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Method for Assessment of Competency to Consent in the Mentally Ill

Rationale, Development, and Comparison with the Medically Ill

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Introduction

The doctrine of informed consent has been widely accepted and the patient's right to self-determination highly respected, particularly in Western countries. In Japan, the doctrine of informed consent was introduced quite recently. The necessity of doctor's disclosure of medical information has been discussed since the 1970s. The term "medical ethics" was introduced in the 1980s and the concept of informed consent was increasingly respected in Japan. In 1988 the Ministry of Health issued an interim report relating to the future medical practice in Japan. It said that in view of the introduction of the concept of informed consent, it is desirable to take into account that patients receive satisfactory medical information—purpose, expected effects, and alternative of the

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proposed treatment—beforehand and that they give consent to the treatment (Iwamori, 1991). It is, however, regrettable that psychiatric patients are exempted from the right to self-determination in medical decision making, by reason of being dangerous or being deemed incompetent.

We argue herein the patient's right to self-determination in the medical sphere from a legal perspective. The review focuses mainly on the American literature and American cases. We claim that the examination of the patient's competency is a safeguard of due process. It is worthwhile reviewing the American literature and cases because Japanese legal theories have been much influenced by the American legal theories and jurisprudence, particularly since the 1950s. We also review the literature on instruments of competency testing, and we present the development of a new clinical instrument to assess the patient's competency to give informed consent. We report data using this instrument and show that, unlike what has been implied by mental health laws in many countries, not all psychiatric patients are totally incompetent. Finally, we offer a justification of the use of such a competency assessment scale in order to protect patients' due process rights.

Self-Determination in Medical Practice

In Anglo-American countries, the right to self-determination of whether an individual receives a proposed treatment has long been recognized in common law. For example, in the *Schloendorff*¹ case (1914) in the United States, medical intervention without the patient's consent was denied. The *Schloendorff* court articulated that "every human being of adult years and sound mind has a right to determine what shall be done with his own body."

Respect for the patient's self-determination was embodied in informed consent, which means that medical decision making must be based not only on the physician's determination but also on *competent* patients' determination, derived from their own value systems. Only if a person cannot exercise his or her right to make a medical decision for one reason or another is a proxy decision justifiable. In such a case, a proxy must be appointed through appropriate procedures. This proxy decision must serve the best interests of the patient, or must be done based on the patient's own will, which he or she would exercise were the patient competent. If the decision made by the proxy does not meet these criteria, it is no longer justifiable. In other words, a patient's right to selfdetermination is then exercised through a proxy. Moreover, once the cause that prevented the patient from exercising self-determination subsides or disappears, the authority of the proxy on behalf of the patient cannot be admissible, and the patient's decision making resumes as the sole basis on which physicians must rely.

It has been established that informed consent consists of three basic elements: disclosure of medical information by physicians, the patient's competency to give consent to treatment, and the voluntariness of the consent (Appelbaum, Lidz, & Meisel, 1987; Grisso, 1986). However, in the early stages of

¹Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).

the development of this doctrine, it was what was disclosed that was given the greatest attention. Thus, for example, three classic court cases in the United States—Salgo v. Leland Stanford Jr. University Board of Trustees (1957),² Natanson v. Kline (1960),³ and Mitchell v. Robinson (1960)⁴—all established the physician's duty to disclose medical information before commencing the treatment.

It must be noted here that the idea of informed consent in experimental research has developed in the Nuremberg trials separately from that in clinical settings. Two sections of the Nuremberg Code dealt with informed consent. After this, many countries set up their own ethical codes for clinical research (Appelbaum et al., 1987). The necessity of an international code had been gradually recognized when the World Medical Association adopted the Declaration of Helsinki in 1964.

As the American civil rights movement in the 1970s spread widely, "the federal courts began to shift the balance of power from the authority of the state (and, by extension, the authority of professionals) to the autonomy of individuals" (Miller, 1994). In 1972, the U. S. District Court for the District of Columbia, in the *Canterbury* case,⁵ stressed the critical objective of assuring the patient's self-determination (Weisbard, 1986).

As mentioned above, in the United States, a patient's right of self-determination in medical practice has been established and recognized in common law. However, the U.S. Constitution does not *explicitly* mention this right in medical care. The question here is whether the Constitution confers a fundamental right upon the self-determination in medical practice. The self-determination to consent to, refuse, or choose an alternative to the proposed treatment is deeply personal. To put it differently, the right of such determination is the personal control over one's body. The individual's bodily integrity must be the privacy interest. The notion of bodily integrity can be traced back to Union Pacific R. Co. v. Botsford (1891)⁶ and later Schloendorff v. Society of New York Hospital (1914).⁷ The right to have choice in certain matters affecting a person's life has been found to be of "fundamental value." In other words, only personal rights that can be deemed "fundamental" or "implicit in the concept of ordered liberty" are included in the guarantee of personal privacy (*Roe v. Wade*, 1973).⁸ If this formulation would extend a fundamental right to the right of the self-determination in medical care, it should be possible that the right must be categorized as the privacy right. Some previous decisions of the Court, however, have not construed the Constitution to confer a right of privacy extending to the right of the self-determination in health care.

In judicial review in the United States, a *fundamental right*, such as privacy, can be overridden only by a compelling governmental interest. On the other

⁷See supra note 1.

²Salgo v. Leland Stanford Jr. University Bd. of Trustees, 317 P.2d 170 (Cal. Ct. App. 1957).

³Natanson v. Kline, 350 P.2d 1093 (Kan. 1960).

⁴Mitchell v. Robinson, 334 S.W. 2d 11 (Mo. 1960).

⁵Canterbury v. Spence, 464 F.2d 772 (D.C.Cir. 1972).

⁶Union Pacific R. Co. v. Botsford, 141 U.S. 250, 11 S.Ct. 1000 (1891).

⁸Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705(1973).

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hand, a right classified as a *liberty interest*—for example, a refusal of treatment, at least when such treatment is deemed less than highly intrusive-may be outweighted by a mere rational or legitimate governmental interest (Cichon, 1992). In other words, the scope of the right to refuse treatment has been diminished by its description as a liberty interest (Cichon, 1992). The right to refuse unwanted antipsychotic medication has also been classified as a liberty interest (Washington v. Harper, 1990).⁹ The U.S. Supreme Court has recently stated that "the principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions" (Cruzan v. Director, Mo. Dep't of Health, 1990).¹⁰ The Supreme Court also assumed that the United States Constitution would grant a competent person a constitutionally protected right to refuse lifesaving hydration and nutrition. From these observations, it is evident the Court is reluctant to classify a right to self-determination in health care as privacy, but it can at least be said that the right is protected constitutionally as a liberty interest.

In Japan, though the doctrine of informed consent has been gradually recognized, the right of self-determination has not yet been declared as constitutionally protected by the Japanese Supreme Court. Some commentators such as Ashibe (1997) and Satoh (1995) mentioned that this right must be protected based on the right to pursue happiness of the Article 13 of the Japanese Constitution. This article plays an important role when drawing unenumerated rights.

This Article provides that "All of the people shall be respected as individuals. Their right to life, liberty, and pursuit of happiness shall, to the extent that it does not interfere with the public welfare, be the supreme consideration to legislation and in other governmental affairs." Article 13 thus consists of two parts: (1) the principle of personal dignity and (2) the right to pursue happiness. The right to pursue happiness was strongly influenced by the U. S. Declaration of Independence. The principle of personal dignity and the right to pursue happiness are tightly connected. It is thus construed that the right to the pursuit of happiness is the right to propose rights based on personal interests that are indispensable to personal existence (Satoh, 1995).

Although the Japanese Constitution defines specific individual rights in subsequent Articles, this does not necessarily mean that all the rights are listed in the text. While many important rights with historical necessity are cited, many other important rights not specified in the text need a constitutional basis on which they can claim justification. Many unenumerated rights have been claimed based on Article 13, but only rights and interests indispensable to personal existence can be said to be constitutionally protected (Satoh, 1995).

Ashibe (1997) also stands on a similar theoretical base. According to Ashibe, for unenumerated rights to be constitutionally protected the following points should be fulfilled: (1) the right in issue has long been regarded as fun-

⁹Washington v. Harper, 110 S.Ct. 1028 (1990).

¹⁰Cruzan v. Director, Mo. Dep't of Health, 110 S.Ct. 2841(1990).

damental to the nation's life; (2) Japanese citizens exercise the right or can exercise it, and (3) the right should not violate other people's fundamental rights. A key issue of recognizing a certain right as constitutionally protectable is whether it is indispensable to personal existence (Satoh, 1995). Article 13 encompasses many rights of personal value itself and personal autonomy (the right of self-determination). The former encompasses rights of reputation and privacy. The way in which the right of privacy is recognized is still controversial in Japan. Ashibe (1997) considers that the right of privacy encompasses not only the right to control one's own information but also personal autonomy. Conversely, Satoh (1995) considers it more narrowly as the right to control one's own information. According to Satoh (1995), the right of self-determination concerning matters of control over one's own life and body, establishing and maintaining family, and reproduction and other matters can be protected under Article 13. Among these, the right of self-determination in health care, or the right to refuse treatment, must be given great weight (Satoh, 1995).

Ashibe and Satoh respect self-determination as utmost importance. A contrary view proposed by Higuchi (1992) suggests the right to choose not to be informed. This argument was based on a survey done by the *Asahi* newspaper indicating that about 40% of the survey participants—random individuals disfavored disclosure of the information about cancer diagnosis. His contention that Japanese patients may choose either paternalistic nondisclosure or complete and thorough disclosure is a "modified version of autonomy."

Self-Determination Versus Interests of the State in Psychiatric Practice

The right to medical self-determination has been protected in private law. However, it is not enough for individuals with mental illness to assert their right to self-determination in health care within the private law sphere, since the legal compulsory commitment is provided by mental health laws. National governments have strong power to commit mental patients, based on legal criteria.

Traditionally, there have been two governmental interests that override the rights of mentally ill people in the United States—police power and *parens patriae*. The state can invoke police power to prevent the mentally ill from harming themselves or others (Harvard Law Review, 1974; Brakel, 1985). The scope of the state's police power authority has been defined in terms of either an "emergency" or "dangerousness" or both (Cichon, 1992). If a mentally ill individual who needs care and treatment or who is dangerous only to himself or herself lacks the capacity to make his or her own treatment decisions, the state may properly use its *parens patriae* authority to compel commitment for the person's best interest (Harvard Law Review, 1974; Brakel, 1985).

Some psychiatric patients have long been deemed not to have a sound mind because of their illness, and therefore to be unable to give proper consent to treatment or hospitalization (Winick, 1991a, 1991b; Marquette Law Review, 1990). In medicine, involuntary confinement is very unusual, except for some life-threatening communicative diseases. However, in psychiatry, civil commitment is still quite usual all over the world. In Anglo-American law, civil commitment based on *parens patriae* is justifiable if the commitment serves the best interests of the subject who is incompetent (Harvard Law Review, 1974). Hence, competency is a key issue in psychiatric treatment.

The Japanese Mental Health and Welfare Law

Like Western countries, Japan has its own mental health law. The Japanese Mental Health and Welfare Law (MHWL) provides civil commitment when (a) a mentally disordered patient is dangerous to self or others (Article 29) or (b) needs treatment (Article 33). Article 29 provides that when a Prefectural Governor (*Chiji*), as the result of the medical examination prescribed in Article 27, has deemed that the examined person is mentally disordered, and is liable to injure himself or others because of his mental disorder unless he is admitted to a hospital for his medical care and custody, the Governor may admit him to a mental hospital established by the National or Prefectural Government, or a designated hospital. In order to commit a person civilly, the results of the medical examinations done by at least two designated physicians (*shitei*-I) must be concordant. Article 33 provides that with regard to a person who has been deemed by the superintendent of a mental hospital, as a result of the medical examination of a designated physician, to be mentally disordered, and thus, to be in need of admission to a hospital without his (the patient's) own voluntary consent; the consent should be given by the patient's *hogosha*—a person responsible for custody. MHWL defines the order of the assignment of the *hogosha*; they are (1) guardian, (2) spouse, (3) a person who exercises parental power over the patient, and (4) a person responsible for the support of the patient.

In this context, a patient is never evaluated for competency to give informed consent to hospitalization and treatment.

Lack of provision of a patient's competency to consent is MHWL's great deficit. In Japan, a patient is committed involuntarily without assessing his or her competency to consent to hospitalization, and also the committed patient's treatment automatically commences or changes without assessing the admitted patient's competency to treatment.

Competency Assessment as a Procedural Safeguard

In the United States, however, the notion that the mentally ill are generally incompetent was challenged in the late 1970s. In *Rennie v. Klein*¹¹ (1978), the court mentioned, quoting *Scott v. Plante*¹² (1976), and Plotkin (1977), that mental illness is not the equivalent to incompetency, which would render one incapable of giving informed consent to medical treatment. The court continued that "before the state can use *parens patriae* as a basis for medication, some hearing on the issue of competency must be held," quoting *Scott v. Plante*.¹³ As Cichon (1992) commented, evidence brought forth in treatment

¹¹Rennie v. Klein, 462 F. Supp. 1131 (1978).

¹² Scott v. Plante, 532 F. 2d 939 (3rd Cir. 1976).

 $^{^{13}}Id.$

refusal litigation and through medical research, however, has documented the fact that many mentally ill individuals are capable of making informed consent decisions.

Nevertheless, treating mentally ill individuals as competent without sufficient evaluation may raise a problem. A recent American court case, *Zinermon v. Burch*¹⁴ (1990), argued that Burch, a psychotic patient, was deprived of a substantial liberty interest without valid consent or an involuntary placement hearing. In this case, a patient, Burch, was asked to sign forms agreeing to admission and treatment several times, though he did not remember what he had done, owing to a severe mental condition, having been hallucinating, confused, psychotic, and even having believed he had been "in the heaven." Its criticism of Burch's 5 months' stay without external review of his need for hospitalization or treatment suggests that such review might satisfy due process (Miller, 1994).

If the proxy's decision is given precedence mistakenly, when the patient *is* able to exercise his or her right to decide, it violates the patient's right to self-determination, whereas if the patient is mistakenly judged to be able to do so when he or she is in reality unable to, the patient is deprived of due opportunity to be guarded by a proxy. Thus, in clinical settings, the assessment of the patient's competency to exercise self-determination is of pivotal importance in protecting both the patient's right to decide and his or her right to be given proper legal protection and care and treatment. Therefore, some inquiry into competency to consent to hospitalization or to treatment must be carried out. It is important to keep a proper balance between assessment criteria in order to promote the idea of informed consent and the patient's health.

Winick (1991a, 1991b) claimed that competency assessment is necessary only when a patient's assent to hospitalization or treatment is deemed to be a product of impairment of his competency or the patient objects to recommended treatment, particularly if the consequences of such refusal would be grave. This contention is that "even in the case of the mentally ill, it is generally appropriate to accept voluntary expressions of individual choice in a variety of contexts without insisting that competency, even when questionable, be ascertained" (Winick, 1991b, p. 40). Although this argument sounds practical, it may have flaws; the consent given by incompetent individuals who agreed with proposed treatment is not based on competent decision making. Therefore, whenever a patient is asked for "consent" to treatment or hospitalization, competency assessment must be carried out for the sake of procedural safeguards.

Nevertheless, there is thus far no clear consensus on how a state should guarantee due process protection to committed persons or on the specific procedures that should be used to override the right to refuse—for example, psychotropic medication in nonemergency situations (Bloom, Faulkner, Holm, & Rawlinson, 1984). These authors introduced three possible models extracted from case law for resolution of these problems: the judicial competency hearing model, psychiatric hearing model, and civil commitment hearing model.

¹⁴Zinermon v. Burch, 110 S. Ct. 975 (1990).

The judicial competency hearing model was laid down by the court in *Rogers* v. *Okin*¹⁵ (1979). It mandates that due process is preserved by a judicial hearing determining whether a committed person is competent or incompetent to refuse psychotropic medication.

On the other hand, in *Rennie v. Klein*¹⁶ (1978), an example of the psychiatric hearing model, the court found due process did not have to be provided by a judicial hearing, but decision making could be carried out by a psychiatric administrative hearing officer.

The third model is different, in that a competency hearing is carried out by medical officers at the time of the civil commitment and does not wait for refusal to occur. This model is the same as what Stone (1981) proposed.

Winick (1991a) proposed (a) a formal process to assess the competency of a patient who objects to hospitalization and (b) an informal process by an independent lawyer or lawyer-supervised lay advocate to assess a patient's competency when he or she seeks voluntary hospitalization and the person's competency is questionable.

It is a difficult matter to ascertain what kind of process is due and when a competency inquiry must be conducted. It is widely recognized that a psychiatric patient's mental state or competency level varies from time to time. If so, a competency assessment must be carried out whenever hospitalization or a new treatment is proposed. In some cases, the hospital administration department would have to know whether a patient gives consent to a newly proposed treatment, and, of course, whether a patient's consent or refusal is based on competent decision making. From these considerations, a competency assessment process must be conducted at any time that it is required. Therefore, it is necessary for the competency assessment device to be as simple as possible and to be sensitive enough to measure different levels of competency. Although the civil commitment model and Stone model require competency hearing at the commencement of the civil commitment, a single hearing is not enough to protect the patient's due process right.

Another issue is who is the right person to assess competency. The judicial hearing is formal and must serve the patient's due process rights. However, the problem of a judicial hearing is that it takes a long time to fulfill procedures. On the other hand, an internal review can be carried out quickly. However, the administrative review may be inappropriate to assess a patient's competency, because the two powers of treating and assessing are not separated. We propose a competency hearing process by a person who is not involved in treatment. In this model, a person who is in charge of competency assessment is not necessarily fully independent from a hospital where a patient is admitted to or is supposed to be admitted, but he is at least independent from the treating physician. The profession of the examiner is not important, providing that an objective assessment is conducted independently from an attending physician. In any case, the competency assessment should serve due process so as to prevent an erroneous commitment by an arbitrary determination.

¹⁵Rogers v. Okin, 478 F. Supp. 1342 (1979).

¹⁶ See supra note 11.

Assessment Devices of Competency

Various devices have been developed to assess patients' competency to give informed consent to different modes of psychiatric treatment. We will briefly review them.

Appelbaum, Mirkin, and Bateman (1981) constructed the Competency Questionnaire. This is a very simple structured interview schedule to assess competency concerning psychiatric admission.

The Two-Part Consent Form (Roth et al., 1982) is a questionnaire to assess competency to consent to electroconvulsive therapy (ECT). This instrument was developed by Miller and Wilner in the early 1970s and adapted by Roth et al. (1982). In Part 1, the details of treatment are presented in a written form to the patient, while in Part 2, the patient is offered a questionnaire to assess whether he or she understands the purpose, nature, benefits, risks, and alternatives of the ECT, and whether the patient is aware of the right to withdraw from treatment.

Weithorn and Campbell (1982) developed the Measure of Competency to Render Informed Treatment Decisions to assess children's competency. In this measure, four different stories—about diabetes, epilepsy, depression, and enuresis—are told to healthy children. They are then asked to think how it would be were they to suffer from each of these conditions. Here again, the same sets of information are provided and the children are asked questions to measure the extent of their understanding of the nature of the conditions and the proposed treatment.

Another test to measure children's competency is the Recognition of Rights Violating Counseling, by Belter and Grisso (1984). A videotape of an introduction to psychotherapy is shown, and the rights of the subjects are explained. Then, another videotape is shown and subjects are asked which part shows infringement of the subject's rights, leading to a quantitative competency score. This is a measure of the children's understanding and awareness of legal rights related to therapeutic decision making.

Grisso and Appelbaum (1992) developed the Manual of Understanding Treatment Disclosure. It consists of two parts. The first part explains in layman's terms three different types of illness; schizophrenia, depression, and heart disease. In the second part, the subjects are asked questions about these illnesses to measure how much they understood the explanation. This has been incorporated into Appelbaum and Grisso's MacArthur Treatment Competency study (Appelbaum & Grisso, 1995; Grisso & Appelbaum, 1995; Grisso, Appelbaum, Mulvey, & Fletcher, 1995).

In the Hopkins Competency Assessment Test (Janofsky, McCarthy, & Folstein, 1992), subjects read a written explanation about durable power of attorney and, after a short interval, are asked six questions.

Bean, Nishisato, Rector, and Glancy (1994) developed the Competency Interview Schedule. Although this was originally designed to assess competency to give consent to ECT, it may be useful for other modes of treatment.

Most of the competency rating scales cited thus far are limited to specified conditions such as schizophrenia (Grisso & Appelbaum, 1992), depression (Weithorn & Campbell, 1982; Grisso & Appelbaum, 1992), and epilepsy (Weithorn & Campbell, 1982), or specified treatments such as ECT (Roth et al.,

1982; Bean et al., 1994), psychotherapy (Belter & Grisso, 1984), and psychiatric admission (Appelbaum et al., 1981), or specified aspects of competency such as understanding of the benefits and risks of the proposed procedures (Roth et al., 1982; Grisso & Appelbaum, 1992; Belter & Grisso, 1984; Janofsky et al., 1992; Bean et al., 1994).

Moreover, because most of these measures were developed as research instruments, they are highly structured. For example, the same predetermined set of medical information is given in the Two-Part Consent Form (Roth et al., 1982); the Measure of Competency to Render Informed Treatment Decision (Weithorn & Campbell, 1982); the Recognition of Rights Violation in Counselling (Belter & Grisso, 1984); the Manual for Understanding Treatment Disclosure (Grisso & Appelbaum, 1992); and the Hopkins Competency Assessment Test (Janofsky et al., 1992). Because the patient's understanding and rational manipulation of medical information is a function of the quality and quantity of information given prior to testing, it is advisable to use the predetermined set of information in order to achieve better validity and reliability of the measuring instrument. However, this is unsuitable for a clinical setting because no two patients have the same illness characteristics or are recommended for exactly the same treatment. Furthermore, the idea of informed consent is not to give the same amount of information to all patients in the same manner, but rather to give different but *sufficient* amounts in such a way that individual patients can appreciate it. Rating instruments of competency should therefore be more flexible for use in clinical settings.

Inspecting the item content of the above scales of competency, we found five different aspects of competency: (1) evidencing a choice, (2) actual understanding, (3) rational manipulation of information, (4) appreciation of the nature of the situation, and (5) reasonable outcome of choice (Appelbaum et al., 1987; Appelbaum & Grisso, 1988; Appelbaum & Roth, 1982; Roth, Meisel, & Lidz, 1977).

"Evidencing a choice" means that a patient can explicitly show whether he or she gives consent to or refuses treatment presented by a physician. In this regard, if a patient answers verbally either "yes" or "no," he or she is deemed competent. This item is situated on the lowest standard of a patient's cognitive ability. Therefore, it is the most powerful and widely encompassing indicator of competency to exercise the right of self-determination.

The item "actual understanding" assesses a patient's ability to understand information such as the benefits and risks of the proposed treatment.

"Rational manipulation of information" means that the patient's determination is not influenced by hallucinations, delusions, or other pathological determinants.

The standard of "appreciation of the nature of the situation" measures a patient's ability not only to recognize the benefits and risks of a treatment but also to take into account the future orientation of his or her own medical decision making by processing information reasonably. This item requires the presence of insight and future perspectives. The patient needs to realize that he or she is suffering from a mental (rather than physical) illness and to understand the nature of the illness. Thus, insight is essential here.

If a patient's conclusion is far from the one that a "reasonable person" would reach, the individual is incompetent according to the "reasonable out-

come of choice" standard. It is, however, important that this standard could wrongly assess a patient's competency. Even if a patient gives consent to the proposed treatment by unreasonable process, this patient is assessed competent simply because his or her conclusion meets the suggestion made by the physician. Conversely, if a patient refuses the treatment in accordance with his or her reasonable value system, the patient might be judged as incompetent.

Structured Interview for Competency/Incompetency Assessment Testing and Ranking Inventory (SICIATRI)

Based on a literature review, we selected items reflecting each domain of competency to give informed consent and constructed a new 12-item structured interview (Table 1), the Structured Interview for Competency/Incompetency Assessment Testing and Ranking Inventory (SICIATRI; Kitamura & Kitamura, 1993a).

Each item was provided with a brief explanation, standard and probe questions, and three anchor points with definitions (Appendix A). The 12 items are ordered sequentially according to the level of cognitive capacity to pass through along to the theories of Martin and Bean (1992). This order also gives both the interviewer and patient an impression that the interview is as natural as possible.

The most basic item—"is aware that he/she was informed"—begins the SICIATRI. This question taps the patient's awareness of having received medical information necessary to give informed consent. This information includes the purpose and nature of the proposed treatment, admission, or other medical procedure such as medical checkups. This may be given by the attending

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|--|-----------------------------|----------------------|--------|
| SICIATRI items | Psychiatric patients (%) | Medical patients (%) | p |
| Is aware that he or she was informed | 84.0 | 95.7 | .3968 |
| Understands that he or she has a right | | | |
| to decide | 45.5 | 80.0 | .2308 |
| Evidences own choice | 100.0 | 100.0 | |
| Does not waive the right to decide | 80.0 | 86.4 | .8419 |
| Understands the expected benefits | 70.8 | 100.0 | .0193 |
| Understands the expected risks | 54.2 | 45.5 | .7679 |
| Understands the alternative treatments | 26.1 | 54.5 | .1003 |
| Wants to get better | 96.0 | 100.0 | 1.0000 |
| Pathological determinants do not exist | 100.0 | 100.0 | |
| Understands benefits expected from | | | |
| no treatment | 9.5 | 13.6 | 1.0000 |
| Understands risks expected from | | | |
| no treatment | 39.1 | 72.7 | .0492 |
| Insight | 92.0 | 100.0 | .5075 |

TABLE 1 Items of SICIATRI and the Rate of "Competent" Response

Note: The *p*-value for χ^2 test (*df* = 2).

physician, nurse, or other health professional. If the patient is unaware that he or she was informed of necessary medical information (due to, e.g., confusion, excessive anxiety, or uncooperativeness), the level of competency should be rated as the lowest. In such a case, we believe that the medical decision should be postponed until the patient has the capacity to understand and consent, unless the treatment is urgently needed to protect the patient's life and safety.

"Understands that he/she has a right to decide" is another basic competency-testing item. This asks whether the patient understands that he or she was requested to decide to either accept or refuse the proposed treatment, admission, or other procedure. This item taps the patient's awareness that the proposed treatment cannot begin without the patient's own decision whether or not to waive the right of decision making.

"Evidences own choice" asks the patient "yes" or "no" to the proposed treatment. The patient showing a definite choice is rated as competent. Even when the patient is still considering but hasn't yet reached a conclusion, he or she is also rated competent on this item. Only when the patient cannot decide yes or no will he or she be rated as incompetent.

The item "Does not waive" measures a patient's ability to exercise his or her right to decide whether to receive a proposed treatment. According to theorists of competency (Appelbaum et al., 1987; Martin & Bean, 1992), the patient should be rated as incompetent if he or she wishes to transfer the decision-making right to other people. Although we rate "Does not waive" in the SICIATRI, we excluded this item when constructing the Ranking Inventory for Competency (see below), because most of the patients who wished to waive their right were found to be competent on the other SICIATRI items, which were ranked higher on cognitive capacity. When the patient wishes to waive the right, he or she is further asked whom the patient wants to take on the right of decision making. The items "Understands the expected benefits," "Understands the expected risks," and "Understands the alternative treatments" are the core items of the competency measure. These items measure whether the patient understands the benefits, risks, and alternatives of the proposed treatment to the extent of his or her knowledge of them. Thus, if the patient recalls three out of ten side effects of the proposed treatment that the attending physician disclosed a few days before, the patient's understanding of the risks is poor, whereas if the attending physician disclosed only three side effects, of which the patient recalls all, then the patient's understanding is excellent. Therefore, the assessment of these three items is determined by the proportion of the patient's recall to the possible maximum of his or her knowledge.

In the SICIATRI, the patient is further asked about how he or she views the future without the proposed treatment. This is tapped by the item "Understands benefits expected from no treatment" and "Understands risks expected from no treatment." Unlike the "Understands the expected benefits/risks/ alternatives," which measures the patient's understanding of the current situation, these two items measure the patient's perspective of the *future* and *insight* into the nature of his or her condition. Thus, they require a higher cognitive capacity.

The patient's decision making may be irrational if it is not based on the desire to recover from the condition and to regain prior functioning. If, for example, a depressive patient wants to die and refuses any care and treatment, he or she is most likely to be deemed incompetent (see Sullivan & Youngner, 1994, for discussion). The SICIATRI contains an item "Wants to get better," which taps the patient's wish to recover from the condition. If the patient wants to be discharged, this is not necessarily a sign of lack of "Wants to get better" because some patients may be motivated by completely different factors (e.g., "I am not crazy!"). The absence of activities that the patient wants to engage in when he or she gets better may indicate incompetency in this regard.

The SICIATRI also contains an item "Pathological determinants do not exist," which taps the influence of symptoms of disturbed reality testing (e.g., delusions, hallucinations, and formal thought disorder) on the rational manipulation of information. In this regard, we deem the patient as incompetent only when psychiatric symptoms distort the rational reasoning process. Patients may, though rarely, manipulate information rationally, even when they are experiencing, for example, auditory hallucinations.

Lack of "Insight" may lead to the patient's irrational manipulation of medical information and reduced appreciation of the nature of the situation in which he or she is placed.

The SICIATRI has been used to measure patients' competency to make treatment decisions since 1993. The interrater reliability of the items was reported by Tomoda et al. (1997).

Disclosure Content Check List

Because the patient's comprehension of the nature of the situation and capacity to manipulate information rationally covary to some extent with the amount and nature of the medical information disclosed by the physician or other health professionals, we developed the Disclosure Content Check List (DCCL) to measure the content of medical disclosure (Kitamura & Kitamura, 1993b). The DCCL items correspond almost identically to the SICIATRI items. The attending physician is required to answer whether he or she (1) informed the patient about one's right to decide the treatment; (2) requested the patient to decide his or her own choice of treatment; (3) recommended a specified treatment; (4) explained the expected benefits of the treatment/admission/ other medical procedure; (5) explained the expected risks of the treatment/ admission/other medical procedure; (6) explained the alternative treatments; (7) explained the benefits expected from no treatment; (8) explained the risks expected from no treatment; and (9) disclosed the diagnosis. When the physician recommended treatment or medication and disclosed a diagnosis, the patient was further asked about the actual terms used (e.g., "schizophrenia" vs. "mental debility"). In the last part of the DCCL, the attending physician rates the patient's overall competency level with a 2-point scale—competent or incompetent—based on all information gathered about the patient. This is called the Global Assessment of Competency and was used as the external criterion against which to examine the concurrent validity of the competency level derived from the SICIATRI.

In our research, the completed DCCL was handed to research interviewers who used the description about the nature and amount of medical information disclosed to the patient on whom the SICIATRI was rated. However, the research interviewers were prohibited from viewing the physician's rating on the Global Assessment of Competency.

Ranking Inventory for Competency

To classify patients into different categories of competency, we developed the Ranking Inventory for Competency. This was based on the work of Martin and Bean (1992), who assumed a continuum of cognitive capacity at any point for which the competency level could be allocated. The inventory consists of a set of algorithms that yields five levels of competency: Level 0 indicates complete incompetency, whereas level 4 indicates complete competency (Appendix B).

The lowest level of competency is Level 0, where the patient would be rated as incompetent by applying any standard of competency. Thus, the patient is not aware that he or she was given necessary medical information, does not understand that he or she has a legal right to choose the favored treatment, or, if he or she knows it, cannot say even yes or no to the proposed treatment. However, before finalizing the competency-level allocation, the patient should be given necessary medical information once more, in such a way that the patient can appreciate it without difficulty, and should be tested repeatedly. If the patient is too confused or anxious to appreciate the given information, competency testing should be postponed until the patient retains the capacity to appreciate the information, except in the case of emergency.

Level 1 is the lowest of the competency levels. The patient is aware of being asked to decide and shows at least his or her own choice of treatment. The patient does not have to remember what was disclosed. Setting the cut-off point of competency/incompetency at this level gives the broadest and most lenient definition of competency. To define competency at Level 2, the patient is required to understand the benefits and risks expected from the proposed treatment/admission/other procedure, as well as possible alternative treatment. The patient needs the capacity to appreciate the nature of the current situation. The patient need not exhibit a desire to get better, a lack of disturbance in reality testing, or insight, but should simply be able to recall given information about the treatment.

In addition to the patient's awareness of being requested to decide his or her own choice of treatment and to understand the nature of the proposed treatment, Level 3 further requires the patient to show evidence that he or she wants to recover from the condition and that symptoms of disturbed reality testing do not influence the rational manipulation of medical information. If, for example, the patient chooses medication because the patient wants to die using possible side effects of medication, the patient could not be regarded as having competency at this level.

The highest cognitive capacity is rated as competent at Level 4, because this includes the patient's awareness of a future perspective of the condition and insight into the illness. The patient cannot have insight that he or she is suffering from, for example, schizophrenia, unless the patient has been informed of the diagnosis. Therefore, the insight required at this level is the patient's understand-

ing of the diagnostic label that the physician used when suggesting treatment (e.g., "nervous breakdown") and its implications.

It should be noted that the levels proposed in the Ranking Inventory for Competency are constructed on the assumption that the mental faculty of competency is a continuous variable with high internal consistency. This is not yet proved empirically, although many clinicians are aware that competency/incompetency is hard to judge in a dichotomized fashion. Therefore, this ranking order of competency is only tentative and would be subject to modification whenever further empirical studies show, for example, more than one factor structure.

Second, the Ranking Inventory for Competency does not necessarily indicate its use in clinical settings without further standardization. Although competency may be assessed in a continuum, clinical judgments are always made in a dichotomized fashion. The cut-off of competency/incompetency on the continuum should be chosen so as to meet the requirements made from both clinical and legal perspectives.

Comparison of Medical and Psychiatric Patients' Competency

We assessed the competency of inpatients in psychiatric and medical wards by using the SICIATRI to see whether there was a difference between them.

The number of psychiatric and medical inpatients were 25 (52%) and 23 (48%), respectively. Male/female ratios were almost the same in the two groups: 9/16 in the psychiatric patients and 13/10 in the medical patients. All the subjects were from Kohnodai Hospital, National Center of Neurology and Psychiatry in Japan. All the psychiatric patients had been admitted voluntarily. Their mean (*SD*) ages were 52.2 (15.1) and 49.6 (19.0) years, respectively; no significant age difference existed between the two groups (p = .608). The mean length of education (*SD*) after junior high school did not show any significant difference between the two groups: 2.9 (2.7) years for psychiatrist made the following diagnoses: affective disorder, 11; schizophrenia, 10; senile psychosis, 2; anxiety neurosis, 1; and epilepsy, 1. The diagnoses of the medical patients were diabetes, 11; pneumonia, 4; spontaneous pneumothorax, 2; bronchial asthma, 2; hyperthyroidism, 1; pleuritis, 1; pyelitis, 1; and virus infection, 1.

The same procedure was adopted for both the psychiatric and medical patients. After admission to hospital, the patients were informed by the attending physician about the purpose and nature of the hospitalization and proposed treatment. Within a week of this, a pair of research interviewers carried out a SICIATRI interview. Four interviewers participated in the study. They were two psychologists with M.A. degrees, one psychologist with a B.A. degree, and one academic lawyer with an LL.M. degree. Every patient gave written informed consent prior to the interview. The study was approved by the Ethical Committee of the National Center of Neurology and Psychiatry (Kohnodai campus).

We set a cut-off point between 0 and 1 of competency; patients with point 1 or over were defined as competent, whereas patients with a score below 1 were defined as incompetent. This is the most lenient definition of competency. Seventy-six percent (19/25) of the psychiatric inpatients and 91% (21/

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23) of the medical inpatients were found to be competent. There was no significant difference in the proportion of competent patients between these two groups (χ^2 (2) = 1.069; p = .3013). When the scores of competency were treated as continuous variables, the competency level among the medical patients was slightly higher than among the psychiatric patients: the mean (*SD*) score of competency was 1.7 (1.6) among psychiatric inpatients and 2.9 (1.5) of the medical inpatients (t = 2.66; p = .011) (Table 2).

We then examined the rate of "competent" responses of the SICIATRI items among the psychiatric and medical patients (Table 1). A competent response rate of 90% or more was observed for both groups in "Evidences own choice," "Wants to get better," "Pathological determinants do not exist," and "Insight," but only for the medical patients in "Is aware that he/she was informed," and "Understands the expected benefits." The difference in the rate of "competent" responses between the two groups reached statistical significance only for "Understands the expected benefits" and "Understands risks expected from no treatment." The "competent" response rate of most of the SICIATRI items was slightly to moderately higher among the medical than among the psychiatric patients. However, the competent response rate was higher among the psychiatric patients for "Understands the expected risks." Across the two patient groups, "Understands benefits expected from no treatment" showed low rates of competent responses. Though not reaching statistical significance, the psychiatric patients showed poorer responses for "Understands that he/she has a right to decide," and "Understands risks expected from no treatment" than did the medical patients.

Understanding the benefits and risks of the proposed psychiatric or medical treatment largely depends on the extent of the information disclosed by physicians. If patients are not given enough information about the treatment, it is hard for them to understand what is being presented to them. Therefore, it is necessary to investigate what kind of information was disclosed to patients by physicians. In this study, physicians were asked to fill in the DCCL (Table 3). The data showed that psychiatric inpatients generally received less information than did the medical inpatients. The explanation of the expected risks was the only item of which the psychiatric inpatients had more information: 60% of the psychiatric inpatients received the information, as against 35% of the medical inpatients.

These findings suggest that psychiatric inpatients are no less competent than are medical inpatients in terms of the dichotomized assessment. Our

| The Level of Competency to Give Informed Consent by Patient Groups | | | | |
|--|--------------------------|----------------------|--|--|
| Ranking inventory for competency | Psychiatric patients (N) | Medical patients (N) | | |
| 4 | 6 | 14 | | |
| 3 | 3 | 2 | | |
| 2 | 0 | 0 | | |
| 1 | 10 | 5 | | |
| 0 | 6 | 2 | | |

TABLE 2 vel of Competency to Give Informed Consent by Patient Groups

| SICIATRI items | Psychiatric patients (%) | Medical patients (%) | р |
|--|--------------------------|----------------------|-------|
| Informs the right to decide | 45.8 | 69.6 | .1771 |
| Requests to decide | 64.0 | 100.0 | .0048 |
| Recommends treatment | 88.0 | 95.7 | .6631 |
| Recommended treatment only $(n = 42; missing cases = 2)$ | | | |
| Medical (formal) terms | 57.1 | 71.4 | .5195 |
| Nonmedical (modified) terms | 42.9 | 28.6 | |
| Medication recommended $(n = 42; missing cases = 2)$ | | | |
| Genetic terms | 30.0 | 26.3 | |
| Terms to describe effects | 15.0 | 10.5 | |
| Classificatory terms | 40.0 | 42.1 | .9385 |
| Formal names | 15.0 | 21.1 | |
| Explains the expected benefits | 88.0 | 95.7 | .6631 |
| Explains the expected risks | 60.0 | 34.8 | .1449 |
| Explains the alternative treatments | 8.0 | 47.8 | .0055 |
| Explains benefits expected from no treatment | 0.0 | 4.3 | .9664 |
| Explains risks expected from no treatment | 52.0 | 78.3 | .1100 |
| Disclosed terms | 68.0 | 91.3 | .1030 |

TABLE 3 Items of DCCL and the Rate of Disclosure by the Patient Groups

Note: The *p* value for χ^2 test (*df* = 2).

finding is quite contrary to Appelbaum's suggestion that a large percentage of the patients who were voluntarily admitted to a psychiatric hospital were not competent to consent to their own admission (Appelbaum et al., 1981). However, it is difficult to compare our results with Appelbaum's because the assessment devices and research designs were different. Because our patients were all admitted voluntarily, they were not a fair representation of the psychiatric inpatient population. Nevertheless, we can tentatively conclude that not all psychiatric patients with major disorders are incompetent.

This may echo the notion that competency assessment should be carried out before the commencement of a forced treatment or hospitalization. Scrutiny of the DCCL items revealed that medical information was not evenly distributed between the psychiatric and medical patients. It is of interest that psychiatric patients were more likely to be given information about risks related to the proposed treatment, and they were also more likely to be rated as understanding the expected risks. Thus, it may be said that the ability to understand is a function of the amount of information given. Similarly, the finding that psychiatric patients were informed less may be associated with the slightly poorer competency of those patients.

As described earlier, our instrument did not provide any a priori determined set of information disclosed to the patient before testing his or her competency. From the perspective of test theory, the same set of "stimuli" should be exposed to measure the ability of the subject to process them. However, we believe that the capacity of the patient to give informed consent is not and should not be treated as a standardized psychometric test but as a measure tailored very specifically to individual needs and ability. We were thus more interested in real clinical settings and devised a measure for information given to each patient (DCCL). This is disadvantageous as a vigorous research instrument (like an IQ test) but advantageous as a clinical instrument.

Our results may be criticized that we studied the subjects about a week after the admission so that what we measured was not the patient's capacity to give informed consent but the patient's capacity to remember what had been disclosed. Time lag was partly due to practical difficulty to conduct an interview for newly admitted patients. We believe, however, what is measured by the SICIATRI is not mere memorizing capacity because the measure covers other areas of capacity and recognition than memory: We measured the patient's awareness that he or she is qualified to decide or that he or she suffers from mental illness. We also believe that if the patient decides but forgets what has been disclosed before our interview (a week later), the patient's decision has much weaker ground to claim competency. We must, however, be cautious about interpretation of our results because we assessed the patient's competency after he or she decided. In future study, we will examine patients after information is disclosed but before they reach a conclusion. This procedure may be used not only as a research protocol but also as a safeguard to protect the patient's voluntary and well-informed decision making.

Another drawback of this paper is its relatively small number of subjects. We can claim no more than the preliminary nature of the study. What we can state is that the difference in competency between medical and psychiatric patients is not so much as was expected. The capacity level of involuntary patients may be much lower. We are presently studying such patients. However, what should be emphasized, as far as the Japanese mental health service system is concerned, is the lack of formal assessment procedure of competency and even the lack of any notion of incompetency as the justification of coerced treatment in law. Our results may cast more light on this issue.

Conclusion

In Anglo-American law, a medical patient's self-determination right has been embodied as informed consent. In psychiatry, however, compulsory commitment is provided by mental health legislation. Psychiatric patients have long been deemed incompetent owing to mental illness itself, but this notion has recently been overridden in cases in the United States such as *Rennie v. Klein*¹⁷ (1978) and *Washington v. Harper*¹⁸ (1990). In the latter, the right to refuse unwanted antipsychotic medication was classified as a liberty interest, protected by the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution. In practice, it has become more important to examine a patient's competency to give informed consent. This should be regarded as a procedural safeguard more than a medical process.

 $^{^{17}}Id.$

¹⁸See supra note 9.

After reviewing the literature on devices to assess patients' competency, we developed a new structured interview, the Structured Interview for Competency/Incompetency Assessment Testing and Ranking Inventory (SICIATRI). We also developed the Disclosure Content Check List (DCCL) to calibrate the nature and amount of medical information disclosed to the patient by the attending physician. By using this scale, we compared the competency level of voluntarily admitted psychiatric and medical inpatients and found that it was slightly higher (better) among the latter, with a considerable overlap. This suggests that not all psychiatric patients are incompetent, and therefore competency assessment should be undertaken before the commencement of psychiatric treatment as a procedural safeguard.

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Appendix A

An Example of the SICIATRI Items, Explanations, Standard and Probe Questions, and Anchor Points with Definition

Understands the Expected Benefits. "What have you heard from your [doctor in charge, nurse in charge, other professionals who have disclosed medical information necessary for informed consent] about good things you can expect from the [treatment, admission, or other procedures against which competency is to be measured]?" If patient answers vaguely that good things will happen: "What are the good things that are expected?"

This question should be based on the disclosed information. Assess whether the patient can demonstrate benefits expected from the treatment or admission objectively (concretely) such as "Particular symptoms may be alleviated," "Symptoms may disappear," and "May be able to do things I have been unable to do."

- 1. Claims "I do not know," or "I have not heard"
- 2. Says he or she can expect good things will happen, but cannot demonstrate them objectively
- 3. Demonstrate benefits expected from the treatment or admission objectively

Appendix B

Ranking Inventory for Competency

Level 0

- A. At least one of the following
 - (1) 2 or 3 in "IS AWARE THAT HE OR SHE WAS INFORMED"
 - (2) 1 in "UNDERSTANDS THAT HE OR SHE HAS A RIGHT TO DECIDE"
 - (3) 1 in "EVIDENCES OWN CHOICE"
- B. Does not meet the criteria of Levels 1 to 4

Level 1

- A. 2 or more in "UNDERSTANDS THAT HE OR SHE HAS A RIGHT TO DECIDE"
- B. 2 or more in "EVIDENCE OWN CHOICE"
- C. Does not meet the criteria of Levels 2 to 4

Level 2

- A. 2 or more in "UNDERSTANDS THAT HE OR SHE HAS A RIGHT TO DECIDE"
- B. 2 or more in "EVIDENCES OWN CHOICE"
- C. At least 2 of the following
 - (1) 2 or more in "UNDERSTANDS THE EXPECTED BENEFITS"
 - (2) 2 or more in "UNDERSTANDS THE EXPECTED RISKS"
 - (3) 2 or more in "UNDERSTANDS THE ALTERNATIVE TREATMENTS"
- D. Does not meet the criteria of Levels 3 and 4

Level 3

- A. 2 or more in "UNDERSTANDS THAT HE OR SHE HAS A RIGHT TO DECIDE"
- B. 2 or more in "EVIDENCES OWN CHOICE"
- C. At least 2 of the following
 - (1) 2 or more in "UNDERSTANDS THE EXPECTED BENEFITS"
 - (2) 2 or more in "UNDERSTANDS THE EXPECTED RISKS"
 - (3) 2 or more in "UNDERSTANDS THE ALTERNATIVE TREATMENTS"
- D. 2 or more in "WANTS TO GET BETTER"
- E. 2 or more in "PATHOLOGICAL DETERMINANTS DO NOT EXIST"
- F. Does not meet the criteria of levels 4

Level 4

- A. 2 or more in "UNDERSTANDS THAT HE OR SHE HAS A RIGHT TO DECIDE"
- B. 2 or more in "EVIDENCES OWN CHOICE"
- C. At least 2 of the following
 - (1) 2 or more in "UNDERSTANDS THE EXPECTED BENEFITS"
 - (2) 2 or more in "UNDERSTANDS THE EXPECTED RISKS"
 - (3) 2 or more in "UNDERSTANDS THE ALTERNATIVE TREATMENTS"

- D. 2 or more in "WANTS TO GET BETTER"
- E. 2 or more in "PATHOLOGICAL DETERMINANTS DO NOT EXIST"
- F. At least one of the following
 - (1) 2 or more in "UNDERŠTANDS BENEFITS EXPECTED FROM NO TREATMENT"
 - (2) 2 or more in "UNDERSTANDS RISKS EXPECTED FROM NO TREATMENT"
- G. 2 or more in "INSIGHT"