Renal Replacement Therapy

REVIEW

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The role of clinical engineers in dialysis therapy in Japan

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Abstract

Traditionally in Japan, dialysis treatment has been performed primarily by physicians and nurses. However, with the advancement of related medical equipment, such as the development of dialyzers and dialysis monitoring equipment, technical support by technicians has become necessary. Therefore, in 1988, the "Clinical Engineers Act" was enacted and recognized as an official national qualification for technicians to operate these devices, in light of the actual status of these technicians and the fact that further advancement and diversification of medical devices will require their expertise in the future. This is a professional qualification unparalleled anywhere in the world. In dialysis treatment, purification of dialysate and efficient removal of uremic substances are fundamental principles. Clinical engineers have contributed significantly to the elimination of biological and chemical contaminants in the process of production of dialysis water, to the development of high-performance membranes, and to the development and advancement of online HDF, a high-volume fluid replacement method. Furthermore, clinical engineers have been involved in the proposal and development of safe devices to prevent medical accidents that occur during continuous dialysis treatment for many patients. Clinical engineers will continue to contribute to the provision of the best treatment methods, not only in the development and deployment of equipment, but also in remote medicine and the utilization of large-scale data, as they are medical professionals with knowledge of both medicine and engineering. Furthermore, the scope of the profession, which started in the field of hemodialysis, has the potential to expand to include peritoneal dialysis and other modalities of renal replacement therapy.

Keywords Automatic priming function, Back-filtrated dialysis fluid, Purified dialysis fluid

Introduction

Dialysis therapy spread rapidly across Japan with the introduction of equipment such as dialysis monitoring systems. In response to this increase in demand, unlicensed technicians in charge of such equipment began participating in patient care alongside physicians and nurses, at the physician's discretion. This was how the role of the clinical engineer was born. In 1988, the Japanese government enacted the Clinical Engineers Act to recognize the expertise required of clinical engineers, based on the realities of these technicians' work and anticipating the increasing sophistication and diversity of medical equipment to come. Indeed, clinical engineers are tasked with operating and maintaining increasingly sophisticated medical equipment under direction from a physician.

Before the Clinical Engineers Act went into effect, clinical engineers were unlicensed and were primarily responsible for preparing equipment for dialysis and providing technical support to physicians and nurses. However, the new law clarified the unique responsibilities of clinical engineers as medical professionals, and expectations of clinical engineers in these areas have grown even

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greater due to increasing reliance on all kinds of medical equipment. This is due in part to newly arising issues with medical accidents involving medical equipment and because the conventional team medicine approach of physicians, nurses, and clinical engineers working in a fragmented fashion under a physician's discretion has failed to ensure sufficient safety. Quality and safety assurance will improve if team medicine can mature into an independent and collaborative model in which team members work independently but share information with each other based on a clear understanding of their own responsibilities and abilities. This article discusses how the work and role of clinical engineers has evolved since the dawn of dialysis therapy, as well as future possibilities for the profession.

The dawn of dialysis therapy and the birth of the clinical engineer role

In the 1960s, flat-plate dialyzers (also known as Kiil dialyzers) began to be widely used. Kiil dialyzers are laborious to assemble and use, making it difficult for physicians and nurses to manage them alone, and this led to the emergence of specialized facilities with staff dedicated to those tasks. The introduction of disposable dialyzers in the 1970s made dialysis much less labor-intensive. This led to greatly increased numbers of dialysis facilities, at which dialysis technicians were hired. During this era, dialysis technicians mostly worked behind-the-scenes and faced barriers to involvement in clinical work. These problems were resolved with the passage and enactment of the Clinical Engineers Act in 1987. After a five-year transitional period, clinical engineers began engaging in clinical work as qualified professionals [1].

Early dialysis systems consisted of a combination of individual devices, instruments, and other equipment with the necessary functions. Later, integrated dialysis systems containing all the essential equipment and instruments for safe dialysis came onto the market. The blood circulation system used for extracorporeal circulation of blood consisted of devices such as an air bubble detector to prevent air from entering the patient's bloodstream and a venous pressure manometer. The dialysate circulation system used to deliver and remove dialysate was equipped with devices such as a blood leak sensor to monitor blood leakage in the blood purifier, a concentration sensor to properly control concentration, a dialysate pressure manometer, and a fluid removal controller to ensure accurate removal of fluid from the dialysate.

Developments in dialysis therapy, enabling long-term dialysis

Gejyo et al. [2] identified beta-2 microglobulin (β2-MG) as the causative agent of dialysis-related amyloidosis, which had become a problematic complication in patients on long-term dialysis. Dialysis-related amyloidosis causes various symptoms including itching, restless legs syndrome, and bone and joint pain, as well as organic diseases such as bone destruction and carpal tunnel syndrome, and it came to be considered a typical complication of long-term dialysis [3]. In recent years, the frequency of its occurrence has reportedly decreased, and the cause is believed to be related to improved β2-MG clearance on hemodialysis [4]. β2-MG later became an index for membrane performance evaluation based on its clearance and sieving coefficient, and it remains so in the current functional classification of dialysis membranes [5]. This development also made the removal of solutes (uremic substances) that are not cleared from the body an important proposition for dialysis [6]. Dialysis membranes now use synthetic polymer membranes rather than regenerated cellulose membranes and target medium-sized molecules and protein-bound solutes for removal rather than small molecules. High-performance membrane (HPM) dialyzers were introduced to clinical practice and modifications were devised to promote internal filtration and increase removal capacity through HPM. The modality of online hemodiafiltration (HDF) was also introduced, which allows for large replacement volumes. The evaluation of HD membranes is also discussed in the ISO. The ISO 8637-1:2017 describes dialysis modality, including evaluation methods for ultrafiltration coefficient, ultrafiltration rate, and sieve coefficient, establishing standards parallel to those in Japan [5]. Clinical engineers were essential to the research and development that led to these dialysis methods, and they collaborated with physicians on many studies whose results were applied back to clinical practice.

Role of clinical engineers in dialysate purification

The importance of clean dialysate, which is the site of solute diffusion and ultrafiltration through the dialysis membrane, has been pointed out from the beginning. In vitro studies have reported that mediator products pass through the dialysis membrane [7]. It was also reported that the use of clean dialysate reduced inflammatory reactions, inflammatory cytokines, and improved nutritional status [8]. It was already analogized that the quality of dialysate was involved in the complications of chronic dialysis such as chronic inflammation, emaciation, and anemia. Particularly in Japan, the use of high-performance, high-flux dialysis membranes and the inevitable back-diffusion and back-diafiltration inevitably led to the demand for clean dialysate. Under such circumstances, if the dialysate is contaminated, pyrogens such as endotoxin will inevitably enter the human

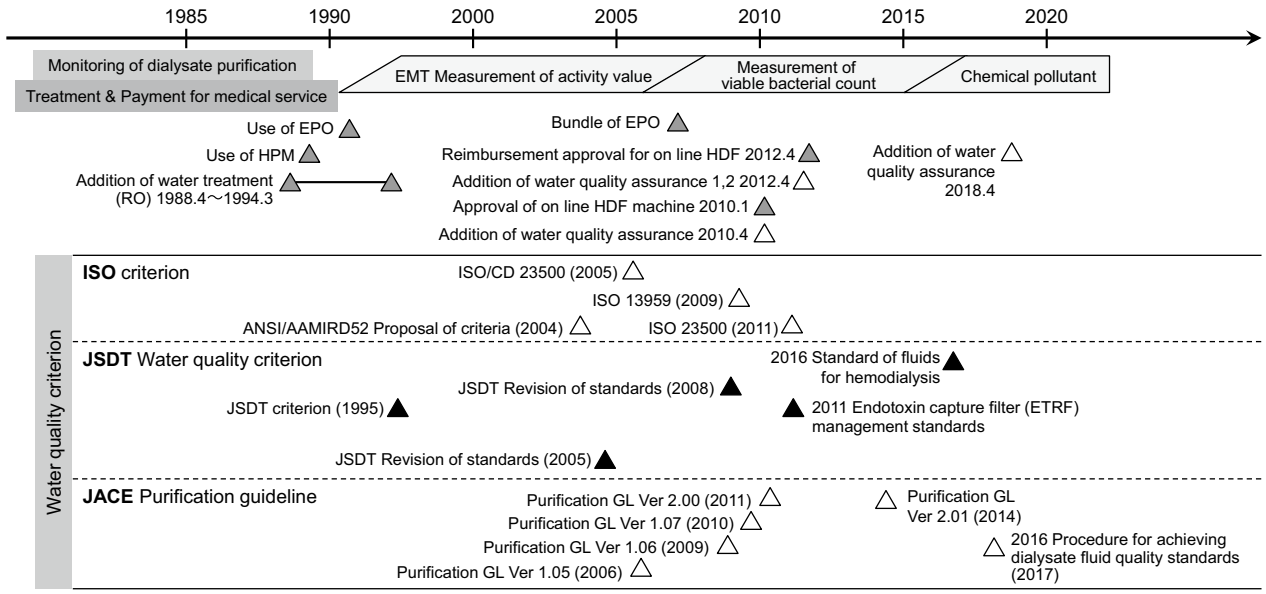
body through reverse filtration and diffusion, and clean dialysate became an essential condition [9].

Biological contamination of dialysate was rarely a problem with conventional dialyzers, but it began to attract attention once HPM became popular. To eliminate contamination, clinical engineers devised and implemented a technique called dialysate purification. Dialysis water is produced by a dialysis water preparation system. Essentially, purification requires the removal of chemical and biological contaminants. Chemical contaminants are removed by two types of equipment, an activated carbon filtration system and reverse osmosis (RO) filters. Biological contaminants are removed by equipment such as an endotoxin-retentive filter, ultraviolet germicidal lamp, and ultrafiltration module [10]. Efforts to promote purification were particularly bolstered by health care provider reimbursements through the Japanese National Health Insurance system, beginning with the introduction of reimbursement for water treatment in 1988. The popularity of RO in Japan dramatically increased when the reimbursement for RO was introduced in1988, prompting medical facilities to begin removing chemical contaminants from dialysis water. Figure 1 shows the history of water quality control and the related reimbursements.

After this point, dialysate purification efforts in Japan paralleled those in the rest of the world. Standards are issued by the International Organization for Standardization (ISO; a non-governmental organization headquartered in Geneva, Switzerland). ISO/CD 23500 was introduced in 2005 [11] proposed the bacterial culture method to monitor purity by measuring viable bacteria, which are the root cause of contamination, rather than measuring endotoxin activity. Its classification of dialysate types into standard, ultrapure, and replacement dialysate, with corresponding viable count limits of 100 CUF/mL, 0.1 CFU/mL and 10^{-6} CFU/mL, had a particularly major impact.

In 2008, the Japanese Society for Dialysis Therapy set water quality standards for biological contamination of dialysate solutions [12]. These standards are the strictest in the world for standard dialysate. In 2007, a one-year prognostic study on dialysate cleanliness and mortality risk by the JSDT confirmed a 22.8% increased risk of mortality at dialysate endotoxin levels of 0.1 EU/mL or higher, validating the appropriateness of setting the standard at 0.05 EU/mL or lower [13].

Since 2005, clinical engineers have joined industry representatives at ISO meetings to continuously investigate current practices and provide input. In addition, the Japan Association for Clinical Engineering (JACE, established in 1990) conducted surveys on viable count control at dialysis facilities in 2005 and 2006 and used the results to propose clinically realistic guidelines for dialysate purification and promote the practice of purification [14]. The guidelines are updated as appropriate (Ver. 1.06 in 2009, Ver. 1.07 in 2010, Ver. 2.00 in 2011, and Ver. 2.01 in 2014) and aim to improve the accuracy of purification techniques.



ET: endotoxin, EPO: erythropoietin, HPM: High performance membrane, HDF: hemodiafiltration, HF: hemofiltration, ISO: International Organization for Standardization, ANSI/AAMI: American National Standards Institute/Association for the Advancement of Medical Instrumentation, JSDT: Japanese Society for Dialysis Therapy, JACE: Japanese Society for Clinical Engineering

Fig. 1 Changes in purification of dialysate solution, reimbursement, and water quality standards

Later, three organizations, JACE, the Japan Society for Dialysis Therapy (JSDT), and ISO, issued guidelines for dialysate quality, but no standardized clinical target was established. Therefore, when JSDT published an update to their standard for fluids for hemodialysis and related therapies in 2016 (Table 1) [15] that addressed these three guidelines, at JACE we adapted our proposed criteria to the JSDT standard and presented them as the 2016 Procedures for Achieving the Standard of Fluids for Hemodialysis and Related Therapies. From the above, it is clear that clinical engineers have played a major role in dialysate purification and supporting the advancement of hemodialysis to where it is today [16].

On the other hand, as well as the cleanliness of the dialysate itself, its management is important, and the management of water treatment equipment, endotoxin-retentive filters (ETRFs), and cleaning and disinfection after each dialysis session are key points. It is also essential to check whether the cleaning and disinfection is being carried out properly and whether the dialysate preparation process is in operation, and to establish water quality testing guidelines at each point. In particular, many dialysis centers in Japan have adopted the CDDS (central dialysis fluid delivery system), where the dialysate preparation process is established by installing multi-stage equipment in a sequential manner [17, 18]. Each dialysis center selects and installs its own equipment. The introduction of the validation concept is necessary for process control and product quality assurance in manufacturing processes where equipment is continuously installed in multiple stages. In chronic dialysis, dialysate management must be carried out routinely and permanently, and the work never stops. Many maintenance dialysis patients today need to repeat this process to perform dialysis without problems, and a clinical engineer is essential to carry out, manage, and validate this process. Currently, each facility is required to verify the management of dialysate and search for problems monthly, and those in charge of management are required to attend a course at the JSDT annual meeting to renew their qualifications.

Development of dialysis systems

Clinical use of HPM dialyzers began after the causative agent of dialysis amyloidosis was discovered in 1985. HPMs are now collectively referred to as membranes with added value, such as albumin leakage rate, in addition to the conventional features of dialyzers with high ultrafiltration rate. Clinical engineers have played an important role in the actual operation of HPMs, in determining their efficacy and in monitoring their cleanliness, a situation that continues to the present day [19–21].

Because the fractionation properties of HPMs allow them to remove β2-MG, it became essential to use a dialysis system with higher permeability and better control of fluid removal than a conventional dialyzer. Therefore, as HPMs became popular, systems with more advanced fluid removal control functions were developed, and clinical engineers worked on the development and maintenance of these systems to ensure their safe use. One

Table 1 2016 Update Japanese Society for Dialysis Therapy Standard of fluids for hemodialysis and related therapies

Chapter 1: water quality standard for biological contaminants	
1.1	Ultimate goals of the standard established for biological contamination
1.2	Test for compliance
1.3	Sampling points
1.4	Day of sampling
1.5	Frequency of monitoring (ET and viable bacteria
1.6	Conditions of dialysis to which the respective dialysis fluid standards are applicable
1.7	Endotoxin-retentive filter (ETRF) management standard
1.8	Safety measures
Chapter 2: water quality standard for chemical contaminants	
2.1	Chemical contaminants and relevant standards
2.2	Control of chemical contaminants: at installation of a water treatment equipment
2.3	Control of chemical contaminants: daily management
2.4	Control of chemical contaminants: in the event of disasters or in case of emergencies
Chapter 3: measurement of the residual chlorine	
Chapter 4: proposal of a "management standard for water treatment equipment"	
Chapter 5: supplement and management standard for water treatment equipment	

of the major challenges in this area was to balance the goal of eliminating medical accidents against the cost of modifications, which decreases as the number of patients increases. In 2007, fully automated machines that substituted dialysate for normal saline were clinically investigated as a means of solving this problem and were shown to be safe and economical. Later, in 2010, an online HDF/HF system was approved through a partial change application and began to be used in clinical practice. This system had built-in online priming, blood return, and fluid replacement functions, and it marked the advent of automated systems in clinical practice [22]. Clinical engineers were heavily involved in the development and modification of these so-called fully automated machines. Clinical engineers have also significantly contributed to safety, the most important aspect of medical care, by not only maintaining and managing equipment but also operating the equipment [23].

Establishment of safety measures

As professionals who handle medical equipment, clinical engineers are also tasked with safety management for that equipment. Since 2006, Japanese law has mandated that all medical facilities assign a Medical Equipment Safety Manager (MESM) to ensure safe management of medical equipment. The MESM has the following duties: (1) plan and properly execute maintenance and inspection of medical equipment, (2) collect information regarding safe use of medical equipment and implement of measures to improve safe use, and (3) train others on the safe use of medical equipment.

The 2006 revisions to the Medical Care Act mandated that medical facilities ensure medical safety, and they clearly defined requirements to enhance and strengthen safety management systems, enhance nosocomial infection control systems, and establish safety management systems for pharmaceuticals and medical devices. When the new law was enacted in 2007, JACE published guidelines for the maintenance/inspection and operation of medical equipment, including dialysis equipment, and we have been periodically revising these guidelines ever since. To address the legal requirement for training, we issued guidelines for proper use training in 2014, and to address infection prevention, we issued guidelines to prevent spread of infection through medical equipment in 2016. In response to the COVID-19 pandemic that started at the end of 2019, we published a compilation of these guidelines and shared them publicly, including with government agencies, incorporating findings pertaining to COVID-19. We will continue to formulate guidelines on safety measures for medical equipment, including dialysis equipment, as measures to ensure the safety of quality medical care and to prevent infection.

Future possibilities for clinical engineers in dialysis care

As the population ages, demographics shift, and medicine continues to advance, health care providers must duly consider patients' psychosocial backgrounds and lifestyles. This will require further promotion of team medicine involving physicians, nurses, clinical engineers, and other health care professionals. In addition, as Japan's working-age population shrinks due to the declining birthrate and aging population, work styles and needs are becoming more diverse. Japanese companies, particularly large ones, have been slowly adopting work style reforms since April 2019 [24] and overtime hours are starting to decrease as well. Physicians, who are responsible for patient care, tend to work longer hours than many other professions because they are required to treat patients day and night. In the past, clinicians believed these long hours were for their patients' sake and that they improved care quality, but the state of health care in Japan was unsustainable and needed to be changed. This led to task shifting and sharing being promoted, which refers to redistribution of less specialized tasks from physicians to other health care professionals.

On October 23, 2019, the Ministry of Health, Labour and Welfare (MHLW) established a task force on task shifting and sharing to promote reforms to physician work styles. On January 22, 2021, the MHLW proposed the Act to Amend the Part of Medical Care Act to Ensure the Establishment of a System to Provide Quality Medical Care (https://www.mhlw.go.jp/english/wp/wp-hw7/dl/02e.pdf). The law was passed on May 21, 2021, and went into effect on May 28, 2021. Legislation concerning clinical engineers was developed in conjunction with this new law, and the amended Clinical Engineers Act went into effect on October 1, 2021 [25]. The amended law legally defines a new scope of work for clinical engineers. The original Clinical Engineers Act allowed clinical engineers to participate in various dialysis care tasks, including "setting and changing dosages of blood, replacement fluids, and drugs through operation of a blood purifier" and "using ultrasound equipment to check parameters necessary for safe and proper connection of the blood purifier to the vascular access, such as vessel diameter and flow rate at the vascular access," whereas the amended law allows clinical engineers to "operate a blood purifier, change dosages, and check the connection to the vascular access." In the revised law, the scope of work now includes, "the act of puncturing a superficial artery or vein, including connection/removal of the tip of a puncture needle or other blood purifier component to/from a superficial artery or vein." Puncturing a superficialized artery (usually a subcutaneously elevated brachial artery) does not include direct puncture of the artery.

Task shifting and sharing in dialysis care will hopefully continue to progress. Because medical care involves multiple professions working together as a team, each profession must further the practice of team medicine to improve quality through attentive patient care and improve efficiency by reducing workload. As experts involved in various hemodialysis modalities, clinical engineers must lead efforts to improve treatment efficiency and safety management, including troubleshooting. In the future, it must be determined how clinical engineers involved in blood purification can actively participate in clinical tasks, including home care, as part of a patient-centered team medicine approach.

New areas and new certifications

One major characteristic of the dialysis care landscape in Japan is that the average age of patients on dialysis is increasing and these patients have comorbidities, which means that many patients have reduced activities of daily living and quality of life. Another is that hemodialysis is by far the most commonly selected renal replacement therapy (RRT) in Japan, used by approximately 97% of patients on chronic dialysis, and other options such as peritoneal dialysis and renal transplantation are only rarely selected [26]. A team medicine approach is essential to improving activities of daily living and quality of life and to promoting appropriate selection of varied RRT modalities, which is why the Renal Replacement Therapy Professional Instructor Association was established to certify specialists in the field of RRT [27]. Peritoneal dialysis is also becoming increasingly important as a home-based option. Widespread use of automated peritoneal dialysis systems has increased the specialized knowledge required for tasks such as patient counseling, equipment management, and remote monitoring, which in turn has increased demand from physicians and nurses for clinical engineers to participate in these tasks. For this reason, the Japanese Society for Peritoneal Dialysis established a peritoneal dialysis certification program for clinical engineers. JACE has decided to actively participate in these new specialty areas and certification programs.

According to statistics from JSDT, the number of clinical engineers engaged in dialysis care (including both full-time and part-time) has tripled over the past 20 years, from 9346 in 2001 to 16,580 in 2010 and 26,263 in 2020. According to JACE membership data from 2022, 60% of members are between the ages of 20 and 39 and 26% are female. Assuming that the age distribution is similar for clinical engineers involved in dialysis care, their relatively young age should ensure enough manpower to continue meeting the demand for dialysis-related tasks in the future. A partial amendment to the Act on Public Health Nurses, Midwives, and Nurses has already authorized clinical engineers to assist with some care tasks, and the recent revision of the Clinical Engineers Act will enable further progress in dialysis-related tasks in general, including these new tasks. Clinical engineers will need to take the lead.

Conclusion

The field of dialysis care has joined the movement to actively address the sustainable development goals unanimously adopted at the 2015 United Nations summit. Dialysis treatment requires disposable products and relies on large amounts of electricity to power medical equipment, which has resulted in continuous consumption of large amounts of energy to sustain human life. In conventional dialysis systems, excess water and dialysate are discharged as effluent during the process of making dialysis water in an RO machine [28]. A system was recently tested clinically that recovers thermal energy by heating this dialysis effluent to around body temperature and temporarily storing it after it contacts the blood, and it was found to be effective. Clinical engineers oversee entire dialysis systems, and their role is critical to the operation of such equipment. Cybersecurity measures are also important for operating medical databases, which are indispensable to modern health care. Clinical engineers are the health care professionals most qualified for this task, due to their knowledge of engineering.

In summary, (1) the clinical engineer is a nationally licensed position, rare in the world, that was created in Japan as a leader in the field of engineering in medicine. (2) In basic medical engineering, the clinical engineer is involved in the theoretical construction and development of new devices, and in actual clinical practice, the clinical engineer is involved in the operation of medical devices in the medical field and in the management of medical devices from the aspect of medical safety. (3) The clinical engineer plays a particularly important role in the fields of renal replacement therapy, especially in hemodialysis. He has managed the long-term treatment of so many patients in Japan with good results. Replacement of kidney function by dialysis requires long-term stable management, operation, and maintenance of equipment, which could not be achieved without the work of clinical engineers. (4) In the future, with the development of new medical devices, the evolution of remote medicine, and the use of AI (artificial intelligence) for the accumulation and analysis of large-scale data, the role of clinical engineers will become more important and indispensable in medical engineering.

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HT planned the review, searched the literature, and prepared the article. TM and UJ 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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