Ethical issues arising in research with people with mental health conditions

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Governance paper
In search for a balance between empowering and protecting research participants with mental health conditions in Malaysia

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Introduction

This Governance paper recommends the establishment of a clear guideline to facilitate the implementation of section 77 of the Malaysian *Mental Health Act 2001* (MHA). Relying on the MHA alone as the governance for research involving individuals with mental health conditions is unsatisfactory due to its restrictive scope that only governs informed consent process for the participation in clinical trials. This section also covers consent for electroconvulsive therapy (ECT) and surgery which constitute medical treatments. Hence, using the same standards of informed consent process for research and treatment may not be accurate considering the need for different approaches. Specific to informed consent for clinical trials, the MHA raised at least three important issues involving participants with mental health conditions that need to be addressed: i) the definition and types of research; ii) the assessment of capacity; and iii) the hierarchy of the proxy decision maker. These issues if not resolved through a separate guideline to govern the research process may lead to the unnecessary exclusion of potential participants with mental health conditions due to the fear of ethical and legal consequences.

Commentary

The MHA is a legislation that consolidates the laws relating to mental disorders in Malaysia. It contains statutory provisions relating to the care of individuals with mental disorders including mental health services.[1] Referring to Section 77 (1), consent must be taken from the patient first if the patient is competent as assessed by a psychiatrist and if the patient is incapable of giving consent, consent can be taken from the patient's guardian or relative. In a situation when there is no guardian or relative of the patient available or traceable, consent can be given by two psychiatrists, one of whom shall be the attending psychiatrist.

In hindsight, the MHA offers little guidance to researchers in dealing with research participants with mental health conditions. The implementation of the MHA seen from the perspective of research ethics governance has several limitations as stated above and will be discussed below. First, the interpretation section of the MHA does not define what a clinical trial is. According to the World Health Organisation (WHO), "clinical trial means a type of research that studies new tests and treatments and evaluates their effects on human health outcomes".[2] By giving clinical trial its ordinary meaning, the MHA categorically excludes other types of research involving individuals with mental health conditions from its scope of governance which should be considered equally important as clinical trials.

Second, capacity can only be determined by a psychiatrist when it involves taking consent for clinical trials, ECT and surgery. Perhaps, it appears more relevant for a psychiatrist to assess capacity for medical treatments but in research, the scope for the assessor can be broader to include medical officers, psychologists, nurse and relevant health professionals that may have the skills to conduct the assessment of capacity which should extend beyond clinical trials to include other types of research. It is important to have a clear distinction on when a psychiatrist should

make the assessment and when other healthcare practitioners can make the assessment. It is also important to define the criteria for the others who can make an assessment besides a psychiatrist to ensure validity of the assessment if it is ever possible.

Third, the MHA does not outline the hierarchy of proxy decision makers in a situation when a person with mental health conditions is incapable of giving consent. The MHA empowers the patients' relatives to provide consent on their behalf. However, there is no guidance to provide the understanding on the hierarchy of the proxy decision maker. Who should be on the top of the list to be contacted to provide consent for the research participation if the individual is incapable of giving his or her own consent? This could ignite worry whether the relative is the appropriate person who understands the participant's wishes that would have been decided when he/she had the capacity to give consent. On the other side, not having a strict hierarchy allows for the flexibility for doctors to obtain consent taking into consideration the practical context in a multiracial society.

Conclusion

The MHA was designed as a protective tool to protect individuals with mental health conditions.[3] This however needs to be balanced with an approach that also empowers individuals in this category. Historically, mental health legislation had been developed based on the assumption that individuals with mental health conditions were a danger to the society.[4] The evolution in the mental health development had forced the mental health legislation to adopt a more protective approach to protect these individuals from discrimination and hence the paternalistic approach in the current system.

The paternalistic nature of the MHA may lead individuals with mental health conditions inappropriately being protected disrespecting their rights to be part of research that have the potential to provide beneficial outcomes. Hence, solely using the MHA alone as a guide for research may not be the best approach to empower the rights of individuals with mental health conditions. Furthermore, it is difficult to amend the law to overcome the inadequacies stated above to ensure the rights of individuals with mental health conditions are appropriately protected and empowered.

Recommendation

This Governance paper hereby recommends that a separate guideline needs to be enforced to support the lack of guidance from the MHA. The informed consent process for research should be separated from informed consent process for medical treatment. Clinical trial should be defined clearly to avoid vague understanding of what it entails. Types of research should also be defined to not discriminate between the importance of clinical trials and other types of research that could also promote benefits to potential participants with mental health conditions. In this guidance it is important to also determine who should make the assessment of capacity for the different types of research. In terms of proxy decision maker, it needs to be determined whether a strict list of hierarchy is needed to guide researchers in seeking consent on behalf of the participants when it is deemed necessary.

Additional guidance from a clear and detailed guideline would empower this group of population to be able to exercise their rights as part of the society that would benefit from research. In determining a balance between empowering and protecting research participants with mental health conditions, the guideline needs to ensure that it does not inappropriately protect individuals with mental health conditions but empower them to make their own decisions. Once a clear guidance is available to both researchers, RECs and other stakeholders, the fear to include participants with mental health conditions based on assumed ethical and legal repercussions can be removed.

References

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