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# REVIEW





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# Abstract

Approximately 340,000 people in Japan are on chronic dialysis, and this number continues to increase. Even today, hemodialysis is the most frequently selected modality for renal replacement therapy in Japan, accounting for approximately 97% of chronic dialysis patients. This is because the facilities and insurance for hemodialysis were developed early in Japan, and the results of treatment were very good. Most cases of kidney disease are associated with diabetes or hypertension, and the average age of patients on dialysis is increasing, which means that many dialysis patients experience reduced activities of daily living (ADL) and quality of life (QOL). To address those issues, shared decisionmaking and advance care planning are now widely used in the process of selecting RRT. Because of the work required, including multiple processes and information sharing, medical professionals must practice team medicine in order to improve ADL and QOL for dialysis patients and renal transplant recipients as well as promote appropriate selection of RRT. Accordingly, the "Renal Replacement Therapy Professional Instructor" certification system was established to meet this need. In addition, due to the aging of dialysis patients, there are more situations where it is necessary to consider forgoing dialysis in terms of general condition and QOL. In such cases, conservative kidney management must be offered, and the "Renal Replacement Therapy Professional Instructor" is also required to participate in them. It is hoped that a comprehensive medical system centered around Renal Replacement Therapy Professional Instructors will be created to meet the increasingly diverse needs of patients with end-stage kidney disease and their families, with the aim of providing support that will enable them to lead richer lives.

**Keywords** CKM (conservative kidney management), EDKD (end-stage kidney disease), Treatment modality, Medical expenses, RRT (renal replacement therapy)

# Background

The environment surrounding end-stage kidney disease is changing as the number of dialysis patients experiencing reduced activities of daily living and quality of

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life continues to increase. Although team medicine is required in the selection and practice of renal replacement therapy, there is no common certification system. Here, the background and purpose of the establishment of such a certification system will be explained in detail.

# Introduction

According to data from 2004, the prevalence of chronic kidney disease (CKD) was about 11% of the population in the USA, China, and Australia [1]. Worldwide, the

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burden of CKD is increasing, with one to two million people dying of CKD each year [2]. Furthermore, CKD is projected to become the fifth leading cause of death worldwide by 2040, which is the largest increase expected for any of the major causes of death [3]. In other words, CKD is becoming a major global public health problem. Patients with end-stage kidney disease (ESKD) require life-sustaining renal replacement therapy (RRT), which may involve chronic dialysis or renal transplantation. However, because renal transplantation is often unfeasible due to age-related comorbidities and lack of donors, dialysis remains the mainstay of treatment for many patients with ESKD. In 2010, an estimated 2.62 million patients worldwide were on RRT, and at least 2.28 million may have died prematurely due to lack of access to RRT [4]. This review discusses the current state of CKD patients in Japan and the problems they face; the current practices and future directions for RRT selection; and the newly established Japan Renal Replacement Therapy Association (JRTTA).

### Trends among CKD patients in Japan

There are an estimated 13.3 million CKD patients in Japan, meaning that around 1 in 8 adults has CKD, and the prevalence is particularly high among elderly adults [5]. As CKD progresses, it leads to ESKD, which must be treated by dialysis or renal transplantation. According

to a statistical survey by the Japanese Society for Dialysis Therapy, 347,671 patients were on chronic dialysis as of the end of 2020. Although the number of patients on dialysis has been increasing year after year, the rate of increase has slowed in recent years [6]. According to the United States Renal Data System, Japan had the second highest prevalence of dialysis patients in the world after Taiwan [7]. As of the end of 2020, the average age of dialysis patients was 69.40 years. Hemodialysis, hemodiafiltration, and hemofiltration accounted for about 97% of all dialysis modalities, while peritoneal dialysis, including its combination with hemodialysis, accounted for the remaining 3%. It is also not clear what is responsible for the fact that peritoneal dialysis patients account for only 3% of the total number of chronic dialysis patients. One reason is thought to be that hemodialysis was covered by national health insurance and thus popularized early on in this small, densely populated country. In 2020, the average age of patients newly starting dialysis was 70.88 years, with 38,263 on hemodialysis and 2481 on peritoneal dialysis [6]. That year, new renal transplants, including both living- and deceased-donor transplants, were performed in 1711 patients [8].

These figures highlight the problems with RRT in Japan. Figure 1 shows the number of patients in each age group from 1982 to 2017, as reported by the Japanese Society for Dialysis Therapy in Japan [9]. It is clear from





the figure that the number of patients has increased over time and that the proportion of patients aged 65 years or over has also increased. Meanwhile, Fig. 2 shows that the Japan Society for Transplantation reported 1711 kidney transplants in 2020, a decrease from the previous year, partly due to slowing in rate of transplants and partly due to the emergence of COVID-19. This number includes 1570 living donor kidney transplants, 17 cardiac arrest donor kidney transplants, and 124 brain death donor kidney transplants. While the number of living donor kidney transplants has gradually risen, there has also been an increase in transplants between married couples as well as blood group incompatibility transplants and transplants in the elderly. However, with approximately 4000 ESKD patients requiring dialysis induction each year, the number of transplant patients remains limited. Furthermore, the number of registered donor kidney transplant recipients remained mostly unchanged at 13,163 as of the end of 2020, with the average waiting period reaching 15-17 years. Figure 3 shows the percentage of each therapy (hemodialysis, peritoneal dialysis, and renal transplantation) in renal replacement therapy around the world, and it is clear that Japan is a very unique region [10].

# Promotion and adoption of transplantation and peritoneal dialysis through revisions to the medical fee schedule of the national health insurance reimbursement system

The cost of hemodialysis is about USD 3100 per month, or an estimated USD 1.25 billion per year, which accounts for roughly 4% of total medical costs in Japan. In contrast, the cost of peritoneal dialysis is around USD 2300–3100 per month, and the cost of renal transplantation about USD 580 per month. Because hemodialysis accounts for the majority of RRT in Japan, as noted previously, adoption and promotion of renal transplantation and peritoneal dialysis are desirable from the perspective of reducing medical costs. In response to this situation, the medical fee schedule of the national health insurance reimbursement system was revised in 2018 to include providing an appropriate explanation of RRT options to patients as a requirement for receiving reimbursement,



Fig. 2 Number of prevalent dialysis patients, patients on the kidney transplant waitlist, and kidney transplantations. KTx, kidney transplants (*source*: The Japan Society for Transplantation, Fact book 2020)



Fig. 3 Percentage of each type of renal replacement therapy selected by country or region (*source*: International Society of Nephrology, Global Kidney Health Atlas, 2nd ed. 2019; Available from: https://www.theisn.org/initiatives/global-kidney-health-atlas. Accessed 2022 Jan 31.)

and new medical fee points were established to promote counseling and management of peritoneal dialysis and efforts to promote renal transplantation [11]. Revisions to the medical fee schedule made in 2020 further increased the reimbursement rates established in 2018, in recognition of the importance of efforts to encourage peritoneal dialysis and renal transplantation. In addition, the new system allows facilities to receive reimbursement for a new management fee for patients with CKD not yet on dialysis whose estimated glomerular filtration rate is less than 30 mL/min/1.73 m<sup>2</sup> by explaining and providing information on RRT-on the condition that this is done as a collaborative effort between physicians and nurses with at least a certain duration of experience in the treatment of kidney disease [12]. These revisions of the medical fee schedule have caused an increasing number of facilities to add specialized outpatient services for the selection of RRT. In addition, they have reaffirmed the importance of team medicine by requiring the involvement of a specially appointed nurse.

This trend was taken even further in the medical fee schedule revisions made in 2022, which require not only mutual information-sharing on renal transplantation (including peritoneal dialysis) between core renal transplant hospitals participating in the transplant network and individual dialysis facilities but also holding conferences to promote the selection of other RRT as a criterion for receiving reimbursement. They also mandate that medical professionals with expertise in RRT participate in these activities.

# Dialysis withdrawal and conceptualization of conservative kidney management

As described above, with the advancement of hemodialysis, peritoneal dialysis, and renal transplantation and their respective specificities in RRT, there is a need for multidisciplinary personnel with the appropriate knowledge and understanding of practices who can handle all aspects of care for ESKD patients and their families.

In the U.S., a law was enacted in 1999 that respects the wishes of terminally ill patients by allowing them to forgo life-sustaining treatment. The following year, the "Clinical Practice Guideline on Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis" was published [13] and later revised in 2010 [14]. In response to these trends, efforts have been made to promote widespread adoption of shared decision-making (SDM) in RRT selection as well as advance care planning (ACP), which involves discussing medical and supportive care options at the time of dialysis withdrawal and in the final days of life after dialysis withdrawal.

Regarding the international situation in CKM, a systematic review of six countries (Canada, England, Finland, France, Switzerland, and United States) reported that forgoing or withdrawing from dialysis increased from 3/1000 person-years to 48.6/1000 person-years between 1966 and 2010 [15]. In Australia and New Zealand, the proportion of deaths due to withdrawing from dialysis increased from 11% between 1997 and 2000 to 32% between 2013 and 2016 [16]. In a systematic review comparing life expectancy between CKM and dialysis, median survival ranged from 6 to 30 months for CKM versus 8 to 67 months for dialysis [17]. While dialysis was better in terms of survival, other reports indicate that quality of life was similar or better with CKM [18]. However, the prognosis and quality of life may be influenced by the individual patient's background, so care must be taken in interpreting the results.

This process of deciding to forgo or withdraw from dialysis is not the only thing that should be emphasized; caring for the patient after they make this decision is also important. The 2018 Oxford University Hospital Kidney Unit guidelines also state that conservative kidney management (CKM) should be provided after the decision is made to forgo or withdraw from dialysis rather than abandoning treatment altogether [19]. CKM is also considered an option for management of ESKD in stage 5 CKD and includes interventions to slow the progression of ESKD through SDM and patient-centered care with an emphasis on ACP, active symptom management, and improving quality of life [20]. Although CKM is increasingly recognized as an important treatment option for patients who are ineligible for dialysis or have elected to forgo dialysis, the specific method in clinical practice of CKM has not yet been fully established at this time [21].

In response to the aging of Japan's population, the Ministry of Health, Labour and Welfare and various academic societies have similarly been creating guidelines for various diseases such as heart failure and dementia, with the aim of helping providers respect patients' wishes and provide better end-of-life medical care and supportive care. It has been reported that some patients have foregone dialysis at dialysis facilities across Japan. Although some of these cases may have been inevitable, some were due to the insistence of a non-terminal patient with the consent of their family, indicating that the medical team was forced to make a difficult decision.

The Japanese Society for Dialysis Therapy has published "Recommendations for the Shared Decision-Making Process Regarding Initiation and Continuation of Maintenance Hemodialysis," which emphasizes SDM and ACP for all ESKD patients, including recommendations for handling cases such as the one mentioned above [22]. The topics discussed in these recommendations include providing sufficient information about the patient's current medical condition and RRT, collecting the patient's information, helping the patient to make the best choice, and providing information about CKM if the patient decides against RRT. Thus, the establishment and spread of CKM demands the development of a sense of mission in the medical professionals involved in all aspects, including SDM and ACP, as well as their expertise regarding the mental and physical palliative care of patients.

# The new renal replacement therapy professional instructor certification system

The number of patients with ESKD is increasing, and diabetes still accounts for nearly half of all underlying conditions, with a long period of conservative management increasing the risk of complications. The steady increase in the average age of patients starting dialysis and patients on maintenance dialysis, and the rapid increases in patients with reduced activities of daily living and quality of life, are becoming major issues. Home health care is considered one of the keys to addressing these issues in Japan's national policy. Peritoneal dialysis offers a true in-home option for RRT, and patients who have undergone renal transplantation no longer require frequent hospital visits for dialysis. These options are not only more convenient for the patient but also reduce the medical costs associated with continuing hemodialysis. As patients begin or continue RRT, their physician will be just one member of a multidisciplinary team of nurses, clinical engineers, pharmacists, dietitians, and transplant coordinators who will support and guide the patient in making decisions about their care. Despite the increasing importance of health care professionals, there is no common certification system for dialysis professionals; rather, each profession has its own system to certify experience and competence.

Therefore, an effort was launched to establish a new system for interdisciplinary cooperation among medical professionals that covers the entire range of RRT, leading to the creation of the "Renal Replacement Therapy Professional Instructor" certification system. This is a cross-professional qualification that certifies professionals who have acquired essential knowledge regarding the selection and guidance of RRT for CKD and are trained to promote not only dialysis treatment but also transplantation treatment and conservative renal therapy (the specific duties are summarized in Table 1). Figure 4 shows that the Japan Renal Replacement Therapy Association (JRRTA) will be a community of directors from academic societies involved in the field of renal disease and will assume responsibility for the training, education, and certification of instructors [23]. The establishment of this system is expected to promote a cooperative system to support patients and their families, centered on newly qualified health professionals, and to increase the proportion of patients undergoing treatment at home. Furthermore, considering the issue of Japan's aging population,

### Table 1 The role of the Renal Replacement Therapy Professional Instructor

- 1. Using a shared decision-making approach to help patients choose renal replacement therapy
- 2. Provide support to patients and their family when they opt for conservative kidney management
- 3. Participate in advance care planning with end-stage kidney disease
- 4. Work to promote home dialysis, including peritoneal dialysis and home hemodialysis
- 5. Continue to push for more kidney transplants
- 6. Promote registration with the Japan Organ Transplant Network
- 7. Work with transplant facilities when a cadaveric donor is encountered
- 8. Promote registration as an organ donor
- 9. Preventing critical illness in patients with chronic kidney disease
- 10. Take a leadership role in multidisciplinary collaboration
- 11. Regularly study and update your knowledge using e-learning
- 12. Addresses all aspects of medical care related to renal replacement therapy



Fig. 4 Relationship of public and private organizations and academic societies whose board members belong to the Japan Renal Replacement Therapy Association with CKD patients and their families

the system aims for certified Renal Replacement Therapy Professional Instructors to develop the ability and ethical foundation to support the decision-making of patients and their families in the final stages of life, including the decision to forgo or withdraw from dialysis.

## Conclusion

When patients who can no longer continue typical conservative management for CKD are forced to choose RRT, most select hemodialysis. Following this trend, dialysis patients would be expected to start hemodialysis at the suggestion of their health care provider and then continue chronic dialysis at a clinic near their home. However, in recent years, as the population has continued to age and the number of comorbidities has continued to increase, the number of patients who are considered poor candidates for hemodialysis has also increased. The urgent need to promote home care such as peritoneal dialysis and renal transplantation to reduce costs is another reason why the appropriate choice of RRT is desirable. In addition, an increasing number of patients are choosing to forgo dialysis, which requires providers to engage in medical decision-making processes such as SDM and ACP. This may include the selection of alternative therapies during the initiation period as well as the initiation of CKM and subsequent palliative care for patients who have decided to forgo dialysis, which requires contributions from specialists across multiple disciplines.

In response to these social circumstances, the new Renal Replacement Therapy Professional Instructor certification system was created to certify renal failure specialists across multiple health care professions. It is hoped that this program will mature into a system led by certified Renal Replacement Therapy Professional Instructors who provide comprehensive support for patients with renal failure and their families, enabling patients to have higher quality of life by linking CKM, initiation of RRT, management of comorbidities, and coordination with social welfare services.

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#### Author contributions

YK planned the review, searched the literature, and prepared the article. NH searched the literature and assisted in writing the article. KT planned the context of this article and assisted in writing the article. All authors read and approved the final manuscript.

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