

Review Article

Assessment of psychiatric patients' competency to give informed consent: Legal safeguard of civil right to autonomous decision-making

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Abstract

Amendment of the Mental Health and Welfare Law in Japan will limit admission for medical care and protection only for those individuals who are incapable of giving consent to admission. This is a first in the history of the Japanese mental health legislation. By reviewing the law and psychiatric literature, it is argued that: (i) informed consent is a legal transaction that embodies the idea of an individual's right to autonomous decision-making in medical settings; (ii) health professionals have a duty to protect those individuals who cannot decide medical matters because of lack of capacity to do so; (iii) some patients are marginally incompetent so assessment of their competency is essential in protecting patients' civil rights; (iv) in order for a competency assessment to be reliable (and hence fair) the method should be psychometrically sound; (v) at the same time, in order for a competency assessment to be valid, the structure of a competency assessment should match the patient's psychological, cultural, and social background; and (vi) because informed consent is a process rather than a cross-sectional event, a competency assessment should be performed in everyday practice. The use of a brief and semistructured interview to assess patients' competency to give informed consent may meet all of the requirements described.

Key words

competency, decision-making, informed consent, law.

INTRODUCTION

Patients have the right to be informed about their care before treatment (or any medical procedure) begins. In medicine, the concept of informing the patient was coined 'informed consent'. In psychiatry, however, many believe that such patients should be protected even if it is against their will. This may be because of some psychiatric patients' lack of competency (capacity), an essential element of informed consent and, moreover, to the assumption that all psychiatric patients are incompetent.^{1,2}

In the present discussion, I will comment first on the legal status of the patients' right to autonomous decision-making as against the psychiatrists' duty to protect patients, and then on the psychometric nature of competency assessment. Finally, I will suggest the possible use of a competency test in everyday practice in psychiatry.

PATIENTS' RIGHT TO GIVE OR REFUSE INFORMED CONSENT: A LEGAL CONCEPT

Informed consent as a legal transaction

Any exchange between two parties should be viewed in legal terms. If such an exchange is based on agreement between two parties resulting from an offer and an acceptance, then it is a contract.³ If there is no offer and/or no acceptance, a contract does not exist. The two parties should be viewed as equal, having the

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same rights and reciprocal responsibilities. Contracts are an essential element of modern society. The doctrine of contracts supports individual autonomy and equal protection, hence contracts are also an important part of contemporary democracy and they underscore many social and interpersonal activities.

Medical service is no exception. Medical professionals are providers of medical services (i.e. diagnosis, prognosis, treatment, rehabilitation etc.) and patients are the recipients of these services. Medical services should always be based on an offer from medical professionals and an acceptance from patients. This interaction should be symmetrical, with both parties sharing equally in the contract. If an offer is not accepted, medical service should not commence. Patients have the right both to accept and to refuse treatment.^{4,5} These principles constitute the doctrine of informed consent. It is widely agreed that informed consent is a basis for respecting patients' autonomous decisions and human dignity.

For any contract to be valid there are a few prerequisites. First, all necessary information should be disclosed to the parties involved so that they are able to decide autonomously. The party accepting services may ask for information from the party offering services. If an important piece of information is not disclosed, the contract may become void because if the individual had been aware of the particular information, he/she might not have entered into a contract with that party.

Second, if a decision is determined by an individual with full knowledge of the nature of the offer and the consequences of the contract, it may even be voidable if it is made under coercion. If, for example, someone bought an item under threat or undue influence, this purchase would be invalid. Thus, voluntariness of the parties is an important element in the validity of a contract.

As with ordinary contracts, for informed consent to medical procedures to be valid, it is required that necessary and important medical information is disclosed and the decision is not made under coercion.⁶ If a patient's consent lacks either of them, it may lose its validity.

Disclosure of medical information

In order for a patient to be a master of his/her fate, sufficient medical information is essential. Thus, the amount of information justifiable as a prerequisite for valid informed consent cannot be determined by medical professionals but should be determined by what patients need to use in order to make autonomous decision-making. However, some people

argue that disclosure of information about life-threatening or extremely stigmatizing medical conditions may have very detrimental effects on the patient's mental state and he/she may even become suicidal.⁷ However, the ethical message of informed consent demands the disclosure of such information because of, rather than in spite of, the serious nature of the condition. Decision-making in such cases goes beyond the physician's discretion. Principles of medical ethics never require medical professionals to realize their patients' happiness but such principles do demand that they do their best to support a patient to achieve happiness, that is, the kind of happiness that the patient prefers. What the patient considers to be happiness varies and it may differ from what the physician defines as happiness.

In order for a patient to deal with medical information rationally, he/she should at least appreciate the nature and purpose of the proposed treatment and this, in turn, will require the disclosure of the reasons for which the physician recommended such treatment in the first place. Accordingly, precise information about the diagnosis and its meanings on which the therapeutic recommendation is based is an essential element of the information to be disclosed. Vague terminology does not suffice.

In reality, however, an exact diagnosis is not frequently given to the patient. An international comparison of diagnostic disclosure to patients was made by McDonald-Scott *et al.*⁸ Six case vignettes were sent to Japanese and North American psychiatrists, who were asked whether or not they disclosed diagnoses to these patients. More than 90% of both groups would give the diagnosis to patients with affective and anxiety disorders. If the diagnosis was schizophrenia or schizophreniform disorder, 70% of the American but only 30% of the Japanese psychiatrists would inform the patient. As expected, Japanese psychiatrists preferred a vague alternative diagnosis such as 'neurasthenia'.

One of the possible reasons for the low rate of disclosure of the diagnosis of schizophrenia may be the strong stigma attached to this word. The issue of stigmatization goes beyond the scope of the present paper. However, it should be noted that the psychiatrist's hesitation or refusal to inform the patient of a diagnosis of schizophrenia may signify that the term schizophrenia is so stigmatized that even the attending physician would feel uncomfortable discussing it openly in front of patients. This attitude could enhance negative societal attitudes towards the illness. Conversely, open disclosure of the exact diagnosis may ameliorate society's negative attitudes.

Japanese institutions seem to be reluctant to adopt the notion of informed consent in medical practice, let alone in psychiatry. Higuchi, a leading professor of Anglo-American law in Japan claimed that, in current Japanese society, people should have the right 'not to be informed' about medical information related to themselves.⁹ He further noted that a 'modified version of autonomy' might be appropriate for the Japanese and that patients should have a 'right to choose' either to be informed or not to be informed of medical information and thus to be continuously treated with medical paternalism. The Japanese Ministry of Health and Welfare sponsored a research committee on informed consent in psychiatric practice chaired by Takayanagi (Takayanagi *et al.*¹⁰). Although they acknowledge the necessity of disclosing diagnosis to patients, they warn that the 'excessive flow of information in a short time without consideration' may make the patient and his/her family anxious. They suggest that the withholding of a diagnosis be justified in some cases.

The claims of Higuchi⁹ and Takayanagi *et al.*¹⁰ seem to oppose Western notions of autonomous decision-making and informed consent, but such claims do reflect, at least in part, the traditional national sentiment in Japan, which is extremely paternalistic.¹¹ Nevertheless, Japan has recently seen a change in this national sentiment. For example, one study asked patients whether they wanted access to their medical records.¹² More than 60% of them said 'yes', whereas 25% said 'no'. Hasui *et al.* showed a case vignette of depression to non-medical Japanese people and asked whether they wished to know about medical information.¹³ More than half of the participants wanted all types of medical information disclosed to them. The information they wanted to know included diagnosis, prognosis and natural course, pros and cons of treatment, alternative treatment, and a description of their medical chart. These findings suggest that the traditional paternalistic relationship between doctor and patient is undergoing a gradual transformation in Japan.

Lack of coercion

Another important element of informed consent is the absence of coercion, that is, threatening or exerting undue influence. The former may be rare in clinical settings but the latter may be prevalent in a subtle form. For example, a psychiatrist may 'suggest' to a patient that he/she sign a voluntary admission form, implicitly or explicitly noting that otherwise the psychiatrist would put the patient on a section. The

patient has only two alternatives: forced voluntary admission or admission as an involuntary patient.¹⁴ There is no alternative of refusing admission (no treatment).

Waiving one's right to decide upon such matters is usually considered a sign of a patient's incompetency.¹⁵ However, Kitamura *et al.* studied both medical and psychiatric patients by a structured interview guide to assess competency to give informed consent.¹⁶ They found that there were many patients who wanted someone else to decide on their behalf, even when they showed competency in other areas of the test (such as recognition of their legal rights, pros and cons of proposed treatment, and insight into the condition). In most cases, this 'someone else' was the attending physician. This suggests that patients often feel that the physician is in a better position to make a final decision and that physicians can easily influence patients.

The balance of power shifts even more towards the physician. Some authors claim, therefore, that the patient should be 'empowered'.¹⁷ In such cases, what is needed is not unilateral conveyance of voluminous medical information from the attending physician to the patient. Someone independent of the physician-patient relationship should ask the patient as to his/her understanding of the information. In so doing, the physician can understand what part of his explanation was difficult for the patient to appreciate, while the patient can understand where he/she needs more information and explanation.

RESPECTING PATIENTS' AUTONOMY VERSUS PROTECTING THE MENTALLY INCOMPETENT

Protection of the mentally incompetent

In the previous section, it was argued that the patient's competency should be assumed in medical practice. The patient need not prove his/her competency before entering a medical contract. However, professionals are also responsible for ensuring the protection of patients who are unable to make decisions about medical matters that will meet their own value system and/or best interests.¹⁸

The recipients' capacity to understand the nature of the offer and handle the information rationally in order to reach a conclusion is called 'competency'. An incapacitated state of mind is referred to as 'incompetency'. If he/she is unable to make a decision in his/her best interest or if he/she is unable to communicate such a decision, he/she should be legally protected. In such cases, decisions should be made by a

designated proxy in order to achieve the patient's best interest.^{19,20}

Having observed some mental health legislation and court cases,^{16,21} it may be seen that lack of competency can be the sole justification for coerced treatment of patients, except for an emergency if patients' autonomous decision-making is to be respected. The State's *parens patriae* power justifies limiting a committed person's right to refuse medication only if the person is incompetent to care for him/herself.²²

Marginal incompetency

Problems arise when the difference between 'competent' and 'incompetent' becomes blurred. Freedman named this state 'marginal' competence.²³ He listed mental illness as an example. Because there is a substantial number of psychiatric patients who are categorized as 'marginally competent',²⁴ mental health professionals and other people involved in psychiatry are justifiably concerned with this topic.

If a competent patient's refusal of a proposed treatment is regarded as incompetent and therefore the treatment is coerced, the patient's autonomous decision is violated (Table 1). If an incompetent patient's acceptance of a proposed treatment is regarded as competent, the legal protection that the patient deserves is not provided. Therefore, he/she may not even have access to knowledge of his/her rights (e.g. rights to require a discontinuation of the medication when side-effects are present). If a competent patient accepts a proposed treatment and he/she is regarded as incompetent, a proxy will be designated. In such a case, the potential damage may be lessened because the proxy is likely to endorse the patient's decision. However, even here the patient's dignity as an

autonomous individual is belittled. If an incompetent patient refuses a proposed treatment but is regarded as competent, he/she loses a chance to be treated properly.

These considerations will lead to the notion that the patient's protection, both legal and clinical, is determined by accurate and reliable assessment of competency and incompetency.²⁵ Misclassification of patients in terms of competency may result in a violation of patients' rights. Thus, competency assessment may function as a legal safeguard.^{16,26,27}

TEST RELIABILITY VERSUS ELICITING PATIENTS' COMPETENCY

Competency as a psychological concept

Because assessing a patient as incompetent can justify coercive admission or treatment (if other criteria of civil commitment or involuntary treatment are met), such assessment should be performed very carefully and not be idiosyncratic. Its methodology should be as clear and explicit as possible. A substantial degree of interrater agreement in the assessment of competency is crucial for guaranteeing the stability of the law.

However, the issue of subjectivity in defining mental competency as articulated in American court cases was pointed out as early as in 1941 by Green.²⁸ He warned that 'as in every situation where the law must draw a line between liability and non-liability, between responsibility and non-responsibility, there will be borderline cases, and injustices may be done by deciding erroneously that a particular individual belongs on one side of the line rather than the other. To minimize the chances of such injustices occurring,

Table 1. Results of discordance of the patient's real capacity and clinical judgement

		Competent	In reality	Incompetent
Clinical judgement	Competent	OK		Acceptance of treatment: lack of legal safeguard (e.g. examination by two independent physicians, report to the tribunal etc.) Refusal of treatment (withdrawal of treatment): lack of necessary treatment (i.e. violation to the right to treatment)
	Incompetent	Acceptance of treatment: violation to autonomous decision Refusal of treatment (commencement of treatment): violation to autonomous decision; battery and assault	OK	

the line should be drawn as clearly as possible'. Green's request had to wait for more than three decades to be embodied as research tools in competency assessment. Many devices have recently been developed to reliably assess different aspects of patients' competency to give informed consent.^{16,29}

Match of disclosed information and patients' attributes

For the informed consent to be valid, however, the information disclosed cannot be sufficient only because it meets the standard practice of current medical professionals or because a set of predetermined information is provided. A patient's capacity to understand and appreciate the disclosed information may vary depending on his/her educational background, personality, current mood, cognitive state and other conditions. Disclosure of information validates informed consent only when it is delivered in such a way that the patient in question can maximize his/her capacity to appreciate the content and nature of the information and manipulate it to reach rationally the decisions that match his/her own value system (not necessarily to reach objectively rational decisions).

Interviewing admitted patients and their attending physicians, German researchers found a substantial difference in what the patients and physicians thought of as the most important aetiological area.³⁰ Thus, of three forced choices, 35% of patients with schizophrenia thought that the most important cause of the illness was the personal characteristics including personality and intrapsychic problems; 41% of patients with schizophrenia thought that it was biographical, such as living conditions and social situations; and 24% of patients with schizophrenia thought that it was a disease in the medical sense of the word. Contrary to this, over 90% of their attending psychiatrists reported that the most important aetiological area was the biological one. This means that schizophrenic patients are very likely to disagree with the notion that their suffering is a 'psychosis'. They may deny the existence of the 'illness' because they believe it was caused either by their intrapsychic conflict or by social adversity.

Should this discrepancy between the psychiatrist and the patient in the aetiological area of the illness³⁰ lead to the conclusion that the patient lacks insight and thus should be treated as incompetent? Is it not merely an indicator of different opinions between the two parties as to the nature and origin of the condition? Is it not that patients cannot admit that it is an illness in the medical sense but admit that it is ill-health? This discrepancy may be resolved only by

more exchange of opinions, questions and answers, and repeated confirmation that the patients have understood fully what the physicians have told them.

Unlike an ordinary psychometric assessment, a competency test can measure a patient's capacity to give informed consent only after disclosure of medical information, the content of which has been determined by the patient's educational and occupational background, religion, personality, and current mental state. A set of predetermined information (such as a video-presentation, a pamphlet, and a structured narrative explanation) is insufficient if offered without consideration of these factors.

Informed consent as a process

Like many commentators, I have thus far discussed informed consent as if it were an event that occurs between a physician and a patient on one day or during a single interview. This is, however, only for the sake of argument. In clinical practice, informed consent is a series of events that take place in almost every session.⁶

For example, a patient may visit an outpatient clinic because of uncomfortable symptoms such as fever. After taking a medical history, the physician might recommend diagnostic procedures (such as an X-ray or a blood analysis). At this stage, the physician has not yet arrived at a final diagnosis. The medical information disclosed at this stage is therefore not the final diagnosis, but the list of possible diagnoses and a rationale for the tests. After the test results are obtained, the physician discloses the information together with their interpretation. This will be followed by a recommendation for treatment (e.g. medication, surgical operation, no treatment). Prompted by the disclosure of the laboratory examination results, the patient may ask questions and express his/her will. In so doing, the physician can understand how the patient views his/her condition and what he/she desires, while the patient can understand how the physician views the condition. Thus, continued exchange of information, questions, and consideration comprise the cascading events involved in informed consent.³¹

Another justification for considering informed consent as a process rather than as single episode is the temporal fluctuation of competence over the course of diagnosis and treatment.⁶ For example, a patient with delirium is clear in consciousness one day but may be less clear on the following day. A patient with depression may have diurnal variations, where he/she is less depressed in the afternoon. Therefore, the judgement of the patient's competency should not

be viewed as enduring. Tests should be repeated as the clinical situation demands.

Theoretically, informed consent is agreement between the physician and the patient in terms of any new medical procedure including diagnostic tests, commencement of medication, changes in prescription and dosage, major and minor surgeries, and medical fees. Therefore, any interaction between the two should be viewed in terms of informed consent. If the patient's competency should be proven in all interactions, it should be tested on all such occasions.

FUTURE DIRECTIONS

Use of a structured interview

Thus far, it has been argued that:

- (1) Informed consent is a legal transaction that embodies the idea of an individual's right to autonomous decision-making in medical settings.
- (2) Health professionals have a duty to protect those individuals who cannot decide medical matters because of a lack of capacity to do so.
- (3) Some patients are marginally incompetent so that assessment of their competency is essential in protecting the patients' civil rights.
- (4) In order for a competency assessment to be reliable (and hence fair) the method should be psychometrically sound.
- (5) At the same time, in order for a competency assessment to be valid, the structure of a competency assessment should match the patient's psychological, cultural and social background.
- (6) Because informed consent is a process rather than a cross-sectional event, a competency assessment should be performed in everyday practice.

I believe that the use of a brief semistructured interview to assess patients' competency to give informed consent meets all of the requirements listed above. A semistructured interview can give testable criteria of competency and incompetency, so that informed consent in psychiatry can be substantially transparent. It may avoid the clinicians' idiosyncrasies in determining patients' competency as used to be the case in the past.³² Training in reliability assessment is easily available if a structured interview is used.³³ In order for the last two requirements to be satisfied, the interview should be brief and give sufficient discretion to clinicians in the context of the structured interview.

Furthermore, the competency assessment should be separated from the patient-psychiatrist relationship because its primary goal is to give patients' the right

to autonomous decision-making or to deprive them of it. Independence of a test may be guaranteed by the introduction of a third-party assessor. This may be Mental Health Review Tribunal, second option psychiatrists, or volunteer workers. Whoever the assessor, this process may give a sense of procedural justice to psychiatric patients even if the test result ends up with their forced treatment.

Based on the past literature of the research devices for competency assessment,²⁹ the last several years have seen the development of clinical methods of competency assessment such as the MacArthur Competency Assessment Tool for Treatment (MacCAT-T).^{34,35} We have also developed a clinical instrument of competency assessment.¹⁶ This interview guide, Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory (SICIATRI), is very brief, taking on average 15 min to complete. The interrater reliability of the SICIATRI items was reported³³ and its three-factor structure has been observed.

Legislation of the test and its justification

I believe that tests of patients' competency should be legislated. This is without doubt in order to provide legal safeguard of due process. But should tests used in everyday practice be legislated? One may argue that psychiatric patients should be treated the same as medical patients, and that in as far as medical patients are not provided with a statutory test application for the appropriateness of disclosed information, psychiatric patients do not need such a statute either. Treating psychiatric and medical patients differently may violate equal protection and evoke stigmatization towards people with mental illness.

Here, I think that paternalistic intervention of the State may be justified. Modern democracy has been enthusiastic in giving States intervention into contracts between two parties, one of which has an excessively strong power. Although a contract is based on the free will of both parties, it may be justifiably regulated if the weaker party might otherwise suffer from undue unfair results of the contract. In such a situation, a State usually enacts laws regulating contracts. This may include the labour market, purchase of land or houses etc. Using this analogy, I want to argue that although a medical contract is made between two equal parties, a patient and a physician, one of the two (i.e. the physician) is actually in a much stronger position. The physician knows much more about diseases and treatments. If the physician does not mention alternative treatment, the patient can hardly be aware of it. Even if the patient wishes to do so,

he/she might have little time to research various treatments on his/her own (e.g. accessing medical databases via the Internet). The physician has a right to refuse contracts but, in such cases, patients may find it difficult to look for care in other hospitals and clinics. This is much more the case in psychiatry.

Use of the tests and embodiment of the ideal of informed consent

In the long run, the differential use of competency assessment may enhance psychiatrists' awareness of the importance of informed consent.³⁶ They may also help in the development of better methods of information disclosure, and openness of medical procedures. Psychiatry has long been criticized for its nature of self-concealment. Psychiatry has been seen as something difficult to understand by lay people. It is often pointed out that this closed nature of psychiatry is the direct or indirect root of the 'scandals' of mental hospitals. Inviting people from the outside to be competency assessors may make mental hospitals and clinics more open and understandable to outside people. This may hopefully result in reduced rates of abuse and violence against psychiatric inpatients.

It may also encourage the patient's active participation in medical decision-making and searching for information. This will, in turn, lead to an increase in the patient's self-esteem and quality of life. I think it is of vital importance to give repeated assurance to patients during the course of tests, for example, that their decisions are of utmost importance, and that even if treatment or admission is coerced, it is in their best interest. Any medical procedures would degrade patients' sense of self-worth if performed without prior explanation. Repeated competency test items such as the question 'Are you aware that you have a right to decide about medical matters related to you?' would certainly enhance the patient's self-esteem.

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