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Proposal

Proposal for the Shared Decision-Making Process Regarding Initiation and Continuation of Maintenance Hemodialysis

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PREFACE

In Japan, the mean age of incident dialysis patients was 68.44 years in 2012, and continues to increase annually (1). Diabetic nephropathy has been the most common original renal disease of incident dialysis patients for the past 15 years, and the number of patients with complications of serious comorbidities, such as cardiovascular disease, showed a remarkable increase. A survey for the cause of death in patients who died within a year after dialysis initiation revealed that 10.7% patients died of malignant tumors; this suggests that dialysis is initiated even for patients with tumors. Furthermore, a survey on the physical activity of patients receiving dialysis conducted in 2010 showed that 5.6% patients were completely bedridden, and that there is an increase in the number of patients who cannot be discharged from the hospital because they cannot visit hospital regularly (2). These recent trends demonstrate that dialysis has transformed from a life-saving treatment aiming for rehabilitation to a life-sustaining treatment. According to these changes surrounding dialysis treatment, to set up a panel to discuss the future of the dialysis providing system and to establish a managing principle at the terminal stage has been called for by our society's members.

In the presence of severe cardiovascular comorbidities, hemodialysis itself places a heavy burden on hemodynamics, thus making dialysis difficult. Maintenance hemodialysis is an intermittent therapy (usually three times a week); therefore, the medical team tries to extend the treatment interval or shorten the treatment time for patients practicing dialysis with difficulty. From this perspective, temporary interruption of maintenance hemodialysis is completely different, compared with weaning from ventilator support, in the sense of requiring continuous treatment. However, discussions and announcements against withholding and/or withdrawal of hemodialysis at the terminal stage have been sporadically reported at academic meetings or in some medical journals in Japan, but no definitive criteria have been reported from Japanese academic circles related to nephrology.

"The study subgroup on withholding and withdrawal of dialysis" has been established as a subsidiary organization of the hemodialysis guidelines commission of the Japanese Society for Dialysis Therapy (JSDT). External members have also joined the discussion, and we have discussed the issue a number of times. Finally, we have come to present the proposal in

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this report. The terms withholding and withdrawal were consolidated into one definition of "forgoing." "Forgoing" implicitly implies that the hemodialysis can be initiated or reinitiated at any time, depending on the situation. Although the right of dying with dignity has not been established by law in Japan, the presence of an ethics committee making a suggestion on ethics issues is desirable. However, the establishment of an ethics committee at a medical clinic where only one physician is working is realistically impossible. To overcome this obstacle, this proposal recommends that an ethics committee composed of a medical team instead of one medical doctor could be a substitution in such a medical clinic. However, it is needless to say that if no agreement is reached between the medical team and the patient/patient's family, then a second opinion from a third party or the cooperation of an institution where an ethics committee has been established should be sought.

The basic policy of this proposal is that the decisions of medical practice should not be made by the doctor alone; instead, they should be made by a medical team[1] with sufficient support and information from the medical staff to the patient, thereby enabling the patients themselves to make an accurate, autonomous decision. The patient's self-determined policy for medical practice pattern should be fully respected by the medical staff. In other words, collaborative decision-making processes involving both the medical team and the patient are considered important (shared decision making). This decision-making process is in compliance with the Renal Physicians Association Guidelines (3) and the Salzburg Declaration (4). In addition, under certain conditions, maintenance hemodialysis itself can impair a patient's ability to lead a dignified life. Such conditions should be specifically presented to the patients and family members so that they can deal with them when they occur. Furthermore, the available palliative care options in the event of forgoing hemodialysis should also be presented. One example style for getting an advance directive is provided on our members' strong request, but we dare to say again that Japanese law does not define a style of advanced directive. It should be used as a template for processing the preparation of a directive by each medical facility or institution. In case of children, according to the "Discussion Guidelines concerning the medical treatment of children with serious disease" created by Pediatric Terminal Medical Care Guideline Working Group Ethics Committee of the Japan Pediatric Society (5), it is recommended that the decision on forgoing of dialysis be made on the basis of the maximum benefit for each patient.

GLOBAL TRENDS AND THE CURRENT STATUS IN JAPAN

There can be some indecision on how to deal with terminal patients[2] undergoing long-term dialysis therapy in Japan. Even if the dialysis patient is not at the terminal stage, sometimes there is inadequate support for patients who cannot make autonomous decisions or when their decisions are not respected. In order to deal with such situations, recommendations and guidelines have been prepared in some countries (6,7); however, no such guideline has been established in Japan. In America, a dignified death enforced by an advance directive is legally recognized, and citizens can receive medical treatment and care according to the contents of the advance directive (8). In 2010, the Renal Physician Association (RPA) presented the revised (2nd edition) "Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis" guidelines (3). In Japan, where the advance directive and dignified death are not legally stipulated, the Ministry of Health, Labor and Welfare (MHLW) created the "Guidelines for the Terminal Medical Care Decision-Making Process" (May 21, 2007), which deal with terminal healthcare (9). Here, in order to implement better end-of-life care, it is recommended that appropriate information and explanation should be provided by the medical and care teams, that discussions between the patient and healthcare workers should be held, and that the patient's decision with regard to the plan of treatment should be respected. Furthermore, any decision to initiate, withhold, change, or withdraw should be carefully made on the basis of medical validity and pertinence by the medical and care team. Respect for the decisions made by the medical and care team and for the patient's intentions is explicitly described, but legal responsibilities that can arise because of no initiation of life-prolonging treatments are not discussed. Under such circumstances, the Proposal for Terminal Medical Care in Emergency Medicine (Guidelines, prepared by the Japanese Association for Acute Medicine on November 5, 2007 (10)) and the Guidelines for the Decision-Making Process during Caring for the Elderly—Focusing on the Introduction of Artificial Hydration and Nutritional Supplementation (created by the Japanese Geriatrics Society on June 27, 2012 (11)) were independently created to provide guidelines for end-of-life care. The JSDT has now determined that a shared decision-making process for withholding and withdrawal of hemodialysis should be established; therefore, the Dialysis Guidelines Commission has initiated a deliberation. In this

proposal, the definition of the terminal stage conforms with the official view of the MHLW (9) and the Japanese Medical Association, 10th Annual Meeting of the Japan Association of Bioethics (12).

PROPOSALS

Proposal 1: The patient is fully informed about his or her diagnosis, prognosis, and treatment options and is assisted in making an informed and voluntary decision.
- The medical team presents adequate information to the patient.
- The medical team collects sufficient information from the patient.
- The medical team participates in and respects the patient's decision-making process.

The medical team presents adequate information to the patient.

The medical team should educate the patient regarding chronic kidney disease and renal replacement therapy. The patient should be made aware of the diagnosis, complications, predicted prognosis, and benefits and risks of treatment options in a way that the patient and his or her family can understand and use this information to reach informed decisions about dialysis and transplantation options.

The medical team collects sufficient information from the patient.

The medical team should listen to the patients carefully in order to evaluate the extent of the patient's grasp of the disease state and treatment options, as well as gather information about the patient's lifestyle and familial environment.

Because the ability of a patient to adapt to the disease can be improved through effective communication, the patient should be encouraged to ask questions and receive answers until he or she is able to fully comprehend the risks and benefits of his or her treatment options for the disease.

The medical team participates in and respects the patient's decision-making process.

Whether the patient can make a sound judgment or not should be evaluated in cooperation with the medical team, the patient, and the patient's family.[3] A patient capable of making a sound judgment should be allowed to make a decision on the treatment options on the basis of the information provided by the medical team, while the medical team should collaborate with the patient and respect the patient's decision-making process.

Proposal 2: Respect a patient's autonomy
- Respect the treatment and care plan requested by the patient.
- Even if the patient is incapable of making decisions at present, the treatment and care plan requested by the patient should be respected accordingly if the advance directive was prepared before the patient became incapable of making his or her own decisions.
- A patient who is capable of making his or her own decisions is made aware of the fact that he or she has the right to prepare an advance directive[4] when maintenance hemodialysis is initiated.

Respect the treatment and care plan requested by the patient.

The medical team and the patient's family should provide and continue the treatment and care requested by the patient as per the contents of the advance directive in which the patient indicated his or her intention with regard to the forgoing of hemodialysis treatment.

If the patient is incapacitated and the family does not agree to the patient's requested treatment and care plan, and if there is a prepared advance directive, the medical team should make every effort to persuade the patient's family to respect the patient's decision and obtain their consent. If such consent cannot be obtained, the matter should be presented before an ethics committee[5] comprising several specialists. The recommendations made by this committee should be adhered to.

If the patient strongly refuses hemodialysis when it is presumed that the patient's life can be sustained more by initiating or continuing hemodialysis, then the medical team should communicate the benefits and risks of the treatment to the patient with help from the patient's family, so that the patient can understand the necessity of hemodialysis treatment. If that still cannot change the patient's mind, the patient's decision should be accepted and respected.

Communicate that the patient has the right to prepare an advance directive.

The medical team should communicate to the patient that he or she has the right to prepare an advance directive for the treatment and care requested by the patient to be provided in the future under any circumstances at any time. In the event that he or she is incapacitated, this will afford the patient an opportunity to exercise his or her right to take decisions regarding medical treatment in advance.

Proposal 3: Acquire the letter of consent
- A letter of consent for starting dialysis is obtained before maintenance hemodialysis is initiated.

A letter of consent for starting dialysis is obtained before maintenance hemodialysis is initiated.

The right to decide treatment options should lie with the patient and his or her family. If a patient is capable of making decisions, a letter of consent should be obtained from him/her before starting dialysis.

It is recommended to obtain a letter of consent from the patient's family when the patient is incapable of making decisions. Furthermore, if a letter of consent cannot be obtained because of the family's inability to visit the hospital, the details of all communication with the patient's family and their informed consent should be described in the medical records. If it is not possible to contact the family in a timely manner, the relevant medical circumstances should be written in the medical records. It is recommended to initiate communication with the patient's family at the earliest opportunity and obtain a letter of consent. The date and details of the family's consent should also be recorded in the patient's medical history.

If there is a disagreement between the patient and/or patient's family (irrespective of whether the patient is capable or incapable of making decisions) about what decision should be made with regard to dialysis, consider a time-limited trial of dialysis for the patient in order to let him/her experience dialysis.

Recently, there has been an increase in the number of cases where it is not possible to obtain a letter of consent from individuals other than the patient himself/herself because of any of the following circumstances: the patient has no blood relatives, he or she led a solitary life and the family registry provides no details, and he or she has broken off contact with all blood relatives. When obtaining a letter of consent from such a patient, the importance of an advance-directive should be communicated.

Proposal 4: If appropriate, forgo (i.e., not initiate or discontinue) hemodialysis for the patients in certain situations.
- To afford the patient his or her dignity, forgoing hemodialysis could be one of the selections from the viewpoint of offering the best treatment
- When considering the forgoing of hemodialysis, it is important that the shared decision-making process is appropriately performed among parties (i.e., patient, his or her family, and a medical team).
- Forgoing hemodialysis is initiated or reinitiated depending on the patients' situation.

Conditions in which hemodialysis can be forgone are listed in Table 1.

In cases where hemodialysis cannot be provided safely.

Those who have a multi-organ failure complicated by severe circulatory or respiratory disorders and/or having continuous profound hypotension, for whom it is difficult to maintain extracorporeal circulation during the hemodialysis session, and hemodialysis itself could be life threatening.

Those whose medical condition precludes the technical process of hemodialysis because the patient is unable to cooperate (e.g., who pulls out hemodialysis needles by themselves) and needs cofines to bed by instruments and sedation with narcoleptics at every dialysis session in order to maintain safe extracorporeal circulation.

Under such circumstances, whatever the technological measure taken, providing hemodialysis is extremely difficult and poses a high risk to the

TABLE 1. *Situations when review of forgoing hemodialysis is necessary*

1) When it is difficult to perform hemodialysis safely and when hemodialysis itself could be life threatening, as in the following situations:
   a) In cases where hemodialysis can further jeopardize the patient's life because of the presence of multi-organ failure with complications of cardiovascular/respiratory problems and profound continuous hypotension
   b) In cases where keeping vascular access and extracorporeal circulation during the dialysis session with safety is not feasible, unless the patient is restrained by instruments or sedation with narcoleptics during every dialysis session
2) When the patient's general condition becomes extremely poor, as listed below, and the patient's wish regarding the forgoing of hemodialysis have been specifically expressed, or when the family can assume the patient's wish definitely:
   a) In cases where the patient has difficulty in understanding necessary information regarding hemodialysis and long-term self-care because of severe brain dysfunction caused by various factors, such as cerebrovascular diseases and head injury
   b) When the patient has complications of incurable malignant disease, with imminent and inevitable death
   c) When the patient cannot eat or drink anymore and cannot survive for long without artificial hydration and nutrition

patient's life. The medical team should then consider forgoing hemodialysis. When it is judged that hemodialysis cannot be performed safely anymore, it is necessary for the medical team to thoroughly discuss with the patient and his or her family about switching to other forms of renal replacement therapy.

In cases where the patient's general condition is extremely poor, and the patient's wish is clearly specified as advanced directives when having decision-making capacity, or in the event that the family presumes the patient's wish

The right to select treatment options should lie with the patient and his or her family. For those whose general condition is extremely poor and the patient has clearly specified his or her wish to forgo hemodialysis when he or she develops a severe irreversible condition, as listed in Table 1, the medical team should respect the wish of the patient and consider forgoing hemodialysis. This policy is the same when the family presumes the patient's wish definitely. Again, the decision to forgo hemodialysis stated in this proposal does not mean permanent withholding or withdrawal, and initiation or re-initiation of hemodialysis should be reconsidered any time when the patient's condition shows a change.

It is important for the patient, his or her family, and the medical team to adequately participate in the decision-making process (Fig. 1).

For those who have decision-making capacity, and his or her decision to forgo hemodialysis is definitive, the patient's decision of forgoing hemodialysis should be respected. However, it is recommended that his or her family give consent to such a patient's decision.

For those who have the decision-making capacity, but are unable to make or are unsure about a decision, the medical team should assist the patient in making an independent decision while respecting the patient's right to live. The medical team should share the patient's intention and respect the decision that emerges out of such a decision-making process.

For those who no longer possess decision-making capacity, and if his or her family can presume the patient's wish to forgo hemodialysis, the medical team respects his or her family's decision, sharing the

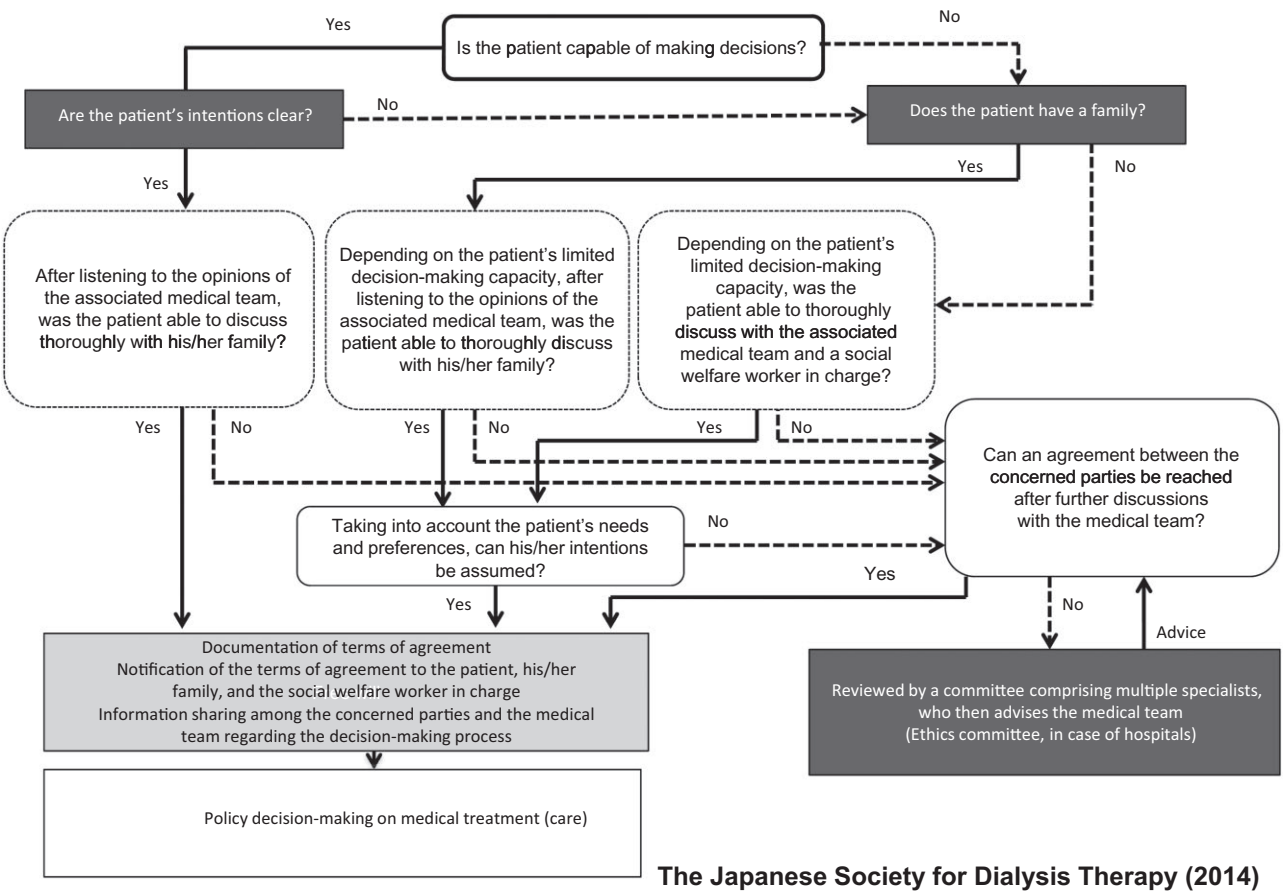

FIG. 1. Decision-making process for the forgoing of hemodialysis.

process of decision making. Even in this case, it is recommended to discuss with the patient according to his or her residual capability to make his or her own decisions.

For those who do not have decision-making capacity and his or her family can presume the patient's wish, but his or her family cannot reach an agreement yet as a family's opinion or are unsure about their decision, the medical team should provide support to facilitate an informed decision. If both parties can reach an agreement on a decision, the medical team respects such a decision, sharing the decision-making process.

In case that forgoing of hemodialysis cannot be agreed upon among the patient, his or her family, and the medical team, even after sufficient discussions for the policy of medical practice and care, it is recommended to establish an ethics committee comprising several specialists separate from the medical team. According to advice from the committee, the three parties reconsider the policy of medical practice and care to the patient, and should try to get a consensus.

If the patient has no family, then the municipal person-in-charge of welfare is considered to be equivalent to family.[6] Furthermore, it is to be distinctly noted here that the person-in-charge of welfare is legally recognized only as the executor in terms of burial after death, not as a legal agent/surrogate for decisions regarding the patient's treatment policy.

Forgoing of hemodialysis can be initiated or reinitiated in some situations.

When the patient's general condition improves.

When the patient and his or her family changed their own decision in regard to the treatment policy for hemodialysis.

Proposal 5: Care plan after forgoing of hemodialysis
- The medical team formulates a care plan that respects the patient's decision to forgo hemodialysis and provides palliative care.

The medical team formulates a care plan that respects the patient's decision to forgo hemodialysis.

The medical team, together with the patient's family, should formulate a care plan. Understanding the patient's high-priority issues, the medical team should aim to encourage his or her autonomy, help him/her find values in life, and gain peace of mind by providing the care suited to the patient.

The medical team should periodically discuss the treatment policy with the patient and his or her family and record the shared decision at regular intervals. When the patient becomes incapable of making his or her own decisions, the last recorded preference of the patient when he or she retained his or her decision-making capacity should be respected (13).

The medical team provides effective palliative care to patients who forgo hemodialysis.

The plan to provide comfort measures for any persisting or expected symptoms and other components of palliative care should be explicitly communicated to the patient and his or her family in advance (14).

With the permission of the patient and his or her family, the medical team should be involved in co-managing the patient's holistic suffering, including the medical, psychosocial, and spiritual aspects of end-of-life care.[7] Symptoms such as pain should be alleviated by means of palliative care, and psychological, social, and spiritual support should be offered to the patient.

Healthcare professionals with expertise in hospice and palliative medicine should be involved in offering comprehensive palliative, medical, nursing, and psychiatric care, as well as home care.

The patient should be offered the option of spending his or her final days where he or she can be comfortable with his or her family.

Psychological and social support should also be offered to the patient's family during care and bereavement.

CONCLUSIONS

The medical team should aid the patient in living a high-quality life with hemodialysis and assist the patient in living the same kind of life even in the terminal phase with hemodialysis. In addition, the medical team should ultimately ascertain its limits and provide guidance to ensure that death is as painless, calm, and dignified as possible and that the family is able to think that they can spend a good terminal period with the patient. Time-bound care that attempts to provide a solution to the question "How would the patient like to live?" is better than that which caters to "How would the patient like to die?", because death is inevitable. However, a majority of dialysis patients do not consider death or the terminal phase as a familiar issue. The option to forgo dialysis is one of the options that must be considered

in order to offer the best possible end-of-life care. Going forward, bioethical issues must be discussed periodically with proactive participation of the patient, and it is important to use common sense to establish guidelines for end-of-life care that offers a high quality of life in Japan.

CONFLICT OF INTEREST (COI) DISCLOSURE INFORMATION

The clinical guidelines prepared by the JSDT require that, hereafter, in order for the members of the preparation working group to execute their tasks with neutrality and fairness, we exert the maximum effort to avoid actual and anticipated problems that can arise from a conflict of interest.

All members of the working group present signed documents as disclosure of any possible or actual conflicts of interest. These documents are renewed annually, and depending on the situation, the information may be appropriately modified. This information is presented in the COI Disclosure Information as shown below, and all supporting documentation is archived at the executive office of the JSDT.

Tadao Akizawa received fellowship grants, a salary as an organization specialist, remunerations for lectures, payments for article submissions, and travel expenses for participation in academic societies from the following companies: Kyowa Hakko Kirin Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals), Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals), Bayer Yakuhin, Ltd. (a company that develops, imports, manufactures, and sells medical products, medical devices, and veterinary drugs), Astellas Pharma Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals), Mitsubishi Tanabe Pharma Co., Ltd. (a company that manufactures and sells pharmaceutical products, with a focus on ethical pharmaceuticals), Daiichi-Sankyo Co., Ltd. (a company that researches, develops, manufactures, and sells ethical pharmaceuticals), Baxter Co., Ltd. (a company that imports, manufactures, and sells dialysis products, plasma protein formulations, and drug delivery systems), Shionogi & Co., Ltd. (a company that manufactures and sells pharmaceutical products and diagnostic drugs), Nippon Boehringer Ingelheim Corporation (Japan; a company that researches, develops, imports, manufactures, and sells pharmaceutical products), and Reata Pharmaceuticals (US; a company that develops pharmaceutical products).

Kunitoshi Iseki received fellowship grants and remuneration for lectures from Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals), Kyowa Hakko Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals), and Bayer Yakuhin, Ltd. (a company that develops, imports, manufactures, and sells medical products, medical devices, and veterinary drugs).

Noritomo Itami received remuneration for lectures from Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals).

Kazuyoshi Okada received fellowship grants and remuneration for lectures from Kyowa Hakko Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals), Shionogi & Co., Ltd. (a company that manufactures and sells pharmaceutical products and diagnostic drugs), and Daiichi-Sankyo Co., Ltd. (a company that researches, develops, manufactures, and sells ethical pharmaceuticals).

Yoshindo Kawaguchi received expenses for collecting data, fellowship grants, payments for article submissions, and travel expenses for participation in academic meetings from Baxter Co., Ltd. (a company that imports, manufactures, and sells dialysis products, plasma protein formulations, and drug delivery systems) and Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports and exports ethical pharmaceuticals) and is affiliated with a lectureship financially supported by private donations.

Ken Sakai receives a salary as an advisor for JMS Co., Ltd. (a company that manufactures, sells, imports, and exports medical devices and pharmaceutical products).

Kazuhiko Tsuruya received a joint industrial and academic research grant and remuneration for lectures from Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals), Kyowa Hakko Kirin Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals), Torii Pharmaceutical Co., Ltd. (a company that manufactures and sells pharmaceutical products), Fuso Pharmaceutical Industries Co., Ltd. (a company that develops and sells pharmaceutical products and medical devices), Takeda Pharmaceutical Company, Ltd. (a company that manufactures, sells, imports, and exports pharmaceutical products and quasi-pharmaceutical products), and Baxter Co., Ltd. (a company that imports, manufactures, and sells dialysis products, plasma protein formulations, and drug delivery systems) and is affiliated to a lectureship financially supported by private donations.

Tadashi Tomo received remuneration for lectures from Kyowa Hakko Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals) and Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals). Hideki Hirakata received remuneration for lectures from Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals), Kyowa Hakko Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals), and Japan Tobacco Inc. (company that manufactures and sells tobacco, pharmaceutical products, food products, and beverages).

Ikuto Masakane received remuneration for lectures from Toray Medical Co., Ltd. (a company that manufactures, sells, imports and exports medical devices and related medical products, as well as pharmaceutical products) and Kyowa Hakko Kirin Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals).

Jun Minakuchi received remuneration for lectures from Nikkiso Co., Ltd. (a company that manufactures and sells hemodialysis devices, dialyzers, blood circuit sets for dialysis, drugs for the dialysis of artificial kidneys, and artificial pancreases, and sells products related to peritoneal dialysis) and Bayer Yakuhin, Ltd. (a company that develops, imports, manufactures and sells medical products, medical devices, and veterinary drugs).

Hiroyasu Yamamoto received remuneration for lectures from Kyowa Hakko Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals) and Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals).

Yuzo Watanabe received remuneration for lectures from Chugai Pharmaceutical Co., Ltd. (a company that manufactures, sells, imports, and exports ethical pharmaceuticals) and Kyowa Hakko Co., Ltd. (a company that manufactures and sells ethical pharmaceuticals).

(Members not mentioned here have no conflicts of interest to declare).

ENDNOTES

[1]The medical team for dialysis treatment should involve, at a minimum, the attending doctor, a nurse, and a clinical engineering technologist, while other individuals can be included on the basis of the scale of the institution and number of staff. However, it is recommended that the team include multiple members of each profession. If possible, other healthcare practitioners (such as social workers, dieticians, pharmacists, and a person-in-charge of welfare) should also be part of the medical team.

[2]The "Guideline Commentary regarding the Decision-making Process at Terminal Care" released by the MHLW described that the accurate definition of terminal stage is difficult. The reasons are that the estimated survival of patients suffering from terminal cancer could be between a few days and 2–3 months maximum, but the estimated survival of patients having a poor prognosis because of chronic illness with repeated acute exacerbations, or patients with complications of after-effects of cerebrovascular disease and an affliction by senility might be a few months to a few years. Thus, it is not adequate to determine terminal stage by the time until death, and MHLW recommended that the medical team should make appropriate and valid judgment for the terminal stage, evaluating the patient's condition individually. According to the "Terminal Care Guidelines" from the Japanese Medical Association's 10th Bioethics Meeting, the narrow definition of terminal phase refers to the period when death is imminent, while the broad definition can include the period during which the patient's well-being progressively worsens despite the best possible medical care, when death is inevitable and the patient awaits death. This guideline recommended that an assessment of the terminal stage should be decided by more than one medical members, including the primary physician, nurses, and other healthcare practitioners. In cases that the patient does not have the capacity of decision making, the definition of terminal stage starts when his or her family members who can presume the patient's wish understand and accept the patient's condition.

[3]The "Commentary on the Guidelines regarding Decision-making for Terminal Medical Care" from the MHLW declared that a definition of family members is not solely decided by blood relatives or recorded in the family register in law alone, but includes more broad members as family, such as an individual who gains the patient's trust and supports the patient in the terminal stage. "The Guidelines for the Decision-Making Process during Caring for the Elderly" created by the Japanese Geriatrics Society defined that an individual who has a deep connection with the patient, who shares a life close together, and who spends a life supporting him/her are eligible as family members. In addition, this guideline described that to denote individuals who are blood relatives or are recorded in the family register as family members is merely formality. According to these exemplifications, this guideline recommends that those who have established a deep connection with the patient and/or his or her family and actively participate in the shared decision-making process should be treated as family members.

[4]Advanced directive is a paperwork that affords the patient the opportunity to exercise his or her right to take decisions about their medical practice in advance. A living will is also translated as an ante mortem will, which describes the treatment plan under particular circumstances. But it contains some gray areas. Actually, it is difficult to predict the future in a precise sense; therefore, giving detailed instructions is difficult. The nomination of a legal representative is based on a system where there is continuous representation for the patient. In this system, the patient entrusts a legal representative with the power to make decisions regarding his or her treatment plan in the event that he or she is incapacitated. Such a system is beneficial when the patient has no family members or when there is a lack of clarity with regard to the key individuals among the many relatives, because the legally nominated individual can consult with the medical team. However, such a system is not legally recognized in Japan. It is difficult to determine with any level of confidence whether the decision of the proxy truly represents the will of the patient. As for advanced directives, there are no defined formats. A template of advanced directives is attached in this proposal, because there are a lot of demands from society members, but it should be emphasized again that this couldn't be said to be perfect.

[5]An ethics committee comprising multiple specialists is separately created for exceptional cases when there is a disagreement among the patient, family members, and the medical team about the decision regarding dialysis. If it is difficult to create an ethics committee because of the limitations of the medical institution, specialists from other institutions should be invited to participate. At medical institutions with a standing ethics committee, an investigation by the ethics committee would be desirable, but if an

interim meeting cannot be scheduled, a relevant committee should be created to investigate.

[6]According to the Cemetery Burial Law, a deceased patient who has no identity, has no blood relatives (even in the family registry), or has severed all contact with blood relatives will be buried by the municipal person-in-charge of the welfare according to the recommendations of the following acts: the Cemetery Burial Law, Act on Treatment of Persons Who Contracted Disease or Died on Journey, and the Livelihood Protection Law in Japan. However, the person-in-charge of welfare is not a legal representative and cannot participate in making decisions about continuation of treatment. Even adult guardians of patients with dementia may not agree with medical instructions such as Do Not Attempt Resuscitation (DNAR). Accordingly, the person-in-charge of welfare in the municipality mentioned in the proposal will become a representative, with emphasis on the fact that there is no legal rationale for their being designated as such.

[7]According to the World Health Organization's "Cancer Pain Relief and Palliative Care," "spiritual" refers to "those aspects of human life relating to experiences that transcend sensory phenomena (15)." To many people, the spiritual aspect of "living" includes religious factors, but "spiritual" does not have the same meaning as "religious." Spiritual factors can be considered to include all aspects of human life, such as physical, psychological, and social factors and commonly involves concerns or distress regarding the purpose and meaning of life. In particular, this is commonly defined as being related to self-forgiveness, reconciliation with others, and recognition of values for those who are approaching the final stage of their lives. It is difficult to translate spiritual pain into Japanese, and it is sometimes translated as incorporeal pain. However, it is understood as existential pain. To be more precise, it is described as grappling with the purpose in life or meaning of life, loneliness, anxiety, despair, a change in values, the meaning of suffering, the awareness of sin, fear of death, quest of the existence of a deity, and distress on the view of life and death.

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APPENDIX

Advance directive for the forgoing of hemodialysis

From the information provided by my attending physician (Dr.) and the medical team, I understand the possible outcomes of forgoing hemodialysis, which is a necessary treatment to survive and/or that I am currently receiving. With that understanding, I request that hemodialysis treatment be forgone and that an appropriate treatment be considered at the time of withholding and/or withdrawal if I am diagnosed with any of the conditions mentioned below. I will consult with my attending physician and the medical team again if I reconsider my decision.

When I will become a condition such as those below
( ) 1. A persistent vegetative state
( ) 2. Severe brain dysfunction
( ) 3. Painful terminal cancer with the prospect of imminent death
( ) 4. Other (please define below)

However, I would like to receive the following treatment even if hemodialysis is forgone.
( ) 1. Fluid replacement
( ) 2. Pain-relieving treatment
( ) 3. Other (please define below)

In addition, I will not receive the following treatment.
( ) 1. Ventilator assistance
( ) 2. Cardiopulmonary resuscitation
( ) 3. Other (please define below)

Signature:

Effective date: Date (mm/dd/yyyy)

Submitted to: (Hospital/institution/clinic)

Dr.
