

EDITORIAL

The Need for Ethics Committees in Evaluating (Women's Reproductive Health) Research Protocols in African Countries

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All humans at one time or the other succumb to illness. Medical science over the years and especially in the 20th century has made significant progress in the treatment of such diseases. However, even after the discovery of a treatment for a medical condition, there is often the need to improve on its efficacy or find a more promising alternative.

When drugs are discovered to be efficacious for a medical condition, over time and with more understanding of the medical condition, there is often the need to seek more effective drugs with fewer side-effects. This is perfectly in order as it amounts to making progress in medical science. Consequently, it means that even in the 21st century medical progress relies on ongoing research on human beings. As a result, an interaction between researchers and research subjects is extremely important even where drugs and treatment already exists. And clearly, it is even more important in the discovery of treatments for hitherto unmanageable diseases. Without research subjects' participation in clinical trials, researchers cannot know the efficacy or side-effects of a new drug, both of which are essential before one can bring a drug to the market.

A scientist who believes that s/he has discovered a new drug for a medical condition would naturally want to conduct his/her trials on research subjects as soon as possible. And given that investigators are usually more knowledgeable about their research area than most of their potential research subjects, imbalances in knowledge make research subjects potentially vulnerable to exploitation and harm.

This is why it is very important to regulate the conduct of medical research in order to protect potentially vulnerable subjects from exploitation in the research context. It is for this reason that international guidelines (such as the Declaration of Helsinki) and Research Ethics Committees are put in place to protect this category of research subjects from exploitation and harm. While research subjects are reasonably well protected in developed countries after the horrors of the Nazis and Tuskegee etc., there is still concern about research subjects in developing (African) countries.

One of the cardinal problems of the conduct of medical research in African countries is the lack of Local Research Ethics Committees (LREC). This has implications for the conduct of medical research amongst subjects on that continent in general and for women's reproductive health in particular. For instance, If women do not enroll in trials in high enough numbers, medical progress on medications specifically developed for women (e.g. sexual and reproductive health) will stall. Even medication for diseases common to men and women need to be tested on women for side-effects, as their physiology differs. But the role of well trained LRECs members is central to the realization of this objective. This creates a serious concern in African countries "as ethics committees are weak and non-existent" in that continent.¹

In a study conducted in 2007, the reason advanced was that 'Research ethics committees in Africa face a number of challenges, including inadequate funding and training ...and a lack of expertise in how to consider the ethical aspects of proposed research'.² The straight forward way to address this problem is to encourage African scholars to undertake bioethics (research ethics) training, make adequate funding available for such training and the integration of research (and clinical) ethics into government health policy. But even more important is the need for the re-orientation of Nigerian physicians. Anya and Raine acknowledged this need when they stated that '...for improvements in ethical practice to become standard, a cultural shift towards acknowledgement of their importance is needed, which in turn relies upon recognition of the close relation between ethical practice in research and in clinical practice'³. In the short-term this means that there is the need to commence inhouse clinical and research ethics training workshops for senior physicians (and for other research investigators) in general and for those in the care of women in particular. They will in turn transfer such knowledge to junior doctors and those in residency. The reason for this approach is that reproductive health researchers in training would less likely treat such research

(clinical) ethics training with cynicism and as a mere burdensome process. Additionally, in the long-term, there is the need to integrate research ethics modules into undergraduate and postgraduate medical training curricula. In the research ethics context in Nigeria and in most African countries, the need for training is even more urgent as researchers need to be trained to identify specific forms (be they contextual or intrinsic) of vulnerability amongst potential research subjects in order to come up with mechanisms of protection for those populations. For instance, on the African continent, the levels of illiteracy and poverty on the continent are high. In Sub-Saharan Africa, the adult illiteracy rate is 51.30% and 74.20% for men and women respectively⁴. Members of LRECs that are well trained would recognize that most research subjects in that context do not understand the proposal being presented to them. Hence, special efforts need to be made beyond those enshrined in guidelines in securing genuine informed consent from such research populations. This is because of the peculiar challenges in conducting studies in African countries. For instance, if studies are designed to be conducted amongst African married women, members of LRECs need to understand the process of securing informed consent from them goes beyond those processes in international research guidelines (such as the Declaration of Helsinki) as applicable in Western countries. This is because amongst African married women the payment of bride-price adds another twist to securing informed consent from them in the clinical and research ethics context.⁵ Where LRECs are absent or members of LRECs are ill-trained the outcomes of medical research might be injurious rather than beneficial. In fact that was the case in the Pfizer Kano meningitis trials.

In 1996, Pfizer a big multinational pharmaceutical company conducted a meningitis study in Kano, Nigeria. According to Stephens (*Washington Post*, December 17, 2000), Pfizer tested trovafloxacin (trade name Trovan), an antibiotic, 'amid a terrible epidemic in a squalid, short-staffed medical camp lacking basic diagnostic equipment'.⁶ Macklin explains that the said trial resulted in the death of eleven children, while 200 became deaf, blind or lame as a result of the trial.⁷

A crucial question in the Kano trial is whether proper consent was given by the research subjects or by their parents. It seems not. Pfizer could not provide signed informed consent forms when the case was publicised. The implication of this is that if a well constituted LREC had reviewed the protocol, the Kano trials would not get an approval for the conduct of the study which resulted in preventable harms. This again underscores the need for well trained and well constituted LRECs in African countries.

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