



HHS Public Access

Author manuscript

Afr J AIDS Res. Author manuscript; available in PMC 2016 March 24.

Published in final edited form as:

Afr J AIDS Res. 2016 March ; 15(1): 9–15. doi:10.2989/16085906.2015.1135295.

Involving parents from the start: Formative evaluation for a large RCT with Botswana Junior Secondary School students

Jessica Vig,

Association of Schools and Programs of Public Health, Washington, DC 20036

Kim S. Miller,

Centers for Disease Control and Prevention, Atlanta, GA

Catherine Chirwa-Motswere,

Centers for Disease Control and Prevention, Botswana

Kate Winskell, and

Emory University Rollins School of Public Health, Atlanta, GA

Elizabeth Stallcup

Centers for Disease Control and Prevention, Atlanta, GA

Jessica Vig: jessicavig@gmail.com

Abstract

While HIV prevention research conducted among adolescent populations may encounter parental resistance, the active engagement of parents from inception to trial completion may alleviate opposition. In preparation for implementing a large randomized controlled trial (RCT) examining the efficacy of a behavioural intervention targeting adolescent sexual risk behaviours, a formative evaluation was undertaken to assess parental reactions to the proposed trial. Six focus groups were conducted with parents of adolescents (aged 13–17) from rural, peri-urban, and urban Botswana junior secondary schools. Focus groups explored comprehension and acceptability among parents of the forthcoming trial including HSV-2 testing, the return of results to the adolescent (not the parent), trial information materials and the parental consent process. Parents welcomed the study and understood and accepted its moral and ethical considerations. Their reactions regarding return of HSV-2 results only to adolescents (not the parent) were mixed. Parents understood the consent process and most agreed to consent, while indicating their desire to remain informed and involved throughout the RCT. The FGDs provided valuable information and insights that helped strengthen the study. As a result of parents' feedback, counselling procedures were strengthened and direct linkages to local services and care were made. Informational materials were revised to increase clarity, and materials and procedures were developed to encourage and support parental involvement and parent-child dialogue. Ultimately, parental feedback led to a decision by the Government of Botswana to allow parents to access their child's HSV-2 test results.

Correspondence to: Jessica Vig, jessicavig@gmail.com.

NOTE: This research was supported by the President's Emergency Plan for AIDS Relief through the Centers for Disease Control and Prevention.

NOTE: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Keywords

adolescents; HIV; prevention; parents; Botswana

Introduction

Adolescents (10–19) in Botswana are a key population cohort for efforts to reverse the HIV epidemic, as high rates of infection occur during adolescence and early adulthood. For those aged 15–24 years, the estimated HIV prevalence for males is 4% and 11% for females (Republic of Botswana Central Statistics Office 2013). Of the population six weeks and above, there is an unadjusted incidence rate of 2.47% (Republic of Botswana Central Statistics Office 2013). These rates are alarming given that young people between the ages of 10–24 years comprise 39% of all people living in Botswana (Population Reference Bureau 2010), constituting the largest group of young people ever to enter adulthood in the country's history (Melles 2009). Consequently, intensified HIV prevention research efforts to improve behavioural, biomedical, and structural interventions among adolescents in Botswana, and within the broader context of sub-Saharan Africa, are needed. Behavioural interventions have been widely evaluated, although chiefly within developed countries, primarily focusing on self-reported adolescent risk behaviours such as sexual initiation, condom usage, and multiple partners, as opposed to HIV incidence (Cowan and Pettifor 2009; Michielsen et al. 2010; Pettifor et al. 2013). Regrettably, behavioural studies utilizing HIV or an alternative biomedical endpoint within sub-Saharan Africa are scarce, although their importance is recognized in the interests of increasing research rigor (UNAIDS Interagency Task Team on Young People 2006).

It is generally recognized that there are unique barriers to conducting research with an adolescent population (DiClemente et al. 2010). Collecting behavioural data on adolescent sexual risk behaviours can be controversial and requires thought and care to ensure that sexually inexperienced adolescents are not asked questions about explicit sexual behaviours. Depending on the age of majority, two layers of consent (informed assent from the adolescent and consent from a parent or guardian—hereafter referred to as a parent) may be needed, requiring parents to achieve sufficient comfort with the research study to provide their consent. Considerations such as these illustrate the complexity of HIV prevention research among adolescents and emphasize the importance of working closely within adolescent spheres of influence—particularly parents—to advance the goal of achieving an AIDS free generation.

HIV prevention research may encounter parental resistance, due to the unique moral and ethical issues in working with this population (DiClemente et al. 2010). However, the active, continual, meaningful engagement of parents from research inception to completion may actually help alleviate opposition to such research efforts. Much of the engagement of parents has focused on parent-child sexual health interventions, aimed at improving communication about sex and impacting knowledge and attitudes (Wight and Fullerton 2013), rather than preparing for research implementation. Closing this research gap will be critical to the advancement of adolescent HIV prevention.

Three well known HIV prevention trials among young people in Africa have utilized herpes simplex virus type 2 (HSV-2) as an endpoint (Ross et al. 2007; Jewkes et al. 2008; Cowan et al. 2010;). The MEMA kwa Vijana trial conducted in Tanzania, tested a multicomponent behavioural intervention and found no effect on HSV-2 (Ross et. al 2007). In Zimbabwe, the community-based, Regai Dzive Shiri trial also tested a multicomponent behavioural intervention, with no impact on HSV-2 outcome (Cowan et al. 2010). However, in South Africa, young people who received the Stepping Stones intervention showed a reduction in HSV-2 incidence in comparison to the control arm (Jewkes et al. 2008).

In preparation for a randomized control trial (RCT) that includes testing for the HSV-2 as a biomarker for sexual initiation, a formative evaluation was undertaken to assess parental reactions to aspects of the proposed trial. This comprised assessing comprehension and acceptability of the upcoming trial, including HSV-2 testing, the return of test results directly to the adolescent (not the parent), trial information materials, and the parental consent process. We share findings and resulting revisions to materials and trial procedures as a source of lessons learned for others considering implementing similar trials and as illustration of the importance and challenges of involving parents in studies of this kind.

Methods

Project AIM

Data were collected to inform planning of a large-scale RCT in Botswana examining the efficacy of Project Adult Identity Mentoring (Project AIM), an evidence-based intervention (Clark et al. 2005). Designed to delay sexual initiation and reduce sexual risk behaviours in adolescents, Project AIM is a 14-session motivational adolescent development program. It is different from other HIV prevention programs which historically take either an abstinence-based or a comprehensive sex education approach, as it addresses social barriers to sexual risk prevention such as hopelessness and low future orientation. The RCT targets junior secondary school students in Eastern Botswana (Form 1, Form 2, and Form 3) or the equivalent to middle school students (sixth, seventh, eighth grade) in the United States. As Project AIM is designed to be implemented in conjunction with HIV prevention education, schools have been randomized to receive either the standard life skills education curriculum in Botswana (called LIVING) or the multi-component adolescent HIV prevention program consisting of LIVING and Project AIM. Two outcome domains, one biological and one behavioural, will be used in the RCT: testing HSV-2 as a biomarker for sexual activity and a 65-question behavioural survey. Blood samples for the HSV-2 test will be collected in a microtainer tube through a finger-prick. Active consent will be utilized throughout the enrollment process. Ethical clearance was obtained through the Centers for Disease Control and Prevention Institutional Review Board and the Botswana Ministry of Health Research and Development Committee.

Participants

Six focus group discussions (FGDs) were conducted with the parents of adolescents (aged 13–17) from rural, peri-urban, and urban area junior secondary schools in Botswana in March 2012. Two focus groups, comprised of four to seven males and females, were

conducted in each area, for a total of 32 participants across groups. Schools were selected based on their willingness and availability to participate and all activities took place on school grounds. Purposive sampling was used for the selection of participants. All parents of current Form 1 students, who reside or work in the same district as the selected school, were eligible for inclusion. Participants were recruited by school administrators through fliers and letters. FGDs were conducted in English and/or Setswana (the official language of Botswana) depending on participants' preferences and were led by local, trained facilitators. Participants did not receive any monetary reimbursement for their time and effort, however refreshments were provided and, if needed, transportation costs to the site were reimbursed.

Procedures

A structured focus group guide was followed. To begin the FGD, participants received a trial information packet including the Trial Information Sheet, HSV-2 Testing Information Sheet, and a Parent Consent Form. Facilitators led parents through each section of the packet to prepare them for discussion of the following: 1) their overall reactions to the trial, including the HSV-2 testing; 2) having HSV-2 results returned directly to the adolescent (not the parent); 3) clarity and acceptability of proposed trial informational materials; and 4) parental consent process including reasons for providing or refusing consent for an adolescent to participate in the trial.

Parents were asked whether there was anything that made them uneasy or uncomfortable about the proposed trial and specifically their reactions to the inclusion of HSV-2 testing. Facilitators sought suggestions for making any part of the trial more acceptable to parents. Informational materials informed parents that HSV-2 testing would take place in a private location at schools, and adolescent participants would be able to receive their results through a toll-free phone line if they wished. Parents were informed they would not have access to a participant's results unless their child voluntarily shared the information with them or voluntarily involved them in the return of results process. They were informed that HSV-2 is treatable, but not curable, and that adolescents with genital sores would be referred for a clinical visit for treatment of the sores and a comprehensive STI screening. Informational materials were written in both English and Setswana using a reading level (Kincaid reading level 6.4) suitable for the target audience and were designed to explain trial rationale and goals, eligibility requirements, procedures (including the behavioural survey and HSV-2 biomarker), any risks or benefits to participation, confidentiality, and the process of informed consent. They were informed that, in order to participate in the trial, adolescents 17 years of age and younger would be required to provide written, informed assent and parental consent, while adolescents 18 years of age or older would provide written, informed consent. Proposed trial materials and FGDs placed great importance on the HSV-2 testing process and return of results, as early research design discussions with key stakeholders suggested this could be an area of concern for parents.

Lasting approximately 1.5 hours, all FGDs were digitally recorded and the digital audio recordings were transcribed verbatim as a Microsoft Word file. Setswana words or transcripts were translated into English by study personnel. Emergent and recurring themes were identified. A codebook was developed by three study personnel to create universal

definitions for each code to ensure consistency during the analysis. Subsequent coding of the transcripts was completed by two coders. Major themes were used for the first level of coding and then subthemes were identified. On-going discussions occurred to ensure coding reliability and, if necessary, resolve any discrepancies. Data was coded and analysed using MaxQDA software. Similarities and differences in response to each topic area were identified. FGDs transcripts from the three sites were compared.

Results

Unless specific differences are noted, findings were consistent across the three sites and across focus groups.

Acceptability of the upcoming trial

Participants expressed a high level of enthusiasm for the proposed trial, stressing its benefits for their children's education, sexual health, and future prospects,

'I feel it is a very important program and I know that it will teach them something about their lives, about their futures. In regards to sexually transmitted infections and other diseases, as we all know they do not know much about these diseases, or how dangerous they are, or the implications they can have.'

Participants contextualized the program's importance with reference to generational changes in sexual behaviour, resulting in increased risk of STIs and pregnancy, and a perception that their children's lives were in danger as a result of HIV. Some expressed benefits in terms of building a healthy nation.

Parents indicated that they would encourage their own children to be part of the study and indicated that the sole condition for its acceptability among other parents in Botswana was clear education and information about the trial. Occasional fleeting reference was made to potential mistrust of trials using placebos or including testing for HIV. Some participants suggested that parents living with HIV might be disinclined to participate out of reluctance to hear more about HIV and that some may fear that their own status may be revealed or that their children would discover for the first time through the trial that they were HIV-positive and on anti-retroviral therapy.

Parental education and involvement

Participants expressed gratitude for their own involvement, seeing the program as a source of education not only for their child, but also for themselves:

'I am also grateful but as you are teaching us, you are also counselling us. As parents we are going to teach our children because you have taught us.'

They were particularly receptive to the news that HSV-2 increased susceptibility to HIV and that treating sores could reduce risk of HIV infection,

'I think the idea of this is that these children should not end up infected with HIV. Should be prevented in time.'

Some parents felt that their children might refuse to participate in the trial,

‘Children nowadays, they will say “ah, these people are going to collect our blood and test it for this one.” Since they are scared about being tested and children don’t want to be tested.’

However, others reassured them that they, as parents, would be able to persuade them of the study’s importance:

‘And I know they will be sceptical to do it, but when I am home I will inform my children that “this is very important for you”. Since I wouldn’t know whether my child has got those sores. But if my child hears me talk comfortably about the sores, that they exist, she will be comfortable to talk to me about them and she will feel free to come to me and tell me “by the way mom, I have got these sores” and she will be open to me.’

One participant’s concern that children who were not enrolled in the trial could disrupt participation was countered by another participant’s emphasis on the importance of parental action:

‘I believe as parents we need to talk to parents about their responsibility.’

HSV-2 testing

Parents expressed no concerns about the HSV-2 test itself, commenting:

‘It’s just a simple test’

like those for malaria and HIV and had no side effects. Several participants framed the HSV-2 test as a preventative intervention in and of itself,

‘It encourages good behaviour in kids, they won’t have early sexual relations and it’s ok if they get tested as early as possible to get help.’

One participant anticipated that fear of parents and those running the trial finding out they have HSV-2 would cause children to refrain from sex throughout the duration of the trial, to wait for marriage, and to tell younger siblings,

‘You know, when you get to Form 1 you are going to be tested, so stop doing those activities here because you might get there and be found with the virus, what are you going to say?’

Some argued that younger children (Form 1) would have no problem participating in the trial, but that it might be more difficult by Form 3.

Return of HSV-2 results to the adolescent

Participants expressed mixed reactions regarding the return of HSV-2 results only to the adolescent (not the parent). Some were comfortable with the plan to return them only to children,

‘It is right for them to receive them, so that from then, they can be able to change their behaviour. If they have the virus.’

Some parents also had no problem with the child choosing not to reveal their results to their parents,

‘As a parent obviously you will have some anxiety about your child going to take the HSV-2 test. But if the child doesn’t want to tell you about the results it’s okay? It’s fine.’

One suggested that if parents were informed of the test results, this would not be well-received by the children,

‘Because sometimes if you tell the parents, maybe the child doesn’t want to the parents to know. So they will tell you “why did you tell my parents? Because I am the one who, I was still preparing myself to tell my parents and now you have told my parents.”’

Some, however, expressed concern about the fact that children would only be given their test results if they requested them, meaning that they could test positive and not know it, with one participant suggesting that this was not fair on the parents. Parents asked study staff to encourage the children to get their results.

‘Please, I would encourage you to encourage them that after testing they should know their results. They should not just test and not know their results. Because they are still children. They might fear that “if I test and I get my results, what am I going to tell my mother.” Please try to explain to them that we are not very much involved, it is up to you.’

Some participants suggested that a note from the study staff might facilitate disclosure of test results by the child to the parent.

Some parents wanted to be a point of contact for receipt of the results,

‘Why don’t you at least include both parents and children. Because I will definitely protect my child. I will not spread rumours about my own child.’

In one focus group in particular, parents expressed considerable discomfort with the plan to return results only to children, saying it was not right for children to determine involvement of parents

Mother 2 ‘These children are still young.’

Mother 3 ‘They can even hide things from us. There is a possibility that if they find out they have the virus they will come to you and pretend that they are fine. Because they wouldn’t want to talk to you about it. And you as a parent will also relax, thinking that they are fine. Yet the child is not. It’s not right. At least the child should say “mama let’s go together for my results.”’

Mother 2 ‘Yes, for support.’

A father in the same focus group argued that it was not right for parents not to be involved at the results stage because the child is not yet old enough to be responsible:

‘If he was responsible, I would say it’s fine.’

Some expressed concern that hiding the test result would place a psychological burden on these young children:

‘After the results have come out, and the child knows his results, do you think it will affect him in his school work? Because this child will have kept it to himself, and as a parent I wouldn’t have had the opportunity to counsel my child, to talk to him as a parent. Don’t you think it will affect his life somehow, because keeping that secret can be a burden. Not feeling well, not feeling alright.’

Parents felt they may not be able to provide adequate support for their child in these conditions, and questioned whether the counselling provided in the context of the trial would be comprehensive. When participants in one focus group expressed fear that receiving their results privately could even lead to suicide, others retorted that this could be avoided through pre-test counselling. One participant commented that this risk would depend on the relationship between the family and the child,

‘There are homes where we do not talk about these things. There are homes where we talk about them. And in families that children talk to their parents and parents talk to their children, there won’t be any problem “mama, today I found something, and even though you thought I was this, I have been cheating on you doing a, b, c, but now the results are here” and then for another child who says “I am going to disappoint my parents. They have never known about me having sex, but now the results are going to reveal that. I better keep it to myself, and treat myself, and not repeat the things that I have been doing.” But then the only, the thing that we really want here, is for the child to change the behaviour, from being negative to being positive.’

Counselling and Clinical Support

Parents had specific recommendations for what should be covered in counselling sessions. Some, for example, wanted reassurance that children who may be sexually active would be told that the testing was not being done on the initiative of parents. Participants entreated counsellors to encourage children to disclose and to outline the pros and cons of sharing and not sharing their test results with their parents so they could make an informed decision about disclosure. They were very specific about timing of this information – that it needed to be provided at the pre-test stage rather than when they received their results:

‘Before the test. So that the child can think about it, “ok, I know for MY family, this is what I need to do.” And if they decide, “in my family, bringing this information home maybe isn’t best.” So that the next question from the counsellor is “ok, where will he get support then.”’

Participants evoked situations where the test results may lead to disclosure to parents of child sexual abuse or the discovery by the child that he or she had sex when intoxicated. Some greeted the trial as a welcome opportunity to strengthen their relationships and communication with their children:

‘I think as parents we should have this mother child relationship, to make our children feel comfortable to talk about anything that is going on with them.... I

think we should take advantage of the study to build that relationship to avoid that anxiety of my child taking the HSV-2 test and them telling the results.’

Parents wanted to know more about the medical help their child would receive if they were found to have HSV-2. They requested additional information about the clinic and who would be there to greet the child. For example, participants expressed concern about potential stigma and adverse reactions from untrained clinic staff,

‘There is a possibility that when he or she gets there she will meet someone saying “a small child like you! How did you get this?” Do you see what I mean? Then the child will run away forever thinking that the protection that he had at the beginning of the study is gone. We have betrayed this child. Do you see what I mean?’

Concerns about confidentiality were also expressed. One participant expressed concern that there may be shortages of acyclovir used to treat HSV-2 sores.

Trial information materials

Participants generally appreciated the clarity of the informational materials:

‘They are very easy and I’m glad this time around you have made this information very clear for us unlike when they gave us information about HIV.’

Through the materials, parents felt they received an introduction to the virus, routes of transmission, and implications for infection. More critically, participants understood that the virus is treatable but not curable, and the potential for HSV-2 to increase the risk of acquiring HIV. However, several parents indicated that they were learning about HSV-2 for the first time that day and expressed a need for more information about it. In addition, after reading the materials, participants displayed a gradation within their levels of understanding, suggesting some additional material strengthening was needed.

It was clear from comments made during the focus groups that further clarification on the difference between HIV and HSV-2 was needed. As one participant commented,

‘Using these big words [HSV-2] parents associated it with HIV and no one will like her kid to have the virus, as much as it is a problem even for us parents to take the HIV test.’

One participant asked for further clarification as to why,

‘At the beginning they were talking about HIV, now they are talking about HSV-2 —why did they choose HSV-2 instead of HIV testing?’

Indicating the need to further clarify the rationale for using HSV-2 as a biomarker and the broader purpose of trial.

Questions from participants also indicated confusion about the potential asymptomaticity of HSV-2 and its presence in the absence of genital sores. Some suggested that images be included to allow people to identify sores. There were questions about how HSV-2 related to HSV-1 and whether it could be transmitted from a mother to her child. Some expressed concern about their own HSV-2 status, asking whether they too were going to be tested,

‘Because sometimes we can get these sores and we don’t know whether it is a virus. Thinking that maybe it is just a rash. Then you stay at home without going to the hospital. And then it will come back and disappear, yet you are sick inside.’

It was evident that many parents may have HSV-2 themselves and that this should be acknowledged in the study materials. While glad they were now informed about HSV-2, some questioned why the study would focus on junior secondary school students and not on parents or older children.

Parents understood that the HSV-2 test results would only be released to trial participants, but the nuances of the rule, such as their child voluntarily wanting to share their test results with them, confused them. When parents asked if they could attend a counselling session with their child, study staff stressed that the parent could be present as long as the child wanted that. However, one father indicated that the forms did not convey this and proposed they be revised,

‘In this form, we are not involved at all. The child is the one who is going to do whatever he wants or she wants... If the form could at least say if you want your parent to be involved, and you want your mother or father to come, it will be fine.... It will be showing you that you as a child, if you are sick, your family should be involved.’

In addition, parents requested that greater encouragement to seek STI screening at local clinics be added into the revised information materials and into all phases of counselling for adolescents.

Parents were asked for feedback on planned informational sessions that would be held to supplement trial information materials, particularly for those with lower literacy levels. While participants welcomed this, they indicated that not everyone would attend, and stressed the potential role children could play in increasing parents’ understanding of the trial:

‘If the students are made to understand why this study, they will go and explain to their parents. So we don’t even have to worry about parents that can’t read. Because the child will tell “Mama, this is what was said.... As long as the child understands, the parent will understand.”’

Parental consent process

FGDs gave no indication that the trial would encounter large-scale resistance to acquiring parent consent for adolescent participation for reasons pertaining directly to the trial itself. Additionally, no concerns were raised regarding the age of adolescent participants (Form 1 and Form 3 students, approximate age range 12–20). Parents understood the consent process and most agreed to consent for their children. One parent suggested,

‘I suggest if it’s possible for all children to participate. But we know that it’s not going to be possible because it is a research study that is voluntary.’

As the trial information packets will be sent home with students, participants were asked how much time is appropriate to review the materials and decide whether or not to allow

their child to participate. Although there was a range of responses, from a few days to two weeks, all FGDs concluded that two weeks would be a satisfactory amount of time. Parents appreciated and encouraged being kept informed of the trial through the trial information materials and planned parent information sessions at trial sites and/or within surrounding communities.

Discussion and implications for the trial

Our key FGDs finding was parents' positive reaction to the overall trial, including the HSV-2 testing, and their support for its overall goal and purpose. A prominent theme across the FGDs was parents' desire for ongoing involvement in the study. They provided key suggestions on ways to strengthen the trial, underscoring the foundational role they play in the success of HIV prevention research among adolescents.

Some understood that trial procedures were created out of respect for minors' right to confidentiality and privacy. However, mixed reactions were expressed regarding return of HSV-2 results only to adolescents (not the parent). As parents provide crucial guidance, support, and comfort for adolescents seeking health services and care, a primary concern voiced in the FGDs was the elimination of their vital role and an uncertainty as to how to remain engaged and involved without knowing their child's results. They emphasized that in their absence, the trial needed to strengthen the counselling provided to adolescents along with the linkages to service and care.

Following the FGDs, comprehensive counselling and support measures were strengthened through the inclusion of pre and post-HSV-2 test STI counselling and through the development of direct referral linkages to local clinics. The trial information packets, reviewed by parents during the FGDs, included an adolescent-focused STI information sheet and HSV-2 information sheet for adolescents and parents to read and discuss. These packets were distributed to adolescents before the trial began. Additionally, adolescents received and discussed the information sheets again during the pre-test counselling before each HSV-2 test. This additional counselling step is another opportunity to explain what STIs are, how they are transmitted, risk reduction techniques, symptoms, treatment options, test procedures and the process for accessing HSV-2 results. Lastly, when test results are available or about to be available, a final counselling layer has been added where adolescents will receive and discuss the information sheet for a third time, along with direct referrals to a local clinic in the vicinity of the school, including contact information for the nurse in charge there, and a telephone number for the Youth On Air Counselling service (YOCA). These resources will also be available to them in the future should they need additional counselling, care, or STI support. Within the information packets and throughout pre and post-test STI counselling, adolescents will be encouraged to visit the clinic for a comprehensive STI screening.

As a result of parent input, staff visited each trial site's local clinics to strengthen the referral linkage and prepare the clinic to receive participants who follow up with concerns about their symptoms or test results. Study staff worked with the clinic staff to inform them about Project AIM and HSV-2 testing among JSS learners and to identify a point of contact for adolescents—someone who enjoys working with young people, will ensure their

confidentiality, and will provide information in a way that is age appropriate. Clinics will be called when test results are ready to be returned to alert them that students may be calling, and to remind them about the study. Study staff confirmed with the clinic that they have the medication needed to treat herpes blisters.

Following parents' suggestions, the study informational materials were revised to increase clarity. Although HSV-2 is being used as the biomarker within the trial, Project AIM is an HIV prevention intervention; therefore both viruses are discussed in the materials. It was clear that the similar acronyms HIV and HSV-2 were a potential source of confusion. Materials were therefore revised to refer to HSV-2 as genital herpes. In addition, a picture of what genital sores look like was added to the information sheet. Materials were amended to ensure that parents understand the differences between HIV and HSV-2, the potential for HSV-2 to increase one's chances for contracting HIV, and the reason that HSV-2 is being used as a biomarker in an adolescent HIV prevention trial.

In line with FGD feedback, the materials and procedures were also strengthened to encourage parental involvement. This included the creation of additional resource materials. In response to parents' concern that their children might not disclose their test results to them, parents were encouraged in informational materials and at parent meetings to actively engage in communication with their child and equipped with information to answer their questions. Parent-centred information sheets about STIs and genital herpes were prepared in both English and Setswana, providing user-friendly information for parents to convey to their children. In addition, talking points were created to help school staff, field staff, and project staff talk about genital herpes.

FGD participants indicated that active consent forms had a high level of readability, that parents understood the consent process, and that most were willing to consent for their children. They suggested allowing at least two weeks for families to discuss the trial and return the forms.

Parents can influence whether a trial moves beyond its initial stages. Their collective power can change trial procedures. They may even determine the overall fate of a trial. Project AIM is a case in point of the significant role parents play in moulding and shaping a trial. After hearing about the mixed parent reactions to the return of HSV-2 results directly to the adolescent, the Botswana Ministry of Education and Skills Development held further consultation regarding the trial procedure with the Botswana Ministry of Health. As adolescents under the age of 18 years old are considered minors under Botswana law, both ministries agreed that a provision for parents to be able to access their child's results needed to be added into the trial protocol. Ultimately, the desire of parents to be involved overrode the importance of protecting the confidentiality of a minor participating in a research study. Moving forward, HSV-2 results will be made available for all participants and parents of adolescents under age 18 years who wish to know them. All informational materials and consent forms were revised accordingly.

This significant change in a trial procedure will create new challenges and opportunities; the possibility for selection bias among adolescents is greater as those who are sexually active

may not enrol in the trial. Additionally, parents may be eager to access their child's HSV-2 test results and inadvertently coerce their child to participate. Parental comfort levels with the new HSV-2 return of results procedure may increase and, with it, their willingness to provide consent for their child to participate and overall support of the trial.

As FGD participants volunteered to take part in this formative evaluation, findings may not be representative for all Botswana parents of JSS students. In addition, the results may not be generalizable outside of Botswana. Additionally, it is possible that parents' approval of the trial and indication of willingness to consent was influenced by their participation in a group situation surrounded by their peers.

As this manuscript went into publication, the Project AIM RCT baseline data collection and intervention implementation were completed.

Conclusion

HIV prevention research among adolescents poses considerable challenges due to moral and ethical issues associated with the population's unique stage of development. However, age-appropriate, effective behavioural, biomedical, and structural interventions are critical to turn the tide on a group disproportionately affected by HIV. The active engagement of parents is critical to the success of HIV prevention research among adolescents. Formative evaluation with parents for a large RCT with Botswana Junior Secondary School students led to the revision to trial materials and procedures. As a result of parents' feedback in FGDs, counselling procedures were strengthened and direct linkages to local services and care were made. Adolescents will be actively encouraged to seek comprehensive STI screening and will be provided with the name and contact details for a youth-friendly point person at a local clinic who is familiar with the study. Informational materials were revised to increase clarity about HSV-2 and its relationship to HIV. Materials and procedures were developed to encourage and support parental involvement and parent-child dialogue. Ultimately, parental feedback led to a decision by the Government of Botswana to allow parents to access their child's HSV-2 test results.

As parents are key stakeholders in the health of their children, they are a critical component in ensuring the feasibility and acceptability of research among adolescents, hence the importance of the meaningful engagement of parents throughout the Project AIM trial. Future HIV prevention trials with youth, utilizing HIV or an alternative biomedical endpoint within sub-Saharan Africa, should seek to include parents within these trials, and contribute to the much needed scientific knowledge in the field.

Acknowledgments

We thank Sarah M. Lasswell for her contributions to the Project AIM formative evaluation.

References

- Biraro S, Mayaud P, Morrow RA, Grosskurth H, Weiss HA. Performance of commercial herpes simplex virus type-2 antibody tests using serum samples from Sub-Saharan Africa: a systematic review and meta-analysis. *Sexually Transmitted Diseases*. 2011; 38:140–7. [PubMed: 20706175]

- Clark LF, Miller KS, Nagy SS, Avery J, Roth DL, Liddon N, Mukherjee S. Adult identity mentoring: reducing sexual risk for African-American seventh grade students. *Journal of Adolescent Health*. 2005; 37:337.e1–337.e10. [PubMed: 16182145]
- Cowan FM, Pascoe SJS, Langhaug LF, Mavhu W, Chidiya S, Jaffar S, Mbizvo MT, Stephenson JM, Johnson AM, Power RM, Woelk G, Hayes RJ, Regai Dzive Shiri trial team. The Regai Dzive Shiri Project: results of a randomised trial of an HIV prevention intervention for Zimbabwean youth. *AIDS*. 2010; 24:2541–2552. [PubMed: 20881473]
- Cowan F, Pettifor A. HIV in adolescents in sub-Saharan Africa. *Current Opinion in HIV and AIDS*. 2009; 4:288–293. [PubMed: 19532066]
- Delany-Moretlwe S, Jentsch U, Weiss H, Moyes J, Ashley-Morrow R, Stevens W, Mayaud P. 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. *Sexually Transmitted Infection*. 2010; 86:46–50.
- DiClemente RJ, McDermott Sales J, Borek N. Barriers to adolescents' participation in HIV biomedical prevention research. *J Acquir Immune Defic Syndr*. 2010; 54:S12–S17. [PubMed: 20571418]
- Jewkes R, Nduna M, Levin J, Jama N, Dunkle K, Puren A, Duvvury N. Impact of Stepping Stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. *BMJ*. 2008; 337:a506. [PubMed: 18687720]
- Melles, MM. Youth Reproductive and Sexual Health in Botswana. 2009. The Facts Series: Advocates for Youth Available at <http://www.advocatesforyouth.org/publications/1335?task=view> [accessed 8 February, 2011].
- Michielsen K, Chersich M, Luchters S, De Koker P, Van Rossem R, Temmerman M. Effectiveness of HIV prevention for youth in sub-Saharan Africa: systematic review and meta-analysis of randomized and nonrandomized trials. *AIDS*. 2010; 24:1193–1202. [PubMed: 20375876]
- Pettifor A, Bekker LG, Hosek S, DiClemente R, Rosenberg M, Bull SS, Allison S, Delany-Moretlwe S, Kapogiannis BG, Cowan F, HIV Prevention Trials Network (HPTN) Adolescent Scientific Committee. Preventing HIV among young people: research priorities for the future. *J Acquir Immune Defic Syndr*. 2013; 63:S155–S159. [PubMed: 23764629]
- Population Reference Bureau. Botswana. 2010. Available at <http://www.prb.org/Countries/Botswana.aspx> [accessed 8 February, 2011].
- Republic of Botswana Central Statistics Office. Preliminary Results: Botswana AIDS Impact Survey IV, (BAIS IV) 2013. 2013.
- Ross DA, Changalucha J, Obasi AIN, Todd J, Plummer ML, Cleophas-Mazige B, Anemona A, Everett D, Weiss HA, Mabey DC, Grosskurth H, Hayes RJ. Biological and behavioural impact of an adolescent sexual health intervention in Tanzania: a community-randomized trial. *AIDS*. 2007; 21:1943–1955. [PubMed: 17721102]
- Tindana PO, Singh JA, Tracy CS, Upshur REG, Daar AS, Singer PA, Frohlich J, Lavery JV. Grand challenges in global health: community engagement in research in developing countries. *PLoS Med*. 2007; 4:1451–1455.
- Ross, D.; Dick, B.; Ferguson, J., editors. UNAIDS Interagency task team on Young People. Preventing HIV/AIDS in young people: systematic reviews of the evidence from developing countries. Geneva: WHO; 2006. Technical Series Report No. 938
- Wald A, Link K. Risk of human immunodeficiency virus infection in herpes simplex virus type 2-seropositive persons: a meta-analysis. *The Journal of Infectious Diseases*. 2002; 185:45–52. [PubMed: 11756980]
- Wight D, Fullerton D. A review of interventions with parents to promote the sexual health of their children. *Journal of Adolescent Health*. 2013; 52:4–27. [PubMed: 23260830]