REVIEW ARTICLE

Enrolment and Retention of African Women in Biomedical Research: the Challenges

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Abstract

Background: *In Africa, women have had minimal participation in biomedical research especially in clinical trials despite the epidemiologic realities of the trends and burden of diseases in the continent. The purpose of this paper is to critically examine the challenges as well as suggesting ways of over-coming them in recruiting and retaining African women in biomedical research.*

Methods: *Relevant biomedical research literatures on Human Research Participants from Scirus, Pubmed and Medline computerized search were critically evaluated and highlighted. Information was also obtained from research ethics training as well as texts and journals in the medical libraries of the research ethics departments of the Universities of Pretoria, Kwazulu-Natal, Johns Hopkins Berman Institute of Bioethics Baltimore and Kennedy Institute of Bioethics Georgetown University, Washington DC.*

Results: *Studies reviewed have shown that African women have an unfair participation in biomedical research. Efforts in enrolling and retaining women in biomedical research are hampered by chain reactions of events viz: gender perception, cultural barriers, ignorance and fear of adverse event, limited autonomy to give consent, lack of confidentiality especially in sensitive trials, and improper research design.*

Conclusion: *Women need to participate in clinical trials because of their different biological and physiological make-up which require proper information about the effects of drugs on their bodies. A variety of harm may therefore ensue from failure to include adequate numbers of women in biomedical research such as exposure to ineffective treatment, occurrence of unexpected side-effects and delayed diagnosis and early treatment of disease.*

Keywords: *Biomedical research; African women; Participation; Challenges*

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Introduction

In order to conduct biomedical research in an ethically acceptable manner, the selection of participating communities and individual must be fair and justified in terms of the scientific goals of the research[1]. Social and cultural factors should be considered by the sponsors and researchers to determine the vulnerability within the community of individual who are either included or excluded. While enrolling women in some biomedical research may be acceptable in certain cases, others may be very difficult considering the gender perception in African context. In most African society, men believed that childbearing is a way of keeping women from infidelity therefore enrolling them in a research that may involve the use of condoms and contraceptive pills will be perceived as instruments to promote extramarital relationship. Such type of research in our contemporary African society will be frowned at and any woman who dared to participate may end up with serious social and communal reprisals. African women need to participate in clinical trials because of their different biological and physiological make-up which require proper information about the effects of drugs on their bodies.[2] Gender inequity in biomedical research has resulted in research outcome too small to yield meaningful information about treatment and burden of disease on different groups. Evidence has also shown that researchers' opinions and findings differed in characterizing the prevalence of some diseases such as AIDS, heart disease and lung cancer among men and women.[3]. There are also other reasons African women should be recruited in clinical trials, and they include, understanding the extent of the health problem, finding out which groups within the

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population are at highest and lowest risk, and characterizing the clinical response of drug trials in women in comparison to that of men. This in turn will assist health policy makers to evaluate the allocation of resources for more research, prevention, treatment, and support services. It therefore means that in order to conduct ethical, valid, and generalizable biomedical research, enrolling women in such research represents an important part of the study design that must be fulfilled[1]. Enrolling and retaining African women in biomedical research in general term is not as easy as in men, one must bear in mind and recognize that apart from cultural background, women expectations and requirements for participation in research may not be the same as in men[4]. In Africa, while men can make decisions freely, women may lack the decision-making freedom to participate in a research that addresses sensitive issues such as sexual behavior. Also they may be burdened with childcare, domestic work and limited mobility which often affect their full participation. The purpose of this paper is to critically examine the challenges as well as suggesting ways of over-coming them in recruiting and retaining African women in biomedical research.

Challenges in recruiting and retaining African Women in Biomedical research

For a research to involve the active participation of women, the sponsors and the researchers should take a look at the complex dynamics involved in the research process considering not only the wider socioeconomic context but also the cultural and religious meanings and practices through which the individual and group engage in health-seeking behaviour in Africa. The challenges include Gender perception, Cultural bearers, Ignorance and fear of adverse event, Informed Consent and Confidentiality among other restrictive factors.

African conception of Gender:

The African perception of gender is not entirely in the same consonance with the Western definition. In African concept, a woman is a woman as far as she has the biological features of a woman which among other things include her ability to bear children and exhibit feminine features. This is to an extent in contrast to the Western concept, which defines gender as a social construct and sex as the biological disposition of individual. Consequently, in Africa, a woman is seen as a weaker sex, whose responsibility is to bear children and take care of the home, they should therefore be protected. In most African countries they are not involved in decision-making even on matters that concerns them. This concept of "woman" in Africa and the paternalistic stance of men had led to a default position of excluding women from research but only including them when it was deemed absolutely necessary[5] It is also important to note that researchers are not exempted from this stereotype gender default position in Africa while conducting clinical research as most of their study designs and methodologies often exclude women. The various and intertwined aspects of gender roles and power dynamics included women's fulfillment of roles as mothers and caregivers are strong impediments to their full participation in clinical research[6].

Cultural Barrier:

Cultural factors that present potential barriers to women recruitment in clinical research in most African community include the importance of strong traditional family values often termed (familismo), respect toward male figures (personalismo), the role of the father (machismo), in family decision making[7,8]. The issues of *familismo*, *personalismo*, and *machismo* in family decision making are potential barriers to clinical trial recruitment involving Africa women, as they suggest the need for the assent or consent of male heads of household. A number of cultural norms relating to gender roles and power dynamics constitute a serious barrier to enrolling and retaining African women in clinical research. Most researches requiring that pregnancy and breast-feeding be avoided may place undue stress upon participants in cultures that place value on women's fertility[9]. In most African society, men believed that childbearing was a way of keeping women from infidelity therefore enrolling them in a research that may involve the use of condoms and contraceptive pills will be perceived as instruments to promote extramarital relationship. Such type of research in our contemporary African society will be frowned at and any woman who dared to participate may end up with serious social and communal castigations.

Ignorance and Fear of Adverse Events:

Apart from family and communal protection, women often expressed concerns that participating in a biomedical research might have negative side effects on their reproductive health, including difficulties in conceiving children, teratogenic effects on the fetus, infection of their breast milk, and interfering with longterm fertility. This is very important in African socio-cultural construct where barren women are more often subjected to objects of ridicule in the community while malformed babies are seen as punishment from the offended gods as a result of transgression committed by the parents of the child. Notwithstanding, women's

concerns in biomedical research participation is entirely not out of place because there may be uncertainties in the out come of some clinical trial depending on the type of study design especially where such research have not been carried out on animals as seen in the thalidomide experience[10]. In some cases the effect of the trials on the animals can not be extrapolated in humans because of diversities in physio-genetic make up of animals in comparison to that of humans.

Informed Consent:

In African countries, considering the cultural setting, informed consent may not be individually based but an issue of reaching a consensus where the family values takes precedence over individual autonomy[11]. Africa women therefore, tend to be more vulnerable because of their social status as such getting adequate informed consent from them may be difficult. Obtaining consent is a further challenge in women who lack formal education and may not understand the uncertainty that exists within the clinical trials which warrant translation to the local language they will understand[12]. In the same vein, out of the uncertainties in obtaining inform consent and the need to conduct research trials without hitches, some research designs, may abinitio exclude women from participating. Also young mothers may be more hesitant to expose themselves to various forms of risks and therefore may not willingly give their consent[13]. There could be proxy consent because of the cultural norms that men can give consent or assent on behalf of their wives which apparently result to mediated autonomy. In such situation, the woman may at some points lose the enthusiasm to continue with the research process.

Confidentiality:

It may be difficult to enroll women in clinical trials that have substantial social risks especially in an environment where ignorance and poverty is common place such as seen in Africa. For example most women may be very uncomfortable to participate in research that involves sexual behaviour such as STD or HIV especially where the research is conducted in centers that are in public view because of the risk of public exposure. This concern to public exposure is understandable especially in an environment that lacks the modern concepts and attitude towards sexual maters. Women may also be concerned about their diagnostic test being disclosed. For them, any breach of confidentiality can lead to increased discrimination and harassment. They may be subjected to violence or abandonment by their male partners or to discrimination from their employers if they are seen entering such trial centers [14].

Other Restrictive Conditions:

These include among other things the study design and methodology. A study that will warrant that participants have many times to visit the research site especially where multiple transportation is involved will have less women willing to participate. This is because they may find several visits to the research site more tasking, time consuming and waste of money considering the socioeconomic condition of most African countries.

How to Overcome the Challenges

To overcome these challenges, the key players in biomedical research must have roles to play to ensure that women are recruited and retained in clinical research. These key players include: the researchers, IRB or research ethics committee, the community and the prospective research participants in this case the woman.

Researchers

The researchers should have to put aside the gender perception of women in African construct that limit women participation in clinical trials and understand the importance of women participation in clinical trials. This will assist them in designing a study that will not only include men but also women especially in drug trials as women have peculiar physio-biological body that differs from that of men. They should also acknowledge that cultural differences in women's rights can be extreme, and that in-depth knowledge of the community, where the trial is being conducted, is imperative to understanding barriers to women participation. This will assist them in designing a research procedure that will accommodate women participants taking into consideration the cultural disposition of the community. Researchers should not only incorporate, but also advocate for the rights and protection of female trial participants especially in the communities and countries where the rights of the participants are threatened. Prior to conducting research they should determine the appropriate means to engage women in research in an environment that frowns at women participating in clinical trials. They should know that overcoming cultural barriers requires innovative strategies, best drawn from within the community and when in doubt on the methods to employ they may seek assistance from the existing human rights monitors and social support organizations in the community. To make the research site gender sensitive, researchers can also provide privacy in terms of being neither seen nor heard when for example interviews are conducted. In the same line researchers should provide convenient

location for women participants as well as a reception area and space that would be welcoming and volunteer friendly.

Institutional Review Board (IRB)

IRB should ensure that research protocol include women in a research where there is a need to evaluate gender differences to determine safety, immunogenicity, and efficacy of some drugs. Clinical research that does not include sizeable number of women capable of generating data that could give reliable and generalizable information in comparable to male participants should not be approved by IRB.

Community

The community should be reoriented to change the paternalistic perception of womanhood in African context. Community advisory committee (CAC) may be formed to establish dialogue (Dialogue ethics) to sensitize them on the need to allow women to participate in research trials. However, changing gender perception in Africa should be a gradual process and there is a need to train many people in Africa in research ethics as to assist in educating the people on detrimental effect of discouraging women to participate in clinical trials. Government and law makers in collaboration with health policy makers should also introduce a system that will empower women to be able to make their own decisions on issue that concerns them especially their health.

Women Participants

African women having been under gender intimidation by men folks for long should take there destiny into their hands and resist male dominance especially on issue that directly concern their health. But this could be done gradually by them changing their gender concept as seen in African construct so that they can confidently consent to participating in clinical researches.

Conclusion

In Africa, efforts in enrolling and retaining women in biomedical research are hampered by chain reactions of events viz: gender perception, cultural barriers, ignorance and fear of adverse event, limited autonomy to give consent, lack of confidentiality especially in sensitive trials, and improper research design. These represent serious challenges considering the fact that Africa is at present burdened with so many diseases that are of public health importance. Researchers and other key players should therefore, ensure the enrollment of women in clinical research where necessary. Since the primary aim of research is to provide scientific evidence leading to a change in health policy or standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or minority and their subpopulations differently. This will assist health policy makers to evaluate the allocation of resources for more research, prevention, treatment and provision of drugs, and support services taking cognizance of which group within the population are at lowest and highest risk

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