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A survey of informed consent in patients with dementia in the US and Japan

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ABSTRACT

This study aimed to confirm the reality of family-focused medical treatment of dementia in Japan and the US. It conducted a questionnaire survey on informed consent from patients with dementia among neurologists and psychiatrists in four prefectures in the Tokai Region (Aichi, Gifu, Mie, and Shizuoka) and dementia specialists in the US. Of the responses, 120 (39.7% response rate) and 20 (5.9% response rate) were obtained, respectively. In obtaining informed consent from patients with dementia, 75 Japanese specialists (62.5%) and 16 US specialists (80.0%) regularly assessed patients' decision-making abilities. The majority of specialists in both Japan and the US used the Mini–Mental State Examination and Hierarchic Dementia Scale-Revised, which are widely used for cognitive function assessment. In the survey, 27 Japanese specialists (22.5%) and 10 US specialists (50.0%) had different considerations when obtaining informed consent for participation in research, compared to their medical practice. The majority of Japanese and US specialists obtained informed consent from both the patient and their family.

Keywords: questionnaire study, research ethics, dementia, informed consent, decision-making ability

Abbreviation:
MacCAT-T: MacArthur Competence Assessment Tool-Treatment

INTRODUCTION

Many countries are transitioning to aging societies, and the number of older adults living with dementia is on the rise. Japan, in particular, has a remarkable rate of aging, with people aged 65 years and over expected to account for 28.9% of the total population by 2022.[1] Consequently, an increasing number of cases need to obtain informed consent for treating patients with dementia. In addition, special consideration is required when incorporating patients with cognitive impairment into clinical research. The right to self-determination of individuals with dementia must be guaranteed, and decision support is required, according to the pathophysiology of dementia.[2]

Experts have noted the challenges in obtaining informed consent from patients with dementia. Their decision-making ability varies depending on the cause and stage of the disease, and

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decision-making support is required according to the severity of dementia.[3] Informed consent is difficult to obtain if the patient is judged to lack or have insufficient capacity to make a decision, because of the ambiguous criteria for obtaining a surrogate's consent in place of the patient's own consent and the lack of decision-making capacity assessment tools that can be easily used in the medical field.

A cautious attitude toward acquiring informed consent is required when it comes to the participation of dementia patients in clinical research. When conducting clinical research, one must abide by international ethical guidelines, such as the Declaration of Helsinki,[4] and the laws and guidelines formulated by each country, including Japan's Ethical Guidelines for Medical and Health Research Involving Human Subjects.[5] Researchers must also seek understanding from research subjects regarding their participation in research.

In this study, we conducted a questionnaire survey among neurologists from the Japanese Society of Neurology[6] and psychiatrists from the Japanese Society of Psychiatry and Neurology,[7] based in four prefectures in the Tokai Region, and specialists on dementia in the US who treat patients with dementia and who may be conducting research on them. The objective of the survey was to clarify the status of and current issues in obtaining informed consent from patients with dementia. In 2016, the author surveyed informed consent in patients with dementia in Japan, and published the results.[8] The present survey further investigates matters pertaining to informed consent in patients with dementia in US, and therefore represents a continuation of the previous work.

METHODS AND PARTICIPANTS

Our survey invited 302 neurologists and psychiatrists (hereafter, "Japanese specialists"), as published on the websites of the Japanese Society of Neurology and Japanese Society of Psychiatry and Neurology, from four prefectures in the Tokai Region (Aichi, Gifu, Mie, and Shizuoka) as of July 1, 2016. Where multiple specialists were affiliated with the same institution/clinic, the senior physician was surveyed. We also invited 356 specialists who were in charge of the departments of neurology, psychiatry, and dementia as per the websites of the top five US hospitals ranked by state in Becker's Hospital Review, 100 great hospitals in America,[9] and US News and World Report, Best Hospitals[10] as of January 2018, with a primary specialization in the treatment of patients with dementia (hereafter, "US specialists").

The survey was conducted over email from August 2016 to April 2018, through self-administered, unmarked questionnaires. The questionnaire included the following items related to obtaining informed consent from patients whom the specialist suspected of having dementia, along with the basic information of the respondents (eg, nature and size of the affiliated medical institution, department name): (1) whether and how the patient's decision-making ability was assessed, (2) source of obtaining informed consent, (3) obtaining informed consent from family, (4) experiences and specific details in obtaining informed consent, (5) considerations related to obtaining consent for participation in research, and (6) the patient's own consent regarding research participation. The survey inquired on these items primarily using the three-subject method. The cover letter clearly specified that responses would be processed statistically, and individual responses would not be published. In addition, responding to the letter was deemed to constitute consent to the survey. Our survey was anonymous, and did not deal with personal information, and was approved by the Bioethics Review Board of the Nagoya University School of Medicine (Approval No.: 2018-0092).

The main medical specialties of the 120 Japanese specialists who responded (response rate

of 39.7%) were internal medicine (3), neurology (66), psychiatry (49), neurosurgery (2), and others (1). As for the 20 US specialists (response rate of 5.9%), the departments of medicine were as follows: 1 respondent in internal medicine (5.0%), 2 in psychiatry (10.0%), and 17 in neurology (85.0%).

RESULTS

Assessment of decision-making capacity

In total, 75 (62.5%) Japanese specialists evaluated decision-making ability in their daily practice for patients with suspected dementia. By specialty, 40 (60.6%) and 33 (67.3%) were specialists in neurology (n = 66) and psychiatry (n = 49), respectively. Meanwhile, of the 16 (80.0%) US specialists who responded, 14 (82.4%) were neurologists (n = 17) and 1 (50.0%) was a psychiatrist (n = 2).

In the multiple-response question (n = 90) from Japanese and US specialists regarding the method of assessment of decision-making capacity, the majority used Mini–Mental State Examination and Hierarchic Dementia Scale-Revised, which are widely used in cognitive function assessment. In total, 62% responded that they regularly assess their patients' decision-making abilities. Each dementia-related index was used in the evaluation method. Some respondents indicated they would not use it. Furthermore, there was no response indicating that the MacArthur Competence Assessment Tool-Treatment (MacCAT-T),[11] which has been reported to be useful for assessing the ability to consent to medical care, is being used (Fig. 1).

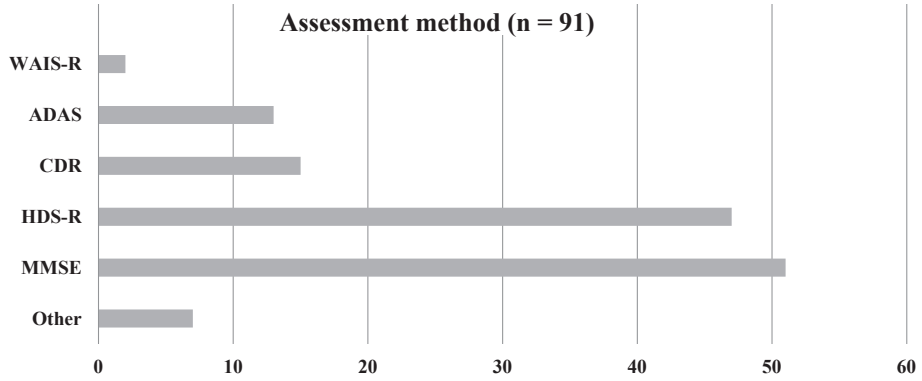

Fig. 1 Method of assessing decision-making capacity
WAIS-R: Wechsler Adult Intelligence Scale-Revised
ADAS: Alzheimer's Disease Assessment Scale
CDR: Clinical Dementia Rating scale
HDS-R: Hasegawa Dementia Scale-Revised
MMSE: Mini Mental State Examination

Source of obtaining informed consent

Japanese specialists tended to focus on family as the source of informed consent, with 94 respondents (78.3%) indicating "Patient and Family," 25 (20.8%) indicating "Family (Proxy)-centered," and 1 (0.9%) indicating "Patient Only." Meanwhile, 13 US specialists responded "Patient and Family," 2 responded "Patient Only," and 3 indicated "Family-centered" (Table 1).

Table 1 Source of informed consent

	Japan	US
Patient only	1	2
Patient and family	94	13
Family (proxy)-centered	25	3
Total	120	18

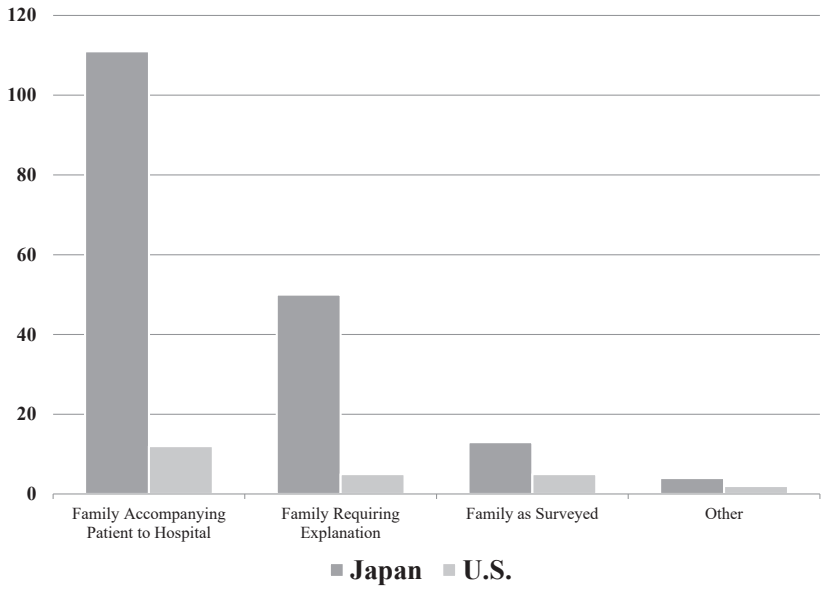

Fig. 2 Family and informed consent

Figure 2 shows the responses regarding the nature of the described family members. Japanese specialists (multiple responses: n = 178) had 111 (62.4 %) responses for "Family members accompanying the patient to the hospital," 50 (28.1%) responses for "Family requiring explanation," 13 (7.3%) for "Family as surveyed by hospital," and 4 (2.2%) for "Others." For the US specialists (multiple responses, n = 24), the corresponding responses were 12 (63.0%), 5 (25.0%), 5 (25.0%), and 2 (10.0%), respectively.

Difficulties in obtaining informed consent

Table 2 shows the number and share of specialists who responded as having experienced difficulties in obtaining informed consent. Table 3 gives the reasons for such difficulties.

Table 2 Difficulty

	Yes	No	Total
Japanese specialists	77 (64.2)	43 (35.8)	120 (100)
US specialists	7 (35.0)	13 (65.0)	20 (100)

Table 3 Specifics of difficult experiences

	Japan	US
Family location unknown	16	7
Conflict of opinion in family	15	6
Refusal of treatment by family	28	2
Long time to make decisions	26	2
Total	85	17

Informed consent in dementia research

Regarding informed consent for participation in clinical studies, very few specialists responded that considerations different from the typical medical treatment were required or necessary (Table 4). However, larger percentages for the "Required" response were recorded for the item on obtaining informed consent (Table 5). Table 6 shows the specialists' responses to the inclusion of patients with dementia who are assessed to have the capacity to consent.

Table 4 Necessity of special consideration regarding informed consent in research

	Required	Not required
Japanese specialists	27 (22.5)	93 (77.5)
US specialists	10 (50.0)	10 (50.0)

Table 5 Necessity of informed consent

	Required	Not essential	Total
Japanese specialists	46 (38.3)	74 (61.7)	120 (100)
US specialists	17 (85.0)	3 (15.0)	20 (100)

Table 6 Research conducted with the consent of the individual only

	Conducted	Family consent required	Total
Japanese specialists	20 (16.7)	100 (83.3)	120 (100)
US specialists	11 (55.0)	9 (45.0)	20 (100)

DISCUSSION

The question of obtaining informed consent from patients with dementia is an important issue when treating and conducting research involving them. Although informed consent should ideally be obtained from the patients themselves, physicians are faced with the need to confirm that patients with dementia have the capacity to make decisions when treating or including them in research. However, the support system for obtaining informed consent is lacking.[12] Indeed, most researchers obtain or substitute traditional competence-based informed consent.[13] In such cases, various supplementary measures are also required. For example, simplifying consent forms, providing visually clear instructions such as illustrations, introducing educational approaches, implementing explanations as needed, and ensuring close cooperation with caregivers are necessary.[12]

An important consideration in obtaining informed consent from patients with dementia is the accurate assessment of their decision-making capacity, based on the cause and stage of dementia. In treating patients suspected of having dementia, cognitive function should be assessed for an appropriate diagnosis, particularly in the case of mild cognitive impairment. However, although diagnostic procedures for mild cognitive impairment have been presented, there is currently no established diagnostic method for this.[14] Moreover, cognitive impairment does not simply correspond to decision-making ability, and even patients diagnosed with mild-to-moderate dementia have the ability to think logically and make decisions pertaining to treatment strategies.[15] Karlawish, for example, reported that 40% of patients with mild-to-moderate Alzheimer's disease have sufficient cognitive ability to make decisions regarding treatment decisions.[16] As such, even if a patient is diagnosed as having cognitive impairment, they can be assumed to retain decision-making capacity. Consequently, judgments regarding decision-making capacity should be made cautiously.

To this point, 62% and 80% of the Japanese and US specialists in our survey, routinely evaluated patients' decision-making abilities. The survey also revealed that specialists in Japan and the US used a variety of depression index tools and other methods of assessment, highlighting the lack of a standardized method. Among the tools that have been proposed are MacCAT-T[11] and a semi-structured evaluation method.[17]

MacCAT-T uses four models with the same ability: (1) understanding (ability to understand the information given, such as the disclosure of information about treatment for informed consent), (2) recognition (patient's thoughts about the disease and possible treatment, especially the ability to realistically apply what they understand to their own situation), (3) logical thinking (ability to process information about treatment and one's wishes in a logical manner), and (4) choice expression (the patient's ability to express their wishes). Kato et al reported on two patients with cognitive decline who were found to have the ability to consent to medical treatment using the MacCAT-T, but whose primary care physicians had judged otherwise.[18] However, few studies have reported on tools such as the MacCAT-T that assess decision-making. Although the assessment of decision-making capacity should be evidence-based, this field is still in its infancy and the accumulation of research data remains an issue.[15]

Kitamura and Kitamura developed a semi-structured assessment method primarily for patients with psychiatric disorders; nevertheless, findings on patients with dementia have been limited.[19] These methods often take the form of patients' responses to questions, which require them to be motivated to answer the questions. In addition, the methods are flawed in that they do not clarify the weights assigned to the abilities of understanding, recognition, logical thinking, and choice expression, and consequently, the evaluation ends up having to be comprehensive and challenging for the patient.[20]

Notably, none of the specialists in our survey mentioned the MacCAT-T as a tool for assessing

decision-making ability. In the free-response section, some respondents stated that the criteria for evaluating decision-making capacity are not clear, indicating that the MacCAT-T may not be widely used, at least in the medical field.

When a patient's capacity to consent cannot be quickly and accurately assessed, informed consent is obtained from family regardless of their cognitive function. Our survey showed that more than 70% of the specialists in both Japan and the US obtained informed consent from family members along with the patients themselves. The percentage of specialists who placed importance on family, including the proxy, exceeded 90%, confirming the reality of a medical practice that places importance on family members regardless of the specialist's area of expertise. It has also been reported that in most cases when family members are present, the treatment plan is determined by their judgment regardless of the degree of its invasiveness.[13] Given the growing number of court decisions that have recognized the obligation to provide explanations to family members,[21] Japanese medical practitioners are taking legal risks into consideration and are thus compelled to place importance on the wishes of family members when treating patients. In many cases, the patient's family members and others who know the patient well are consulted, and their consent will be obtained after receiving an explanation from them together. Such cases should ideally use a concise document.[22]

Given the diversity of family relationships, it is not sufficiently clear which family members should be briefed. In the US, family members are allowed under case law to make decisions on behalf of the patient, as guardians. Some states have legislation that grants a certain range of family members, and other states grant immovable medical opinion, thus clarifying the position of family members in the system.[22] In Japan, family members, such as spouses and children (89%), are overwhelmingly ranked first as the preferred proxies, followed by other relatives in second place, and adult guardians in the third place.[13] In our survey, the most common family members from whom specialists obtained informed consent were those who accompanied the patient to the hospital, and those requiring explanations. Family members accompanying the patient are considered as taking care of their medical needs and are in a position to know the patient well. Explanation to such family members is considered an appropriate response, as it allows them to provide the patient with proper care.

However, the family's consent on behalf of the patient must be conducive to the patient's self-determination. There is a risk that explanations to family members may be inclined to be given under legal or judicial pressure, and that explanations to the patient may be neglected. It is important to reaffirm the basic premise of obtaining informed consent with the framework of explanations to the patient themselves in principle, and to family members in exceptional cases.[23]

Among our respondents, 64% of the Japanese specialists had experienced difficulties in obtaining informed consent for patients with dementia, much more than their US counterparts (35%). The differences in the medical environments in the two countries and the fact that the US specialists in this survey were affiliated with prominent hospitals may have contributed to this result, but further study is required. In a previous survey, more than 70% of physicians reported having experienced difficulties in obtaining consent.[13] The specific reasons for the difficulties included "conflict of opinions in family," "refusal of treatment by family members," "long time to make decisions," and "family location unknown." In some cases, family members do not function to decide the course of treatment, and decisions made by family members are not necessarily in the best interest of the patient. In such cases, physicians may have difficulties dealing with them in making treatment decisions.

In fact, proxy decision-making by family members is beset with issues. Although the patient's own decisions and those of their family, who are third parties, cannot be considered the same, the use of the term "proxy consent" in effect delegates the authority to make treatment decisions

based on the objective judgment of the patient's family.[24] Patients and their families are separate personalities, and their relationships vary. The patient's family is an entity that can make objective decisions based on the family's own values, under the specific circumstances of the individual patient, and can guarantee the rights and interests of the patient themselves under their specific circumstances. Unless a situation can be secured in which they can make an objective decision based on their own values, the medical philosophy of realizing the best interests of the patient will remain a fantasy.

Meanwhile, obtaining informed consent for participation in clinical research requires different considerations than those for medical treatment. This is because the primary objective of clinical research is not to directly benefit research subjects (patients). For medical treatment, the benefit of restoring the patient's own health awaits them undertaking the high-risk treatment. Clinical research, on the other hand, is not for a patient's own benefit but rather for the sake of future patients and the development of medicine.[25] To achieve the purpose of research, researchers (physicians) must confirm the willingness of the patients to actively and positively participate in the research; verbal explanations are not sufficient—written consent is required.[26]

In our survey, 22.5% and 50.0% of the Japanese and US specialists stated that they have different considerations when obtaining informed consent for participation in research than in their medical practice. Affiliation with top-ranked hospitals may be a factor in the higher rate among US specialists. Further investigation is needed to determine whether different considerations are made when obtaining informed consent for participation in research and for medical care.

According to Japan's "Ethical Guidelines for Medical and Health Research Involving Human Subjects,"[5] obtaining informed consent is mandatory. However, only 36.1% of the Japanese and 85% of the US specialists in this survey answered that it is necessary, suggesting that obtaining informed consent is not necessarily a widespread practice in Japan.

If the patient's self-determination to participate in research is to be respected, especially if their decision-making capacity has been found to be sufficient, their informed consent is all that is necessary to include them as a participant in research. However, when asked whether or not they would include a patient in a study with only their consent, provided they have the decision-making capacity, only 16.7% of Japanese specialists answered "Yes," compared with 55% of US specialists. This reveals that Japanese specialists are reluctant to include these patients in research based solely on their own consent. The difference between Japan and the US can be attributed to the difference in the "family-oriented" medical practice in Japan and the US. In Japan, obtaining consent from the patient's family is a risk-management approach that can reduce the possibility of problems occurring later on.

The method of obtaining informed consent differs depending on the risks involved in the treatment or research to be conducted. Constantly assessing the patient's ability to make decisions is not a realistic approach in the medical field. In this regard, when including high-risk treatments or clinical research, the decision-making capacity must be rigorously evaluated. Physicians must confirm that the patient fully understands the details and risks of the treatment or research. If the patient's capacity to make decisions is assessed as inadequate, informed consent from family members or others should be obtained before administering the necessary treatment. Proxy consent for participation in the study should be carefully considered. Indeed, careful consideration should be given to whether the purpose of the study cannot be achieved without the inclusion of the patient, and whether the risks are acceptable. Meanwhile, including patients in studies and providing them with low-risk treatment does not seem to be a major problem if they do not clearly refuse.

We conducted this survey to clarify the status of obtaining informed consent from patients with dementia by surveying medical specialists in Japan and the US regarding the evaluation

of decision-making capacity. Although we produced essential findings for considering how to obtain informed consent from patients with dementia, our study is not without limitations. The survey did not have a high response rate (39.7% in Japan and 5.9% in the US), and may not necessarily provide an accurate picture of the thinking of specialists as a group. Other limitations were the inclusion of US specialists who belonged to top-ranked hospitals, and the fact that the survey method did not take into consideration the stages of dementia from mild cognitive impairment to severe dementia, or the causative pathology of dementia. Future research should reexamine the survey targets and consider methods that focus on mild cognitive impairment or on the causative pathology of dementia in particular.

CONCLUSION

In obtaining informed consent from patients with dementia with cognitive impairment, physicians must respect their right to self-determination and fully safeguard the patient's rights and interests. When providing medical treatment, obtaining informed consent from the patient is necessary, if they are assessed to have the capacity of making decisions. However, given the absence of a standardized method for assessing decision-making capacity that can be used easily in medical practice, physicians cannot appropriately assess the decision-making capacity of patients on a daily basis. Specialists in Japan and the US have thus tended towards emphasizing informed consent from the patient's family. Tools should therefore be developed for assessing decision-making. Moreover, medical institutions should establish support systems for determining a way to guarantee self-determination among patients with dementia. Although laws, regulations, and guidelines require drawing a line based on the ability to make decisions, in practice, the situation of patients with dementia varies, and must thus be carefully considered individually.[10]

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CONFLICTS OF INTEREST

There are no conflicts of interest to declare.

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