

psychologists (VI-11) were working on PCTs. All items of this domain indicated an incremental trend.

Domain V: Activities of PCTs. The median number of annual referrals to PCTs increased significantly, from 60 (28–120) to 80 (40–137) over the three years ($P < 0.001$). More than three-quarters of the surveyed DCCHs had a PCT with greater than 50 referrals a year (V-1). Most PCTs provided direct medical care (V-2) and convened a conference and ward rounds (V-5) at least once a week. An increasing trend was seen in all items of this domain.

Domain VI: Regional Medical Cooperation. Many Japanese DCCHs collaborated with regional medical institutions through discharge meetings (VI-1, 65.6% in 2010) and through the consultation service (VI-2, 93.1% in 2010). Community outreach programs were not available in most DCCHs (VI-3, 9.0%–12.6%, $P_{\text{trend}} = 0.05$). Outpatient palliative care clinics needed a further increase (VI-4, 27.0%–58.9%, $P_{\text{trend}} < 0.001$).

Domain VII: Education. Basic palliative care education programs for in-hospital (VII-3) and regional physicians (VII-5) were being developed using the PEACE program across the country. Education for nurses (VII-8, 9) was highly available beginning with the 2008 survey. On-the-job training for regional health care providers (VII-7, 10) was not available in most DCCHs. In-hospital palliative care education programs related to communication skills (VII-11) and cancer rehabilitation (VII-12) were insufficiently provided. Most DCCHs

prepared an annual budget for education and training activities in 2010 (VII-2, 56.8%–95.1%, $P_{\text{trend}} < 0.001$).

Comparison Among the Major Domains

All seven domains showed an increasing trend over the three years. Among them, domains III (Members of PCTs), VI (Regional Medical Cooperation), and VII (Education) showed lower sufficiency levels than the others (Table 3).

Discussion

Cancer Control Programs have been implemented in DCCHs in Japan. After the formulation of the Cancer Control Act in 2006, palliative care services in these hospitals have improved significantly. Analysis of our surveys revealed 1) institutional framework, such as declaration of philosophy and goals of palliative care, improved substantially; 2) information to patient and family displayed the best advance; 3) the practice of palliative care was high throughout the surveys; 4) full-time PCT physicians and nurses significantly increased, but other medical professionals, except pharmacists, working on PCTs did not increase; 5) the number of referrals to PCTs increased slightly but significantly, whereas PCT activity expanded gradually; 6) regional medical cooperation, including outpatient clinics and community outreach programs, needed further advancement; and 7) basic education for physicians had been introduced nationwide, using PEACE programs; however, education for regional health care providers was not common in Japan. In addition to the implementation of

Table 3
Comparison of the Averaged Sufficiency Levels Among the Seven Domains ($n = 349$)

Domains	Year			Change ^a	P^b
	2008	2009	2010		
I. Institutional framework	65.6	70.6	77.2	11.6	<0.001
II. Information to patient and family	50.2	64.6	73.6	23.4	<0.001
III. Practice of palliative care	79.4	82.8	84.7	5.3	<0.001
IV. Members of PCTs	55.9	61.9	68.6	12.7	<0.001
V. Activities of PCTs	73.3	80.2	87.8	14.5	<0.001
VI. Regional medical cooperation	42.4	48.4	56.6	14.2	<0.001
VII. Education	47.7	50.9	55.4	7.7	<0.001

PCTs = palliative care teams.

Average values of each domain are expressed in %.

^aChanges between the 2008 and 2010 surveys.

^bCalculated using analysis of variance for repeated measurements.

the Cancer Control Act, this three-year survey itself contributed to these improvements by clarifying the concrete actions necessary to develop palliative care services. Structural changes, such as institutional framework and information delivery, were the first to be improved to meet the requirements of the law because they can be set up with relative ease. Staffing PCTs with more specialists, regional medical cooperation, and education are the next challenges. The relative insufficiency in these areas might reflect the additional costs and manpower required compared with preparation of the institutional framework and information services. Among the issues raised by the surveys, the insufficiency of regional medical cooperation was most important because being the hub among regional medical institutions is one of the fundamental roles of DCCHs.

Development and enhancement of palliative care is recognized as an important health care issue. The American Society of Clinical Oncology has declared that palliative care should be integrated into comprehensive cancer care.² The European Association for Palliative Care has placed access to palliative care as a human right.³ Previous reports have identified several subject areas to consider when developing and disseminating palliative care.⁴⁻⁸ The World Health Organization Public Health Strategy highlighted that appropriate policymaking is the key component to enhance national palliative care services, in addition to drug availability, education, and implementation of palliative care services.⁴ The European Association for Palliative Care pointed out five important domains, including policy, access to palliative medications, education, quality measurements, and research.⁵ Behmann et al. proposed that integration of generalist and specialist palliative care and strengthening generalist palliative care were the top priorities to improve palliative care.^{6,7} Key common issues in the development of palliative care are policymaking, access, coordination of care, and education.⁴⁻⁸

Nationwide surveys of the major cancer centers are necessary to describe the current status of national palliative care services. Hui et al. conducted a nationwide mail survey of 101 U.S. cancer centers in 2009.¹⁶ The availability of palliative care service, defined as the presence of at least one palliative care physician,

was 92% in National Cancer Institute cancer centers and 74% in non-National Cancer Institute cancer centers. Inpatient PCTs were available in 74% of the centers surveyed. Of them, 80% and 47% of PCTs had full-time physicians and nurses, respectively. Poor reimbursement and limited institutional resources were cited as the major barriers to the enhancement of palliative care services. Japan shares these same issues. Additional strengths of the present study were the fact that it was a complete census and its longitudinal design, which allowed us to assess the effects of policymaking on the development and enhancement of national palliative care services.

We found that essential drugs for palliative care, including opioids, adjuvant analgesics, and others, were accessible across Japan. However, it is known that the total amount of opioid consumption in Japan is much lower than that in other Western countries.¹⁷ An additional study is needed to assess opioid accessibility, opioid consumption, and symptom relief. The number of full-time PCT physicians and nurses increased significantly. Even so, PCT physicians, psychiatrists, and pain clinicians were not available in many DCCHs. This finding may reflect a lack of specialists in this field and poor staff compensation.¹⁸ Absence of a psychiatrist was one of the major barriers to be certified for "additional fee for palliative care." Poor reimbursement and lack of palliative care specialists could become a vicious cycle in many DCCHs. Regional medical cooperation was offered at outpatient clinics or through community outreach programs. Opening an outpatient clinic was one of the certification requirements for DCCHs, and this item increased by 31.9%. Community outreach programs were available in 12.6% of DCCHs. A recent regional intervention study in Japan demonstrated the possibility of educational visits by palliative care specialists to improve palliative care outcomes in the region.¹⁹ Regional medical cooperation may be the focus of future health care challenges. The development of PEACE promoted a significant improvement in basic palliative care education to physicians engaged in providing cancer care. Specific education programs for specialists are necessary.

Several limitations of this study should be noted. First, our results could be biased

because we collected recalled information. Second, the outcomes of palliative care services were not assessed. Because the major aim of the study was clarifying the structure and processes of palliative care in Japan, outcome measurement was beyond the scope of this survey. Third, we could not evaluate the effects of the increased availability of palliative care in DCCHs observed in this study on overall medical cost because of lack of data. Finally, this survey indicated changes over a relatively short period of time after the revision of the national cancer program. We plan to replicate the survey in 5–10 years to evaluate the long-term effects of policymaking on palliative care services nationwide.

The present study indicates the future direction of palliative care in Japan. More than 80% of terminally ill cancer patients died in hospitals in Japan in 2011,²⁰ although as shown in one population-based survey, most Japanese people considered home as the preferred place of death.²¹ Concerns about burden on family caregivers, sudden disease exacerbation, availability of home care, and expense are the major barriers to dying at home.²² Regional cooperation, including community outreach by palliative care specialists of DCCHs, could play the key role in increasing concordance between preferred and actual place of death. Future studies, including measurement of palliative care outcomes such as home death rate, quality of care, and quality of life at the end of life, are warranted. In addition, to develop and disseminate palliative care to non-cancer populations is another indispensable issue in Japan because a recent survey among DCCHs showed that the proportion of non-cancer patients was only 2.5% of the total number of patients referred to PCTs.²³

In conclusion, this three-year nationwide survey with excellent response rates demonstrated that the formulation of the Cancer Control Act allowed a significant advance in the national palliative care services of Japan. The number of physicians and nurses engaging in palliative care increased substantially; however, our study highlighted the difficulties of improving areas that need a large workforce. More outpatient clinics and outreach programs are needed to use regional medical resources. Although basic education for in-hospital physicians and nurses has

developed during the three-year period, education for regional health care providers was insufficient. Regional medical cooperation and palliative care education may be the health care challenge in the next decade of palliative care in Japan.

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Assessing medical decision making capacity among cancer patients: Preliminary clinical experience of using a competency assessment instrument

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ABSTRACT

Object: This study investigates the usefulness of the Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory (SICIATRI) for cancer patients, which is a structured interview that assesses a patient's competency in clinical practice.

Methods: The SICIATRI, originally developed to measure patients' competency to give informed consent, were administered referred cancer patients who needed for assessing medical decision making capacity. The usefulness of the SICIATRI was investigated retrospectively. Recommendation for modification of the SICIATRI for cancer patients if applicable were made by the research team.

Results: Among the 433 cancer patients referred for psychiatric consultation, 12 were administered the SICIATRI and all of the administration were conducted without big problems. All patients were 60 years or older. The most common purpose for competency evaluation was to analyze patients' understanding of the anti-cancer treatment proposed by oncologists, followed by their refusal of the treatment. Half of the patients ($n = 6$) were diagnosed with delirium and three among them were judged as having the most impaired status of a patient's competency. Two patients (17%) were diagnosed with major depression and another two (17%) were mental retardation and each one patient was diagnosed with dementia and past history of alcohol dependence. Among 6 patients without delirium 5 subjects including a dementia patient were judged as fully competent. Total of 5 small potential modifications of the SICIATRI for its use with Japanese cancer patients were recommended.

Significance of results: Our experience suggests that the SICIATRI is a useful instrument for psycho-oncology clinical practice.

KEYWORDS: Cancer, Decision making, Informed consent, Psychiatric co-morbidity

INTRODUCTION

An appropriate decision-making process between patients and physicians is an essential component of all medical practice. However, although the patient's decision-making capacity (competency) should be guaranteed in the informed consent

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process, (Appelbaum, 2007) this ability may not be evaluated in routine practice, and overestimating patients' capacity is considered to be a problem. (Leping, 2011)

Cancer patients often face several important decision-making issues; for example, the choice of treatments, such as surgery, chemotherapy, radiotherapy, and palliative therapy, which may influence both their survival and quality of life. Some previous studies have reported that many cancer patients are asked to make difficult decisions under distressing circumstances. (Clark, Wray, & Ashton, 2001; Knowles, Liberto, Baker, Ruskin, & Raskin, 1994; Tamburini, Bucchieri, Brunelli, & Ferrigno, 2000) In addition, many studies have shown that cancer has a serious psychiatric impact on patients that renders them incapable of making a medical decision. For example, previous studies indicated that more than half of the cancer patients suffer from psychiatric disorders, the most common being adjustment disorders, major depression, and delirium. (Derogatis et al., 1983) (Lawlor et al., 2000; Minagawa, Uchitomi, Yamawaki, & Ishitani, 1996)

Although competency is a legal concept and can only be determined by a judge, psychiatrists are often asked to assess patients' competency in oncology practice. (Akechi et al., 2003) Based on this background, we began using the Structured Interview for Competency and Incompetency Assessment Testing and Ranking Inventory (SICIATRI) (Tomoda et al., 1997), a structured interview that assesses patients' competency, in our psychiatric consultation. Since we have learned some important lessons from our clinical activities, we are reporting our experiences of the usefulness of the SICIATRI for assessing the competency of Japanese cancer patients.

MATERIALS AND METHODS

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

The SICIATRI was originally developed in Japan to measure patients' competency to obtain informed consent. (Tomoda et al., 1997) It mainly focuses on psychiatric patients; however, its validity and reliability for physically ill Japanese patients have also been confirmed. (Tomoda et al., 1997)

The SICIATRI consists of several items: (1) Understands that he/she has a right to decide; (2) Evidences his/her choice; (3) Does not waive responsibility; (4) Understands the expected benefits; (5) Understands the expected risks; (6) Understands

the alternative treatments; (7) Understands the risks expected from no treatment; (8) Understands the benefits expected from no treatment; (9) Wants to get better; (10) Psychological determinants do not exist; and (11) Insight. Each part is scored according to the patient's responses, and the patient is finally rated as one of five different levels of competency (Levels 0–4). Level 0 is considered to be the most impaired status of a patient's competency, whereas Level 4 suggests that the patient is fully competent. The interview form and administration methods of the SICIATRI can be downloaded (<http://www.institute-of-mental-health.jp/right.html>). After the necessary training sessions, medical staff other than psychiatrists can also conduct the interview.

Because our experience demonstrated that a non-negligible number of referred cancer patients should have been evaluated for their competency (Akechi et al., 2003), we began using the SICIATRI in April 2011 in our routine psychiatric consultation when assessment of patients' competency should be needed.

To examine the usefulness of the SICIATRI, we reviewed all psychiatric consultations referred to the Department of Psychiatry and Division of Palliative Care and Psycho-oncology at Nagoya City University Hospital from April 2011 to March 2012. A computerized database was used to identify the cancer patients referred to these divisions. Finally, we identified the referred cancer patients who were administered the SICIATRI, and the relevant data including the detailed reason for consultation and the outcomes of the SICIATRI and neuropsychological tests (if available) were extracted from patients' records. After obtaining these data, the potential problems of administering the SICIATRI to Japanese cancer patients and proposals for its modification were discussed among the trained psycho-oncologists (T.A., T.O., M.U.).

This study was approved by the Institutional Review Board and Ethics Committee of Nagoya City University Graduate School of Medical Sciences, Japan. Since this was a retrospective study using a data set obtained during routine clinical practice, written consent from the patients was not obtained. However, we disclosed information about this study via the hospital web site and stated that patients could refuse to participate in the study, according to the ethical guidelines for epidemiological studies clinical studies developed by the Japanese Ministry of Health, Labour and Welfare (<http://www.mhlw.go.jp/general/seido/kousei/i-kenkyu/ekigaku/0504sisin.html>).

Several items of personal information have been modified in the following cases to preserve the patients' anonymity.

RESULTS

Patient Demographic and Medical Characteristics

Among the 433 cancer patients referred during the study period, 12 (2.8%) were administered the SICIATRI in several clinical settings and all of the administration were conducted without big problems. Patient characteristics are shown in **Table 1**. All patients were 60 years or older, and their mean age was 73 (SD = 9).

Purpose of Competency Evaluation and Psychiatric Diagnosis

The most common purpose was to check patients' understanding of the anti-cancer treatment proposed by oncologists (67%), followed by their refusal to undergo the recommended treatment (25%).

Regarding psychiatric diagnosis, six (50%) of the 12 patients were diagnosed with delirium. Two patients (17%) were diagnosed with major depression and another two (17%) were mental retardation. Four patients were administered the Mini-Mental State Examination (MMSE; a score of 23 or less suggests existence of cognitive impairment) to check their cognitive function, and their scores were variable, as shown in **Table 1**.

Outcome of Competency Evaluation

Regarding levels of competency, three patients (25%) were judged as Level 0 (the most impaired status of a patient's competency), four (33%) as Level 1, and five (42%) as Level 4 (fully competent). Among the six patients diagnosed with delirium, three were judged as Level 0 and three as Level 1. Among the two patients with mild mental retardation, one was judged as Level 1 and one as Level 4. Among the two patients diagnosed with major depression (one in a current episode and the other in remission), both were judged as Level 4 (fully competent). Interestingly, a patient diagnosed with moderate dementia and cognitive impairment (MMSE 13) was judged as Level 4 (fully competent).

Potential Issues Concerning Administration of SICIATRI to Japanese Cancer Patients

Most patients could be easily administered the SICIATRI in actual clinical settings. However, because our discussions yielded some ideas with regard to 5 modifications of the SICIATRI when administered to Japanese cancer patients, we would like to recommend these modifications to the original SICIATRI based on our experiences: (1) Because the item, "Understands that he/she has a right to decide," is self-evident for most cancer patients, it can often be omitted. (2) The item, "Does not waive responsibility"

Table 1. Characteristics of 12 cases receiving competency assessment interview

Age	Sex	Cancer	Clinical situation	Psychiatric diagnosis	Test results	Results of SICIATRI
94	female	colorectal	understanding of operation	delirium	—	Level 1
79	male	stomach	understanding of diagnosis and operation	dementia	MMSE 13	Level 4
78	female	bladder	poor adherence to treatment	mental retardation (mild)	MMSE 26	Level 4
77	female	primary unknown	understanding of chemotherapy	delirium	—	Level 0
75	female	pancreas	understanding of operation	major depression (remission)	—	Level 4
73	female	lung	understanding of treatment (chemotherapy or BSC)	major depression	—	Level 4
71	male	lung	understanding of phase III trial of chemotherapy	delirium	—	Level 0
71	male	gall bladder	understanding of chemotherapy	history of alcohol dependence	MMSE 24	Level 4
67	male	lung	refusal of chemotherapy	delirium	—	Level 0
67	male	lung	understanding of radiotherapy	delirium	—	Level 1
62	male	lymphoma	routine assessment before SCT	mental retardation (mild)	MMSE 21	Level 1
61	male	lymphoma	treatment refusal and desire for death	delirium	—	Level 1

MMSE: mini-mental state examination, BSC: best supportive care, SCT: stem cell transplantation

("Do you think that someone else should decide to accept or refuse the treatment [admission, or other procedures against which competency is to be measured] for you?"; "Because you cannot decide for yourself, do you want your doctor or family members to decide for you?"), should often be considered from the Japanese cultural perspective. It has been reported that elderly Japanese people do not always weigh individual autonomy or right during decision making. Our previous study suggested that elderly patients are likely to value the traditional paternalistic attitude of physicians, and not all patients want to be actively involved in decision-making and prefer the physicians' paternalistic approach. (Akechi et al., 2012) Thus, because a patient's waiver does not necessarily imply his/her incompetence in Japanese culture, we should carefully consider it when a patient waives responsibility. (3) Since, in actual clinical practice, physicians sometimes omit explanations of alternative treatments and the benefits expected from no treatment, whether patients were informed of these items by physicians often needs to be checked directly. (4) The item, "Wants to get better," is not understood by many incurable cancer patients. Paraphrases, such as "Wants symptoms to be alleviated," are sometimes useful. (5) Lastly, regarding the item, "Insight," although the manual says "The patient should be assessed as 'complete insight,' if he/she can recall the diagnosis they were told and explain what it was," some names of cancer diagnoses are difficult for them to recall completely (e.g., malignant fibrous histiocytoma and acute promyelocytic leukemia). Since this item essentially tests a patient's recognition of the life-threatening nature of cancer and not the name of the diagnosis, when a patient can state that his/her disease is "cancer" or describe its life-threatening nature, the item is rated as "3" (moderate insight) and not "2" (between no insight and moderate insight).

DISCUSSION

To the best of our knowledge, this is the first report about the clinical utility of a competency assessment tool for cancer patients in Japan. Our experience suggests that the *SICIATRI* is a useful tool for various clinical situations that require evaluation of a cancer patient's competency. Especially, since a patient's competency cannot be judged from a psychiatric diagnosis or psychological test battery (e.g., MMSE), (Akechi et al., 2003; Sessums, Zembrzuska, & Jackson, 2011) specific instruments that focus on decision-making capacity, such as the *SICIATRI*, are essential for evaluating patients' capacity.

Despite the potential usefulness of the *SICIATRI*, we have proposed 5 modifications for its use with Ja-

panese cancer patients based on our experience, which are summarized in the result section. Kitamura et al. have compared the components of the *SICIATRI* to those of the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-T) that is often used for evaluation of patients' capacity in Western countries and suggest that some components of the *SICIATRI* including "Understands that he/she has a right to decide", "Does not waive responsibility", and "Wants to get better" are not involved in the MacCAT-T although other components are almost same in these two instruments. (Kitamura & Kitamura, 2012) They suggest that these differences are partly caused by culture, especially with regard to individual autonomy. When taken with our findings, our one proposed modification ("Understands that he/she has a right to decide" can be often omitted because this is self-evident for most cancer patients) may reflect the westernization of the Japanese culture while one other proposal (a patient's waiver does not necessarily imply his/her incompetence) can be associated with traditional Japanese culture. Especially from a cross-cultural perspective a paternalistic approach between a patient and physician is still acceptable and even preferred by many Japanese elderly patients, (Akechi et al., 2012; Ruhnke et al., 2000) we should carefully consider a patient's passive decision-making style and not consider his/her waiving responsibility as a lack of competence. This is consistent with our previous findings obtained from the study investigating concepts relevant to a good death among elderly cancer patients. (Akechi et al., 2012) To be more precise, our study has suggested that some elderly patients value the traditional paternalistic attitude of physician, "omakase (leaving the decisions to a medical expert)", and that not all patients want to be actively involved in decision-making. Thus, our proposed modification of the *SICIATRI* may reflect rapid, but partial change of recent Japanese culture.

The present findings are very limited because our case series is seriously flawed by many methodological weaknesses including many types of bias resulting from systematic and random errors. However, our experience indicates that the *SICIATRI* is a promising instrument that should be evaluated in further well-designed clinical investigations in Japanese clinical oncology settings. We are now conducting a study to investigate the prevalence of incompetency and its associated factors using the *SICIATRI*.

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Prospective Clarification of the Utility of the Palliative Prognostic Index for Patients With Advanced Cancer in the Home Care Setting

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Abstract

Aims: This study aimed to prospectively clarify the accuracy of the Palliative Prognostic Index (PPI) for advanced cancer patients in home care settings. **Method:** The study included 66 advanced cancer patients who received home visiting services between April 2010 and June 2012, and who died at home or in the hospital. Using medical records from initial home visits, we prospectively calculated PPI scores along with sensitivity and specificity. **Results:** For 3- and 6-week survival, prognostic prediction showed respective sensitivities of 60% and 70.6%, and specificities of 87.0% and 71.9%. **Conclusion:** The sensitivity of the PPI for advanced cancer patients in home care settings was lower than that reported for patients in palliative care units. Development of prognostic tools suitable for home care settings is needed.

Keywords

palliative prognostic index, patients with advanced cancer, home care setting, prospective study, prognostic prediction, palliative care

Introduction

Making prognostic predictions is one of the core skills of physicians engaged in end-of-life care¹ and is a component of approaches to multidisciplinary palliative care.² In addition, patients with advanced cancer face difficult decisions regarding their treatment and choices related to end-of-life care.^{3,4} Accurately predicting prognosis is therefore helpful not only for patients and their families but also for health care professionals who support their decision making,⁵ especially those in the home care setting.

In general, it is difficult to predict the prognosis of patients with advanced cancer, especially those in the home care setting, because of limitations in the number of blood tests and radiological evaluations performed. Clinicians usually predict prognoses based on their own experience. A previous study revealed that prognostic prediction tools improved the accuracy of physicians' predictions.⁶ Several prognostic prediction tools have been examined for patients with cancer, for example the Palliative Prognostic Index (PPI),⁷ Cancer Prognostic Scale,⁷ Palliative Performance Scale (PPS),⁸ Palliative Prognostic Score (PaP score),⁹ PaP Score with Delirium,¹⁰ Japan Palliative Oncology Study-Prognostic Index,¹¹ and Prognosis in Palliative Care Study model,¹² and each was properly validated. These tools are intended for use in assessing inpatient and ambulatory patients,

and the appropriateness of their application to patients with advanced cancer in the home care setting is uncertain.

The PPI, which resulted in significant improvement in prognostication,⁶ was defined based on the performance status assessment using the PPS version 2 (PPSv2),⁸ oral intake, and the presence or absence of dyspnea at rest, edema, and delirium. The PPI was developed and successfully validated for patients with cancer in palliative care units by Morita et al in Japan.¹³

The PPI does not require blood tests or radiological evaluation and would therefore be very useful for patients with cancer in the home care setting when compared to other validated

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