Background: Patients receiving hemodialysis have various complications with a high mortality rate and require specialized treatment at an institution equipped with an appropriate workforce, equipment, and facilities. The Korean Society of Nephrology (KSN) is conducting hemodialysis unit accreditation to manage the quality of hemodialysis institutions, present standard treatment guidelines, and establish a network between regional medical institutions for the safe treatment of hemodialysis patients. This study aimed to summarize the previous accreditation results and discuss future directions.

Methods: After the proposal of hemodialysis unit accreditation in 2009, pilot projects were undertaken for hemodialysis units and dialysis subspecialist training hospitals in the metropolitan area for 5 years. Since 2016, five hemodialysis unit accreditation projects have been conducted.

Results: The cumulative number of participating units was 599, and the number of accredited units was 473 (average accreditation rate, 79.0%). The participating units consisted of clinics (58.6%), non-university hospitals (28.2%), and university hospitals (13.2%). Overall, 92.4% of university hospitals, 81.2% of clinics, and 68.0% of non-university hospitals were accredited. Over 5 years, new units were added annually to apply for accreditation, and the rate of previous participants applying for reaccreditation was high (77.7%). However, considering that the total number of member institutions of the KSN is 637, the number of units with valid accreditation as of 2020 was low (267 [41.9%]).

Conclusion: The efforts of the KSN and its members, as well as institutional support from the government, are required for quality management of hemodialysis units through hemodialysis unit accreditation.

Keywords: Accreditation, Dialysis unit, Hemodialysis, Nephrology
Introduction

The prevalence and incidence rates of end-stage renal disease (ESRD) are increasing every year worldwide. The number of patients on hemodialysis in South Korea increased by 22.8%, from 74,013 in 2014 to 90,901 in 2018, and the total medical cost increased by 45.5%, from Korean won (KRW) 1.81 trillion in 2014 to KRW 2.63 trillion in 2018 [1]. In 2018, the average medical cost per patient was KRW 29 million, which is the highest medical cost for a single disease. In addition, the number of hemodialysis centers is also steadily increasing; the number increased by 18.0% to 1,042 in 2018 from 2014, and the number of hemodialysis machines increased by 28.7% to 26,837 machines in the same time period [1].

Most patients with ESRD already have various comorbidities, including heart disease, stroke, vascular disease, diabetes, high blood pressure, and infection, prior to starting dialysis. Since complications of almost all organs such as the heart, lungs, brain, blood vessels, and digestive organs can occur even after the start of dialysis, proper management of the facilities and equipment in the dialysis unit as well as the expertise of the healthcare workers in charge of these patients is essential [2].

Despite the rapid increase in the number of patients with ESRD, the expansion of the number of hemodialysis units, and the continuous increase in medical costs, some hemodialysis units still do not have adequate staff and facilities, thereby threatening patient access to healthcare [3,4]. According to the data of the sixth hemodialysis adequacy evaluation by the Health Insurance Review and Assessment (HIRA), dialysis specialists account for 75.0% of the total number of physicians working in hemodialysis units in South Korea, while in the hemodialysis units of nursing hospitals, only 39.7% were dialysis specialists [1]. As there is no regulation on the quality of hemodialysis units, each dialysis unit is dependent on its own management [5]. Therefore, it is necessary to continuously examine the status of hemodialysis centers, resolve problems, improve the quality of medical services, protect the right of patients to healthcare, and further establish medical orders. Hence, the Korean Society of Nephrology (KSN) is conducting hemodialysis unit accreditation to recommend and evaluate standard medical guidelines, to manage the quality of hemodialysis facilities for the safe treatment of patients on hemodialysis, and to establish a network of regional medical institutions. After the proposal for hemodialysis unit accreditation in 2009, pilot projects were undertaken for hemodialysis units and dialysis specialist training hospitals in the metropolitan areas over a period of 5 years [5]. Since 2016, five hemodialysis unit accreditation projects have been conducted [6–9]. This study aimed to summarize the previous accreditation results and discuss future directions.

Methods

Process of accreditation

Unlike other countries, South Korea currently does not have a hemodialysis center quality management system or a hemodialysis unit installation standard. Accordingly, in 2009, the KSN initiated a hemodialysis unit certification evaluation system. Prior to fanning out the accreditation project across the country, pilot projects were conducted. The first pilot project was conducted in the southwest region of Seoul and Gwangmyeong from 2009 to 2010; the second pilot project was undertaken in the southeast region of Seoul, Seongnam, and Icheon from 2010 to 2011; the third pilot project was carried out in the northeast region of Seoul, Ui-jeongbu, and Guri from 2011 to 2012; the fourth pilot project was conducted in the northwest region of Seoul, Ilsan, and Paju from 2012 to 2013; and the fifth pilot project was carried out for the dialysis specialist training hospitals from 2014 to 2015. In total, 183 units participated in the series of pilot projects, with a 70% participation rate and 73% accreditation rate.

After the pilot projects, nationwide hemodialysis unit accreditation was conducted from 2016. The medical institution eligible for the evaluation was a hemodialysis unit that had performed hemodialysis for a year or longer and where a KSN member worked. Patients who had been receiving hemodialysis for 3 months or longer were included in the evaluation. Each unit wishing to participate in the evaluation of accreditation entered data on the hemodialysis unit accreditation website (http://ksn.nephline.com). Once accreditation is approved, the accreditation is valid for 3 years.

The process of accreditation begins with the application for the accreditation project after the notice, and an online review is conducted based on the data entered online (Fig. 1). The online review was conducted by the dialysis
Assessment were combined, and if necessary, the participating units were requested to supplement the data. The final evaluation was then performed, and a certificate of accreditation was issued when all evaluation items were satisfied.

Accredited units were given the “Excellent Hemodialysis Unit Accreditation Mark,” which notifies patients and the community that they are hemodialysis units accredited by the KSN. Hemodialysis units accredited by the KSN can be found on the KSN website (www.ksn.or.kr) and the hemodialysis unit accreditation website.

**Evaluation items for accreditation**

The four evaluation items used for hemodialysis unit accreditation include structure, process, ethics, and medical records and reports. All four evaluation items must be satisfied for accreditation (Table 1).

The first evaluation item, structure, includes the staffing, facility and equipment, and water treatment system. The staffing requirements of the structure were evaluated based on the proportion of dialysis specialists, the average number of daily hemodialysis cases performed by a physician, the proportion of nurses with more than 2 years of experience in hemodialysis, and the average number of daily hemodialysis cases performed by a nurse. For the proportion of dialysis specialists, 3 points were given for 50% or more, 2 points for 30% to 49%, and 0 points for 30% or less. The average number of daily hemodialysis cases performed by a physician was evaluated according to the standard for the size of the unit. The standard was 24 cases a day for dialysis specialists in university hospitals, 26 cases for non-university hospitals, and 36 cases for clinics. Three points were allocated for the number of cases below the standard, 2 points for 101% to 120% of the standard, and 0 points for 120% or more of the standard. The scores for the proportion of dialysis specialists and the average number of daily hemodialysis cases performed by a nurse were summed and a score of 4 points or higher was necessary to meet the requirements. Concerning the ratio of nurses with more than 2 years of experience, 3 points were given for 50% or more, 2 points for 40% to 49%, and 0 point for 40% or less. Regarding the average number of daily hemodialysis cases performed by a nurse, 3 points were given for ≤5 cases per day, 2 points for ≤6 cases per day, 1 point for ≤6.5 cases per day, and 0 points for more than 6.5 cases. Similar to the

**Figure 1. Flow chart of the hemodialysis unit accreditation process and accreditation certificate.** After the application for accreditation is submitted, the online review, ethics evaluation, and on-site assessment take place, followed by a comprehensive evaluation. Once all the necessary data are provided, the final evaluation is conducted. If the unit passes the evaluation, the accreditation certificate is sent to the accredited unit.

Committee of the KSN, and an ethics evaluation was conducted by the ethics committee. One or two members of the KSN committee then audited each unit through on-site assessment. The results of the online review and on-site assessment were combined, and if necessary, the participating units were requested to supplement the data. The final evaluation was then performed, and a certificate of accreditation was issued when all evaluation items were satisfied.

Accredited units were given the “Excellent Hemodialysis Unit Accreditation Mark,” which notifies patients and the community that they are hemodialysis units accredited by the KSN. Hemodialysis units accredited by the KSN can be found on the KSN website (www.ksn.or.kr) and the hemodialysis unit accreditation website.
### Table 1. Evaluation standards for accreditation

1. **Structure**
   1) **Staffing**
      
      (1) Indicator: physician
      The sum of points ① and ② must be at least 4.
      ① Proportion of dialysis specialists among all regular working physicians in the hemodialysis unit
         - Over 50%: 3 points
         - 30%–49%: 2 points
         - Less than 30%: 0 points
      ② Average number of daily dialysis cases performed by a physician
         - Less than standard*: 3 points
         - 101%–120% of standard: 2 points
         - Over 120% of standard: 0 points
         ※ Standard according to the size of institution:
         - University hospital: 24 cases a day
         - Non-university hospital: 26 cases a day
         - Clinic: 36 cases a day
      
      (2) Indicator: nurse
      The sum of points ① and ② must be at least 4.
      ① Proportion of nurses with more than 2 years of experience among total nurses working in the hemodialysis unit
         - Over 50%: 3 points
         - 40%–49%: 2 points
         - Less than 40%: 0 points
      ② Average daily dialysis cases performed by a nurse
         - ≤5 cases a day: 3 points
         - ≤6 cases a day: 2 points
         - ≤6.5 cases a day: 1 point
         - More than 6.5 cases a day: 0 points
   
   2) **Facility and equipment**
      
      (3) Indicator: safe and comfortable environment
      ① Air-conditioning and heating facilities
      ② Ventilation system
      ③ Separate disposal of infectious waste
     
      (4) Indicator: compliance of regulation on fire and firefighting in buildings
      ① Fire safety inspection
      ② Emergency exit open
      ③ Evacuation route signs
         
      (5) Indicator: quarantine of hepatitis B surface antigen-positive patients
      
      (6) Indicator: emergency equipment
      ① Oxygen and oxygen supply system
      ② Suction equipment
      ③ Airway
      ④ Electrocardiograph and monitor
      ⑤ Defibrillator
      
   3) **Water treatment system**
      
      (7) Indicator: regular water quality inspection for microorganisms, endotoxins, and contaminants
      ① Microorganism test: once a month
      ② Endotoxin test: once every 3 months
      ③ Contaminants: once a year

   *(Continued to the next page)*
score for the physicians, the scores given for the proportion of nurses with more than 2 years of experience and the average number of daily hemodialysis cases performed by a nurse were summed and a total of 4 points or higher was necessary to meet the requirements. The facility and equipment requirements included compliance with firefighting and fire regulations, emergency equipment, and quarantine of hepatitis B surface antigen-positive patients. The water treatment system requirements included regular inspection of microorganisms, endotoxins, and contaminants.

The second evaluation item, the process, included regular hemodialysis adequacy tests and regular laboratory testing of patients. The third evaluation item, ethics, prohibited any fee-for-service that did not meet the standard, unauthorized provision of transportation, patient solicitation, and exaggerated or false advertisement to prevent accreditation in units with unethical practices. Lastly, the fourth evaluation item, medical records and reports, included participation or enrollment in the ESRD registration program, keeping medical records, and documenting reports on deceased or transferred patients.

### Investigation method

The results of the accreditation were analyzed based on the data collected by the KSN during the accreditation period from 2016 to 2020. After the application of each unit for accreditation was received, the units that passed all of the online reviews, the on-site assessment, comprehensive evaluation, and final evaluation were accredited; those who failed to pass the process were unaccredited. The units that withdrew their applications during the process were also unaccredited.

### Results

#### Participation in accreditation and accreditation status

From 2016 to 2020, 599 units participated in accreditation over the five accreditation projects, and 473 of the units were accredited (79.0%). Table 2 shows the number of participating units and the number of accredited units per year. In 2016, the largest number of units participated in

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**Table 1. Continued**

2. Process
   1) Hemodialysis adequacy
      (8) Indicator: regular evaluation of hemodialysis adequacy
         ① Single-pool Kt/V or urea reduction ratio
         ② Once every 3 months
   2) Regular laboratory testing
      (9) Indicator: regular laboratory testing of patients

3. Ethics and obligation of members
   1) Fee-for-service
      (10) Indicator: receiving appropriate medical expenses
   2) Transportation
      (11) Indicator: not providing unauthorized vehicle transportation
   3) Patient solicitation
      (12) Indicator: not undertaking patient solicitation
   4) Advertisements
      (13) Indicator: not producing false or exaggerated advertisement

4. Medical records and reports
   1) ESRD registration program
      (14) Indicator: enrollment in the ESRD registration program of the KSN
   2) Medical record
      (15) Indicator: regular medical record
   3) Patient report
      (16) Indicator: deceased or transferred patient record

ESRD, end-stage renal disease; KSN, Korean Society of Nephrology.
the first year of accreditation; 190 units applied for accreditation and 170 units obtained accreditation. In 2017 and 2018, there were continued new accreditation applications. In 2019, 163 units applied for accreditation and 133 units successfully obtained accreditation. Over the past 5 years, an average of 120 units participated in the accreditation per year, and 95 units were accredited. In the first year of 2016, the accreditation rate was the highest at 89.5%, and the accreditation rate was the lowest in 2017 at 52.2%.

Over the 5-year accreditation period, there were 126 cumulative cases of failure to obtain accreditation. The most common cause of failure to obtain accreditation was staffing shortages of physicians, accounting for 31.0% (39 cases). Other causes of failure to obtain accreditation included staffing problems of nurses (29 cases), ethics problems (25 cases), inadequate facility and equipment (five cases), and nonparticipation in the ESRD registration program (three cases). Withdrawals for unknown reasons accounted for 23 cases and in two cases, the applicant was not a member of the KSN. Regarding the evaluation committee, the highest number of committee members participated in 2016 (133 members), and an average of 96 members participated in the on-site assessment.

As the accreditation is valid for 3 years, the enrolled institutions were duplicated because of reapplication after expiration of the validity period. Fig. 2 shows the number of units with valid accreditation by year. The number of units with valid accreditation by year has gradually increased since 2016; the total number of accredited units reached a maximum in 2018, with 282 units. As of March 2021, the total number of valid accredited units is 267. In each bar, the number of institutions according to the year of first accreditation is indicated.
with valid accreditation increased from 170 units in 2016 (the first year) to 206 units in 2017 and 282 units in 2018. As of March 2021, there were 267 accredited units in total, accounting for 41.9% of the 637 KSN member institutions.

Evaluation results by region and size of the unit

The region with the highest number of participating and accredited units was Seoul, with 171 units accredited out of 195 units that participated, followed by Gyeonggi and Incheon, with 103 units accredited out of 139 units that participated. The least number of units (10 units) participated in Jeju, but all 10 of the participating units were accredited. Fig. 3A shows the accreditation rate by region. The accreditation rate was the highest in Jeju (100%), followed by Seoul and Jeollanam-do - Gwangju (87.5%). The accreditation rate in Chungcheongnam-do - Daejeon was the lowest at 59.6%.

Concerning the number of applications by unit size, clinics accounted for most of the applications (351 [58.6%]), followed by non-university hospitals (169 [28.2%]) and university hospitals (79 [13.2%]). The accreditation rate was the highest in university hospitals (92.4%), compared with 81.2% in clinics and 68.0% in non-university hospitals (Fig. 3B).

Discussion

The hemodialysis unit accreditation evaluates whether all basic requirements and minimum conditions for hemodialysis services are satisfied, rather than ranking by grade. This system aims to create a reliable medical environment for patients on hemodialysis and to establish a network and system among local medical institutions. It is based on the voluntary participation of KSN members, and online reviews and on-site assessments are conducted to ensure objective evaluation as much as possible. The KSN conducted five hemodialysis unit accreditation projects from 2016 to 2020. Since 2016, a total of 599 units have participated in accreditation, and 473 units have been accredited (79.0%). Among the 206 accredited units whose valid accreditation...
expired after 3 years, 132 units applied for reaccreditation, indicating a relatively high application rate for reaccreditation. In addition, new units apply for hemodialysis unit accreditation each year.

As of 2020, there were 267 valid accredited units, accounting for 41.9% of the 637 KSN member institutions; this proportion is rather low. The number of target institutions was not the same as that of the hemodialysis registry program because our accreditation project included only hemodialysis units of KSN members. The low participation rate may be because there is no clear economic compensation for accredited units and there is a lack of institutional regulation against unaccredited units. Furthermore, there are many hemodialysis units that do not meet the conditions of the KSN accreditation even among the KSN members’ institutions. We surmise that the hemodialysis units did not participate in the KSN accreditation projects and this also resulted in a low participation rate. In addition, since the HIRA hemodialysis adequacy evaluation is conducted every 1 to 2 years, the inconvenience of inputting data and the burden of work because of the overlapping evaluations may have contributed to the low participation rate. To resolve such limitations, the necessity of integrating the hemodialysis unit accreditation of the KSN and the hemodialysis adequacy evaluation of HIRA has been suggested. HIRA has been conducting hemodialysis adequacy evaluation for dialysis units since 2009 to improve the quality of nursing institutions and provide information to the public. With the hemodialysis adequacy evaluation of HIRA, the quality management of hemodialysis units has been improved in terms of the hemodialysis adequacy test. However, the available emergency equipment, water quality assessment, and the proportion of dialysis specialists and the proportion of nurses with more than 2 years of experience in hemodialysis have not improved. Moreover, the hemodialysis adequacy evaluation does not assess ethical issues. Since the hemodialysis adequacy evaluation in 2015, a pay-for-performance system has been introduced. However, this cannot be a fundamental countermeasure because it is applied only during the evaluation period. Integrating the hemodialysis unit accreditation of the KSN and the hemodialysis adequacy evaluation of HIRA will allow more efficient management of hemodialysis units in South Korea based on the experience of the experts in quality management and nationwide evaluation. The lack of ethics evaluation and onsite assessment in the hemodialysis adequacy evaluation by HIRA can be supplemented by the KSN’s accreditation project to ensure objectivity of the evaluation and additional reflection on quality management.

It is also necessary to make efforts to reward and promote accredited units. Considering that clinics account for 58.6% of all units participating in the accreditation, these clinics should be given priority for the referral of patients on hemodialysis from a higher level of medical institution to a clinic. It is also important to form networks within the community. Since the accredited units are posted on the KSN website, these materials should be more actively used. Currently, accredited units are given an accreditation mark, which may have an effect on public relations among patients and the community. In addition, the KSN should promote accredited hemodialysis units to patients and encourage patients to attend those institutions.

Finally, national support is urgently needed to create a safe medical treatment environment for patients on hemodialysis. Several countries worldwide implement quality management for hemodialysis units in the form of legal regulations or accreditation [10]. The United States operates both permit and accreditation systems [11]. In Germany and Singapore, the operation of hemodialysis units requires permission [12,13], whereas Hong Kong and Taiwan operate an accreditation system [14,15]. In Hong Kong, the Hong Kong College of Physicians and Central Renal Committee of Hospital Authority has issued guidelines for the accreditation of renal dialysis units. The guidelines state that only qualified nephrologists and renal nurses can provide hemodialysis services. The guidelines provide accreditation standards for equipment, water treatment systems, and hemodialysis machines. Similarly, in Taiwan, only nephrology specialists are allowed to operate hemodialysis units. The accreditation system in Taiwan provides management standards for hygiene and infection and dialysis units are inspected every 2 years by audit teams that consist of the Taiwan Society of Nephrology members and staff from insurance companies. The insurance coverage is affected by the results. In contrast, in South Korea, no permission is required to establish a hemodialysis unit and there are no laws and regulations related to facilities, staffing, quality management, and safety measures for patients on hemodialysis. Therefore, to ensure patients’ rights to an adequate hemodialysis service, improve the quality of medical services, and manage unethical
hemodialysis units, it is necessary to introduce standards for the establishment of a hemodialysis unit. In 2011, the Ministry of Health & Welfare and the Korea Health Promotion Institute conducted a study on the establishment of standards for hemodialysis unit accreditation in South Korea, but no subsequent actions have followed [10]. Additionally, it is necessary to introduce a registration system for patients with ESRD to understand the exact health and management status of patients with chronic kidney disease (CKD). The government has initiated many discussions on the systematic prevention and management of CKD. In November 2019, a CKD management bill was proposed, but it was automatically abolished after the end of the 20th National Assembly. If patient registration and hemodialysis unit accreditation are implemented with the approval of a CKD management bill, the start time of dialysis can be delayed by preventing deterioration of patients with CKD, and the survival rate of patients undergoing dialysis can be increased. This will allow the creation of a safe medical environment for patients with CKD and reduce unnecessary financial waste in healthcare through the quality management of hemodialysis units.

The KSN has been striving to improve the quality of hemodialysis units for a safe hemodialysis service through the five hemodialysis unit accreditation projects from 2016 to 2020. Although the number of accredited units is gradually increasing based on the voluntary participation of the expert group, the participation rate is not yet high compared with the total number of KSN members’ institutions. It is hoped that an environment in which hemodialysis patients are safely treated can be achieved based on the continuous efforts of the KSN, the active participation of experts, and national support.

**Conflicts of interest**

All authors have no conflicts of interest to declare.

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**Authors’ contributions**

Conceptualization: YKL, KK, DJK
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