Yes No Don't know	1 2 9
09.02	Did you go with your primary school class to visit a hospital/health facility/ dispensary?	*(Circle one)* q0902	Yes No Don't know	1 2 9
09.03	Did a health care worker ever visit your class in primary school?	*(Circle one)* q0903	Yes No Don't know	1 2 9
09.04	Did any of your primary teachers ever talk to your class about resisting pressure to make love?	*(Circle one)* q0904	Yes No Don't know	1 2 9
09.05	Did any of your primary teachers ever talk to your class about using condoms to avoid HIV?	*(Circle one)* q0905	Yes No Don't know	1 2 9
09.06	Were you a MEMA kwa Vijana CPE (Class Peer Educator)?	*(Circle one)* q0906	Yes No Don't know	1 2 9

All respondents should be directed to the Laboratory

MEMA kwa Vijana Trial Further Survey (2007-2008)

10. LAB SPECIMENS			(completed by LAB WORKERS)
10.01	Lab workers' staff codes	q1001a, q1001b	
10.02	When did you last urinate?	(Swahili time)	. Morning Afternoon Evening q1002a : q1002b (circle one) q1002c
10.03	Time urine container given to respondent Leave as is for now, to review after pilot study	(Swahili time)	. Morning Afternoon Evening q1003a : q1003b (circle one) q1003c
10.04	Number of serum aliquots taken If <3, specify reason:		q1004 __________
10.05	Number of urine aliquots taken *[take 2 samples]*	q1005	If 2 samples taken → q. 10.07
10.06	Why were < 2 urine aliquots taken?	q1006 *(Circle one)* Other (specify): ______	No urine 1 Insufficient urine 2 Refused 3 4
10.07	RBC result	*(Circle one)* q1007	negative 0 + 1 ++ 2 +++ 3 ++++ 4

MEMA kwa Vijana Trial Further Survey (2007-2008)

11. CLINICAL (completed by CLINICIANS) Sticker_numberc

Place Stiker Here	
If Eligible:	*FS_ _ _ _ _ _ _*
If not Eligible:	*XFS_ _ _ _ _ _*

		SYMPTOMS	EXAM
11.01	Clinician's staff code	q1101	
	< Males > skip to q 11.04		
11.02	< Females > Are you pregnant?	*(Circle one)* q1102	Yes 1 No 2 don't know 9
	< Females > Only examine genitals if report symptoms of ulcers (GUS) < Males > Examine genitals of all males.		
		SYMPTOMS	**EXAM**
11.03	Do you have either pus or an abnormal discharge coming from your private parts (vagina or penis) at the moment (GDS)?	q1103a Yes 1 No 2 NK 9	q1103b Yes, seen 1 No, not seen 2 Refused exam 7 Not examined 8
11.04	*Type of discharge (Women only)*	Curdlike 1 Non-curdlike 2 Not applicable 8	q1104
11.05	Do you have an ulcer or sore or blister on your private parts at the moment (GUS)?	Yes 1 No 2 NK 9 q1105a	Yes, seen 1 No, not seen 2 Refused exam 7 Not examined 8 q1105b
11.06	Do you have any genital itching at the moment?	Yes 1 No 2 NK 9	q1106
11.07	Do you have any pain during micturation/urination?	Yes 1 No 2 NK 9	q1107
11.08	< Males > skip to question 11.09 < Females > Do you have any lower abdominal / pelvic pain at the moment or pain in your abdomen when you have sex?	Yes 1 No 2 NK 9	q1108

11.09	Do you have any genital warts at the moment?	Yes 1 No 2 NK 9 q1109a	Yes, seen 1 No, not seen 2 Refused exam 7 Not examined 8 q1109b
11.10	Do you have any lumps in the groin at the moment?	Yes 1 No 2 NK 9 q1110a	Yes, seen 1 No, not seen 2 Refused exam 7 Not examined 8 q1110b
11.11	< Females > skip to question 11.12 < Males > Examine for circumcision	q1111	Circumcised 1 Not circumcised 2 Refused exam 7 Not examined 8

11.12 DIAGNOSES

	diagnosed	treated	referred	refused
None	q1112a			
GUS (men or women)	q1112b1	q1112b2	q1112b3	q1112b4
Genital blisters or vescicles	q1112c1	q1112c2	q1112c3	q1112c4
VDS without curd-like discharge (women only)	q1112d1	q1112d2	q1112d3	q1112d4
VDS with curd-like discharge (women only)	q1112e1	q1112e2	q1112e3	q1112e4

		PID (women only)	q1112f1	q1112f2	q1112f3	q1112f4
	Tick all that apply	Urethral discharge (men only)	q1112g1	q1112g2	q1112g3	q1112g4
		Epididymo-orchitis (men only)	q1112h1	q1112h2	q1112h3	q1112h4
		Bubo	q1112i1	q1112i2	q1112i3	q1112i4
		Pubic lice	q1112j1	q1112j2	q1112j3	q1112j4
		Scabies	q1112k1	q1112k2	q1112k3	q1112k4
		Warts	q1112l1	q1112l2	q1112l3	q1112l4
		Signs of secondary syphilis	q1112m1	q1112m2	q1112m3	q1112m4
		Symptoms of malaria	q1112n1	q1112n2	q1112n3	q1112n4
		Schistosomiasis	q1112o1	q1112o2	q1112o3	q1112o4
		Cough	q1112p1	q1112p2	q1112p3	q1112p4
		Headache	q1112q1	q1112q2	q1112q3	q1112q4
		Other (specify): ________________	q1112r1	q1112r2	q1112r3	q1112r4
		________ q1112s (string)________________				

	<MALE> If participant needs treatment then complete Q11.16, if no treatment needed then end interview <FEMALE> If needs treatment for GUS, VDS, PID, Bubo or Schistosomiasis then please ask Q.11.13 If treatment not needed for these conditions then you may proceed to Q11.16 and provide other treatment.
11.13	Is this participant visibly pregnant? q1113 Yes 1 → q11.16 No 2 → q11.14
11.14	When was your last menstrual period? (99 / 99 / 2009 if unknown) IF MORE THAN 1 MONTH SINCE LMP THEN TEST FOR PREGNANCY / /200 q1114a q1114b q1114c
11.15	Result of Pregnancy Test (Circle one only)
	q1115 Positive 1 Negative 2 Refused 3 Not Done / Not applicable 8

11.16	TREATMENT GIVEN		tick if given
GUS			
GUS 1st line treatment	Benz. Penicillin 2.4 MU, im stat ½ in each buttock		q1116a1a
	Cotrimoxazole 400/80 mg, 5 tabs bid for 3 days		q1116a1b
GUS 1st line treatment if allergic to penicillin	Erythromycin 500mg qds for 7 days		q1116a2a
	Cotrimoxazole 400/80 mg, 5 tabs bid for 3 days		q1116a2b
GUS 1st line treatment if pregnant	Benz. Penicillin 2.4 MU, im stat ½ in each buttock		q1116a3a
	Erythromycin 500mg qds for <u>15</u> days		q1116a3b
GUS 2nd line treatment	Ceftriaxone 250 mg im, stat		q1116a4
VDS			
VDS (No curdlike discharge) 1st line treatment	Ciprofloxacin 500 mg, stat		q1116b1a
	Doxycycline 100 mg, bid for 7 days		q1116b1b
	Metronidazole 2 g, stat *warn about alcohol*		q1116b1c
VDS (no curdlike discharge) 1st line if in 1st trimester of pregnancy	Erythromycin 500mg qds for 7 days		q1116b2a
	<u>OR</u> Ceftriaxone 250 mg im, stat		q1116b2b
VDS (no curdlike discharge) 1st line if in 2nd or 3rd trimester of pregnancy	Erythromycin 500mg qds for 7 days		q1116b3a
	<u>OR</u> Ceftriaxone 250 mg im, stat		q1116b3b
	<u>AND</u> Metronidazole 2 g, stat (i.e. give with either erythomycin or cetriaxone) *warn about alcohol*		q1116b3c
VDS 2nd line treatment	Clotrimazole pessaries 100 mg, OD, PV		q1116b4a
	Ceftriaxone 250 mg im, stat		q1116b4b
	Doxycycline 100 mg, bid for 7 days		q1116b4c
	Metronidazole 2 g, stat *warn about alcohol*		q1116b4d
VDS 1st line if complains of curdlike discharge (<u>add</u> to standard 1st line treatment for VDS)	With vulval itching	Clotrimazole pessaries 100 mg, OD, PV	q1116b5a1
		Clotrimazole cream, 1 tube	q1116b5a2
	No vulval itching	Clotrimazole pessaries 100 mg, OD, PV	q1116b5b

PID		
PID 1st line treatment	Ciprofloxacin 500 mg, stat	q1116c1a
	Doxycycline 100 mg, bid for 14 days	q1116c1b
	Metronidazole 400mg bid, for 14 days *warn about alcohol*	q1116c1c
PID 1st line treatment if lactating mother or pregnant	Erythromycin 500mg qds for 7 days	q1116c2a
	OR Ceftriaxone 250 mg im, stat	q1116c2b
	AND Metronidazole 400mg bid, for 14 days *if not in 1st trimester of pregnancy warn about alcohol*	q1116c2c
PID 2nd line treatment	Ceftriaxone 250 mg im, stat	q1116c3
URETHRAL DISCHARGE		
Urethral discharge 1st line treatment	Ciprofloxacin 500 mg, stat	q1116d1a
	Doxycycline 100 mg, bid for 7 days	q1116d1b
Urethral discharge 2nd line treatment	Doxycycline 100 mg, bid for 7 days	q1116d2a
	Ceftriaxone 250 mg im, stat	q1116d2b
	Metronidazole 2 g, stat *warn about alcohol*	q1116d2c
EPIDIDYMO-ORCHITIS		
Painful scrotal swelling (epididymo-orchitis)	Ciprofloxacin 500 mg, stat	q1116e1
	Doxycycline 100 mg, bid for 7 days.	q1116e2
BUBO		
Bubo 1st line treatment	Doxycycline 100 mg, bid for 14 days	q1116f1
Bubo 1st line treatment if pregnant	Erythromycin 500mg qds for 14 days	q1116f2
PUBIC LICE		
Pubic lice treatment	Lindane 1% lotion or cream. Apply and wash off after 8hrs	q1116g1
	OR Lindane shampoo. Apply and wash off after 4 minutes	q1116g2
BLISTERS/VESICLES		
Blisters/vesicles	Gentian Violet paint	q1116h
SCABIES		
Scabies treatment	Benzyl Benzoate 25% lotion nightly for 2 nights	q1116i
SKIN CONDITIONS		
Skin conditions	Whitfield's ointment	q1116j

PAIN RELIEF		
Analgesia	Paracetamol 500mg (no more than 6 tablets per day for 2 days) *write number of tablets given*	q1116k
SCHISTOSOMIASIS		
Schistosomiasis	Praziquantel *tick here if given* Weight in kilograms State number of tablets given	q1116l1 NNN kg q1116l2 N q1116l3
COUGH		
Cough	Erythromycin 500mg, tid, 5 days	q1116m1
	Cotrimoxazole 960mg, bid, 5 days	q1116m2
MALARIA		
Malaria	ALU 4 st, 4 after 8 hrs, 4 bid for 2 days	q1116n
OTHER MEDICATIONS		
Indication ________________	Other (specify name of drug, number of tablets and dose) ________________	q1116o1a q1116o1b (string)
Indication ________________	Other (specify name of drug, number of tablets and dose) ________________	q1116o2a q1116o2b (string)

12. VOLUNTARY HIV TESTING				(completed by COUNSELLOR)
All participants should be given the following information about the voluntary HIV testing service. As the interviewer told you earlier, all the information and the results of the tests on the urine, and blood you have given us will be kept secret. However, if you would like to know whether you are infected with HIV, there is a separate procedure to be followed. If you are interested, I can tell you about this procedure. If, after that, you want to continue, we can do a test now and I can tell you the results of your HIV test. I will also give you further advice. Nobody except you, me and the project's senior staff in Mwanza will know the results **Washiriki wote wapewe taarifa hii ya huduma ya kupima virusi vya UKIMWI kwa HIARI** Kama msaili alivyokueleza hapo awali, taarifa zote na majibu ya vipimo vya mkojo na damu tulivyochukua vitakuwa vya siri kabisa. Hata hivyo, kama unataka kujua kama umeathirika na virusi vya UKIMWI, kuna utaratibu tofauti wa kufuata, kama utapenda ninaweza kukuelezea utaratibu wa kufuata, na kama baada ya hapo utapenda kuendelea nitafanya kipimo na kukupatia majibu yako sasa hivi, na nitakupatia ushauri zaidi. Hakuna mtu zaidi yako wewe, mimi na mkuu wa mradi huko Mwanza atakayejua majibu ya kipimo chako.				
12.01	Counsellor's staff code	q1201		
12.02	Do you want to be told your HIV test result? ***If Yes, give the pre-test counselling.***	q1202 *(Circle one)*	Yes 1 No 2	 → end
12.03	Are you satisfied with this pre-test counselling? ***If NO, then do not proceed with test but carry out full pre-test counselling***	q1203 *(Circle one)*	Yes 1 No 2	→ 12.05 → 12.04
12.04	Are you <u>now</u> satisfied with this pre-test counselling?	q1204 *(Circle one)*	Yes 1 No 2	 → end
12.05	Do you want to be told your HIV result?	q1205 *(Circle one)*	Yes 1 No 2	 → end
	If participant wants to be told HIV result complete the Request for HIV Test Results Form, carry out the rapid HIV tests and carry out post-test counselling			
12.06	Have you completed a Request for HIV Test Results form?	q1206 *(Circle one)*	Yes 1 No 2	 → end
12.07	Have you given full post-test counselling? If no, why was full post-test counselling not given?	q1207 *(Circle one)*	Yes 1 No 2	
	If the Request form is completed and you have given full post-test counselling then give the participant their result. Provide further counselling and advice.			

Appendix 6. MkV1FS Research and ethical clearances

THE UNITED REPUBLIC OF
TANZANIA

National Institute for Medical Research
P.O. Box 9653
Dar es Salaam
Tel: 255 22 2121400/390
Fax: 255 22 2121380/2121360
E-mail: headquarters@nimr.or.tz

Ministry of Health
P.O. Box 9083
Dar es Salaam
Tel: 255 22 2120262-7
Fax: 255 22 2110986

NIMR/HQ/R.8a/Vol: IX/404

21st November 2005

Dr David Ross
C/O National Institute for Medical Research
P O Box 1462
MWANZA, Tanzania

CLEARANCE CERTIFICATE FOR CONDUCTING MEDICAL RESEARCH IN TANZANIA

This is to certify that the research entitled: Study on evaluation of the long term impact of an adolescent sexual health intervention programme (MEMA kwa Vijana) in Mwanza Tanzania: a community randomized control trial *(Ross D et al)*, whose Principal Investigator is David Ross, has been granted ethics clearance to be conducted in Tanzania.

The Principal Investigator of the study must ensure that the following conditions are fulfilled:

1. Progress report is made available to the Ministry of Health and the National Institute for Medical Research, Regional and District Medical Officers after every six months.
2. Permission to publish the results is obtained from National Institute for Medical Research
3. Copies of final publications are made available to the Ministry of Health and the National Institute for Medical Research.
4. Any researcher who contravenes or fails to comply with these conditions, shall be guilty of an offence and shall be reliable on conviction to a fine

Name: Dr Andrew Y Kitua

Signature

CHAIRMAN
MEDICAL RESEARCH
COORDINATING COMMITTEE

Name: Dr Gabriel L Upunda

Signature

CHIEF MEDICA L OFFICER
MINISTRY OF HEALTH

LONDON SCHOOL OF HYGIENE
& TROPICAL MEDICINE

ETHICS COMMITTEE

APPROVAL FORM
Application number: **3039**

Name of Principal Investigator	**Dr David Ross**
Department	**Infectious and Tropical Diseases**
Head of Department	**Hazel Dockrell**

Title: **Evaluation of the long-term (7-year) impact of an adolescent sexual health intervention programme (MEMA kwa Vijana) in Mwanza, Tanzania: A randomised controlled trial**

Approval of this study is granted by the Committee.

Chair ....T. W. Meade..........
Professor Tom Meade

Date ....3.2.2005..........

Approval is dependent on local ethical approval having been received.

Any subsequent changes to the consent form must be re-submitted to the Committee.

Appendix 7. Additional Results Tables

Table A7.1 Summary of households interviewed, absent and refused during the MkV1FS census

No.	Community	Estimated total households *(Source: Mobilisation reports)*	Households visited *(Source: Team reports & census data)*	% of households visited	*Difference between estimated number and visited number of households*	Households interviewed *(Source: census data)*	% Interviewed *(of households visited)*	% Interviewed *(of total households)*	Households Refused *(Source: team reports)*	% Refusal *(of households visited)*	Households absent *(Source: team reports)*	% Absent *(of households visited)*
1	Nkome	5086	4843	95	*243*	4770	98	94	9	0.19	64	1.3
2	Katwe	3679	3723	101	*-44*	3638	98	99	1	0.03	84	2.3
3	Nyehunge	4654	4860	104	*-206*	4677	96	100	1	0.02	182	3.7
4	Nyakalilo	3814	3947	103	*-133*	3781	96	99	6	0.15	160	4.1
5	Katunguru[1,2]	3301	2303	70	*998*	2301	100	70	2	0.09	Missing	
6	Busisi	2873	2834	99	*39*	2790	98	97	5	0.18	39	1.4
8	Katoro	7272	8341	115	*-1069*	8304	100	114	2	0.02	35	0.4
9	Kagu	6518	5856	90	*662*	5768	98	88	17	0.29	71	1.2
10	Lubanga	3242	3132	97	*110*	3109	99	96	2	0.06	21	0.7
11	Kasamwa[3]	4292	3759	88	*533*	3759	100	88	Missing		Missing	
12	Ihanamilo	2619	2480	95	*139*	2423	98	93	2	0.08	55	2.2
13	Bukoli	2965	2916	98	*49*	2873	99	97	1	0.03	42	1.4
14	Nyang'hwale[3]	2644	2474	94	*170*	2474	100	94	Missing		Missing	
16	Hungumalwa	3946	3582	91	*364*	3422	96	87	1	0.03	159	4.4
17	Fukalo	3459	3486	101	*-27*	3338	96	97	1	0.03	147	4.2
18	Misasi	2473	2377	96	*96*	2318	98	94	11	0.46	48	2.0
21	Usagara	3483	3222	93	*261*	3182	99	91	5	0.16	35	1.1
22	Koromije	2296	2542	111	*-246*	2493	98	109	12	0.47	37	1.5
23	Mwagi	3252	3176	98	*76*	3088	97	95	7	0.22	81	2.6
24	Malya	3847	3715	97	*132*	3579	96	93	16	0.43	120	3.2
	TOTAL	**75715**	**73568**	**97**		**72087**	**98**	**95**	**101**	**0.14**	**1380**	**1.9**
	Mean	3786	3678		107	3604			6		81	
	Range	2296 to 7272			from -1069 to 998				1 to 17		0 to 182	

[1]Katunguru (5) was the first community visited and reporting by the field team was not complete. The number of households visited may be an underestimate of the total number of households visited. There were some initial problems with the PDA data in Katunguru community and some census data seem to be missing for the following dates: 30-31 May 07, 01-02 Jun 07.

[2] Katunguru (5)- The number of households (HH) absent are missing from the village report.

[3]Kasamwa (11) & Nyangwhale (14)- The number of HH refused/absent are missing from the village reports

Table A7.2. Number of young people invited in each community during the MkV1FS census

	Community	Male	Female	Total
1	Nkome	487	398	885
2	Katwe	485	438	923
3	Nyehunge	505	516	1021
4	Nyakalilo	455	419	874
5	Katunguru[1]	267	177	444
6	Busisi	380	333	713
8	Katoro	554	472	1026
9	Kagu	433	291	724
10	Lubanga	346	348	694
11	Kasamwa	546	458	1004
12	Ihanamilo	403	315	718
13	Bukoli	415	288	703
14	Nyang'hwale	491	331	822
16	Hungumalwa	519	509	1028
17	Fukalo	574	482	1056
18	Misasi	388	326	714
21	Usagara	430	379	809
22	Koromije	407	366	773
23	Mwagi	391	360	751
24	Malya	485	433	918
	Unknown[2]	81	66	147
	TOTAL	**9042**	**7705**	**16747**
	Mean	448	382	830
	Range	267 to 574		444 to 1056
	% of total by sex	**54**	**46**	

[1]There were some initial problems with the PDA data in Katunguru community and some census data seem to be missing for the following dates: 30-31 May 07, 01-02 Jun 07.

[2] Community of interview is missing when household data for a young person is missing from the dataset.

Table A7.3.Number of eligible MkV1FS survey participants in each community

(a)

Intervention communities		Male	Female	Total
2	Katwe	310	322	632
3	Nyehunge	358	349	707
5	Katunguru	298	294	592
8	Katoro	429	329	758
9	Kagu	380	255	635
11	Kasamwa	435	404	839
12	Ihanamilo	335	238	573
17	Fukalo	496	388	884
18	Misasi	369	331	700
24	Malya	397	366	763
Total		**3807**	**3276**	**7083**
Range		298 to 496	238 to 404	573 to 884

(b)

Comparison communities		Male	Female	Total
1	Nkome	345	287	632
4	Nyakalilo	381	328	709
6	Busisi	291	262	553
10	Lubanga	308	298	606
13	Bukoli	338	232	570
14	Nyang'whale	401	320	721
16	Hungumalwa	435		837
21	Usagara	348	357	705
22	Koromije	329	361	690
23	Mwagi	317	391	708
Total		**3493**	**3238**	**6731**
Range		291 to 435	232 to 402	553 to 837