

Current status and standards for establishment of hemodialysis units in Korea

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The number of hemodialysis patients and dialysis facilities is increasing each year, but there are no surveillance programs validating that the services and equipment of each hemodialysis unit meet specified safety and quality standards. There is a concern that excessive competition and illegal activities committed by some dialysis facilities may violate patients' right to health. Contrastingly, developed countries often have their own survey program to provide initial certification and monitoring to ensure that these clinics continue to meet basic requirements. Because hemodialysis units provide renal replacement therapy to critical patients suffering from severe chronic renal failure, appropriate legal regulation is important for the provision of initial certification and maintenance of facility, equipment, and human resource quality. Therefore, several standards providing minimum requirements for the area of hemodialysis unit, equipment for emergency care, physician and nurse staffs, water purification and quality management are urgently needed.

Keywords: Hemodialysis units; Renal dialysis; Reference standards

INTRODUCTION

Hemodialysis patients are gradually increasing every year. According to the statistics of National Health Insurance Service (NHIC) on medical aid, the number of hemodialysis patients increased by 31.9% from 44,136 in 2006 to 58,232 patients in 2010. Hemodialysis centers have been increased in number by 30.2% from 545 to 710 centers. The total medical cost for hemodialysis surpassed KRW 1 trillion in 2008 from KRW 848.8 billion in 2006. However, there is an excess supply of hemodialysis machines relative to the number of patients. The recommended number of patients is 4 per

hemodialyzer, but there are 2.6 patients per machine as of 2011. There is therefore an excess investment of around 50% [1]. As was the case for computed tomography and magnetic resonance imaging machines in the past, the introduction of innovative diagnostic and treatment methods led to an early surge in demand, oversupply, cut-throat competition, illegal conduct, and the inflow of unqualified healthcare providers, ultimately resulting in concerns being raised over the potential threat to patients' rights.

The 5-year survival rate of hemodialysis patients is 67.8%, similar to the survival rate of stomach and colon cancer. Moreover, dialysis patients are at high risk

of various complications such as cardiovascular diseases, stroke, and infection that often result in death [1]. Proper treatment is not performed when unqualified medical providers, who have no experience in end stage renal disease (ESRD) patients, operate dialysis centers. In many countries, there is adequate quality management for dialysis centers, because they are either subject to a government approval system prior to establishment or an accreditation system after establishment.

The distribution and definition of the welfare budget may vary depending on welfare environment and circumstances of each country. However, national welfare policies, schemes, and laws on the regulation and management of dialysis center operation and ESRD patient care are crucial for improving public health. Therefore, planning and preparation of measures for quality management of ESRD patients are essential, which fit the systematic environment of the welfare in Korea. This study aims to establish the standards for facilities, equipment, and workforce in dialysis centers that should be stipulated by medical law by examining the current state of dialysis centers in Korea.

FACILITY CRITERIA OF HEMODIALYSIS CENTERS IN OVERSEAS

In many countries, approval and accreditation constitute the two main forms of regulation for dialysis centers. Approval involves the evaluation of whether certain criteria are met at the time of establishment, while accreditation involves regular evaluation and recertification after a certain period of time has lapsed since establishment. Germany and Singapore follows the approval system, while Taiwan and Hong Kong implement an accreditation system. The United States has adopted both systems, while Japan applies a system close to self-regulation (Table 1). Table 2 shows the criteria for the workers, qualification, facilities, and equipment of dialysis center operation by each country.

The United States

The 42 Code of Federal Regulations Part 494 provides the legal foundation of hemodialysis centers and explains in detail matters related to infection control, fluid management, reuse of dialysis membranes, building and dialysis center environment, medical staff responsibilities, patients rights, the quality control of dialysis [2]. In addition, each state has statutory provisions regarding accreditation based on Federal Law. To obtain operational approval for a dialysis

Table 1. Summary of overseas guidelines/laws

	Guidelines/Laws	Dialysis unit establishment	Workforce standards	Equipment (dialysis machine) standards
United States	42 CFR Parts 488 and 494 State Guidelines	Approval/Accreditation	○	○
Germany	Act (Statutory Health Insurance Modernization Act)	Approval	○	○
Singapore	Ministry of Health Guidelines	Approval	○	○
Hong Kong	Accreditation standards (Hong Kong College of Physicians and Hospital Authority)	Accreditation	○	○
Taiwan	Standard operating procedures (Taiwanese Department of Health and Taiwan Society of Nephrology)	Accreditation	○	○
Japan	Management standards (Japanese Society for Dialysis Therapy)	-	Dialysis specialists	○

CFR, Code of Federal Regulations.

center, required documents must be submitted to the United States Secretary of Health and Human Services. In terms of manpower requirements, the medical director of a dialysis center must be a physician certified in internal medicine or pediatrics with a minimum of 12-month clinical experience in nephrology. The head nurse must have a minimum of 12-month clinical experience, with an additional 6 months in dialysis. The qualifications of nutritionists, social workers, dialysis technicians are also specified in the same statute.

The ESRD network was founded in 1978 as the first organization to promote autonomous quality management of dialysis centers. The network mandates each dialysis center to be registered to the local ESRD network [3]. Registered dialysis centers are required to report patient conditions and treatments administered to the ESRD network information system. The federal government has delegated the authority to approve, manage, and accredit dialysis centers to the ESRD network, and they decide the approval or renewal of approval for dialysis centers by submitting an inspec-

tion report to the Secretary of Health and Human Services.

Germany

Since 2002, Germany has begun to manage dialysis centers by adopting the Statutory Health Insurance Modernization Act [4], stipulating that hemodialysis should be done by nephrologists. Moreover, patient allocation has been restricted to 29 hemodialysis patients per nephrologist. Up to 99 patients can be allocated to two nephrologists. To participate in training programs for dialysis nurse, a nurse should have at least 2 years of clinical experience in nursing practice and at least 6-month work experience in the field of nephrology. The German government monitors dialysis and medical services through a regular inspection to assure the adequacy of dialysis and limits insurance coverage based on the inspection [5].

Singapore

Singapore government has established the guidelines for private healthcare hospitals providing renal dialy-

Table 2. Quality management of overseas workers, facilities, and equipment

	Workforce	Facility/Equipment
United States	Nephrologists with a minimum 12-month clinical experience	Professional inspection, monitoring, and reporting obligations by the AAMI, stipulated by the law to perform quality management through the Quality Assessment and Performance Improvement Program.
Germany	Physicians who completed nephrology training programs for more than 3 years	Stipulated by the law to monitor and report hygiene and infection control, and adequate hemodialysis. The insurance coverage is affected by the results.
Singapore	Nephrologists registered with the Singapore Medical Association and with a minimum 12-month work experience in an accredited dialysis center	Established the standards for the size and equipment of dialysis centers and stipulated by the law to manage water quality, dialysis fluid testing, and infection control.
Hong Kong	Nephrologists certified by and registered with the Hong Kong Internal Medical Association	Operate dialysis centers by proposing accreditation standards for equipment, water quality, systems, and dialysis-related machines.
Taiwan	Only nephrologists can operate dialysis units.	Provide the management standards for hygiene and infection and inspect dialysis centers every 2 years in audit teams that consist of the Taiwan Society of Nephrology members and staff of insurance companies. The insurance coverage is affected by the results.
Japan	Dialysis specialists	Provide the care guidelines and management standards for hemodialysis.

AAMI, Association for the Advancement of Medical Instrumentation.

sis for the quality control (“Regulation 4 of the Private Hospitals and Medical Clinics Regulations”) [6]. Proposals for setting up and licensing of a renal dialysis center shall be submitted together with the application form to the Director of Medical Services for approval not less than 30 days before the intended commencement of operations of the renal dialysis center, and the physician in charge of a dialysis center must be registered with the Singapore Medical Council’s Register of Specialists in Renal Medicine and have experience in nephrology in a recognized center, including at least 1 year’s experience in dialysis. Moreover, the nurse in charge of a dialysis center must be a qualified registered nurse, have at least 2 years of experience in dialysis nursing in a dialysis unit in a major hospital. Regulations on the building, water quality, equipment, infection control, responsibility to patients, safety report obligation on transfers, and deaths of patients are stipulated in the law. Furthermore, the Ministry of Health designated audit teams comprising a nephrologist inspect dialysis centers on a regular basis.

Hong Kong

The Hong Kong College of Physicians and the Hospital Authority have established and implemented accreditation standards. Standards are categorized as “recommended” and denoted (R) or as “desirable” and denoted (D) based on the strength of evidence that such practices will affect the patients’ outcome [7]. Hemodialysis and peritoneal dialysis services are provided in centers with qualified nephrologists and nurses. In addition, the guidelines on equipment and water quality system, reuse of hemodialyzer and related devices, hygiene, and infection control are clarified in the accreditation standards.

Taiwan

The Taiwanese Department of Health founded the Committee for Evaluation and Accreditation of Hemodialysis Centers and Hospitals in the Taiwan Society of Nephrology in 1986 to regulate the quality control of dialysis centers [8]. Dialytic medical organizations should complement the Dialytic Medical Services Quality Improvement Scheme and report on how the monitoring items are being executed, which are regularly checked and managed by the Department of

Health. A dialysis center is required to assign 15 hospital beds per doctor and certified nephrologists should be more than half of total doctors in the center. Moreover, four hospital beds are assigned per nurse. Dialysis centers can only be managed by certified nephrologists who have completed at least 2 years of kidney-related training program. Nephrology specific nursing training system is also implemented. Furthermore, audit teams consisting of the Taiwan Society of Nephrology members and the Taiwan Nephrology Nurses Association members inspect dialysis centers every 2 years and differential rates of fee are determined by audit outcomes.

Japan

The Japanese Society for Dialysis Therapy has set up the accreditation committee for dialysis facility but the facility management is voluntarily operated with no obligation [9]. Nephrologist system is being implemented by requiring physicians in internal medicine, urology, and pediatrics departments to receive clinical practice on dialysis therapy for more than 5 years. The license renewal of nephrologists is required every 6 years by meeting certain conditions. Nephrology nurse system is implemented as well. In addition, the Japanese Society for Dialysis Therapy recommends the management standards on anemia, blood vessel care, and infection prevention of dialysis patients.

CURRENT STATUS OF HEMODIALYSIS UNITS IN KOREA

Analysis of the evaluation of the adequacy of hemodialysis

To establish facility standards for hemodialysis units, their current status should first be defined. The evaluation data on the adequacy of hemodialysis are the only available data from all current hemodialysis units that were collected by the Health Insurance Review and Assessment (HIRA) Service. The evaluation was conducted three times, and the analysis was conducted based mainly on the disclosed data on the hemodialysis adequacy evaluation in 2009 and partly in 2010. It included 621 dialysis units that lodged insurance claims from NHIC out of 627 units and used the data

on the dialysis sessions for outpatients in those units for 3 months from July to September 2009.

Out of the 957 full-time physicians in the evaluated dialysis units, 729 (76.2%) specialized in dialysis and 228 (23.8%) did not. A total of 122 units (19.6%) did not have a single physician who specialized in dialysis (Table 3). When categorized by type of unit, 45.7% of hospitals did not have a dialysis specialist, and 18.9% of general hospitals and 14.9% of clinics didn't. Actually, not all of the full-time physicians in dialysis units that have more than one physician should be dialysis specialists, but units without a dialysis specialist—19.6% of all units—may be inadequately operated. Apart from the qualifications of full-time physicians in dialysis units, their workload can also degrade their patient care, which will lead to the poor operation of the units. In clinics, a physician performs an average of 26.2 dialysis sessions a day (the result showed great gap between units); but the 2009 and 2010 evaluations

showed that in 12.1% and 12.5% of units, respectively, a physician performed more than 35 dialysis sessions a day (Fig. 1).

The units should have experienced nurses, considering the characteristics of hemodialysis treatment; otherwise, the quality of patient care may be seriously affected by the absence of nurses with more than 2 years of experience. The analysis revealed that all the units had nurses with more than 2 years of experience; but in 99 (16%) and five (0.8%) units, less than 50% and only 25% of the nurses were experienced, respectively. The average number of dialysis sessions per nurse daily, which reflects the nurses' workload, also showed an asymmetric distribution—that of the dialysis unit in the clinics was 4.1. In 10% of the units, a nurse performed an average of 5.5 to 6.5 dialysis sessions daily; and in 5% of the units, more than 6.5 sessions (Fig. 2). However, there were units that performed up to 194% of the average number of dialysis sessions.

Table 3. Number of dialysis specialists based on the type of medical center

Center type	Total	No. of dialysis specialists				Nonspecialists
		Total	1	2	3	
Tertiary hospitals	213	176 (82.6)	137	25	14	37 (17.4)
General hospitals	258	210 (81.4)	136	39	35	48 (18.6)
Hospitals	118	56 (47.5)	22	17	17	62 (52.5)
Clinics	368	287 (78.0)	152	47	88	81 (22.0)
Total	957	729 (76.2)	447	128	154	228 (23.8)

Values are presented as number (%).

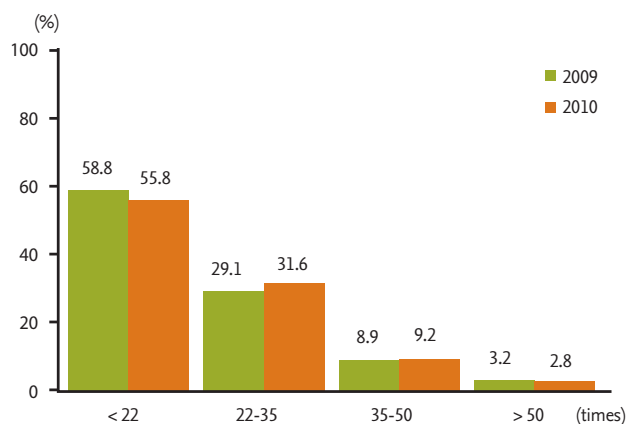


Figure 1. Distribution of the average number of dialysis sessions per physician daily less than 22, 22 to 35, 36 to 50, and more than 50.

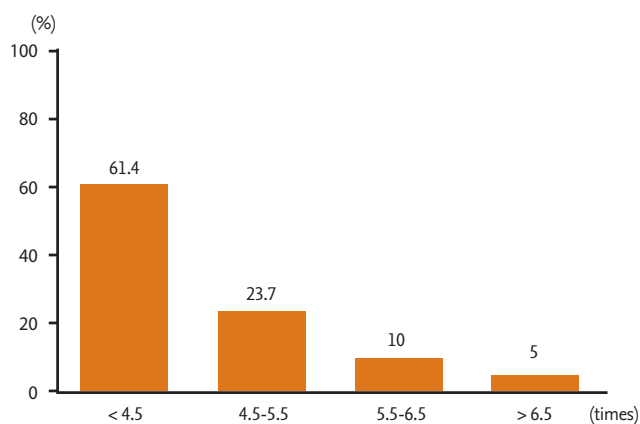


Figure 2. Distribution of the average number of dialysis sessions per nurse daily.

Cardiovascular diseases are seen as the main causes of the death of dialysis patients [10]. The early detection of cardiopulmonary arrest and immediate cardiopulmonary resuscitation increases the survival of patients. As such, dialysis units should be equipped with emergency medical supplies for acute cardiopulmonary arrest. In the results of the evaluation of the adequacy of hemodialysis, only 394 (63.4%) units had complete emergency medical supplies that included equipment for tracheal intubation such as the airway, laryngoscope, endotracheal tube, ambu-bag, stylets and suction devices for removing foreign bodies, electrocardiography (ECG) monitors, oxygen supplies, and a defibrillator. Two units did not have oxygen supplies; 84 units, suction; 39 units, ECG; 22 units, tracheal intubation equipment; and 191 units, a defibrillator.

Moreover, the management of the quality of the dialysis water has been recognized as important with the improvement of hemodialysis technology. Other countries have established dialysis water manage-

ment guidelines; but in Korea, there are no accredited guidelines for the inspection of water for dialysis. The results of the evaluation of the adequacy of hemodialysis suggested a bacteria test monthly, an endotoxin test once every 3 months and a contaminant test yearly. However, 34% of the units fell short of these standards.

The number of aged care facilities has been increasing recently along with increased population aging and the increased incidence of chronic diseases among the elderly. According to the evaluation of aged care facilities by the NHIC in 2009, their number increased to 777 in 2009 from 109 in 2004 (712%) with the increase in their dialysis units. An evaluation of 34 aged care facilities with dialysis units revealed a significant shortage of dialysis specialists and emergency supplies, and lack of adequate management of water quality (Table 4). The regular inspection of dialysis adequacy and other tests in aged care facilities is similar to the inspection of other dialysis units, but differs in the achievement rate of dialysis adequacy, systolic blood pressures, the

Table 4. Comparison of aged care facilities and other centers apart from hospitals

	Aged care facilities	Other centers apart from hospitals
Number	34	529
Percentage of dialysis specialists, %	32.4	80.8
No. of hemodialysis machines per physician	14.7	18.4
No. of daily hemodialyses per physician	19.3	22.8
Emergency equipment retention, %	35.3	66.5
Hemodialysis isolation for hepatitis B virus infection, %	100	99.4
Percentage of units that perform water quality test required	77.5	86.3
Percentage of units that perform dialysis adequacy test required	94.9	94.2
Percentage of units that perform regular test required	91.8	94.7
Percentage of units that meet dialysis adequacy	81	85.4
Patients with a hemoglobin level of less than 10 g/dL, %	36.3	28.5
Average hemoglobin level, g/dL	10.2	10.4
Percentage of units that meet storage iron level	47.3	52.5
Percentage of units that meet systolic blood pressure	37.4	45.1
Percentage of units that meet diastolic blood pressure	84.5	86.3
Percentage of units that meet Ca × P level	77.2	73.8
Serum albumin level, g/dL	3.92	4.0

ratio of the number of patients with less than 10 g/dL of hemoglobin, the average level of hemoglobin, the achievement rate of storage iron and the albumin level in the blood. As such, the quality of dialysis in aged care facilities can be predicted as lower than that in other units where patients are treated based on the test results.

Dialysis unit accreditation project

As discussed earlier, the HIRA evaluates the adequacy of hemodialysis to evaluate the quality level of dialysis units, and discloses the results to the public to induce voluntary improvement of quality and reasonable choice by patients. However, the reality is that an on-site evaluation cannot be conducted for entire units, and units with low dialysis quality due to the heavy workload of their doctors and nurses may obtain a grade higher than the average if they get higher scores in other criteria. As such, HIRA's evaluation is insufficient for the accurate investigation of the current status of dialysis units.

The Korean Society of Nephrology piloted dialysis unit accreditation in 2009. For such accreditation, the Seoul and Gyeongin district was divided into six areas. The first pilot project was carried out in Gangseo-gu, Yeongdeungpo-gu, Yangcheon-gu, Guro-gu, Geumcheon-gu, and Gwanak-gu in Seoul, and Gwangmyeong-si in Gyeonggi-do; and the second pilot project was implemented in Gangnam-gu, Songpa-gu, and Seocho-gu in Seoul and Seongnam-si and Icheon-si in Gyeonggi-do.

The evaluation criteria of the accreditation project consisted of essential and report items. The essential items included the structure (workforce, facility/equipment, and water quality inspection), process (hemodialysis adequacy test and regular inspection), ethics (fee-for-service, transportation, patient attraction, and advertisements), and medical records or reports (participation or enrollment in the project, medical records, and reports on deceased/transferred patients). The report items included three evaluation indicators: management of hemodialysis adequacy, anemia, and minerals. Units that satisfied all the essential items were accredited. The report items were not used for the accreditation but as references for the identification of the current status of the dialysis units because

their results were not adjusted based on the severity of the patient's condition.

Twenty-five of 37 (80%) units participated in the first pilot project and 28 out of 41 (68%) were involved in the second project, which showed more than 75% participated in the project on average. At the first project, only 48% of units were accredited but the figure increased to 89% in the second project. The increase was considered due to the improved recognition on the evaluations and efforts to make improvement after first accreditation pilot projects and HIRA's hemodialysis adequacy evaluation. The reasons of failure to obtain accreditation in pilot projects are shown in Fig. 3.

In all the units in the first project and in 97% of the units in the second project, dialysis was performed by specialists. The daily average number of dialysis sessions per physician was 23.5 in the first project and 26.4 in the second project, which showed that only 9.4% of the units exceeded 120% of the number of sessions (43 sessions a day) recommended for clinics or equivalent units (less than 36). In the first project, 76.1% of the nurses had more than 2 years of experience; and in the second project, 83%. The daily average number of dialysis sessions per nurse was 3.29 in the first project and 4.97 in the second project, which showed that 14.5% of the units exceeded 120% of the number of sessions recommended (6 sessions a day).

All the units met the fire safety management plan standards or the regulation on the use of a dedicated machine for patients with hepatitis B virus infection. Sixteen percent of the units had no or worn-out ma-

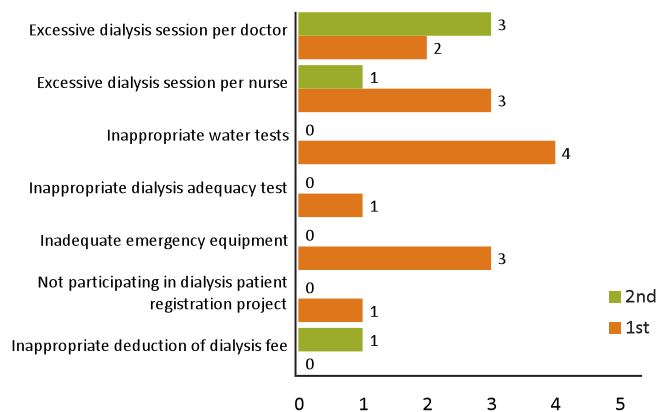


Figure 3. Reason for failure to obtain accreditation.

chines for emergency in the first project, but all units had adequate machines in the second project. One unit failed to obtain accreditation in the second project due to the following: inappropriate deduction of the fee, patient attraction acts such as provision of transportation service, false advertisements, and bribery.

The results of the hemodialysis adequacy evaluation and accreditation project were closely related but not identical. For example, four units failed to meet the evaluation standards for accreditation but got the highest grade in the evaluation of their hemodialysis adequacy. This difference is attributed to the difference in the evaluation designs. The accreditation project was implemented to assess if the units were equipped with all the essential and minimum requirements for patient care, whereas the evaluation of the hemodialysis adequacy used the grade rating system that summed up all the scores for the evaluation indicators. Moreover, HIRA could not perform on-site evaluation of hemodialysis adequacy for entire units. In practice, units should meet the minimum requirements. As such, the following facility standards for dialysis units should be considered the minimum requirements for dialysis units and should be used in this sense.

PROPOSED FACILITY STANDARDS FOR DIALYSIS UNITS

There are no established standards for facilities, equipment and workforce in dialysis units in Korea. These standards are critical to the protection of the rights of dialysis patients. First, dialysis units should have sufficient space to enable the appropriate conduct of the required activities for patient treatment. The ancillary room should include a purifying room for provision of dialysis water, a disposal room for handling of syringes and wastes after the treatment, a washing room for cleaning medical supplies before the sterilization, a changing room, a nurse room, and a nurse station [11].

The dialysis unit must be equipped with a laryngoscope, ambu-bag (with a face mask), oxygen and oxygen supplies, a suction tube, an ECG monitor and a defibrillator for emergency treatment, and a power

system for continued dialysis during a power failure. An emergency power supply system is essential for units because patients may be put at risk if a dialysis machine stops suddenly, as during the massive power outage of the Korea Electric Power Corporation in September 2011.

As for the standards for physicians, the units must have a dialysis specialist. However, considering the current status of domestic dialysis units, at least more than 50% of all physicians should be specialists. Also, the average number of dialysis patients daily per physician should not exceed the recommended standards for coverage of medical benefits in dialysis centers (numbers of daily dialysis sessions per specialist: less than 24 for general hospitals, 26 for hospitals, and 36 for clinics) because a heavy workload may lead to poor patient care. However, considering the current status of domestic dialysis units, the average number of dialysis patients daily per physician can be within 120% of the number in the standards for coverage of medical benefits in dialysis centers.

As for the standards for nurses, the units must have nurses who are solely in charge of dialysis and have more than 2 years of dialysis experience. For an appropriate workload, the average number of dialysis patients daily per nurse must not exceed the recommended standards (number of daily dialysis sessions per nurse, 5) for coverage of medical benefits in dialysis centers. However, considering the current status of domestic dialysis units and their nurse workforce, the average number of dialysis patients daily per nurse can be limited to within 120% of the number in the standards for coverage of medical benefits in dialysis centers (6 sessions).

On the average, 120 L of dialysis fluid per session comes in contact with the blood of patients. As such, regular testing of dialysis fluids is important to detect microorganisms, endotoxin, and contaminants. Various countries have established guidelines for water quality management to audit the quality of their dialysis fluids. These guidelines include the Association for the Advancement of Medical Instrumentation guidelines of the United States, the Japanese Society for Dialysis Therapy Guidelines and Europe's European Best Practice Guidelines. However, in Korea, there are no guidelines for water quality management for dialysis

fluids, so such water quality management guidelines for all medical centers should be urgently drafted. Chemical and microbiological testing of dialysis water must be regularly conducted, and hard copies of the results must be kept. Particularly, action should be taken to address excessive chemical and microbiological substances in dialysis water. Microbiological tests of the water flowing into the dialysis machine should be performed weekly during the adequacy evaluation of the system. Even if the system has already been used, the test should be performed at least once a month. The system must be sterilized monthly to maintain the hygiene of the purification system. The frequency, method, disinfectants (chemical agents, heat, or combined) or changing intervals for filters or resins should follow the manufacturer's guidelines, and in particular, the results of the microorganism test should meet the standards in the guidelines.

To prevent infections in dialysis patients, necessary measures should be taken such as separate machine use for patients with hepatitis B virus infection. Regular tests, including of anemia, the mineral level, the

liver function, the lipid panel, and viruses, and X-ray and ECG tests, should be conducted in the hemodialysis adequacy evaluation, and appropriate medical action should be taken if required. The medical records should be completed for all patients, and the cases of patient transfer and death should be properly handled and reported. These relevant regulations should not only be enforced at the opening of the facility but also continuously, to maintain the quality of its service, and the facility's compliance with such regulations must be evaluated regularly. As addressed earlier, other countries are actively ensuring the quality of their dialysis units through legal actions, regulations, or accreditations. In particular, Germany and Taiwan audit their dialysis units regularly to assess the adequacy of their service, and limit the units' insurance coverage according to the results. They also cancel the license of a dialysis center whose medical quality has significantly dropped. The detailed facility standards for dialysis centers are shown in Table 5.

Table 5. Proposed dialysis center facility standards

Dialysis centers shall be equipped with a purifying room, nurse room, nurse station, washing room, waste disposal room, changing room, and other facilities.

The floor area per bed in dialysis centers shall be more than 8 m². The dialysis center area shall include patient-occupied spaces such as the purifying room, nurse room, nurse station, washing room, disposal room, and patients' changing room, divided by the number of beds.

Dialysis centers shall be located separately to control access to the center with an emergency exit.

Dialysis centers shall be able to supply sufficient power to maintain the hemodialysis system during a power failure.

Dialysis centers shall be equipped with a laryngoscope, an ambu-bag (with a face mask), oxygen and oxygen supplies, a suction tube, electrocardiography monitors, and a defibrillator.

Dialysis centers shall have dialysis specialists.

The number of dialysis patients daily per physician shall not exceed the standards for coverage of medical benefits (number of daily hemodialysis sessions per specialist: less than 24 for general hospitals, less than 26 for other hospitals, and less than 36 times for clinics).

Physicians working in a dialysis center shall treat patients according to the ethical guidelines for full-time dialysis specialists.

Dialysis centers must have nurses who are solely in charge of hemodialysis. The number of dialysis patients daily per nurse must not exceed the standards for coverage of medical benefits.

The fluid in hemodialysis machines shall be regularly tested for microorganisms, endotoxin, and fine particles.

Proper measures shall be taken to prevent infection, including hemodialysis isolation in case of hepatitis B virus infection.

A regular test should be performed on dialysis patients, including a hemodialysis adequacy test.

Dialysis centers shall manage their quality and shall be audited regularly.

CONCLUSIONS

Precise analysis of the current status of dialysis centers is the cornerstone of the establishment of dialysis centers. Strict standards must be applied to dialysis centers because they treat patients with severe diseases. The Enforcement Regulations for Medical Services include the facility criteria (Attachment 3) and standards (Attachment 4) based on the type of medical center, but there is no regulation for dialysis units. As such, dialysis units can be categorized as 'others' in Section 20 of Attachment 3 (Enforcement Regulations for Medical Services) and can be included among the facilities to which the following shall apply: "general hospitals, hospitals, aged care facilities, and clinics can equip and operate dialysis units." Also, the facility standards and other requirements should be included in Attachment 4. The standards for facility establishment must include essential items and details for the following aspects: professionals (nurses and physicians), the facility (size of the dialysis center, environment and safety regulations), equipment (dialysis machine, emergency supplies, and emergency power system), water quality testing, evaluation of hemodialysis adequacy, regular inspection, appropriate patient treatment (including reporting of transfers and deaths of patients), ethics, and others.

The standards for regulation may be applied gradually in the consideration of the current status of domestic dialysis units. Changes in the medical environment should be reflected in the facility standards rather than rigid rules and the continuous update of standards is important through further studies.

Conflict of interest

No potential conflict of interest relevant to this article is reported.

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