Ethical issues arising in research with people with mental health conditions

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Governance paper
Scoping review of ethics regulations for research on cognitively impaired adults in Sub-Saharan Africa

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Background
Studies have shown that there is a complex relationship between mental health problems and dementia, with conditions like depression, anxiety and schizophrenia being shown to increase the risk of dementia incidence.[1,2] In addition, symptoms typical of dementia such as cognitive dysfunction, apathy, deficits in attention, deficits in executive functions, and social reasoning are also common symptoms seen in some mental health illnesses such as schizophrenia, depression, and bipolar disorders.[3–5]

The conduct of research to better understand the complex relationship between mental health and dementias is important to the control of both mental health illness and dementias. Because people with mental health illness and dementia are likely to have impaired cognition, a situation that may affect their ethical inclusion in research, guidelines that ensure the ethical inclusion of persons with these conditions are important.

Peer reviewed literature on regulations from African countries for the ethical conduct of research involving persons with cognitive impairment, such as persons with mental health conditions and dementia, is scarce. We conducted a review of existing guidelines, legislations and policy documents to examine provisions for the ethical inclusion of persons with cognitive impairment in research in African countries using the OHRPs International Compilation of Human Research Standards.

Methods
We extracted and grouped the documents into three categories: 1) North America and Europe; 2) Asia/Pacific and Middle East/North Africa; and 3) Latin America and The Caribbean and Africa. Using a common template, three researchers retrieved the documents from each of the countries in each of these three categories and extracted texts that addressed ethics of inclusion of persons with cognitive impairment in research. We also sourced secondary guidelines identified in the process of the review of those provided in the OHPR compilation. We used a deductive approach from existing literature to search for key terms in the documents. Key terms used to search the documents were cognitive impairment, dementia, Alzheimer's disease, consent, informed consent, proxy consent, surrogate consent, and advance directives. We only included information from documents written in or with English translations.

Results and discussion
Guidelines from a total of 26 African countries were included in the 2019 version of the OHRPs compilation. Of the 26 African countries only documents from 13 countries were included in our review. The others were excluded because they were not written in English, we could not assess their English

translated versions, the links for the relevant documents were no longer functioning (e.g. Australia and Cameroon), or the documents assessed did not discourse ethical issues in involving persons with mental, cognitive, legal disability or dementia or Alzheimer's disease.

The documents were mostly guidelines (11 countries), with a few regulations/legislations (2 countries). We grouped our analysis into two broad areas - controlling instruments and empowering instruments. The former are instruments that stipulate what should be fulfilled before including persons with cognitive impairment in studies – actions from other than the participant. While empowering instruments recognize and seek to uphold the rights of the research participant to self-determination to the extent possible.

Documents from all 13 countries, except Uganda mostly contained provisions that were of the 'controlling' type. All country documents except those from Botswana, Ghana and Zimbabwe, provided conditions under which participation of persons with cognitive impairment is permissible. For example "*The Authority shall not consent to health research…where—.....(a) the objectives of the health research or experimentation may also be achieved if conducted on the general population; (b) the health research or experimentation is not likely to significantly improve scientific understanding of the special group's condition, disease or disorder to such an extent as shall result in significant benefit to their health or well being; (c) the reasons for the consent to the health research or experimentation are contrary to social norms and public policy; (d) the health research or experimentation poses a significant risk to the health of the special group under consideration; or (e) there is some risk to the health or well being of the special group and the potential benefit of the health research or experimentation shall not significantly outweigh that risk. [The National Health Research Act, 2013, Zambia*]. Proxy or surrogate consent is only provided for, where the participant is deemed to lack capacity to consent. All country documents, except Ethiopia, Uganda and Zambia required the consent of a legally authorized representative (LAR)/guardian only, as the person to provide the surrogate or proxy consent. Some countries however provided some guidance on who qualifies as LAR: Kenya (other appropriate representatives), Malawi (parents or legal guardians), Sierra Leone (responsible family member or LAR), South Africa (legally appropriate person: spouse or partner; parent; grandparent; adult child; brother or sister, according to the National Health Act 2002).

Empowering instruments/provisions in the documents reviewed include provisions that required research participants to pay attention to consent or assent by the research participant where possible, recognition of advance consent or advance directive as a means of respecting the participant's wishes in addition to proxy consent and respecting refusal by research participants. Ethiopia, Ghana, Kenya, Uganda and Zimbabwe did not have any provisions regarding consent/assent by the participant. Only Liberia and South Africa had provisions recognizing advance consent or advance directive. In addition, only Sierra Leone and South Africa had provisions recognizing and upholding the participant's refusal to participate as being superior to any proxy consent.

The preponderance of 'controlling' rather than 'empowering' instruments may be a general reflection of the state of development of the laws and regulations regarding human research participants and indeed care considerations for the mentally ill and persons with cognitive impairment. For example, out of all the documents reviewed, only South Africa had a Mental Health Law and that captured some of the stipulations guiding research involving persons with mental disability. Further, Nigeria is yet to enact a 'modern' mental health law despite ongoing efforts dating back to 2003.[6]

Conclusion

This review was limited by our review of documents written in English or with English translated versions, and to documents that were accessible online. However, it provides a useful documentation of the provisions for the protection of persons with cognitive impairment due to ill mental health and other related conditions such as dementia and Alzheimer's disease. The absence of provisions for the use of advance directive is perhaps a reflection of the prevailing practices in African countries as it

relates to similar issues as making of wills. There is a need to explore in-depth legal provisions for advance directives in African countries, the practical applications of the legally authorized representative provisions as stipulated in the guidelines reviewed, as well as the issue of respect for participant dissent, either verbally or behaviorally.

References

1. da Silva, J., Gonçalves-Pereira, M., Xavier, M. & Mukaetova-Ladinska, E. B. Affective disorders and risk of developing dementia: systematic review. *Br. J. Psychiatry* **202**, 177–186 (2013).
2. Zilkens, R. R., Bruce, D. G., Duke, J., Spilsbury, K. & Semmens, J. B. Severe psychiatric disorders in mid-life and risk of dementia in late- life (age 65-84 years): a population based case-control study. *Curr. Alzheimer Res.* **11**, 681–693 (2014).
3. Millan, M. J. *et al.* Cognitive dysfunction in psychiatric disorders: characteristics, causes and the quest for improved therapy. *Nat. Rev. Drug Discov.* **11**, 141–168 (2012).
4. Banks, S. J. *et al.* The Alzheimer's disease cooperative study prevention instrument project: longitudinal outcome of behavioral measures as predictors of cognitive decline. *Dement. Geriatr. Cogn. Dis. Extra* **4**, 509–516 (2014).
5. Cooper, C., Sommerlad, A., Lyketsos, C. G. & Livingston, G. Modifiable predictors of dementia in mild cognitive impairment: a systematic review and meta-analysis. *Am. J. Psychiatry* **172**, 323–334 (2015).
6. Ugochukwu, O. *et al.* The time is now: reforming Nigeria's outdated mental health laws. *Lancet Glob Health* **8**, e989–e990 (2020).

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