Can involuntarily admitted patients give informed consent to participation in research?

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The article argues that a functional approach is ethically better than a categorical approach in deciding whether involuntarily admitted patients have the capacity to give informed consent to participation in research. Congruent with current South African laws, a functional approach requires that a patient's capacity to give informed consent to participation in research should be assessed clinically rather than assumed by virtue of his/her belonging to a category of legal admission status. Concerns about protection against exploitation may cause a categorical approach to appear attractive, but these concerns can be addressed deliberately through a functional approach without attracting the infringements of rights and entitlements of patients that are brought about by a categorical approach.

Researchers in psychiatry, sponsors of psychiatric research and research ethics committees are confronted with an ethical question, viz. whether patients admitted involuntarily to a psychiatric hospital can give informed consent to participate in research. Some studies resort to an exclusion criterion that precludes these patients from participation in research. This article compares two approaches, and I argue that a functional approach is ethically preferable to a categorical approach to this question.

A categorical approach predicates that people should be considered incapable by virtue of their belonging to a certain category, for example, being involuntarily admitted to a psychiatric hospital. In contrast, a functional approach requires that incapacity should not be assumed by virtue of a patient's belonging to any one category (e.g. the category of having been involuntarily committed to hospitalisation), but instead it allows that a patient may be incapable of deciding about hospitalisation yet be capable of making other decisions such as giving informed consent to participate in research.

Functional approach

A functional approach requires that a patient's capacity to give informed consent to participation in research should be assessed clinically rather than be assumed by virtue of his/her belonging to any one category. Accordingly, the clinician needs to assess whether a mental disorder prevents the patient from: (*i*) understanding what he or she is consenting to; (*ii*) choosing decisively for or against participation; (*iii*) communicating his/her choice; or (*iv*) accepting the need for an intervention.[1] It is therefore possible that a mental disorder could prevent a patient from accepting the need for hospitalisation, in which case he or she would be incapable of consenting to hospitalisation. Yet the same patient could at the same time be capable of giving informed consent to treatment with medication when a mental disorder does not prevent him/her from accepting the need for it, all other things being equal.

A functional approach to incapacity due to mental disorder has gained considerable support locally and abroad. South Africa's recently promulgated Mental Health Care Act[2] follows suit, requiring that one 'may intrude only as little as possible to give effect to the appropriate care, treatment and rehabilitation' (section 8(3)).

In the previous Mental Health Act of 1973[3] voluntary or involuntary status was a categorical status of admission that served as a framework within which treatments were provided. In contrast, the current Mental Health Care Act does not take the admission status as a framework. For example, patients may also be treated involuntarily while they are outpatients. Voluntary or involuntary status is now taken as a functional status indicative of the patient's capacity to decide about specific interventions for appropriate care, treatment and rehabilitation – interventions that may or may not be about admission to a hospital, depending on the particular needs/situation of the individual patient. Thus, admission status is not the categorical factor by virtue of which a patient is rendered capable or incapable of giving informed consent.

For example, regulation 35 of the current Mental Health Care Act assumes explicitly that an involuntarily admitted patient can have the capacity to give informed consent to interventions other than those concerning his or her admission. It states that 'an involuntary mental health care user, an assisted mental health care user, a state patient or a mentally ill prisoner who is capable of giving informed consent to treatment or an operation, must decide whether to have the treatment or operation or not'.[4] Another example in the current Act of a functional approach to capacity to consent concerns the intimate relationships of both voluntary and involuntary adult mental health care users, which may be limited

'... only if due to mental illness, the ability of the user to consent is diminished' (section 14).[2]

A functional approach to incapacity due to mental disorder has been evident in South African criminal law for much longer than in our laws governing mental health. The mere presence of a mental disorder, that is merely belonging to the category of the mentally disordered, renders an accused neither incapable of participation in court proceedings nor unaccountable for a criminal act. A functional component is required in addition before these respective incapacity judgements are made. That is, the mental disorder should be of such an extent that it prevents the individual from following and contributing meaningfully to court proceedings, or that at the time of the alleged offence it afflicted him or her to such an extent that he or she could not appreciate the wrongful nature of his or her actions as they relate to the offence.[5] Congruent with a functional approach, this law considers the extent to which someone is affected. The courts have accepted, moreover, that capacity in this regard may be diminished, rather than necessarily being absent in the presence of a mental disorder.

The British government and the Mental Health Act of England and Wales have also adopted a functional approach to decision-making capacity.[6] Accordingly, the Code of Practice for the British Mental Health Act[7] prescribes that informed consent to treatment be obtained from a patient when he or she is capable of giving it, whether or not the patient has been admitted to hospital involuntarily.

Categorical approach

A persuasive reason for taking a categorical approach to a patient's capacity to give informed consent to participate in research is to prevent potential exploitation, for example through implicit or explicit coercion, of a population we assume to be vulnerable.[8] With this line of reasoning, involuntarily admitted patients can easily be protected from potential exploitation by simply excluding all of them from participation in research. This categorical approach may of course also protect researchers, research sponsors, and research ethics committees against accusations of exploitation of vulnerable populations.

Protection of vulnerable populations, researchers, research sponsors, and even research ethics committees is important, which lends some appeal to a categorical exclusion of these patients from research, no less so in that it provides an apparently safe and easy recourse to ensure this protection. However, this categorical exclusion is open to serious objections.

The main objection to a categorical approach is that it follows an 'all or nothing' method. That is, a patient is either fully capable or not capable at all; if the patient is incapable of one critical action, such as deciding about his or her hospitalisation, then the patient is incapable of all critical actions, including a decision about participation in research. This dichotomous approach does not accord with clinical variability in the nature and extent of incapacity resulting from mental disorders. Moreover, although an 'all or nothing' approach seeks to protect patients from exploitation, it may be paternalistic in that it denies them the autonomy to make choices about aspects of their life that are not affected by mental disorder.

Furthermore, an objection based on the rights or the entitlement of the patient holds that a categorical exclusion of involuntarily admitted patients from research may constitute unfair discrimination (which is prohibited in the Mental Health Care Act (section 10 (1)),[2] because people who are involuntarily admitted can still have a right or an entitlement to participate in research.

A view based on rights or entitlement would emphasise the potential benefits to the patient of participating in research. Concordantly, the need for research in this population of patients should be considered because they pose specific challenges – they are often severely ill, some with conditions in critical need of research.[9] Moreover lack of research in this population could be damaging to their mental health interests in the long run. This objection to a categorical exclusion calls for protection of these patients from scientific and professional ignorance and inertia regarding appropriate interventions for them.[10,11]

The Royal College of Psychiatrists[12] takes a strong stance against the categorical exclusion of detained patients, stating that 'it would not be ethical to deprive automatically all detained patients of the opportunity to contribute to research that could improve their own or other patients' care in future'.

Protection that is ethically sound

Protection of involuntarily admitted patients is an important and legitimate consideration for both proponents and opponents of categorical exclusion of these patients from research, even though the proponents are concerned with protection against exploitation, whereas opponents are concerned with protection of further scientific advances, as well as protecting patient benefits and autonomy. A functional approach does not preclude upholding the important and legitimate concerns of both proponents and opponents of categorical exclusion. A functional approach requires deliberate effort to ensure this protection.

Efforts to ensure protection in a functional approach crucially involve the researcher-patient relationship, where the researcher must act responsibly and accountably.[9] In particular, efforts to ensure protection must begin with a proper, ethically and scientifically informed, clinical assessment of whether a particular patient is capable of giving informed consent to participation in research. Furthermore, researchers must take extra care about the general requirements for obtaining informed consent, such as providing sufficient information, establishing rapport and mutual trust, respecting the patient's autonomy, and ensuring the absence of real or perceived coercive factors.

Notwithstanding the critical responsibility and accountability of the researcher, regulatory and supervisory efforts could help to ensure the protection of these patients. For example, research protocols could explicate procedures for the assessment of capacity to give informed consent to participation in research, by which these assessments are made transparent and accountable. I recommend that even in the absence of such protocol requirements researchers make a clear note that they have clinically assessed an involuntarily admitted patient regarding whether he or she is prevented by his or her mental disorder from: (*i*) understanding the research proposal; (*ii*) choosing decisively for or against participation; (*iii*) communicating his or her choice; or (*iv*) accepting the need for an efficacious intervention.[1]

Much more could be added about the ethically sound protection of vulnerable patients, as is evident from an abundance of literature on the topic.[13-15] The point here, however, is that an involuntarily admitted patient's capacity to give informed consent to participation in research should not be confused with the need for ethically sound protection of these potentially vulnerable people. More specifically, someone cannot be incapable merely because he or she comes from a potentially vulnerable group.

Conclusions

South Africa's previous Mental Health Act made the presumption that a patient would be incapable of making critical decisions by virtue of his or her belonging to the category of involuntary admissions. In contrast, the Law Commission of the British Government[6] called for a 'presumption against a lack of capacity' – which implies a putative call for the presumption of capacity. Better than both these options, as I have argued, is not to make a presumption at all, but to take a functional approach to capacity by making a proper clinical assessment of the actual state of affairs concerning a particular patient's capacity or lack thereof to give informed consent to his or her participation in research. A functional approach derives its strength from the sophistication of both clinical expertise and ethical theory, whereby patient autonomy is protected without precluding ethically sound ways of protecting involuntarily admitted patients from exploitation.

References

1. Van Staden CW, Kruger C. Incapacity to give informed consent owing to mental disorder. *J Med Ethics* 2003; **29**: 41-43.
2. Republic of South Africa. Mental Health Care Act No.17 of 2002.
3. Republic of South Africa. Mental Health Act No.18 of 1973.
4. Office of the President. Mental Health Care Act No.17 of 2002 General Regulations. *Government Gazette* 2004, vol. 474, no. 27117.
5. Republic of South Africa. Criminal Procedure Act No. 51 of 1977.
6. Lord High Chancellor. Making Decisions: The Government's Proposal For *Making Decisions on Behalf of Mentally Incapacitated Adults*. London: HMSO, 1999.
7. Department of Health and the Welsh Office. *Code of Practice: Mental Health Act, 1983*. London: HMSO, 1993.
8. Moser DJ, Arndt S, Kanz JE, *et al*. Coercion and informed consent in research involving prisoners. *Compr Psychiatry* 2004; **45**:1-9.
9. Davies T. Informed consent in psychiatric research. *Br J Psychiatry* 2001; **178**: 397-398.
10. Fulford KWM, Howse K. Ethics of research with psychiatric patients: principles, problems and the primary responsibility of researchers. *J Med Ethics* 1993; **19**: 85-91.
11. Osborn DJP. Research and ethics: leaving exclusion behind. *Curr Opin Psychiatry* 1999; **12**: 601-604.
12. Royal College of Psychiatrists. Guidelines for research ethics committees on psychiatric research involving human subjects. *Psychiatric Bulletin* 1990; **14**: 48-61.
13. Welie SP, Berghman RL. Inclusion of patients with severe mental illness in clinical trials: issues and recommendations surrounding informed consent. *CNS Drugs* 2006; **20**: 67-83.
14. Rosenau H. Legal prerequisites for clinical trials under the revised Declaration of Helsinki and the European Convention on Human Rights and Biomedicine. *European Journal of Health Law* 2000; **7**: 105-121.
15. Rosenstein DL, Miller FG. Ethical considerations in psychopharmacological research involving decisionally impaired subjects. *Psychopharmacology* 2003; **171**: 92-97.