

ADVANCES IN BIOETHICS

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ADVANCES IN BIOETHICS

VOLUME 8

TAKING LIFE AND DEATH SERIOUSLY BIOETHICS FROM JAPAN

EDITED BY

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Kumamoto University, Japan

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COMPETENCY TESTING IN MEDICAL AND PSYCHIATRIC PRACTICE: LEGAL AND PSYCHOLOGICAL CONCEPTS AND DILEMMAS[☆]

Toshinori Kitamura and Fusako Kitamura

ABSTRACT

Health professionals are in an ethical dilemma. The patients should be assumed as competent. Involuntary treatment is a violation of human rights. Therefore incompetent patients should be protected. However, one cannot determine a patient's incompetency without testing him/her, which is a violation of the assumption of competency. Thus, we propose two different types of uses for competency tests. One is to measure the appropriateness of information disclosed, but with a poor test result the information should be repeated. Another is to measure the competency of the patients when making major decisions. A poor test result will be followed by the designation of a proxy so that incompetent patients can be protected.

[☆] Parts of this article were published in earlier publications: Kitamura, T. (2000). Assessment of psychiatric patients' competency to give informed consent: legal safeguard of civil right to autonomous decision-making. *Psychiatry and Clinical Neurosciences*, 54, 515–522.

1. INTRODUCTION

Patients have the right to be informed about their care before treatment (or any medical procedure) begins. Such claims have enjoyed wide acceptance in recent times. In medicine, the concept of informing the patient was coined 'informed consent'. Patients' right to self-determination about medical matters related to themselves has a long history in Western societies. Grisso and Appelbaum (1998, p. 4) quoted *Slater v. Baker and Stapleton* in 1767 which declared that it was improper to carry out surgical operation without a consent obtained from the patient. The traditional concept of informed – rather than simple – consent in medical practice appeared as a court case in the U.S. as early as in 1914 in the *Schloendorff v. Society of New York Hospital*. The contemporary concept of informed consent dates back to the Nuernberg trials and has developed through case laws and legislatures in Western countries and subsequently in other parts of the world. It is widely agreed that informed consent is a basis for respecting patients' autonomous decisions and human dignity.

In Japan, however, the development and introduction of the idea of informed consent and its implementation has been delayed in some branches of medicine. For example, before the appearance of the notion of informed consent and competency, psychiatric patients admitted to an asylum in Japan were all thought to lack insight; they were considered to be unaware of the nature and severity of their own illness even today. Legal and psycho-medical professionals often encounter substantial discrepancies in opinions on these matters (Kitamura et al., 1999a,b).

In this chapter, we will review the psychometric properties of competency. In so doing, we will note that there are two conflicting flows of thoughts. Finally, we will try to resolve the discordance between the two approaches to competency testing in both legal and psychological requirements.

2. LEGAL AND PSYCHOLOGICAL CONCEPTS OF COMPETENCY AS A SOURCE OF CLINICAL DILEMMA

2.1. Patients' Right to Give or Refuse Informed Consent and Protection of Mentally Incompetent Patients: A Legal Concept

2.1.1. Informed Consent as a Legal Transaction

Any exchange between two parties should be viewed in legal terms. If such an exchange is based on an agreement between two parties resulting from an

offer and an acceptance, then it is a contract (Geldart, 1985). If there is no offer and/no acceptance, a contract does not exist. The two parties should be viewed as equal, having the same rights and reciprocal responsibilities. Contracts are an essential element of modern society. The doctrine of contracts supports individual autonomy and equal protection, hence they 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 on 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 (Annas & Densberger, 1984; Saks, 1991).

In any area of human activity, when an individual who has reached the age of majority enters into a particular transaction, it is legally presumed that he/she has a sound mental competency to carry out such a transaction unless the contrary is proved. Normally, no adult is required to prove his/her competency before entering into a contract. Again, medical services present no exception. When an adult patient accepts an offer of a diagnostic or therapeutic procedure from a medical professional, his/her decision should be presumed as grounded in competency and therefore it should be considered valid.

2.1.2. Protection of the Mentally Incompetent

Another principle of ethics related to patients' right to decision-making is that the medical professionals are 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 (British Medical Association, 1995). Mentally sound individuals' decisions should be respected, while mentally incapable individuals' decisions, such as the refusal of necessary medication, should be revoked for the protection of their life, health, and dignity. Included in the mentally incapable may be those patients suffering from severe mental illnesses, dementia, disturbed consciousness, and immature minors. As discussed shortly, however, not all people with mental illness are mentally incapable.

This distinction is without difficulty only when the distinction between 'competent' and 'incompetent' is obvious. For example, nobody would doubt if a comatose person is incompetent. Problems arise when the

difference between the two terms becomes blurred. Freedman (1981) named this state 'marginal' competence. He listed mental illness as an example. Because there is a substantial number of psychiatric patients who are categorised as 'marginally competent', mental health professionals and other people involved in psychiatry are justifiably concerned with this topic.

2.1.3. Marginally Incompetent Patients

Respecting superficially the patient's decision to accept treatment may lead to a violation of the patient's right to be legally protected. Theoretically, incompetent patients are not aware of or able to make decisions based on their best interests. However, they have a right to attain what is in their own best interests and thereby to arrive at decisions about medical matters. A proxy will be designated on behalf of such incompetent patients in order to decide medical matters to achieve their best interests (Areen, 1987; Lynn, 1992). Therefore, the proxy's decision is valid only if it resonates with patients' best interests or prior will before becoming incompetent. Furthermore, this decision is valid only while patients are incompetent. Therefore patients' rights to self-determination will be exercised by a proxy merely on behalf of them only while they are incompetent.

Because proxies are not the patients themselves and are likely to abuse their power, many countries provide mechanisms to avoid such abuse of power. These safeguards protect patients from being deprived of individual rights. For example, if a patient is assessed as incompetent (and of course if he is indeed incompetent), admitting him into a hospital should take a legal course of an involuntary one, which ensures a variety of safeguards. Therefore, considering a patient's acceptance of treatment as a sign of his/her competency may undermine incompetent patients' legal safeguards.

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 (Blackburn, 1990). 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, and 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

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

	In Reality	
	Competent	Incompetent
Clinical judgement	Competent	OK
	Incompetent	OK
		Acceptance of treatment: violation to autonomous decision
		Refusal of treatment (commencement of treatment): violation to autonomous decision; battery & assault
		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)

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.

Therefore, the competency assessment may function as a legal safeguard (Drane, 1984; Kitamura et al., 1998). Without testing the patients' competency to give informed consent, health professionals cannot decide whether to respect patients' self-determination or to protect and commence necessary treatment despite their (superficial) refusal. These considerations will lead to the assumption that the patient's protection – both legal and clinical – is determined by where to fix the boundary between competency and incompetency (Winick, 1991).

This issue is particularly important in Japanese mental health services. The first Japanese mental health legislation was Psychotic Patients' Custody Law in 1900, which allowed confinement of mental patients at home. This was banned in 1950 by the first modern Japanese mental health legislation, which in exchange provided systems of civil commitment only in designated

hospitals. Although subsequent revisions of the Mental Health Law saw improvement in the care and welfare of psychiatric patients, little respect has been paid to the autonomous decision-making of the sufferers. Despite solitary cases in 1970s in which courts held that an involuntarily admitted patients may have a right to decide whether he/she receives a proposed psychosurgery, the Mental Health Law, on several occasions of revision, never referred directly to the patient's incompetency as a ground to justify civil commitment. The paternalistic situation of Japanese psychiatry received bitter international criticism triggered by a scandal in 1984 involving civilly committed patients' death caused by abuse by hospital staff. The latest revision of the Law in July 1999 notes that admission to a mental hospital require the consent of a patient and involuntary admission is permissible only when the patient's consent is unavailable. Nevertheless, it does not mention the patient's capacity to give consent.

2.2. *Dilemma of Competency Testing: A Legal Perspective*

2.2.1. *To be Respected or Protected*

Health professionals should respect patients' decision including refusal of the proposed treatment if they are competent whereas health professionals should protect and commence treatment for patients despite their refusal if they are incompetent. Because health professionals cannot determine patients' competency without testing it, the use of competency tests is of vital importance for respecting and protecting patients. In this case, however, a legal dilemma arises. Thus, although it is an ethical principle to treat patients as competent, paradoxically, treating them without a competency test may result in a violation of their right to be protected.

When a contract is made between two adult parties, both are regarded as competent unless there appears to be sufficient signs suggesting their incompetency. Refusal of a treatment that many of us believe to be reasonable may be such a sign. Therefore, one may argue that those patients who accept a physician's suggestions for treatment should be treated as competent. Only when a patient refuses such a proposal should competency be assessed (Searight, 1992). This means that a patient is competent as far as his/her decision is consistent with the physician's decision. However, this argument may be criticised because it runs contrary to the idea of equal treatment. Winick (1991) noted that mental illness alone does not and should not justify an enquiry into competency, criticising the U.S. Supreme Court's

articulation in *Zinermon v. Burch* (1990). Winick argues that a general assumption of competency should be applied as far as the patient is able to communicate a choice of his/her favour.

Health professionals face a dilemma in cases of 'marginal' competence; they are caught between two requirements – to assume the patient's competence on the one hand, and on the other, to test the patient's competency to offer protection in case he/she is found incompetent. Any transaction between two adult parties should rest on the assumption that both parties are competent. Any decision by an adult should be given the utmost respect. Questioning the competency of a specific group of people such as the mentally ill digresses from this principle and may violate the idea of equality. However, medical ethics require physicians to give optimal care to those people who are unable to do so for themselves. To carry out this task, health professionals may find it unavoidable to test the competency of patients, because, giving optimal care may violate a patient's autonomy. It appears that this historical conflict remains unresolved in the fields of ethics and health care.

2.3. *Patients' Competency to Give or Refuse Informed Consent: A Psychological Concept*

2.3.1. *Psychometric Approach to Patients' Competency*

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 done carefully and not be idiosyncratic. Naturally, one can claim that its methodology should be as clear and explicit as possible. If a patient's competency is assessed differently by two clinicians (as competent or incompetent), one of the two is wrong and thus the patient's rights are violated. The extent to which one rater agrees with another rater in terms of assessment of a particular observation is reliability. Unreliable assessment is a cause for serious concern because one patient's refusal of a treatment may be accepted as an autonomous decision by one clinician but the refusal may be deemed incompetent by another clinician. Nevertheless, relatively little has been studied as regards the reliability of clinicians' assessments of competency (Grisso, 1986; Kitamura et al., 1998). In a questionnaire, Kitamura, & Kitamura (2000) reported a very low inter-rater agreement about the judgment of psychiatric patients' competence made by members of the Japanese Association of Psychiatry and Neurology. This result would be alarming were it replicable in studies with clinical samples.

The issue of subjectivity in defining mental competency as articulated in court cases was pointed out as early as in 1941 by Green (1941). 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 minimise the chances of such injustices occurring, 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.

Thus, reliability of the competency testing is of a prerequisite of treatment for competent and incompetent patients in medical practice. The concept and definition of competency/incompetency should be embodied by substantial reliability of a means to assess it. Competency should be treated as a psychological concept. Many devices have been developed to reliably assess different aspects of patients' competency to give informed consent (Grisso, 1986; Kitamura et al., 1998). They include Competency Questionnaire (Appelbaum, Mirkin, & Bateman, 1981), Two-part Consent Form (Roth, Lidz, Meisel, Soloff, Kaufman, Spiker, & Foster, 1982), Recognition of Rights Violation in Counseling (Belter, & Grisso, 1984), Manual for Understanding Treatment Disclosures (Grisso, & Appelbaum, 1992a), Manual for Thinking Rationally About Treatment (Grisso, & Appelbaum, 1992b), Hopkins Competency Assessment Test (Janofsky, McCarthy, & Folstein, 1992), MacArthur Competence Assessment Tool-Treatment (MacCAT-T; Grisso, & Appelbaum, 1998; Grisso, Appelbaum, & Hill-Fontouchi, 1998), Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory (SICIATRI; Kitamura, & Kitamura, 1993) and others.

2.3.2. Multiple Facets of Competency: Categorical vs. Continuous Nature of Competency

Competency is continuous and multifaceted. Psychologically, competency has more than one dimension. Competency is often thought of in terms of 'yes' or 'no'. This is because the clinical reality requires a judgement that classifies patients into categories of competency and incompetency for the sake of involuntary admission (or respecting autonomous decisions). However, like many other psychological faculties, the capacity to give informed consent may be better understood as existing along a continuum (Freedman, 1981). Existing scales to measure patients' competency to give informed consent provide scores with multiple anchor points. Thus, a patient's capacity may be assessed as being somewhere between 'complete competence'

and 'complete incompetence'. When used in clinical settings, the cut-off point between competency and incompetency should be explicitly stated within one legal system; Otherwise a patient might be judged as competent by one psychiatrist and incompetent by another.

Almost 30 years ago, Roth, Meisel, & Lidz (1977) reviewed the literature and concluded that the concept of competency would include (a) evidencing a choice, (b) "reasonable" outcome of choice, (c) choice based on "rational" reasons, (d) ability to understand, and (e) actual understanding (see Appelbaum, Lidz, & Meisel (1987)). This has become the traditional classification of the dimensions of competency. Although there is little empirical evidence, it is very likely that these five dimensions of competency are independent from each other (Grisso & Appelbaum, 1995a).

2.3.3. Test Theory of Competency Assessment

Having observed that a test for competency to give informed consent should be high in agreement between different raters, one can argue that competency tests should be constructed in such a manner that most psychometric tests are constructed to achieve substantial reliability. To this end, the tests should (a) explicitly state the items to be measured, (b) operationalise a definition of the items, (c) define different anchor points for each item, and (d) standardise questions to elicit the subject's response. Theoretically, psychometric tests assess something that one cannot directly observe or measure; hence, the subject's responses are observed instead, after a *predetermined* standard set of stimuli are given. For example, intelligence is something we cannot observe directly in real life. This is a concept and is not seen, touched, or heard. Thus, we design a set of specific stimuli such as requests for the subject to calculate, read, speculate, or carry out a command. By measuring the subject's behaviour towards this set of requests, we assume we can measure the subject's intelligence. Psychometric tests are a speculation about the quality or quantity of something we cannot perceive directly; they rely on observing a subject's outwardly expressed behaviour. Therefore, if raters use different sets of stimuli we cannot expect high inter-rater reliability. Thus, establishing equivalent stimuli (e.g. cards, sounds, questions, etc.) is a very important prerequisite of reliable psychometric measures. When past investigators developed competency measures, they paid utmost attention to the standardisation of stimuli. For example, Roth, et al. (1982) developed a competency measure, the "two-part consent form", and designed separate explanations for different conditions (i.e. electroconvulsive treatment and sleep EEG in affective disease). The explanatory sheet was read by the subject, after which he/she was asked if he/she had understood it.

2.4. *Dilemma of Competency Testing: A Psychological Perspective*

The concept of informed consent has been advocated as a means to guarantee the patients' right to decide medical matters. Thus, for the informed consent to be valid, 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 appreciate the content and nature of the information and manipulate it to reach the decisions rationally that match his/her own value system (not necessarily to reach rational decisions). Therefore, this means that unlike a usual psychometric assessment, a competency test should measure a patient's capacity to give informed consent 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. For example, the term 'multiple sclerosis' may suffice for medically educated people (doctors, nurses, midwives, etc.) but it may only signify unfamiliar jargon for other people. Educated people may speculate that different parts ('multiple') of their body are getting stiff ('sclerosis') but they cannot be expected to understand more. This should not be taken as suggesting that medically educated people are more competent to give informed consent than non-medically educated people. It simply means that the information given (mere term of 'multiple sclerosis') is not sufficient or appropriate for people without a background in medicine. It is contrary to the concept of informed consent to claim that people are incompetent if they do not appreciate the meaning of things like 'degeneration', 'autoimmune disease', or 'brain stem'. Non-medically educated people can obtain as high level of appreciation of information as among medically educated people if the information is provided with greater care.

To quote Freedman (1981), "Judgement that an informed consent was obtained must depend not upon what the doctor said, but upon what the patient has heard". He further argued that "the most serious harm we can visit upon a human being is to tell him that his viewpoint, his innermost self, is of no worth. Whatever the outcome, the very attempt to *elicit* (italic by the

author) a competent opinion, if conscientiously carried out, can serve to allay this harm". Advocates of competency assessment, Appelbaum & Grisso (1988), once noted that "testing patients' ability to appreciate a situation requires eliciting their conceptions of their illness, their need for treatment, the likely outcomes, and the motives of those involved. Such questioning will necessarily need to be modified, to suit each patient's situation".

Because patients' competency to give informed consent is a psychological faculty, its assessment should be valid and reliable. Thus, we need structured instruments to measure patients' competency. However, the patients' response to such a structured testing is largely a function of what has been disclosed by health professionals. Thus, modifying the disclosed information according to the patient's understanding and attitude towards the aetiology of the illness, we may avoid labelling 'incompetent' for those patients who are indeed competent but have different cultural, social, religious, or economical backgrounds causing their response to be unacceptable in the eyes of the assessor/psychiatrist.

As in the legal concept of competency, we have encountered a dilemma when discussing the psychological aspect of competency. In order for the assessment of the competency to be reliable, the assessment tools to measure should be structured like any other psychological tools. This means that the same nature and amount of stimuli should be given for the patients whose response will be used as a reflection of their capacity of understanding and appreciating the information (stimuli) provided. However, the concept of patients' self-determination, which can be embodied by using the informed concept as a useful tool requires "different" nature and amount of information given to the patients to match their individual differences.

3. TOWARDS RESOLUTION OF LEGAL AND PSYCHOLOGICAL DILEMMAS

3.1. *Informed Consent: A Process*

3.1.1. *Diagnosing Process and Consenting Process*

Like many commentators, we have thus so far discussed informed consent as if it were an event that occurs between a physician and a patient in 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 (Appelbaum et al., 1987). For example, a patient may visit an out-patient 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. Usually the physician has a list of possible diagnoses (for example, pneumonia, cystitis, meningitis, etc.). Together, these are called differential diagnoses. Examination and treatment commences based on the differential diagnosis. Thus, the physician may prescribe Aspirin simply to alleviate fever while performing examinations to identify the cause of the fever. The medical information disclosed at this stage is, therefore, not the final diagnosis but the list of possible diagnoses. The patient may at this stage also be given a rationale for the tests. Hence, the patient understands that Aspirin does not cure the disease and that the physician has several possibilities in mind and X-rays and other tests will be performed in order to identify the most plausible diagnosis from the composite list. 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 test 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 reviews the condition. Thus, the continued exchange of information, questions, and consideration comprise the cascading events involved in informed consent.

Similarly, patients may gain a better understanding of the nature of the condition which they suffer from as the consultation proceeds. This understanding is called insight. Thus, repeated explanation can give patients more opportunities to think rationally about what is wrong. Also, legal rights to decide upon medical matters related to themselves are more likely to be appreciated if they are exposed to repeated explanation. Different facets of competency may become better with repeated exchange of explanation, questions, and answering. As Katz (1977) claimed, "neither a call for "patients' self-determination" nor for "physicians' discretion" adequately protects the participants in medical decision-making process". It should be "a joint understanding and depends much more on the nature and quality of the entire give-and-take process". To quote Katz (1977), "mere disclosure does little to expand opportunities for meaningful consent, particularly in surrender-prone medical settings".

3.1.2. Temporal Fluctuation of Competency Level

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 (Appelbaum et al., 1987). 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. A patient with schizophrenia might have an acute episode followed by another with only a short interval of remission in between. In these cases, the patients' competency level varies from one episode to another, from one day to another, or even within one day. Therefore, the judgement of the patient's competency should not be viewed as enduring. It should be repeated as the clinical situation demands.

If patients can expect the illness to recur in a relatively short time (e.g. schizophrenic episode, bipolar disorder etc.), they can give advance directives (Halpern & Szmukler, 1997), that is, they can issue instructions about the therapeutic procedures in advance. Alternatively, patients can assign someone as a proxy in advance. This avoids the situation where a proxy is designated who, in the patients' view, does not represent their value in life. Advance appointment may thus circumvent the often difficult problem of choosing between the patient's best interest (objective judgement by others) and the patient's prior wishes (subjective judgement). In these cases – advance directive and advance appointment of a proxy – it will be crucial to perform a competency test on the patient because it is only the evidence of the patient's incompetency that enables the physician to override the patient's refusal of treatment for his/her prior instruction to accept it or prior appointment of a proxy (or vice versa). Even during an episode of the illness in question, the patient, if competent, can make a decision that differs from a previous one. This decision should be respected. Thus, the physician can commence nothing unless identifying the patient's level of competency.

3.1.3. Sequential Informed Consent and Competency Testing

If all the patients should be tested in their competency to give informed consent in every occasion of information disclosure, such a competency test will be extremely cumbersome and impractical. Taking into account the facts that informed consent is necessarily continuous events and patients' mental state may vary from one occasion to another, we assume that the formal competency testing should take place only when such a testing is of vital importance to protect the patients' right to self-determination as well a right to treatment. Yet, at the same time, we are aware that informing

patients about what is going on in their body has therapeutic effects. Hence, it may be of vital importance for health professionals to measure the extent to which patients understand and appreciate what health professionals have disclosed.

3.2. *Patients' Autonomy vs. Paternalistic Intervention*

3.2.1. *Power Balance of Physicians and Patients*

Thus so far, we have argued that health professionals should pay utmost respect to patients' right to make autonomous decisions. Only when patients are found incompetent should a proxy be designated to represent either the patients' best interest or their will. All therapeutic and diagnostic procedures should be based on a valid contract between the attending physician and the patient, or if the patient is incompetent, the designated proxy. In such a contract, the two parties are symmetrical, having equal rights and reciprocal duties. For example, the proxy of an incompetent patient can refuse treatment on behalf of the patient, just as a competent patient can refuse treatment on his or her own behalf.

This is a basic assumption of informed consent. However, there are a few difficulties in establishing the equal participation of both physician and patient (or the proxy) in making a contract. Firstly, the patient (or the proxy) is usually unfamiliar with medical terminology and basic medical concepts. Many patients do not know even where the heart is located. It is more difficult to understand how the kidney filters metabolites from the blood stream into urine. For these patients, the first encounter of voluminous information about anatomy, physiology, pharmacology, and pathology is too much to learn in a day or two. In addition, medical knowledge and technology advances at such a fast pace that even medically qualified people are often able to remain updated only in their own field of specialisation. Patients may be often lost astray in the course of a conversation with an attending physician and may be ignorant of what they do not know. They may not even have a hint of where to begin asking about the nature of the disease and the pros and cons of the proposed treatment.

Thus, the balance of power shifts even more towards the physician. Some authors claim therefore that the patient should be 'empowered' (Opie, 1998). This is particularly the case in the Japanese medical setting. While non-medical people respect patients' self-determination in medical matters (Hayashi, Hasui, Kitamura, Murakami, Takeuchi, Katoh, & Kitamura, 2000), professionals often take paternalistic approaches towards their patients. In such cases, what is needed is not unilateral conveyance of voluminous

medical information from the attending physician to the patient. Someone independent on the physician-patient relationship should ask the patient as to his/her understanding of the information. In so doing, the physician can realise which part of his explanation was difficult for the patient to appreciate, while the patient can realise in which area he/she needs more information and explanation.

3.2.2. *Patients' readiness to face reality*

Most people are not ready to accept the fact that they have a disease (Katz, Abbey, Rydall, & Lowy, 1995). They have a psychological 'schema' in which they believe that they will be free from serious illnesses forever. The psychological distance from their ideal ('I will be free from a serious disease.') and their reality ('I suffer from cancer.') may be determined by many factors, but it may be longer as the illness is more serious. Thus, it may require more time and energy for the patients to adapt to new situation (to change their psychological 'schema') than for their family members, friends, and medical professionals. Thus the patients' failure to respond to the questions of a competence test does not necessarily mean that their incompetence but indicates that medical information needs longer time to be explained to them.

Due to anxiety, even competent patients may not think rationally for the time being (Appelbaum & Roth, 1981). Alternatively, they may feel depressed and temporarily lose their desire to get better or live longer. When a person is depressed, his/her values, beliefs, desires, and dispositions are dramatically different from when he/she is healthy because depressed individuals lose self-interest and even minimal concern for their own welfare (Elliot, 1997). Although the situation is more complex if coupled with physical diseases (e.g., Sullivan, Ward, & Laxton, 1992; Sullivan & Youngner, 1994), depression can be reduced. In such cases, it may be premature to conclude that the patient is incompetent. Psychological support may be needed for patients to restore their reasoning abilities (Katz et al., 1995). Proposed medical procedures should be postponed until patients regain such faculties and are able to make final decisions unless, of course, the nature of the condition (emergency) prohibits them from doing so.

3.3. *Competency Assessment: Two-Stage Hypothesis*

3.3.1. *Paradigm Change of Competency Testing*

Lack of medical knowledge and denial of the situation do not indicate *real* incompetency in patients even if a competency test shows poor results. This

means that, unlike standard psychometric tests, a competency test should not be used as a final indicator of a patient's capacity. A poor result includes (1) patients' real incompetency (which may endure) or (2) patients' temporary difficulty in using their capacity. Having considered the competency test in this manner, the test is *not* a psychometric test at least if patients find it difficult to "digest" what has been disclosed. Although developed and standardised as a measure to assess *patients'* competency, these tests can also be used as a means to assess *physicians'* capacity to convey medical and legal information to the patients in such a way that they can appreciate them. For example, in the MacCAT-T the patient was recommended a treatment and explained about two of the most important benefits of the treatment. Then they will be asked to answer what they think are the benefits of the proposed treatment. Poor response of the patient to such a question does not directly suggest his/her lack of capacity to understand the benefits of the treatment but rather insufficient amount or inappropriate mode of disclosure of the benefits of the treatment. If the test result suggests lack of the patient's understanding or appreciation, the disclosure of information should be repeated (unless the medical condition requires an emergency disposal) in such a way that corresponds better to the patient's educational, occupational, cultural, religious, or other important attributes until the subject understands it. Stimuli (medical information) should be accordingly extended, paraphrased, or otherwise modified. The number of times the information is repeated depends on the degree of emergency nature of the condition, general (rather than disease-specific) cognitive disability, and other factors.

Taking into account what has been discussed so far, we propose to separate the purposes of competency testing into two (Table 2). We think that the same test, even developed originally as a test of competency, can be used for the two purposes. What differs is not the type of tests but the purpose and situation of the use of tests. What we propose here is a change of paradigm – use of two-type of testing. One of them is to determine the 'digestibility' of the information given to patients, whereas the second purpose is to determine the patient's current competency. In every day practice, it should be assumed that the patient is competent unless the contrary is strongly suggested. Thus we perform a test but this is to examine if disclosed information is 'digestible' for the patients. The nature and amount of information should be tailored for individual needs and situation. The results of a test do not indicate patients' competence (or incompetence) but they do indicate the appropriateness of conveyed information. The test should not identify any patient as incompetent. In so doing, the assumption of adult patients' competency is maintained. It is used only to encourage patients' self determination.

Table 2. Two types of competency tests..

Target of assessment	Informal	Formal
	Appropriateness of information disclosure	Patient's competency
Areas for assessment	Medication Minor surgery Minor diagnostic procedure Others	Admission Major surgery Electric convulsive treatment Major diagnostic procedure
Assessor	Attending physician Other hospital staff Advocates, Students etc.	Independent persons
Method	Unstructured	Structured
Training	Informal	Formal
Reliability of assessors	Not necessary	Strictly examined
Judgement	(a) sufficient disclosure (b) insufficient disclosure	(a) competent (b) temporarily incompetent (c) incompetent
Disposal	(a) Respect patient's decision (b) Repeat disclosure of information	(a) Respect patient's decision (a) () Repeat disclosure of information (b) () Designate a proxy
Assumption of competency	Should stand	Questioned
Justification	Physicians' <i>bona fide</i> effort	Legislation

Only when repeated disclosure of information is followed by poor test results of the patients can we suspect their competency and perform a formal test of competency of the patients. This test should be psychometrically reliable. Thus the format of testing should be predetermined and the same test can determine (a) if the necessary information was disclosed and *appreciated* by the subject and therefore information disclosure need not be repeated and (b) if the patient is competent he/she does not need a proxy.

3.3.2. Tests of Appropriateness of Disclosed Information

The first type of purpose of tests is for the attending physician or other people to assess if the information disclosed was fully appreciated by the patient. The tests are used as a part of continuous events of informed

consent. These events may include (a) decision to undergo a diagnostic procedure (e.g. haematology) and discussion on its results, (b) commencement of medication or minor surgery, (c) change of the dose of medication and the type of medication, (d) simple but repeated tests such as blood pressure and urine analysis, and (e) any other medical procedures for which the attending physician thinks that the test will be necessary. In these cases, informed consent is less formal (not requiring a written form) and often takes the form of bilateral exchange of information and opinions. This type of tests should be as flexible as possible to suit individual differences.

For this purpose, tests are used to measure the *appropriateness* of the disclosed information and should not be used as a means to determine the patient's incompetency. Assumption of competency should always stand. Thus, the results of the test should be deemed (a) 'appropriate' or (b) 'inappropriate' in terms of what has been disclosed. If 'appropriate', the patient's decision should be respected. If 'inappropriate', the information should be given again in a modified way so that the patient is able to understand it. If a patient repeatedly fails to produce answers suggesting that the content of information was 'appropriate', then this may be a sign that he/she is incompetent, and if necessary, he/she will be referred for the second type of testing – test of patients' competency.

These tests of the first type should tap the appropriateness of information as to all elements necessary for informed consent: (1) the proposed treatment, (2) the nature of the patient's condition, (3) the patient's right to decide, and (4) the physician's regard for the patient's best interest. If there exists a lack of appropriate information in any of these areas, the information should be repeated. For example, a patient might be fully aware of the pros and cons of the proposed treatment as well as of the nature and possible consequences of his or her medical condition. However, he/she may want the physician to decide rather than making a decision on his/her own, simply because he/she is not aware of patients' right. In such a case, the patient should be taught that he/she has a legal right to decide. A patient's hesitation may come from a lack of legal education; the initial explanation about patients' rights as regards informed consent may be misunderstood as a mere courtesy of the physician.

Tests used for this purpose can also identify patients who respond poorly due to anxiety, depression, or denial. If these tests are used frequently for the same patients, assessors can identify these patients with fluctuating mental states. The results of tests used for this purpose give the attending physician as well as the assessor an opportunity to reconsider patients' psychodynamics, mood states, and cognitive functions; they also help reconstruct the

therapist–patient relationship. Repeated and informal use of these tests can also give patients an opportunity to think more about their condition and the proposed treatment. In addition, these tests can help them to readjust psychologically to the difficult situation which they are facing. Patients may have more time to cope with a situation positively and constructively by seeking advice from other professionals or friends, seeing positive aspects of the situation, and thinking about how to solve the most difficult problems first. If, however, these patients were not given time to think over the situation, they were likely to cope with it by emotional reaction or denial of the situation. If fluctuation of the patient's mental and cognitive state is observed, the physician can more easily discern when the formal consent of the patient should be requested, and if necessary, can arrange for advance directives from the patient or for the appointment of a proxy by the patient in advance.

Because use of tests for this type of purpose does not require so many resources as in the second type of tests, they are recommended for everyday practice. Such tests may be performed by the attending physician, other hospital staff (e.g. nurses, clinical psychologists, social workers, pharmacists), or with the patient's permission, volunteers. Relatively new systems of patients' rights advocate and bioethicists may be used as assessors (Dukoff & Sunderland, 1997; Krajewski & Bell, 1992). Students from medicine, nursing, psychology, and other related disciplines may also become assessors.

Use of tests for the first type of purpose will meet the following requirements: (a) an assumption of competency regardless of diagnosis, (b) better information disclosure, (c) more time for the patient to think about decision, (d) more chances to encourage patients' autonomous self determination, and (e) identification of those who may be incompetent thus need protection.

Because competency should be presumed in every case before going into a competency assessment (Pepper-Smith, Harvey, Silberfeld, Stein, & Rutman, 1992), a patient can by theory refuse to participate in the assessment. The patient's capacity to give consent to testing may be less strict because he/she is required only to have a general understanding of the issue at hand. If evidence strongly suggests the patient's incompetency and yet he/she refuses to be assessed, the assessors cannot perform the assessment. In order to protect legal rights both to the due process and to the bodily integrity of such patients, there should be legislation to allow relatives or physicians to apply for a court hearing or other equivalent institutions such as an ethical committee (Institutional Review Board). In court, the patient's competency to refuse the test of the first type can be judged. Only with authorised

permission can the assessor administer the test to those patients who refuse to be assessed. With such legislature, the assumption of patients' competency remains within the medical service system.

3.3.3. *Tests of Patients' Competency*

Another purpose of test use is for independent assessors (e.g. lawyers, judges Zito, Craig, & Wanderling, (1991), advocates, and third-party health professionals (e.g., Bloom, Faulkner, Holm, & Rawlinson, 1984; Hargreaves, Shumway, Knutsen, Weinstein, & Senter (1987) to assess the patient's capacity and to give consent to a single-event type of clinical procedure.

This test may be viewed in analogy to the assessment of competency to make a will (e.g. Spar & Garb, 1992). For example, when a person writes a will, whether this will is valid or not depends on the competency of the testator at the time of writing. This is an all-or-none event. There is no 'grey zone' in such matters. In medicine, these events may include (a) admission to a hospital, (b) final decision to undergo a major surgical operation, (c) extraordinary treatment, (d) electroconvulsive therapy, and (e) major and serious diagnostic procedures. In these cases, decisions are, to some extent, irreversible, occur less frequently, and they may have a serious impact on the patient's present and future welfare. Because the findings from tests of this type may result in the deprivation of many types of civil rights, competency tests should be as standardised as ordinary psychometric tests.

Competency as regards understanding admission should be different from competency as regards understanding treatments. Cichon (1992), though admitted that the concept of competency was illusive and confusing, claimed that even if the basis of civil commitment of mentally ill people was a finding that the patient was unable to care for himself, this did not address the individual's capability of contributing to treatment decisions. Consent to admission does not automatically mean that the patient has given consent to treatment without the disclosure of all the necessary information. Thus, a single test result of incompetency for a specific procedure does not automatically indicate incompetency in other areas of decision-making.

The second type of purpose of testing is to measure the *patient's* competency to give informed consent. Thus, the output of the test should be (a) competency or (b) incompetency of a patient. If the patient is competent, the patient's decision should be given the utmost respect. If the patient is incompetent, a proxy should be designated (or summoned if appointed by the patient in advance) and the proxy should decide according to the patient's best interest or what he/she would have decided were he/she competent. We also recommend an intermediate output except for an emergency situation.

This is a case where a patient who failed to reach the competency level due to, as evidence suggests, a lack of information or due to anxiety, depression, denial or another mental states or mechanism which may be alleviated in time before the final decision should take place.

Tests of the second group require independent assessors, and more time and financial resources (Hargreaves et al., 1987; Zito et al., 1991) than those of the first group. Therefore, they are more formal procedures for determining competency and incompetency. The assessors should receive standardised formal training by specialists. Concordance of the assessment made by these formal assessors (inter-rater reliability) should not only be examined before assessors are dispatched to clinical settings but it should also be re-examined within a certain interval after assessors are certified.

Because of the complexity of the tests with this second type of purpose, it is practically impossible to repeat the test over a short time of treatment. Protection of the due process rights of the patients will be provided by the more informal tests of the appropriateness of information disclosure.

The use of the tests for the second type of purpose will meet the requirements of (a) respecting a competent patient's autonomous decision-making; (b) protecting an incompetent patient's right to be given proper treatment as well as procedural protection; (c) protecting a patient from undue influence, and (d) providing a chance for a temporarily non-competent patient to regain capacity to exercise autonomous decision-making.

3.3.4. *Use of the Tests and Embodiment of the Ideal of Informed Consent*

In the long run, the differential use of competency assessment may enhance health professionals' awareness of the importance of informed consent (e.g. Appelbaum, 1988). They may also help in the development of better methods of information disclosure, and openness of medical procedures. Inviting people from the outside to be competency assessors may make mental hospitals and clinics more open and understandable to outside people. The Japanese medical settings – particularly the psychiatric settings – have been criticised as secluded from outside, thus have a potential of abuse. Our suggestion of introduction of tests used by people from outside may hopefully result in reduced rates of abuse and violence against psychiatric in-patients.

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. We presume it is of vital importance to give repeated assurance to patients, for example, that their decisions are of utmost importance, and that even if treatment or admission is coerced, it is for their best interest. Any medical procedures

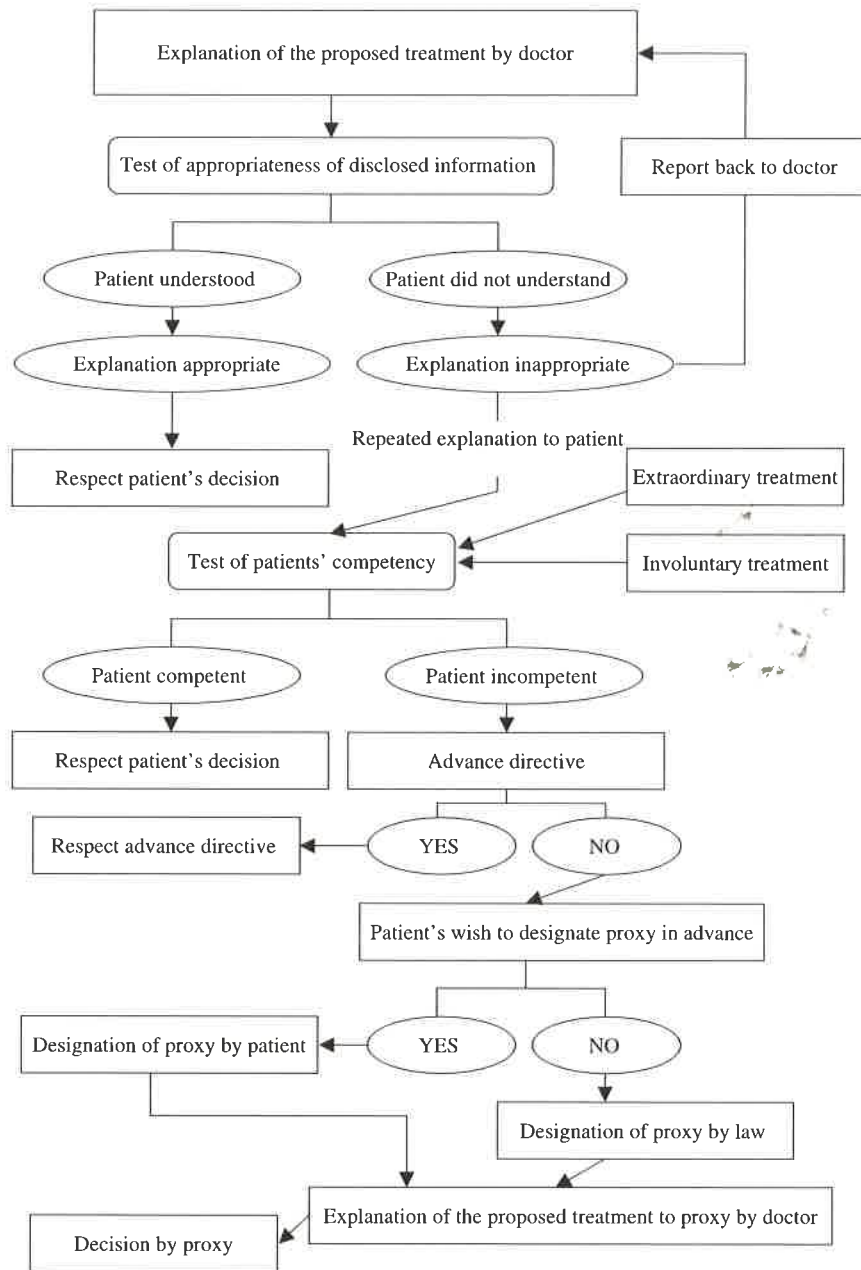


Fig. 1. Two Types of Tests: Decision Tree.

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 (Fig. 1).

4. CONCLUSION

Health professionals have been in an ethical dilemma for some time. On the one hand, all the patients, be they medical or psychiatric, should be assumed as capable of understanding what is involved in their care and thus of making their own autonomous decisions. Forcing competent patients into treatment is a violation of human rights. On the other, mental health professionals are expected to protect those patients who are unable to make medical decisions in their own best interest. Respecting their refusal for treatment superficially is a violation of their right to be protected as well as the deprivation of legal due process, yet one cannot determine a patient's incompetency without testing him/her. However, testing the patient in terms of competency (its hypothesis being that he/she is incompetent) is a violation of the assumption of competency. If such testing is performed only among psychiatric patients, it may be criticised as lacking equal protection between medical and psychiatric patients.

Even if a competency test is justified, health professionals find themselves in yet another dilemma. A patient's competency varies temporarily and informed consent should be sought for any new diagnostic and therapeutic procedures. Theoretically, this will lead to the administration of a competency test in every situation where anything new commences. This will be burdensome for both the professionals and the patients. It may also have detrimental effects on the therapist-patient relationship.

Taking into account these two dilemmas, we have proposed the two different types of purposes of test use (even the same test). The first purpose is to measure the appropriateness of information disclosed by professionals. The patients' competence should be assumed. A poor test result will require that the information be repeated in a more accessible manner, because tests of this kind are short and informal, they may be used in everyday practice. The second purpose of test use is to measure the competency of the patients on occasions when they need to make major decisions. Because the patients' incompetency is hypothesised by definition, the tests should be formal and carefully performed by independent assessors who have been rigorously trained. The methods and contexts for use of these tests should be legislated.

A poor test result will be followed by the designation of a proxy who will represent the patient's value system or best interest. Thus, incompetent patients can be protected. Because such occasions are infrequent, testing may not be burdensome.

Tests of the appropriateness of disclosed information are justifiable because the balance of power between professionals and patients is strongly skewed. This power imbalance is due to (a) excessive and rapidly growing medical information, (b) special conditions of patients such as anxiety, depression, and denial. Furthermore, we believe such procedures will render all the people involved in patient care (including the patients themselves) more aware of the importance of respect for the autonomous decisions made possible by a mutual exchange of opinions and information.

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CARE FOR THE ELDERLY IN JAPAN: PAST, PRESENT AND FUTURE

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ABSTRACT

Care for the elderly is the most pressing problem now facing Japan. For maintaining a long and healthy life, it is important to refine the self-care of people and to create a well-balanced system of support involving health care, welfare, nursing care, and medical treatment. Mutual support within each local community is also indispensable for restructuring care-minding areas. Due attention should also be paid to the ethical aspects concerning care of the elderly. This chapter attempts to reflect on the brief history of the care for the elderly in Japan.

1. INTRODUCTION

Care becomes an inevitable subject for both the elderly and the aging society. An aging society requires not only the diverse development of care as a skill, but also the development of what the idea of care for a human being actually means. Care emanates from our basic way of being, or rather the question of care is the very basic question of our way of being (cf. Takahashi, 2001; Nakayama, 2001). For this reason, the theme of how well

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