

Ethical issues arising in research with people with mental health conditions

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Governance paper: Governance in bioethics and mental health research in Nigeria: are we there yet?

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Introduction

Existing evidence show that over 80% of people who live with mental health problems worldwide reside in low- and middle-income countries (LMICs).¹ Despite this, there is a dearth of research which should guide appropriate interventions and strategies in these parts.² Poor research governance has been postulated as a plausible explanation for this gap in LMICs.^{1,3,4} An example is Nigeria, a West African country where mental health research is not regulated through a clearly defined legislation.⁵

Commentary

This paper provides an overview of governance in health research and aims to highlight areas of improvement in governance and ethics in mental health research in Nigeria. The UNESCO defines governance as the structures and processes that are designed to ensure accountability, transparency, responsiveness, rule of law, stability, equity and inclusiveness, empowerment, and broad-based participation.⁶ Good governance in health research can dissuade poor ethical practices, enhance standards in research and ensure that integrity and ethics are upheld. Conversely, poor governance results in subpar research with possible untoward consequences on participants, stakeholders, and the larger society. The role of good governance in promoting ethics and excellent research is vital and galvanizes optimistic outlook for interventions, enactment and the implementation of policy, and programs.⁷

Before 2006, Nigeria had no codes, laws, or regulation of research conducted within its borders.^{8,9} The National Health Research Ethics committee of Nigeria (NHREC) was inaugurated in 2005 and it is the national body responsible for enacting the standard and norms for research on human and animal subjects.¹⁰ The NHREC governs ethical issues on research at both state and national levels, in addition to the registration and auditing of institutional health research ethics committees. In 2006, the NHREC developed the National Code of Health Research Ethics.⁹ A review of current research ethics codes such as the revised Helsinki Declaration¹¹, CIOMS¹², the CFR 45 Part 46⁸, ethics guidelines from India (ICMR)¹³, and South Africa¹⁴ using the Delphi approach and the Nigerian constitution and other relevant laws were also considered.¹⁰

Health research in Nigeria has evolved from a largely unsupervised activity carried out by individuals to a practice regulated by recognized institutions governed by established codes and laws. It has over 43 registered Health Research Ethics Committees (HREC) across the country and is speculated that there may be more of these ethics committees considering the poor coordination and monitoring of their activities in the country.¹⁵ However, governance in mental health research and ethics in Nigeria lag in comparison with international recognized standards. Factors identified as roadblocks to good governance of mental health research in Nigeria include the mode of selection and qualifications of committee members, inadequate knowledge of their tasks, deficient research infrastructure, research-policy dissonance, lack of regular and proper monitoring of approved research protocols and poor funding.^{3,16,17} In LMICs, a great number of mental health investigators pay out of pocket to fund their researches.^{18,19} Other factors include inadequate training in research methodology, insufficient

number of mental health researchers, and a general apathy towards mental health conditions and inappropriate protection for participants and researchers.^{20,21}

Nigeria does not have a mental health law despite over 20-30% of its population living with mental health problems.²² Nigeria currently operates the lunacy act of 1958, an adapted version of the 1916 ordinance which was inherited from the colonial masters.²² This act does not recognize concepts such as research and fundamental human rights and uses pejorative terms such as lunacy and insanity and criminalizes suicide. Presently, Nigeria has on paper a policy that lacks implementation.²³ Several attempts are being made by key stakeholders for the enactment of a mental health law however, this remains a mirage. As a result, individuals with mental health problems are often routinely excluded from etiological and intervention studies on account of lack of “decision-making capacity”.²⁴ Considering that capacity can be time and event specific²⁵, it is argued that denying people with mental illness of making such decisions or the exclusion is a violation of their rights.²⁶ In the absence of a mental health law which safeguards the patient and researcher, protection by exclusion may be a safer alternative which exempts this subset of people from research. Although logical, it invalidates the generalization of research findings if the mentally ill population are under-represented. Similarly, is the evaluation of the effectiveness of their medications when they have been excluded from research that pertains to them.²⁷ It is a paradox then, that individuals with severe forms of mental health problems are relegated to receiving treatments for which there is only inferential evidence of efficacy from inadequate research.²⁸

The tenets of medical practice necessitate conducting research in accordance with the four ethical principles autonomy, beneficence, non-maleficence, and justice, viz a viz equality, respect for fundamental human rights and inclusion. Therefore, the exclusion of some participants perceived to lack decisional capacity such as dementia, schizophrenia, or chronic delirium from research represents a breach in ethical values and principle. Phrases such as “the exclusion criteria include individuals with cognitive impairment, dementia, frank psychosis or obvious debilitating illness” used by some researchers, inadvertently perpetuate this breach. This worsens the stigma associated with mental illness, decreases social opportunities and the possibilities of appropriate interventions. Unjustified exclusion from research has been described as a form of discrimination, notwithstanding how germane the reason may be by the American Psychiatric Association.²⁸

The practice of maintaining ethical values and principles in mental health research is a challenging one considering the uniqueness and intricacies of mental disorders. In some parts of the world, an advance directive or lasting power of attorney may be utilized to navigate the challenges of participants lacking capacity,^{24,29} which has been argued as the central component of a legally valid consent form³⁰. Conversely, the cultural practices, and belief system in Nigeria may interfere with the smooth adoption of this practice even among the enlightened. Likewise, the practice of the justice system to appoint a surrogate decision maker is still relatively alien to our practice in Nigeria particularly in the context of research. Rarely do researchers in Nigeria conduct studies on patients who lack capacity as this requires third party consent. The onus rest on clinicians and mental health researchers to maintain integrity and uphold guiding ethical principles. Circumventing these will only lead to disastrous consequences and repeating the mistakes of the past.

Conclusion and recommendations

To produce culturally sensitive yet quality research in mental health, there must be changes in the existing paradigm and practices, likewise, the enactment of legislation which protects participants and researchers. Increased advocacy and public enlightenment campaigns through various media platforms to promote mental health generally. Multisectoral collaborations with key stakeholders such as community leaders, religious leaders, service users, caregivers, healthcare providers, civil societies, and law makers at all stages of governance from the grassroots up to the highest level of government. Additionally, collaborative, and inclusive research in mental health which focuses on the subset of participants presumed to/ who lack capacity thereby producing excellent quality and

evidence-based research. Encouraging partnership with recognized associations and civil societies involved in mental health with both local and international influence. Consequently, the establishment of a reformed mental health law that is culturally sensitive yet takes into cognizance international and human rights standards approved by the International Covenant on Economic, Social and Cultural Rights and the African Charter on Human and Peoples' Rights. Culminating in improved and ethically balanced mental health research with increased benefits to the global community.

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