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

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Introduction

Governance for Research involving Individuals with Mental Health Conditions in Malaysia

No specific guidelines: research involving individuals with mental health conditions.

Mental Health Act (MHA) 2001 is available but inadequate guidance.

Stigma and discrimination – considered vulnerable → excluded from research.

Commentary

S77, Mental Health Act 2001

(1) Where a mentally disordered person is required to undergo surgery, electroconvulsive therapy or **clinical trials**, consent for any of them may be given—

(a) by the patient himself if he is capable of giving consent as **assessed by a psychiatrist**;

(b) by his guardian in the case of a minor or **a relative** in the case of an adult, if the patient is incapable of giving consent;

(c) by two psychiatrists, one of whom shall be the attending psychiatrist, if there is no guardian or relative of the patient available or traceable and the patient himself is incapable of giving consent.

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Issues with S77 of the Mental Health Act

- The same standards of informed consent process for research and treatment.
- Definition and types of research.
- Only psychiatrists can make assessment for capacity for participation in clinical trials.
- Hierarchy of proxy decision maker.

Same standards of informed consent

- Section 77 combines both the process of informed consent for treatment (ECT and surgery) and research (clinical trials).

- May not be suitable considering the need for different approaches.

Definition and types of research

The MHA does not define what clinical trial is.

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.

Capacity Assessment

Capacity can only be determined by a psychiatrist when it involves taking consent for **clinical trials**, ECT and surgery.

In research, the scope for the assessor should be broader to include medical officers, psychologists, nurses and relevant health professionals that may have the skills to conduct the assessment of capacity.

Hierarchy of proxy decision maker

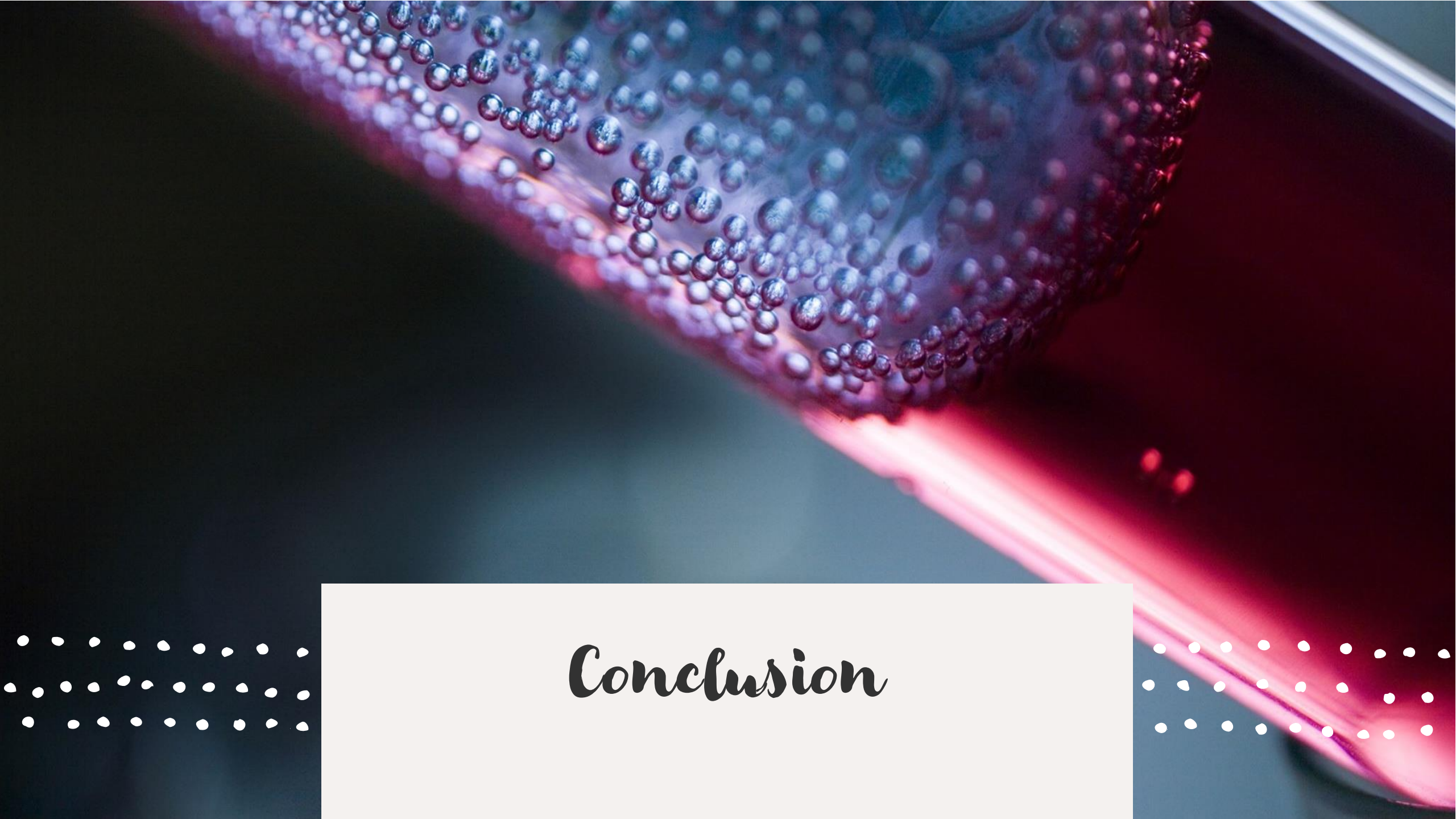
The MHA does not outline the hierarchy of proxy decision makers in a situation when a person with mental health conditions is incapable of giving consent.

The MHA empowers the patients' relatives to provide consent on their behalf.

The term 'relative' covers a broad range of individuals that are related to a person with mental health conditions. The term "relative" includes any of the following persons of or above eighteen years of age: (a) husband or wife; (b) son or daughter; (c) father or mother; (d) brother or sister; (e) grandparent; (f) grandchild; (g) maternal or paternal uncle or aunt; (h) nephew or niece.

However, there is no guidance to provide the understanding on the hierarchy of the proxy decision maker.

At the same time, 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 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.

- 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.

- It is difficult to amend the law to overcome the inadequacies stated to ensure the rights of individuals with mental health conditions are appropriately protected and empowered.

Recommendation

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 the separate guidance, it is important to also determine who should be making the assessment of capacity for the different types of research.

For 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 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 researchers, RECs and other stakeholders, the fear to include participants with mental health conditions based on assumed ethical and legal repercussions can be removed.