## Ethical issues arising in research with people with mental health conditions

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# Governance paper: Strengthening research capacity in mental health research in low- and middle- income countries

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*This paper makes note of gaps and gives recommendations on the Mental Health Policy in Kenya, which are relevant to policies in other low- and middle- income countries.*

**Introduction**

The World Health Organization (WHO) estimates that 10% of the world population is suffering from some mental illness and 25% of people experience some mental illness during their lifetime. The stigma of mental illness in Kenya and by extension in Africa has caused many people to suffer in silence. In Africa mental issues are attributed to either witchcraft or spiritual problems. The continued suffering and disability due to mental illness calls for newer treatments and continued research in the field of psychiatry (Nyawira, 2015).

The Kenya Mental Health Policy 2015-2030 provides a framework of interventions that seek to address the systemic challenges, emerging trends and mitigate the burden of mental health problems and disorders. Although many of the issues confronting clinical trialists working in resource-limited settings are similar in most low- and middle- income countries (LMICs), the human and other resource capacity of developing countries lags far behind those of higher income countries (Lang TA, et al. 2010), affecting how research for mental health is conducted, resulting in a situation where the care given to persons with mental conditions in a research setting is poorer than for other populations.

This paper discusses ethical challenges to conducting mental health research in LMICs, with a focus on Kenya's Mental Health Policy 2015-2030 and puts forward possible solutions. It will highlight gaps in the policy in key areas that greatly affect the conduct of research in relation to wider ethical standards of research practice which include the lack of research capacity of researchers to fully and adequately handle persons with mental illness during the conduct of a research.

**Gaps in the mental health policy**

Government statistics indicate that at least one in every four Kenyans suffers from a mental illness at one point in their lives, this is about 11.5 million people. However, as Dr. Kamau (2011) stated, Kenya has only 88 psychiatrists, 427 psychiatrist nurses who are trained to handle mental illness, about 10 medical social workers and a few mental psychologists and counselors who are competent to handle mental issues, budgetary allocation for mental health is only 0.5% of health budget thus leaving the mental equation completely overstretched. He further notes that psychiatrists are very few, and support professionals like psychologists and counselors are equally very few who are skilled and trained in mental health. It is a universal held principle that psychologists and counselors are management pillars of mental health.

Despite the Health Policy promoting the conduct of scientific mental health research, and in accordance with international health legislations, it does not specifically address ethical issues concerning mental health research conduct or the ethical training of staff conducting such research. It is silent on health research conduct in mental health research. Therefore resulting in only a few

regulations to protect the human subjects with mental health illness from exploitation, which are either too broadly or too narrowly applied/implemented by researchers. Further, Kenya, which has a population estimated at 53,771,296 people in 2020 according to UN data, equivalent to 0.69% of the total world population is rapidly attracting human research. The concern here is that research in developing countries, such as Kenya, with lack of sufficient ethical guidelines in context of mental health research conduct will further lead to exploitation.

Research capacity building is defined as the ability to conduct, manage, disseminate, and apply research in policy and practice (Thornicroft, et al 2012). The lack of sufficiently trained and experienced local researchers carries ethical implications when research is conducted by those without sufficient expertise to maintain ethical research standards (Goodhand, 2000).

**Ethical issues in mental health research**

Demyttenaere et al (2004), notes that despite the high prevalence of mental disorders in LMICs, international health surveys show that only 80% of those with serious mental disorders receive any treatment. To address this gap, meaningful research is required to advance the health of people with mental health conditions. Research is the key to preventing and effectively treating mental illness. Yet even as research holds out promise, mental health researchers face numerous ethical challenges. Technical and research capacity and lack thereof is the greatest challenge. All research involving human subjects should be conducted in accordance with four basic ethical principles, namely respect for persons, beneficence, non-maleficence, and justice (Beauchamp & Childress, 1989).

There is also the possibility of at times research staff nature and attitude may sometimes be incongruent with the ethics in research (Research GFfH, 2000). It is usually assumed that these principles guide the conscientious conduct of health research. However, many African countries have critically low densities of physicians and skilled healthcare workers. Despite 25% of the global burden of disease, sub-Saharan Africa has <1% of global financial health resources and 3% of the global health workforce (Anyangwe & Mtonga, 2007). Yet, qualified personnel are needed to propose, initiate and implement clinical trials. Such human resource development requires relatively stable, well-resourced research and higher education institutes, and well established science governance systems, which is not the case in developing countries as noted in a study conducted by the Global Forum for Health Research (2000), adding that medical schools and teaching hospitals in LMIC have poorly prepared their graduates to conduct scientific trials and clinical research.

This means that most of the researchers have not received training on how to adequately handle persons with mental health illness and therefore how to ethically conduct trials. These issues are related to informed consent, respect for anonymity and confidentiality, conflict of interest, therapeutic misconception, placebo related, vulnerability, Beneficence - do not harm, Respect for privacy exploitation, operational challenges, among others.

**Recommendation**

Continued research is essential to improve knowledge and practice of science. Ethics is at the heart of any research which balances rights of participant in keeping up with interest of research. Unethical medical research has grown over decades. This poses increased risk to persons with mental illness. Mental health research has several specific issues which need to be taken care of and researchers need to be trained specifically for these issues. Managing ethical issues in health research, as with all human subjects' research, must be ethical and maintain high standards of researcher integrity. Consequently, there is a need to confront the ethical challenges inherent to conducting mental health research. Strengthening capacity building would also need to extend beyond the trained medical personnel conducting research to all staff involved in the research.

I recommend that the mental health policy should be based on principles of responsibility, competence, benevolence, moral standard, patient welfare, and confidentiality. Despite the existing resource

challenges, LMICs can mitigate the capacity gap through continuous training, short courses and an effective management policy. Ethical research committees should be cognizant of importance on this aspect in relation to the research staff. Investment in capacity building with supportive supervision should be established for all personnel. The recently launched mental health policy could incorporate the integration of ethical training in mental health care in collaboration with the ministry of health on health research and robust regulation on research ethics.

The policy would benefit from a report of the American Psychiatric Association's task force on research ethics, which addresses ethical issues related to the conduct of research involving human participants with mental illness (Psychiatric Services 57:552–557, 2006). The report recommends Investigators should receive education in research ethics that addresses rules and norms governing research; sensitivity to ethical implications of decisions and actions; and skills in ethical problem solving, including ascertainment and disclosure of conflicts of interest. Ethical research design must ensure that a study has scientific merit, methods used should yield knowledge of value, and procedures must minimize risks to participants and optimize benefits.

**Conclusion**

Considering various issues involved in mental health research, ethics plays a crucial role in protecting rights of persons with mental illness and simultaneously safeguarding the interest of researchers. Ethical guidelines in research help maintain transparency and accountability during research. Therefore, it is paramount that ethical guidelines be applied to mental health research capacity at every level: individual, organizational and national. The benefits of building this capacity will ensure that the human rights of persons with mental illness are not violated, thereby reducing stigmatization and discrimination.

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