Competence of voluntary psychiatric patients to give valid consent to neuroleptic medication*

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Aims and method To ascertain the competence of voluntary psychiatric patients to consent to neuroleptic medication and whether there is a hierarchy of tests of competence. A prospective, observational study of consecutive, voluntary admissions to an acute ward using a questionnaire designed to test four levels of competence, the Mini-Mental State Examination and the Brief Symptom Inventory.

Results All subjects (n=40) could communicate a choice; 5% were competent at all levels. Tests were arbitrary and not hierarchical. Symptom relief/trust in doctors motivated most decisions to accept treatment.

Clinical implications The number and identity of individuals identified as competent will vary with the test set, and tests limited to cognitive criteria will not cover the complexity of the task.

Any medical intervention requires the patient to give his or her uncoerced agreement, that is, his or her consent to the procedure or treatment. This concept of consent is central to the doctor–patient relationship and has as much to do with the legal conditions that pertain to the context of medical treatments as it does with defining the patient as a moral and autonomous agent, that is, one whose self-regarding choices are under self-rule. The Law's concern is to strengthen both self-determination and the fiduciary relationship between patient and doctor. Fiduciaries are people on whom others rely because of their superior knowledge, and on whom trust and confidence are placed to act in the best interests of their clients. The ethical concept of consent, although related to the legal principles, is broader, both informing and defining how we ought to treat one another in the medical context. In essence, it forms the basis for our moral judgements in often complex human situations, such as under what circumstances we may coerce another, deciding on the limits of our duty or on the boundaries of autonomy.

There are at least three main elements to the concept of consent. The subject who consents must have the 'capacity' or 'competence' to give consent. Capacity itself presupposes the availability of relevant 'information' upon which the subject can base any meaningful judgement about proposed treatment options. The subject must also be able to act 'voluntarily'. 'Informed consent' has been called a "modern American invention" (Silverman, 1989) and is not recognised by the Law in England and Wales (Sidaway *v.* Bethlem Royal Hospital Governors And Others, 1985), which uses the terms 'valid' or 'true' consent, recognising the fiduciary relationship between doctors and patients.

Legal competence or mental capacity refers to the patient's ability to reach decisions in accordance with his or her goals, concerns and values. The Lord Chancellor's consultation document on mental capacity (1997) suggests a legal test of capacity that includes the patient's capacity to understand information, retain it and weigh it in the balance in order to reach a decision. This is a cognitive test and ignores problems that may be posed by individuals who can fulfil such criteria yet are impaired in their ability to value all possible outcomes appropriately (e.g. because of depression). It also treats capacity as a discrete variable, although daily practice suggests capacity to be continuous and temporarily variable. Competence to give consent can be classified (Appelbaum & Grisso, 1988) into one or more of four categories: communicating choices; understanding relevant information; appreciating the situation and its consequences; and manipulating information rationally.

Recent bio-ethical (Smith, 1998) and legal (Law Commission, 1993*a*,*b*, 1995) discussion about consent and competence has been spurred on by

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L. *v.* Bournewood Community and Mental Health Trust *ex parte* L. (1998) and interest in the potential use of the legal concept of capacity as the organising principle of any amendment to the Mental Health Act 1983. However, there has been little empirical research on the current status of consent and competence in clinical practice. Our study aimed to ascertain: what proportion of voluntary psychiatric patients prescribed neuroleptic medication were competent to consent to their treatment; the main factors behind patients' decisions to accept or reject medication; whether competence can be predicted; whether there is a hierarchy of tests of competence; and whether different tests of competence agree on which patients are competent.

The study

Eligible patients for the study were consecutive, voluntary admissions to an acute, general, psychiatric ward during the study period (June 1995–January 1996) who were prescribed neuroleptic medication that was either a new treatment or a change from another neuroleptic. The term neuroleptic has been used rather than 'antipsychotic' to include other indications for their use. Each patient was approached by one researcher (M.P.) within 72 hours of the prescription of neuroleptic medication. The patient was given a copy of an information leaflet on neuroleptics, which was also read out. The request to participate in the study was made after the information-giving session, to retain the naturalistic nature of the enquiry. Potential subjects were told that participation was optional, confidential and would not affect their care in any way.

The following questionnaires were administered: Folstein's Mini-Mental State Examination (MMSE) (Folstein *et al*, 1975) – a widely used method for assessing cognitive mental status in research and clinical practice; the Brief Symptom Inventory (BSI) (Derogatis & Melisaratos, 1983) – a self-report inventory designed to assess psychological symptomatology (the General Severity Index (GSI) of the BSI was chosen as the single best indicator of current distress levels); and a questionnaire designed to assess competence to consent to neuroleptic medication at Appelbaum & Grisso's (1988) hierarchy of levels of competence. Responses to the parts of the questionnaire related to the ability to communicate a choice, the ability to understand relevant information and the appreciation of his/her own situation and the consequences of treatment were scored using the hierarchical Consent Rating Scale (CRS) (see Table 1). The remaining parts of the questionnaire related to the highest level of competence in Appelbaum & Grisso's hierarchy – the standard of 'manipulating information rationally'. This standard was difficult to quantify and was thus assessed by requesting qualitative responses to the questions "What made you agree/disagree to taking the medication?" and "What was the most important factor?". The highest standard of competence was therefore not scored using the CRS. Age, gender, race, educational history, diagnosis, number of previous psychiatric admissions and indication for neuroleptic use were noted.

All interval variables were considered non-normal in distribution. The hierarchical CRS was identified as an ordinal variable, but the extra criteria required to score 3 and 4 on the CRS were also identified as nominal variables representing distinct tests of competence. The χ^2 test and Fisher's exact test (two-tailed), when

Table 1. The hierarchical Consent Rating Scale (CRS)

Consent Rating Scale score	Questionnaire response
1 No consent at any level	
2 Able to communicate a choice but nothing else	Able to make a choice whether or not to accept medication
3 Able to communicate a choice and understand relevant information	As above, plus: Correct choice of drug type identified 6/11 or more of the side-effects stated in the information leaflet correctly identified
4 Able to communicate a choice, understand relevant information and appreciate his or her own situation and the consequences of treatment	As above, plus: Answer yes to having a psychiatric problem Answer yes to needing treatment for that problem Self and doctor identified as responsible for treatment decisions Knows that he or she is able to refuse medication Answer yes to extra care needed when driving and drinking alcohol while on the medication

appropriate, were used for relationships between nominal variables. For other combinations of variables, Spearman's rank correlation was used.

Findings

Forty-six subjects were eligible for inclusion in the study, of which one patient took his own discharge before the assessment and five refused to participate. No participating subjects refused medication. Demographic and illness-related variables are summarised in Tables 2a and 2b. On the CRS, 21 subjects (52.5%) were only able to make a choice and 17 (42.5%) were able to communicate a choice and understand relevant information. Only two patients (5%) were able to give consent when assessed at a sophisticated level (i.e. were able to communicate a choice, understand relevant information and appreciate his or her own situation and the consequences of treatment).

In response to the question "What made you agree or disagree to taking the medication?", 22 subjects (55%) suggested a need for relief from symptomatic distress, such as "When I go too high". A small proportion suggested trust in doctors, one reflected coercion ("They said either you take the medication or we will Section you") and others a wish to change from other medication or to be discharged sooner. Some responses did not appear rational (*n*=7), such as "I woke up in these clothes". When asked what was the most important factor in the decision to accept or reject the medication, 17 (42.5%) indicated symptom relief, four (10%) indicated trust in doctors, three (7.5%) mentioned the usefulness of the medication and others suggested family relationships or gave no specific response. No demographic or illness-related variables were significantly associated with an increasing CRS score or with any distinct category of competence.

Comment

Ours is a modest study in a research area where there are very few empirical studies. We have shown that only a small minority of voluntary patients (5%) admitted to an acute psychiatric ward were competent when assessed in a sophisticated way. The Mental Health Act 1983 Code of Practice (Department of Health & Welsh Office, 1993), Section 15.10, states that in order to have capacity an individual must be able to "understand what medical treatment is and that somebody has said that he needs it and why the treatment is being proposed; understand in broad terms the nature of the proposed treatment; understand its principal benefits and risks; understand what will be the consequences of not receiving the proposed treatment; and possess the capacity to make a choice".

However, case law recognises that the understanding required need only be in general terms, that is, patients need not have a detailed understanding of the proposed treatment. Our study suggests that expectations expressed in documents such as the Code of Practice are in conflict

Table 2a. Summary of demographic and illness-related nominal variables (*n*=40)

		No.	%
Gender	Male	21	52.5
	Female	19	47.5
Race	Caucasian	38	95.0
	African/Caribbean	2	5.0
Educational qualifications	Achieved (CSE/GCSE or above)	17	42.5
	Not achieved	23	57.5
Working diagnosis at time of assessment	Schizophrenia and related disorders	15	37.5
	Affective disorders	21	52.5
	Anxiety-related disorders	4	10.0
Indication for prescription of neuroleptic	Psychosis	25	62.5
	Agitation/anxiety	15	37.5

Table 2b. Summary of demographic and illness-related interval variables (*n*=40)

	Range	Mean	(s.d.)
Age (years)	18–62	37.23	12.31
Number of previous admissions	0–10	2.67	2.96
Mini-Mental State Examination (Folstein *et al*, 1975) score	13–30	24.65	3.09
Global Severity Index of the Brief Symptom Inventory (Derogatis & Melisaratos, 1983)	0.08–3.70	1.65	0.94

with how people perform in real life. We do not wish to argue that every effort should not be made to provide people with the information that they want and need to make decisions about their treatment, but it is important to recognise that patients appear to be making their decisions based on subjective distress and trust in doctors. This is not the way that competence is usually construed, but we believe that our study demonstrates that they are more important to patients than information about the nature and purpose of proposed treatments.

Our study found no correlation between subjects' understanding of their own situation or the consequences of treatment with their cognitive state, although the MMSE may be poor at assessing the cognitive function of patients with functional psychiatric disorders as opposed to those with organic disorders. We believe that it is better to assess patients' recognition and recall of information specific to the healthcare decision at hand rather than to use an instrument to assess cognitive function as a proxy for determining the subject's cognitive ability to make a valid decision. Roth *et al* (1982) postulated that cognitive understanding was an insufficient measure of the individual's capacity for interpreting his or her own situation. This point is exemplified in Linda Grant's book *Remind Me Who I Am, Again* (1998), in which she describes her mother's cognitive decline, a result of vascular dementia. In a poignant section, her mother is examined by a doctor for the purpose of determining whether she is competent to transfer power of attorney to her daughters. The mother is clearly disorientated in time and place but quite able to understand the extent of her property and why it would be reasonable for her children to have the power to act on her behalf. In addition, in this study, no variable predicted competence at any level, indicating that evaluations of competence must always be undertaken on an individual basis.

Tancredi (1982) suggests that only a small "critical mass" of patients can give informed consent but "affirmative efforts" to gain informed consent improves the care of the majority of patients. However, legal standards of high/multiple level competence, if accepted within clinical practice, will result in large proportions of patients being labelled and treated as incompetent. It is the pragmatic approach that clinicians take to the issue of consent in clinical settings that prevents many patients from being treated as if they were incompetent. Our current understanding of consent is conceptually driven and in many respects distant from the world that real patients inhabit. There is a need for more studies of this kind, so that our conception of competence can be based on valid, empirically derived grounds.

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