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SOCIO-CULTURAL FACTORS INFLUENCING CONSENT FOR RESEARCH IN NIGERIA: LESSONS FROM PFIZER'S TROVAN CLINICAL TRIAL

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ABSTRACT:

This paper discusses the controversial Trovan study conducted by Pfizer in 1996 in Kano, Nigeria, the peculiar socio-cultural factors that researchers should consider as well as the relevance of the 2007 National Code for Health Research Ethics in enforcing researchers' compliance with ethical standards in informed consent process.

Researchers are expected to be sensitive to the many sources of exploitable vulnerability in those whose participation they invite. The failure to give attention to peculiar socio-cultural factors influencing the process of informed consent in Nigeria might have contributed to the failure of many investigators to apply and conform to related local and international research regulations

Genuine respect for human dignity requires deeper understanding of patients' values, culture, family and community. Nigeria is socio-culturally diverse in terms of language, religion, economy, and traditions. Investigators require adequate familiarity with the local socio-cultural characteristics in order to meaningfully communicate the research purpose and method upon which free and informed consent is based.

The centrality of informed consent in socio-behavioural and health related researches can not be over emphasized. Negotiating informed consent with the designated authorities in human research with non-Western populations requires investigators to move beyond narrow definitions of personhood, autonomy, and "self" determination. Without these, researchers' efforts would be mere exploitation and abuse of fellow human beings.

Background

Conducting human research within the limits of international regulations could present enormous challenges to both the investigator and participants. Features of many developing countries such as poverty, endemic diseases and illiteracy

sometimes influence the conduct of research in resource limited settings such as Nigeria. Researchers' compliance with laid-down standards in the conduct of scientific researches in developing countries calls for a critical review in the spirit of global justice, equity and non-malfeasance. The controversial Trovan study conducted by Pfizer in Nigeria is examined as a case in point in this paper.

National and international guidelines recognize informed consent as an essential requirement for ethical conduct in scientific research (Ijsselmuiden & Fadenm, 1992). There is consensus about the core components and process of informed consent (Belmont Report, 2000, Lindegger & Ritcher, 2000). Despite this, the application of the process of informed consent by some foreign and indigenous researchers in developing countries has often been alleged to contravene ethical standards and laid down regulations (Ahmad, 2001). It is imperative to stress that insufficient consideration and knowledge of peculiar socio cultural factors influencing the process of informed consent might have contributed to this. It is appropriate to consider the situation in Nigeria.

In modern times, behavioural and biomedical researchers repudiate coercion to obtain others' participation in their studies, but are expected to be sensitive to the many sources of exploitable vulnerability in those whose participation they invite (Dickens, 1999, Levine, 1986). Many researchers consciously exploit circumstances or at other times allow personal interests to override the interests of research participants. These were condemned in the days of Nuremberg, but sadly a recurring feature among many present day researchers.

A review of the context of the Pfizer's Trovan Study in Northern Nigeria

In 1996, a group of researchers from Pfizer in the United States recruited about 200 children in an effort to conduct a clinical trial of Trovan (a drug being developed for the treatment of bacterial meningitis) during an outbreak of cerebrospinal meningitis in Kano, in Northern Nigeria. Various allegations of impropriety were made (Ahmad. 2001, Stephens, 2000). About thirty Nigerian families claimed that Pfizer violated 'autonomy' and 'non-maleficence' principles (Budapest, 2001) . Among the 200 stricken children enrolled in its experiment, 5 died and 6 others suffered meningitis-related symptoms such as deafness, lameness, blindness, seizures, disorientation and, in one case, inability to walk or talk (Stephens, 2000). To many Nigerians, this raised serious questions about the safety of Trovan. Both social and clinical scientists all over the world also raised fears about the enormity of the hazards of the 1996 Kano clinical trial.

Based on Kabir Ahmad's publication in Lancet (Ahmad, 2001) and Joe Stevens' (Stephens, 2000) review of the Pfizer's Trovan study in Northern Nigeria, a variety of ethical flaws could be observed. First, the parents of the children who participated

in the trial alleged that they were not informed of the procedure or risks of the study. Pfizer officials insisted that they received verbal informed consent from the largely illiterate population.

Second, despite the availability of Chloramphenicol, the drug of choice in the treatment of bacterial meningitis, Pfizer chose to give oral Trovan during the trial instead of the intravenous injection which is the standard therapy in the United States. One-third of the recommended dose of the standard drug was given to the children in the control arm of the study suggesting a substandard practice. The study has been trailed by a myriad of other allegations, which are sub-judice in both Nigeria and United States courts.

Implications of the Pfizer's Trovan Study

History of research abuse is the history of racism, class injustice, exploitation and other forms of bias and discrimination. Genuine respect for human dignity requires deeper understanding of patients' values, culture, family and community.

The Trovan clinical trial may have created the perception in the minds of affected parents and their children that researchers do not care about safety of the research participants. This may lead to difficulties in enrolling participants in the community for genuine scientific research in the future. Unless otherwise proven, research conducted in the fashion of the Trovan study will yield scientifically un-reliable data, in addition to being unethical.

Adherence to research guidelines is a sine qua non of ethical scientific research (NCHR, 2007). Researchers in all disciplines need beyond a mastery of their research protocol. Investigators require adequate familiarity with the local socio cultural characteristics in order to meaningfully communicate the research purpose and method upon which free and informed consent is based (Christakis, 1992). In the light of the above, this paper presents a synopsis of peculiar local factors that local and foreign investigators need to consider when conducting research involving human participants in Nigeria.

Recruiting research participants: Peculiar Socio-cultural Factors to be considered in Nigeria

The ethnography of Nigeria shows that the Hausa/Fulani, the Yoruba and the Igbos make up about 70% of the 140 million population. Added to this, nine other ethnic groups: the Ijaw, Tiv, Nupe, Edo, Ibibio/Efik, Urhobo, the Kanuri, the Annang, the Gwari account for about 90% of the population (Aluko, 2000).

Nigeria is socio-culturally diverse in terms of language, religion, poverty level, value attached to children and other cultural traditions. A great percentage of the population is highly vulnerable due to structural inequalities, ethnic rivalry, poverty,

low literacy, and gender disparity (Africa Industrial Development Bank, 2007). These factors invariably impact significant influence on the conduct of human researches. Local, multi-institutional and international researchers therefore need to understand the specific characteristics and values of the setting and the people to be recruited as research participants.

The centrality of informed consent in socio-behavioural and health related researches can not be over emphasized. Even though there is consensus in the adoption of international regulations guiding research among nations, each society has its distinctive socio-cultural features which influence attitude to research and unfamiliar intervention procedures. Efforts by investigators to understand these peculiar socio-cultural factors in a non-familiar research setting could influence the development of research protocol and process by which informed consent is obtained. This becomes a pre-requisite for incorporating bioethical principles in the informed consent process in order to guarantee understanding, voluntariness, and authorization (Beauchamp & Childress, 2001). Research in Nigeria is no doubt influenced by these factors.

Most western bioethical principles do not fit into Nigerian culture without first being filtered. This does not mean that sub-standards are acceptable, but rather a careful blending of the set standards in international research with the socio-cultural values of the study population is required.

Some of the greatest challenges of researchers in Nigeria include the development of an effective mechanism for informing participants about the purpose, methods, risks and benefits of research. Without adequate caution, consent forms may appear too technical, lengthy, or difficult to understand. Because of the widespread low literacy level, especially in rural areas, risks and benefits are often unclear or misconstrued. However, this does not imply low intelligence.

Many research and western terminologies do not have perfect translations in local Nigerian languages. Similarly, many western terms are also not freely used in local conversations because of cultural taboos. For instance, among the Yorubas of South-western Nigeria, it is often resented to use certain words such as sexual intercourse among the young and unmarried persons without caution. In traditional Yoruba language such terms as "sleep together" are used in place of sexual intercourse, which in back-translation does not precisely mean sexual intercourse. The meaning of most scientific terms and chemical names are often lost in interpretations. Even common words such as snow are abstract, as it is not a feature of tropical climates such as Nigeria. Interpreting a consent form and research protocol therefore demands a more rigorous re-validation of participants' understanding of the information to ensure comprehension. A unique feature of Nigeria is the

universality of a local (adulterated) variety of English language popularly called "pidgin English" which serves as a universal language among various strata of the society.

Obtaining informed consent in Nigeria for international and multi-institutional scientific researches presents peculiar demands. Different settings present different traditional institutional challenges. In the north, the line of authority in community research differs in nomenclature and hierarchical arrangement compared to other regions in Nigeria. First, beyond obtaining the host country's ethics committee approval, foreign researchers will need to obtain approval in line with the national health research ethics committee in Nigeria (NCHR, 2007). In practice, for research participants to be recruited for community based researches, the "emir", who is the paramount ruler and the feudal lord, need to be consulted. He in turn consults the village heads, or the local chiefs, who in turn consult compound heads and family heads. The family head is the contact person of the household.

Ityavyar earlier observed that in a male dominated society such as in northern Nigeria, women often need to obtain their spouse's permission before participating in research. It is a taboo for a woman not to be under the control of a husband. In this society, the husband is the head of the woman. Among the Hausas of northern Nigeria, there is the saying "miji sine kai na mata na shi" meaning that the husband is the head of the woman. Similarly, members in many rural communities are subject to the control of the "emir" or the traditional ruler: The "emir" being literally unquestionable influences community decision making including community participation in research (Ityavyar,1985). As a result, a prospective research participant irrespective of the gender may be less resistant to the view of the local community where the community does not support a research. Those that jettison community's opinion are often labelled as deviants (National Bioethics Advisory Commission, 2001) with possible sanctions. Similarly, communality and attachment to the extended family system is very typical of rural communities in Nigeria (Marshall, 2001) where about three-quarter of Nigerians live! However, with increasing awareness, cultural diffusion and urbanisation individuals are becoming more assertive on issues concerning health and autonomous choices.

As a result of poverty or corruption, some people could give consent to a clinical investigation exclusively for momentary financial reward, even when they are not clear about the purpose of the study. On the other hand, the offer of excessive financial compensation, bribes, un-realistic promises may constitute coercion, especially if the participant is vulnerable because of social factors such as poverty or low social status (Marshall, 2001). Researchers need to be conscious of participants' ulterior motives, making deliberate efforts to ensure that participants' consent is based on informed, understood and autonomous decisions and not on

undue influence. It is the ethical responsibility of researchers to guide against participants' offer of participation in research based on perceived inherent financial gains. Besides, significant variations exist in the three main regions of the north, south east and south western Nigeria.

The relevance of the Nigeria National Code for Health Research Ethics

All the existing international regulations such as the Nuremberg code, Helsinki Declaration, Council for International Organisations of Medical Sciences (CIOMS) guidelines (Nuremberg Code, 1949, World Medical Association, 2000, CIOMS, 2002) etc are operational in the conduct of research on human participants in Nigeria. The development of the National Code for Health Research Ethics in 2007 forms the highpoint of regulation of human researches in the country (NCHR, 2007). The significance of the document is two-fold. It specifies requirements for obtaining informed consent for researches in Nigeria. Additionally, the document is legally enforceable compared to the mere advisory nature of other research regulations. Foreign researchers as well as their Nigerian collaborators are expected to seek approval from local research ethics committees at the institution overseeing researches in the study-setting (e.g., universities, hospitals or research institutions). The National Agency for Drugs Administration and Control (NAFDAC) and professional organisations also have additional guidelines for local and international research studies especially where more than minimal risks are involved. The variations in the constitution and implementation of the process for ethical review between institutions in Nigeria (Marshall, 2001) is therefore expected to stop forthwith.

The Moral Question

The history of vulnerability and exploitation in research pre-dates this generation. The abuses that necessitated drafting of the Nuremberg Code exploited the complete powerlessness of inmates of concentration camps and of marginalised minority and disabled populations living under fiercely repressive military regimes that considered them a sub-human species, and were committed to their eradication. The Pfizer's Trovan study in Nigeria might not have been driven by the above scenario. However, it is critical to investigate the possibility of scientific curiosity within the purview of racial disrespect for Nigerian children.

Negotiating informed consent with the designated authorities in health research with non-Western populations requires investigators to move beyond narrow definitions of personhood, autonomy, and "self" determination. A number of scholars (Angell, 1998 Newton, 1990) have noted that the application of Western ethical standards to scientific research conducted in developing countries with divergent cultural norms may be construed as a form of ethical imperialism (Marshall, 2001). Communication between health researchers and potential subjects may be difficult

to achieve when the relationship extends across cultural boundaries. Misunderstandings and miscommunication about scientific research are more likely to occur when patients and practitioners speak different languages.

International ethics demand equality among nations of the world, and also between people across lands irrespective of colour, wealth or other considerations. The concept of dichotomising the peoples into developed and developing based on per capital income and gross domestic product is suspect. It is suspect in that the poverty in the so-called third world is an indirect product of Western imperialism and neo-colonialism. This attitude of perceived superiority unconsciously drive many so-called "first-world" investigators in researcher-participant relationship, which often leads to subtle compromise of international regulations guiding foreign behavioural and biomedical researches. This raises a moral question.

Reflecting on Pfizer's Trovan Study with Research Ethics Lenses

The Pfizer's study presents a typical case of exploitation of research participants where the socio-cultural weaknesses of potential research participants were used to the researchers' advantage. In agreement with the view of Solomon Benatar, it is widely recognized (although perhaps less openly acknowledged) that research, even under the best of circumstances, is potentially exploitative. Because "powerful researchers (individuals and corporations) usually have more to gain than any single research participant, much effort over recent decades has gone into designing protection for research subjects (Benatar,1998). Even where adequate protection is provided in protocols, some researchers often do not strictly follow their protocols as approved by ethics committees. There is always a gap between concern expressed for the well being of distant others and its translation into practice (Benatar, 1998).

It is now widely accepted that any type of study involving humans must be carefully designed and monitored to protect the physical and psychological well- being of the participants. In addition to obtaining informed consent from each participant, scientists are required to monitor study participants closely, and have strict procedures for reporting any adverse experiences, be it physical or psychological. Also, additional safeguards are needed to protect vulnerable populations, such as children, prisoners, and people with limited education or mental capacity (Devlin, 2001).

In the light of the foregoing, Pfizer scientists are yet to publicly accept any blame in the Trovan clinical experiment. It would be recalled that Stanley Milgram also vehemently denied that his subjects suffered any lasting arm from his test of obedience to authority in the famous Milgram experiment (Milgram, 1963). If the local ethical review board in Kano, Nigeria had done a sufficiently thorough review, the study would not have been approved in the form in which it was eventually

conducted (Stephens, 2000). The activity of an inefficient local review board coul be likened to authorizing a drunken pilot to fly a faulty passenger aircraft across th Atlantic.

Conclusion

In international settings, particularly in resource poor nations, individuals an communities involved in public health studies may be vulnerable to coercion becaus of their poverty and high levels of illiteracy. Whether research conducted i developing countries should be held to different standards from those applied i the developed countries is a subject of intense debate (Angell,1997).

In Nigeria, factors such as gross differences in cultural norms and tradition influenc research processes in both local and international research endeavours. Researchers' compliance with the Nigeria National Code for Health Research Ethics is a sure antidote to the ethical flaws identified in Pfizer's Trovan study. Local or foreign research could be valuable to participants and society, and no ethical standards of either the host or foreign countries should be compromised. These standards must be strictly adhered to when conducting research in developing countries, irrespective of participants' race, socioeconomic status, or religion.

An important component of research is informed consent, and adequate stress should be placed on it. Irrespective of the location, respect for the research participant is paramount, and is reflected in part through the quality of informed consent. Researchers need to be patient, meticulous and innovative to make sure that informed consent is truly voluntary, and there is adequate understanding of the process among the participants. Above all, both local and international researchers have a moral responsibility of sincerity and integrity. Without these, their efforts would be mere exploitation!

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