

Guidelines for the ethical review of mental health research protocols from a culturally-sensitive perspective

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Abstract

Background: In most of Africa, mental illness is considered a silent epidemic due to structural and systemic barriers such as inadequate health care infrastructure, insufficient number of mental health specialists, stigma and discrimination related to mental illness, and lack of access to all levels of care. The continued suffering and disability due to mental illness calls for newer treatments and continued research into the field of mental health treatment and therapy. Research ethics committees are cognizant of the importance of this aspect yet, the road to this innovative future is fraught with ethical dilemmas as well as ethical, legal, and

social implications. There is an urgent need to have guidelines that give guidance to research ethics involving mental health participants.

Methods: Guidelines were developed for the ethical review of mental health research protocols with the aim of increasing health equity and access in Africa and other low-income countries. We systematically analyzed 13 programme, research, and policy evaluation tools in light of mental health and cultural attributes.

Results: A 54-item assessment tool was created to guide the process of mental health research protocol evaluation taking into account ethical, gender, and sociocultural factors in Africa.

Conclusions: The emerging themes i.e. research governance, background and justification, methodology and ethical impact of the research forming the basis of the assessment tool are interlinked with the bioethical principles of respect for autonomy, beneficence, non-maleficence and justice. When they are applied to the evaluation of a study they will not only underscore these principles, they enhance their application and increase access to equitable health in Africa and other low-resource settings regardless of the varied contexts.

Keywords: Bioethics, Mental health, Research ethics, Ethics review; gender

Introduction

Ethics involves a set of principles – the four principles of Beauchamp and Childress i.e. autonomy, non-maleficence, beneficence and justice. (Beauchamp & Childress, 2001). These principles have been extremely influential in the field of medical ethics, widely used frameworks offering a broad consideration of medical ethics issues generally, not just for use in a clinical setting

and are fundamental for understanding the current approach to ethical assessment in health care. These principles were argued to be mid-level principles mediating between high-level moral theory and low-level common morality (Holm, 2002). In as much as these approaches do not necessarily solve problems, they provide a basis for resolving ethical dilemmas in different common themes. However, some of the ethical issues for African psychiatry and psychosocial

health are different from those in developed nations, therefore necessitating an approach that is adaptive or considerate of the sociocultural, political, and economic context of Africa and other low income countries.

The importance of research ethics was acknowledged and underscored in response to the atrocities committed during and after World War II. This was especially because of the inhumane medical experimentations undertaken in Germany during the Nazi era (Hazelgrove, 2002). This led to the emergence of different codes of ethics over the years starting with the Nuremberg Code (1947), the World Medical Association's Declarations of Geneva (1948), and the Helsinki Declaration (1964) among others. These form the ethical foundations of biomedical research (Israel & Hay, 2006). Research ethics would be brought to the fore in later years as a result of ethical violations and questionable research practices from studies such as the Tuskegee Syphilis Study, (Brandt, 1978) the Stanford Prison Experiment (Zimbardo, 1973) and the Tearoom Trade study. (Holden, 1979; Lenza, 2004). The Belmont Report, drafted in 1978, highlighted the three fundamental principles of respect, justice and beneficence that

guide research involving human participants until today (Sales, & Folkman, 2000).

The application of these principles has primarily focused on protecting the well-being of study participants. The main ethical concerns being the informed consent process, anonymity and confidentiality concerns, as well as the potential exploitation or coercion of study participants (American Psychological Association, 2000; Flicker, 2007; ChiseriStrater). Mental health research conducted in low and middle-income countries (LMICs), is gaining prominence impelled by the 'evidence revolution' that cuts across disciplines and that is linked to the rise of impact evaluations (ChiseriStrater; Schroeder et al, 2019).

Research on mental health is scarce in Africa and other developing regions, with the ones being conducted encountering a myriad of ethical concerns. Research conducted by Abuhammad & Dalky (2019) confirmed that stigma associated with mental illness has many ethical implications in the context of research including the use of consent forms, fair treatment, and respect for individual rights concerning treatment choices.

Ethical discourse in mental health treatment has typically focused on paradigmatic

concepts of individual autonomy, competence, paternalism, and appropriate justifications for overriding individual decision-making and restricting individual liberty. However, ethical challenges in mental health research are predominant especially in Africa, leading to a reduction in equitable access to health.

While the quest for more evidence may be justified by the ultimate goal to improve the living conditions of research subjects, research in Africa often takes place in settings marked by extreme poverty, socio-cultural and religious disparities, political instability and in some cases the inclusion of highly vulnerable study participants (Kaplan et al, 2020; Casale et al, 2011), Thus creating more pronounced ethical complexities concerning research projects in these contexts.

There remains a large disparity in the quantity, quality and impact of mental health research carried out in LMICs, relative to both the burden and the amount of research carried out in other regions (Schneider et al. 2016).

Epidemiology

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. In most of Africa, mental illness is considered a silent epidemic due to structural and systemic barriers such as inadequate health care infrastructure, an insufficient number of mental health specialists, and a lack of access to all levels of care, (Collins et al., 2011; Becker & Kleinman, 2013). Mental illness has been characterized as a neglected and increasingly burdensome problem affecting all segments of the population throughout Africa. Prioritizing mental health has also been difficult due to lack of resources, limited funding and no or ineffective mental health policies. Some challenges are related to the economic and development inequalities that are common to low and middle-income countries, while others are more specific to the social and cultural contexts in Africa (Monteiro, 2015).

The stigma of mental illness in Africa has caused many people to suffer in silence. In some contexts, across Africa, many mental issues could be attributed to either witchcraft or spiritual problems, thus rendering access to mental and psychosocial health support difficult or unattainable. Mental illness is a general term describing a range of disorders that affect thinking, behaviour and mood. Mental disorder is a more specific term that

describes a condition characterized by clinically significant disruption in various aspects of mental functioning (American Psychiatric Association, 2013). The continued suffering and disability due to mental illness calls for newer treatments and continued research into the field of mental health treatment and therapy. Ethical research committees are cognizant of the importance of this aspect yet, the road to this innovative future is fraught with ethical dilemmas as well as ethical, legal, and social implications (ELSI).

Justification

This brings to the fore the urgent need to have guidelines for the evaluation of mental health research from a culturally congruent perspective. This is expected to ensure that the research team is competent, the ethical research design has scientific merit, the methods used yield knowledge of value, and procedures to minimize risks to participants while optimizing benefits, all while taking into account the various sociocultural nuances and health inequities in the context of the study. In this regard, ethics plays a crucial role in protecting the rights of persons with mental illness and simultaneously safeguards the interest of researchers. Therefore, it is paramount that ethical guidelines be applied to mental health

research capacity at every level: individual, organizational and national as they help maintain transparency and accountability. There exist assessment guidelines for reviewing research protocols/proposals including from a gender and socioculturally sensitive perspective, however, these guidelines often do not take into account the specificities of mental health research, particularly in the African continent.

Ethical challenges experienced in mental health research

Research plays a crucial role in shaping health policy and decision-making. The benefits that the research brings however come at the expense of the research participants whose contributions can be undermined during the research process. Ethical issues often surround health research and are of special concern when vulnerable populations like those with mental health problems are involved. (Slowther, et al, 2006.)

Research in mental health like any other research should follow ethical principles and should be guided by national ethical guidelines. Ethical challenges in Psychiatric/mental health research are usually related to study design, the autonomy of the research participants, justice,

beneficence and non-maleficence, respect for the environment and consent taking process (Chiumento, A., et al., 2016; Siriwardhana, C., et al., 2013). Respecting the human rights of those with mental health problems is necessary during research and this requires research stakeholders to be responsible (Khanal & Maharjan, 2018)

Psychiatric/mental health research is conducted and regulated by general bioethical principles which are guided by ethical guidelines applicable to human subject research ethics, and clinical trial ethics similarly to other forms of biological research. However, there are many specific ethical issues related to psychiatric/mental health research in low income countries that need to be taken into consideration. These issues stem from the economic, cultural and social backgrounds, including lack of knowledge and awareness about proper ethical practices among researchers and the lack of awareness/education among the participant communities themselves about potentially harmful research. The existing regulatory frameworks, ethical guidelines and expertise of ethics review committees may not be sufficient to provide adequate regulation of mental health research.

Some of the ethical challenges experienced in LMICs include issues related to the confidentiality of participant information, difficulties and suitability of eliciting information on past trauma and dealing with participants identified to be suffering from serious mental illnesses. Issues related to the specifics of religion, culture and traditions of the study participants. e.g.

The assurance of confidentiality of the information obtained from the participants including inducement and pressure to participate, especially in the background of cultural and social contexts of the population, the eventuality of discovering suicidal ideations/attempts by a participant and how to address such situations, the accuracy of diagnosing serious mental illness among participants and proposed measures to deal with such instances.

The process of informed consent is a crucial ethical aspect of mental health research, as a vulnerable group. The dialogue between the researchers and the participant is a key component of the study process, and may (or may not) convey the purpose of the study to potential participants. Autonomy is a key factor in the decision-making process leading up to the participation in any given research, for participants as well as for researchers

(Mackenzie et al, 2007). However, the concept of autonomy varies in different cultural settings, especially in Africa and some LMICs. The informed consent process in certain contexts in LMICs raises additional cultural considerations, including the issue of gatekeepers and differing conceptualizations of ethics and rights, power relations related to religious, community and political leaders, as well as the status accorded to medical professionals and researchers which can create undue inducement to participate.

Siriwardhana et al (2013), also note that in some instances the organizations responsible for providing ethical oversight, namely the ethics review committees, lack relevant expertise and knowledge in regulating mental health research among vulnerable groups. This is critical especially when studies are carried out in different cultural contexts other than those familiar to committee members, especially in developing country settings. Their lack of understanding translates into either unnecessary hindrance to proposed research or recommendation of appropriate changes in the research population context.

It is noteworthy to highlight the issue of researcher integrity, which plagues most

LMICs (Siriwardhana et al., 2013) with pressures with deliverables and deadlines, accountability to funding agencies, prospective chances of career advancement, personal life pressures and various other factors play a role in influencing researchers to take liberties and cut various corners during the research process (Mackenzie et al, 2007; Roberts LW & Roberts, 1998) consequently giving room for actions that can lead to unsound ethical practices, reducing research quality and causing a negative impact on the participant community.

Objective

These guidelines aim to facilitate a comprehensive ethics review of mental health research considering the culture, limited time and other resources available to the communities. This background forms the basis of this research and will provide an assessment tool that will guide the ethical review of research from a mental health perspective in Africa and in low-resource settings. The benefits of providing these guidelines include ensuring that the human rights of persons with mental illness are not violated, thereby reducing stigmatization, and discrimination and promoting equity.

Methods

We used grounded theory to analyze qualitative data acquired through secondary documents. This is an inductive technique of interpreting recorded data about a social phenomenon to build theories about that phenomenon. This technique was developed by Glaser and Strauss (1967) as a method of constant comparative analysis of grounded theory research and was additionally advanced by Strauss and Corbin (1990) who identified specific coding techniques through the process of classifying and categorizing text data segments into a set of codes (concepts), categories (constructs), and relationships. The interpretations are “grounded in” (or based on) observed empirical data.

This approach requires us to suspend any pre-existing theoretical expectations or biases before data analysis, and let the data dictate the formulation of the theory.

Strauss and Corbin (1998) describe three coding techniques for analyzing text data: open, axial, and selective. Open coding is a process aimed at identifying concepts or key ideas that are hidden within textual data, which are potentially related to the phenomenon of interest.

We conducted a desk review that would inform us on existing ethical challenges in mental health research in Africa and LMICs which was used to form the literature review. We used English search terms only and set up the search words to reflect a broad range of anticipated ethical challenges.

We systematically reviewed 13 assessment tools that were geared towards evaluating mental health research, programmes, and policies, examining their overall approaches, factors considered relevant to quality, how they compare to each other, and what they leave out. For each tool, we performed primary extraction where we derived 11 themes or dimensions i.e. *Governance, Justification, Objectives, Design, Results, Translation, Tools, Ethics, Social value, Background and Technology*. We subdivided this into areas that have ethical relevance through primary extraction and came up with 4 themes i.e. Research governance, Background and justification, Methodology and Ethical impact of the research

Using the open coding process, raw textual data was examined to identify discrete ideas and interactions of relevance which were coded as concepts. Each concept is linked to specific portions of the text (coding unit) for later validation.

Secondly using axial coding similar concepts were grouped into higher order categories that were broad and generalizable to different thematic areas as follows. The following concepts were the first extraction made: *Governance, Staffing, Justification, Objectives, Design, Results, Translation, Tools, Ethics, Social value, Background and Technology.*

These categories reduce the number of concepts to work with and to build a “big picture” of the issues salient to understanding the different thematic areas relevant to mental health. This categorization was done in phases.

Primary extraction and secondary extraction led to the creation of the different ethical dimensions that will be looked at later in the text.

Finally, using selective coding four main core thematic areas were identified that will include all the categories that had been earlier identified. Research governance, Background and justification, Methodology and Ethical impact of the research.

Data analysis

The emerging themes were common to some of the ethical issues arising from health research, however distinct issues emerged that are specific to mental health research, with some specificity in African psychiatry.

The specific steps followed for the development of the guidelines can be seen below in Table 1.

Table 1 Steps taken to develop the guidelines

Steps	Action	Details
Step 1	Literature review	Identify existing ethical challenges in mental/psychiatric health research.
Step 2	Locating existing guidelines in mental health	Identify 13 guidance and assessment tools that were used to identify key thematic areas in mental health and gender and intersectionalities.

1. APA Guidelines for Psychological Assessment and Evaluation, APA Task Force On Psychological Assessment and Evaluation Guidelines, 2020
2. Ethics of psychiatric research, Royal College of Psychiatrists London, 2011
3. Recommendations for conducting ethical mental health and psychosocial research in emergency settings, Inter-Agency Standing Committee (IASC) Reference Group for Mental Health and Psychosocial Support in Emergency Settings, 2014
4. Identifying Ethical Issues in Mental Health Research with Minors Adolescents: Results of a Delphi Study, Elisabeta Ioana Hiriscau, Nicola Stingelin-Giles, Danuta Wasserman and Stella Reiter-Theil, 2016
5. Design, implementation, monitoring, and Evaluation of mental health and psychosocial Assistance programs for trauma survivors in low resource countries: A user's manual for researchers and program Implementers (adult version), Applied Mental Health Research Group, 2013
6. Practice Guidelines for the Psychiatric Evaluation of Adults, Third Edition, APA, 2016
7. Checklist for evaluating a mental health policy. World Health Organization. Geneva, Funk, M., Drew, N., Faydi, E., Freeman, M., & Ndyabangi, S. ,2010
8. An Ethics Checklist for Digital Health Research in Psychiatry., Shen, F. X., Silverman, B. C., Monette, P., Kimble, S., Rauch, S. L., & Baker, J. T. ,2022
9. Ethics in psychiatric research: Issues and recommendations. Indian journal of psychological medicine, Jain, S., Kuppili, P. P., Pattanayak, R. D., & Sagar, R., 2017
10. Ethical standards for mental health and psychosocial support research in emergencies: review of literature and current debates. Globalization and health, Chiumento, A., Rahman, A., Frith, L., Snider, L., & Tol, W. A., 2017
11. Key considerations for the appropriate integration of sex and gender in research. Canadian Institutes of Health Research, 2019
12. The ethicist's practical guide to the evaluation of preclinical research from a sex and gender perspective. Nabil, F., 2021
13. A Framework for the Ethical Evaluation of Research Protocols from a Sex and Gender Perspective during the COVID-19 Pandemic and Other Epidemics. Nkoum, N., Gacko, N., Camara, S., Toure, A., Diallo, M., Penali, L., Nabil, F., Sarr, S. C., Mbaye , E. H., & Martínez-Pérez, G., 2020

Step 2	Identifying areas that affect the research in mental health	<ol style="list-style-type: none"> 1. Identify key concerns in mental health research. 2. Categorize the areas into themes
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Step 3	Data extraction	Grouped selected items into primary, secondary extraction where 4 dimensions emerged, namely: Research Governance, Background and Justification, Methodology, and Ethical Impact of the Research.
Step 4	Data analysis and synthesis	
Step 5	Refine the guidelines	

Results

Our analysis identified 4 key thematic areas for the guidelines. The following 4 sections

look in more detail at several interacting aspects that formed the guiding questions for research protocol evaluation.

Table 1. Research governance evaluation items

Research governance
1. Have the researchers placed mechanisms to address safety concerns that could arise considering participant and researcher safety (i.e. in form of training) in response to participant and researcher vulnerability and protection needs?
2. Have the researchers placed mechanisms to address safety concerns that could arise considering participant and researcher vulnerability and protection needs? N.B: This includes referral pathways to accessible services and safety measures for participants prior to starting research, and additional safeguards for those with intellectual disabilities, detained patients, prisoners, children or vulnerable groups such as refugees.
3. Have all study personnel undergone training in mental health research from a culturally sensitive perspective? N.B This may include cross-cultural communication skills, empathetic communication, and Mental Health First Aid ¹ .
4. Does the research team have the necessary knowledge and skills to undertake the proposed study?

¹ Mental Health First Aid® (MHFA™) training aims to improve mental health literacy and the practical skills required to help someone experiencing psychosocial distress until appropriate professional help arrives.

<p>5. Has the research proposal considered recommendations, other guidelines and legal standards, demonstrating that the research has been designed taking into account the country or regions:</p> <ol style="list-style-type: none"> a. Mental health law b. General health law c. Patients' rights d. Disability law e. Mental health policy f. Social welfare policy g. Poverty reduction policy h. Development policy i. Gender equality policy
<p>6. Have the researchers demonstrated an understanding of the environmental and sociocultural variations that affect how people understand trauma-mental health (e.g. education, political environment, mental health stigma)?</p>
<p>7. Have the researchers described how they plan to maintain principles of equity and impartiality through nondiscriminatory sharing of resources and services?</p>
<p>8. Do the researchers describe how their own biases, prejudices and double standards could affect the design and implementation of the study?</p>
<p>9. Is the process of selecting research teams and auxiliary staff fair through transparent procedures?</p>
<p>10. Have the researchers ensured that the eligibility criteria do not exclude any socially marginalized groups with specific mental or psychosocial disorders without scientifically sound justification?</p>
<p>11. Have the researchers contemplated a fair selection of participants ensuring that anyone who meets the inclusion criteria does not get excluded based on their sex, gender identity, socioeconomic status, religion, sexual orientation, the severity of their mental illness, etc.?</p>
<p>12. Have the researchers declared no conflict of interest regarding patients' welfare or validity of research?</p>
<p>13. Is at least one person on the research team trained in sex and gender considerations in data collection and analysis?</p>

Table 2. Background and justification evaluation items

Background and justification	
1.	Have the researchers clearly stated the reasons for conducting the research?
2.	Are the objectives consistent with the research questions and with the expected impact of the research?
3.	Have the researchers provided how they will address research gaps without duplication of efforts?
4.	Have the researchers justified the theoretical and practical relevance of the study, avoiding over researching a population, including those considered “at risk”?
5.	Have the researchers detailed the measures put in place to identify research participants according to the scientific objectives of the study?
6.	Is the research based on relevant data? Have the researchers examined similar studies conducted in countries with similar mental health epidemiology, culture, and demographics?
7.	Have the researchers included multiple sources of relevant and reliable clinical information according to established principles and methods of assessment?
8.	Have the researchers included information on any known sex and/or gender differences in the epidemiology, risk factors, conditions, diseases or effects of treatment under study?
9.	Have the researchers described how their conceptual framework reflects the experiences of women, men, and gender-diverse individuals, if applicable?
10.	Have the researchers demonstrated an understanding of the differences in biological sex and in the gendered and social roles between women and men concerning the study population and phenomenon?
11.	Have the researchers mentioned that the objectives of their research are set to unveil any unknown sex and/or gender differences with regard to the phenomena studied?

Table 3. Methodology evaluation items

Methodology
1. In single sex studies, have the researchers provided a compelling justification for not including both sexes?
2. Has the protocol avoided labelling, stigmatising or anthologizing participants while considering contextual realities including mental illness stigma; culture; patterns and dynamics of conflict; inequity of healthcare; gender inequalities; and political and socioeconomic vulnerabilities of individuals and communities?
3. Have the researchers included procedures for research monitoring and evaluation?
4. Does the research methodology involve transparency on the methods, results, and limitations including potential sources of bias such as sentimentality?
5. Has the researcher involved the local women and men of the community in research design, conduct and dissemination?
6. Have the researchers consulted with the local communities and patient representative associations to identify fair compensation for research participation?
7. Have the researchers described how they plan to design and distribute gender representative recruitment materials?
8. Will the research include a Community Advisory Board representative of the different religions, ethnicities, genders, age groups, socioeconomic classes, and academic disciplines to ensure the research is well designed and culturally sensitive?
9. Have the researchers mentioned their intent to use state-of-the-art technologies and/or tools for screening, testing, and assessing the participants' mental and psychological status?
10. Are the screening or diagnosis tools adapted to different sexes and genders? Were they previously piloted with a representative population?
11. In the case of translated assessment or data collection tools, have the translators translated all signs, symptoms, problems and topics in the tools that were mentioned in the original language version? Has the terminology used by translators been adapted to that used by the local population?
12. Have reasonable steps been taken to ensure the security, transmission, storage, and disposal of data?
13. Are security measures in place to protect data and information related to their clients/patients/examinees from unintended access, misuse, or disclosure?
14. Have the researchers described their sex and gender based analysis plan?
15. In research involving medication, have the different sex based side effects been considered?

16. In single sex studies, do the researchers plan to investigate gender based differences within the study population?
17. Do the proposed data collection tools capture relevant sex and gender variables?
18. Has the researcher identified the exit strategies, gatekeepers, and power security for planned research, including the circumstances under which research could be suspended or terminated such as in an acute crisis?

Table 4. Ethical impact of the research evaluation items

Ethical impact of the research
1. Have the researchers carried out a thorough risk and benefit assessment and developed risk management plans to be shared with participants and staff?
2. Social value: does the study deliver immediate and direct benefits to the men, women, and vulnerable groups of the communities?
3. Have the researchers described the plan for dissemination of research findings to participants, collaborators and others (information on study design and conduct, both negative or non-significant and positive or significant findings)?
4. Have the researchers evaluated and taken into account the gender specific and sociocultural barriers to knowledge acquisition and retention in the preparation of the research dissemination plan?
5. Is there a provision to allow people with a mental illness the right to decide for themselves whether or not they wish to take part in a study?
6. Have the researchers described how they plan to ensure that no coercion to participate takes place, especially in cases where the potential participant has a reported decisional incapacity?
7. Have the researchers proposed a culturally competent regimen for evaluating the potential participants' decision-making capacities?
8. Have researchers demonstrated awareness of the differences between the capacity to consent and the capacity to participate?

9. Is the informed consent process continuous and not one time following the 3 C's: Clear, Concise, Continuous with a legal guardian keeping in the best interest of rights of the patient in case of decisional incapacity?
10. Have the researchers detailed how they will guarantee the protection of participants' anonymity, confidentiality and right to privacy?
11. Have the researchers explained how they plan to maintain the participants' confidentiality and privacy during the referral and linkage to care process if needed?
12. What are the steps taken in regards to diagnosis e.g. labelling a person with mental illness while considering the psychological and social consequences of the diagnosis over that person in putting the person's interest must be favoured over research interest?

Ethical approval

This study did not require ethical approval, as it involved the review of publicly available documents. The researchers were bound by all of the standard research ethics, research integrity and publication ethics guidelines.

Conclusion

The four principles of biomedical ethics remain the most widely used frameworks in maintaining good ethical practices in health research, including mental health and psychiatric research. The emerging themes for the guidelines i.e. The research governance, background and justification, methodology and ethical impact of the research are interlinked with the principles of respect for autonomy, beneficence, non-maleficence and justice. When they are

applied to the evaluation of a study they will not only underscore these principles, they enhance their application.

Thus ensuring that there is respecting the decision-making capacities of autonomous persons, and putting in effort to ensure that those with diminished capacity are protected; there is a balance of benefits of research against the risks and costs; taking measures to avoid the causation of harm and its minimization and the distribution of benefits, risks and costs fairly.

These guidelines will ensure that there is access to equitable mental healthcare in Africa and LMICs regardless of the varied contexts.

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