HIV: Current Research

Extended Abstract

Socio-behaviour challenges to phase III HIV vaccine trials in Sub-Saharan Africa

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Abstract

A number of countries in sub-Saharan Africa are preparing for HIV vaccine efficacy trials. Social and behavioural factors related to HIV transmission require examination in each setting where these trials are considered. As part of this, several countries have also recently begun preparatory research investigating relevant social and behavioural issues. There is a need for a review of the literature to help focus such research efforts in Sub-Saharan Africa. The objective is to examine key social and behavioural issues that may impact on the conduct of HIV vaccine efficacy trials in sub-Saharan Africa. The design used for these is Literature review. The methods are Major databases (PubMed, PsychInfo, EBSCOhost, and AIDSline) were searched for literature that discussed social and behavioural issues related to HIV vaccine trials. Three areas are highlighted as being particularly significant for HIV vaccine research: (1) willingness to participate in future HIV vaccine efficacy trials, (2) retention of participants in studies, and (3) sexual risk reporting during trials. For each of these topics, major findings from both developed and developing countries are described and avenues for further research are discussed.There are few data from Sub-Saharan Africa regarding willingness to participate in HIV vaccine trials. Data on participant retention rates varies widely, and maintaining large cohorts of individuals within Phase III trials presents an important challenge. In addition, the possible impact of trial participation on sexual disinhibition, and response bias on sexual risk-reporting remain as issues for HIV vaccine trials in African contexts.Social and behavioural research forms an important part of preparations for HIV vaccine efficacy trials, and there is a clear need for more research of this type in Sub-Saharan Africa. Innovative approaches are required to address issues such as willingness to participate in vaccine research, participant retention during efficacy trials, and the accurate reporting by participants of sexual risk behaviours.

Keywords: Africa, HIV, vaccines, clinical trials, preparation, behaviour, review

The decision to take part in a HIV vaccine efficacy trial is embedded within a context of personal, emotional and cognitive factors. Cross-sectional studies often strip the answer (willing or not) from these contexts and does not provide insight into how different contexts may

The ability to recruit and retain large numbers of participants is a key concern in HIV vaccine efficacy trials. Before the first phase III trials were conducted, longitudinal studies examined recruitment and retention in a range of different sub-groups in America. These studies reported the ability to retain between 70 – 90% of participants between 9 and 18 months after enrollment, which suggested that phase III trials would indeed be feasible. Similarly, studies in Thailand reported high retention rates - about 90% in CSW, army conscripts and MSM. The retention rates of the two AIDSVAX trials have not yet been made available, but early reports suggest that retaining participants, while possible, were not without difficulties and required an extensive investment from study staff.
Retention data from other forms of HIV prevention research are highly variable. In studies of HIV prevention in pregnancy in Uganda, for example, very low rates of attrition have been maintained over relatively long periods , while researchers working with CSW in Kenya reported high drop-out rates (up to 33.7% after enrolment) and a very high attrition rate due to seroconversion (37% in the first year).

Incarceration, migration and homelessness constituted major problems in finding participants who missed their follow-up visits in longitudinal studies of inner city drug-users in the USA. The North American AIDSVAX trial, which also recruited IDU reported similar reasons for attrition. In contrast, in African studies, attrition was associated with higher risk behaviour and fear of knowing your HIV status in heterosexual population in Kenya and Tanzania. This suggests that factors related to attrition may differ between population groups, and may require different approaches to retention.

Sixty recruitment sites were strategically located across a large geographic region during the North American AIDSVAX trial. This prevented loss-to-follow-up due to migration since participants could be transferred to another recruitment site in a neighbouring area. Other studies have formed alliances with social service agencies (governmental and other) to track participants or provided counselling, assistance with housing and employment, food parcels, toiletries and small gifts. However, a concern is that providing incentives for retention in populations where even basic provisions are limited may have ethical implications. Logistical factors, such as travelling long distances to trial-sites, inadequate roads, a lack of public transport and electricity may also negatively impact retention in these settings. Retention strategies require a significant investment in human, financial and

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technological resources, which can be costly and time-consuming. It is therefore imperative to understand attrition in different context, to be able to intervene effectively and in a resource-efficient manner during efficacy trials.

Apart from the challenge of retaining trial participants, there is also a concern that participants in a vaccine trial may increase their risk-taking behaviour by thinking the vaccine is protective against infection. A range of studies, including phase I and II trials, have reported that participants either increased or stated that they would increase their risk behaviour if part of a vaccine trial. Concerns have been raised that this may lead to a perverse outcome where phase III HIV vaccine trials result in more, rather than less HIV infections. Related to this, condom distribution and promotion for sexual risk reduction is a necessary component of HIV vaccine trials, though there is no evidence to suggest that increasing the availability or accessibility of condoms alters sexual activity itself.

For ethical reasons it is thus essential that HIV risk behaviours are carefully monitored and that effective risk reduction procedures are in place to prevent sexual disinhibition during trials. Apart from the fact that there is little data available on sexual disinhibition during trials, another concern is that the reliability of sexual risk-reporting is constrained by memory biases and a range of demand characteristics, which have been shown to negatively impact on vaccine preparedness research in developed countries and must also be addressed in African contexts.

Since ethical and practical issues prevent measuring sexual behaviour through direct observation, research on sexual behaviour aims to provide conditions that will facilitate reliable and valid reports. The assumption is that honest reports are more accurate and will increase when privacy and anonymity is assured. Self-administered questionnaires are thus preferred as they offer more privacy than face-to-face interviews, but requires a high level of literacy and familiarity with questionnaire completion. In cases where this is not possible interviews remain the best method to obtain information of sensitive behaviours. However, this method can introduce response biases which may affect the accuracy of the data.

Social desirability is one of the key biases that can influence data based on self-report. It refers to self-presentation, a tendency to present personal information in a way that will enhance one's status in interpersonal situations. In HIV research where safe sexual practices may be considered desirable, participants may thus bias their responses accordingly, especially when negative outcomes are feared. Social desirability may also be prominent when there is a large discrepancy in race, class or social status between the researcher and respondent, which is often the case when research is conducted in African contexts.

Conclusion

Socio-behavioural research is essential in preparing for HIV vaccine efficacy trials and should be strengthened in sub-Saharan Africa. Few data exist on how different cultural, economic and social contexts may influence the decision to enter a trial, the reasons for leaving a trial and the honest reporting of sexual risk behaviour and needs further investigation.