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Chronic kidney disease (CKD) and Kampo medicine

Chronic kidney disease (CKD): management and outcome improvement

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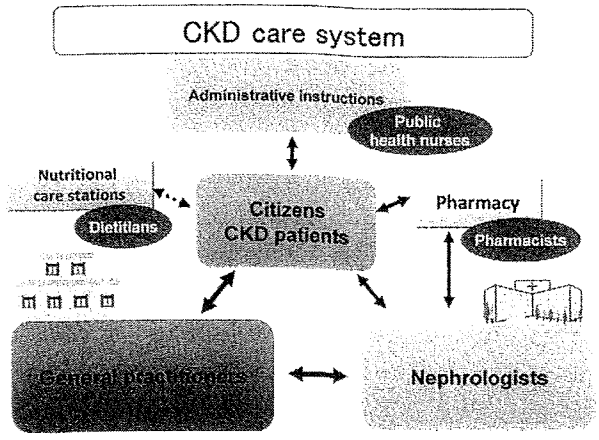
Chronic kidney disease (CKD) is defined as kidney damage or glomerular filtration rate (GFR) <60ml/min/1.73m2 for 3 months or more, irrespective of cause. The definition of CKD first appeared in the Kidney Disease Outcome Quality Initiative Guidelines (KDOQI) issued by the National Kidney Foundation (NKF) in 2002,[1] and was revised by the KDIGO in 2005.[2] Since then, the definition of CKD and renal function assessment methods are accepted worldwide.

CKD is also one of the important risk factors for cardiovascular disease among known other risk factors; diabetes, hypertension, hyperlipidemia, obesity, smoking, and lifestyle-related diseases.[3,4] Therefore, the early detection and control of CKD are exactly important in terms of preventing ESKD, cardiovascular complications and death.

The concept of CKD is comprehensive which includes diabetic nephropathy, nephrosclerosis due to hypertension, chronic glomerulonephritis and other renal diseases. Since there are many patients with CKD, not only nephrologists but also all physicians, should care CKD patients for early detection and treatment at early stage. And it is important to establish appropriate, consistent, and specific treatment and prevention-based care system according to the progression of kidney disease.

Recently, the CKD Clinical Practice Guide was published by the Japanese Society of Nephrology[5] and treatment target for every CKD stage had been shown. From this guide, lifestyle and dietary advice on obesity prevention, smoking cessation, a sodium-restricted diet, treatment for metabolic disorders, hypertension, and hyperlipidemia are recommended to prevent the progression of CKD. Although every single item of the treatment method had clinical evidences, there was no prospective study to show the effect of practices as combination of CKD Clinical Practice Guide targets on renal and cardiovascular outcome in certain number of the CKD patients.

A strategic outcome research project for kidney disease has started in Japan since 2007, supported by a grant from the Ministry of Health, Labor and Welfare of Japan. This study has been designed to encourage CKD patients to consult physicians consecutively, enhance cooperation between general practitioners and nephrologists, and prevent the progression of kidney disease. If effective collaboration is established, it will have a significant positive impact on renal care systems (Figure)



Figure

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and improve outcomes of CKD patients. This study is expected to develop the infrastructure required for clinical practice of kidney disease, and to generate valuable findings.

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ORIGINAL ARTICLE

Design and methods of a strategic outcome study for chronic kidney disease: Frontier of Renal Outcome Modifications in Japan

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Abstract
Background The continuous increase in the number of people requiring dialysis is a major clinical and socioeconomical issue in Japan and other countries. This study was designed to encourage chronic kidney disease (CKD) patients to consult a physician, enhance cooperation between nephrologists and general practices, and prevent the progression of kidney disease.

Methods Subjects comprise CKD patients aged between 40 and 74 years consulting a general physician, and patients in CKD stage 3 with proteinuria and diabetes or hypertension. This trial is a stratified open cluster-randomized study with two intervention groups: group A (weak intervention) and group B (strong intervention). We have recruited 49 local medical associations (clusters) in 15 different prefectures, which were classified into four

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regions (strata) based on the level of increase rate of dialysis patients. The patients in group A clusters were instructed initially to undergo treatment in accordance with the current CKD treatment guide, whereas patients in group B clusters were not only instructed in the same fashion but also received support from an information technology (IT)-based system designed to help achieve the goals of CKD treatment, consultation support centers, and consultations by dietitians visiting the local general practice offices. We assessed the rates of continued consultation, collaboration between general practitioners and nephrologists, and progression of CKD (as expressed by CKD stage).

Conclusion Through this study, filling the evidence-practice gap by facilitating effective communication and supporting general physicians and nephrologists, we will establish a CKD care system and decrease the number of advanced-stage CKD patients.

Keywords Chronic kidney disease · Evidence-practice gap · Cluster-randomized study · Educational intervention · Cooperation between nephrologists and general physicians

Introduction

The number of dialysis patients is continually increasing, with consequent rises in medical costs for the treatment of end-stage kidney disease (ESKD) patients becoming a socioeconomical concern worldwide. In fact, there are 2,153.2 dialysis patients per million of population in Japan [1]. Chronic dialysis treatment not only reduces the quality of life (QOL) of patients [2, 3] but also places considerable financial strain on society, with annual medical costs of five to six million yen per dialysis patient, or total expenses of one trillion yen. Moreover, it is estimated that there are more than ten million chronic kidney disease (CKD) patients in Japan [4]. Previous studies suggested that CKD is one of the most important risk factors for cardiovascular disease, among known risk factors of diabetes, hypertension, hyperlipidemia, obesity, smoking, and lifestyle-related disease [5–8]. Therefore, early detection and control of CKD are also important in terms of preventing cardiovascular complications and deaths.

The definition of CKD first appeared in the Kidney Disease Outcome Quality Initiative (KDOQI) Guidelines issued by the National Kidney Foundation (NKF) in 2002 [9], and was revised by Kidney Disease: Improving Global Outcomes (KDIGO) in 2005 [10]. Since then, the definition of CKD and renal function assessment methods are being accepted worldwide. CKD is defined as kidney damage or glomerular filtration rate (GFR) <60 ml/min/1.73 m^2 for 3 months or more, irrespective of cause. The concept of CKD comprehensively addresses a wide range of kidney patients, including ESKD and transplant patients. It is important to establish appropriate, consistent, and specific treatment and prevention-based care systems according to the progression of kidney disease. The Ministry of Health, Labor, and Welfare organized a study group to design strategic outcome studies and discuss the following research subjects: prevention of diabetes, prevention of suicide and depression (2005), cancer prevention, and AIDS/HIV prevention (2006), which have been started. Following these studies, a strategic study to improve the progression of CKD was planned based on these social and scientific demands to reduce new patients with initiation of renal replacement therapy due to ESKD, termed the Frontier of Renal Outcome Modifications in Japan (FROM-J).

Diabetic nephropathy, nephrosclerosis due to hypertension, and chronic glomerulonephritis are three major primary renal diseases in ESKD, not only in Japan but also in Western countries [1]. In Japan, the proportion of new ESKD patients due to chronic glomerulonephritis has recently been decreasing, while that of diabetic nephropathy is rapidly increasing. If this trend continues, in 5 years, patients undergoing dialysis due to diabetic nephropathy will account for 50.82% of the total whereas those with chronic glomerulonephritis will account for 19.54%. In other words, the primary renal disease in half of dialysis patients will be diabetic nephropathy, and the number of dialysis patients with chronic glomerulonephritis will decrease by 17%. The decreasing trend in chronic glomerulonephritis is due to annual urinalysis screening programs established by the Japanese government [11]. Also, more attention should be paid to preventing deterioration of renal function in patients with diabetic nephropathy and nephrosclerosis.

Although diabetic nephropathy is the primary underlying disease in dialysis patients in many developed countries, it has been showing a decreasing trend in some regions and countries, including Denmark. In Denmark, after a steady increase from 52 in 1990 to 183 in 2002, the number of dialysis patients with diabetic nephropathy decreased by 15%, to 155–156 patients per million people [12]. This indicates that aggressive management of both blood pressure and glucose, administration of renin angiotensin system (RAS) inhibitors, and advice on lifestyle can reduce ESKD with diabetic nephropathy by more than 15%. According to the 2002 diabetes survey conducted by the Ministry of Health, Labor, and Welfare of Japan, only 33.3% of patients in Japan had controlled their HbA1c to less than 6.5%, and these interventions are expected to achieve marked effects. Furthermore, although 50.2% of males and 38.3% of females aged 40 years or

older in Ibaraki Prefecture showed hypertension, only 41.9% and 49.2% of them, respectively, were receiving antihypertensive treatment [13], and blood pressure was not adequately controlled in about 50% of those who were receiving treatment [14]. Appropriate interventions are assumed to bring about noticeable effects in Japan, in which RAS inhibitors have not been used effectively as antihypertensive therapy, although a slight increase has occurred in recent years [15].

Recently, the CKD Clinical Practice Guide for future treatment methods was developed by the Japanese Society of Nephrology [16], describing the treatment target for every CKD stage. Although all items of the treatment method were supported by clinical evidence, there were no prospective studies showing the effect of practices such as the CKD Clinical Practice Guide targets on renal and cardiovascular outcomes in sufficient number of CKD patients.

In this strategic CKD study, a prospective stratified cluster-randomized trial to examine the effectiveness of a care system designed to prevent progression of CKD through collaboration between nephrologists and general physicians was selected. One of the goals of the study is a 15% reduction in the estimated number of new dialysis patients in 5 years by increasing the rates of compliance with the CKD Clinical Practice Guide. The study also aims to encourage CKD patients to see their family physician, consult a nephrologist, and receive nutritional and lifestyle advice, while discussing health care measures to reduce the number of new dialysis patients.

Hypotheses of study

The study hypothesis encompasses the following four core issues:

1. Clinical practice in accordance with the Japanese CKD Clinical Practice Guide will improve the prognosis of CKD patients and reduce the speed of renal function deterioration.
2. Education-based interventions for CKD patients by registered dietitians and other co-medicals will help achieve strict CKD treatment goals in accordance with the Japanese CKD Clinical Practice Guide.
3. Collaboration concerning clinical practices among general physicians, nephrologists, and co-medicals will reduce the gap between clinical practice and evidence-based care measures, and improve the rate of continued consultation and prognosis in CKD patients.
4. These active interventions to improve CKD treatment will achieve the desired effects in terms of medico-economics.

Subjects and methods

Study organization and duration

Since the increase in the rate of dialysis patients varies from region to region in Japan [17], we divided the country into four regions (Fig. 1) as strata, so that they would

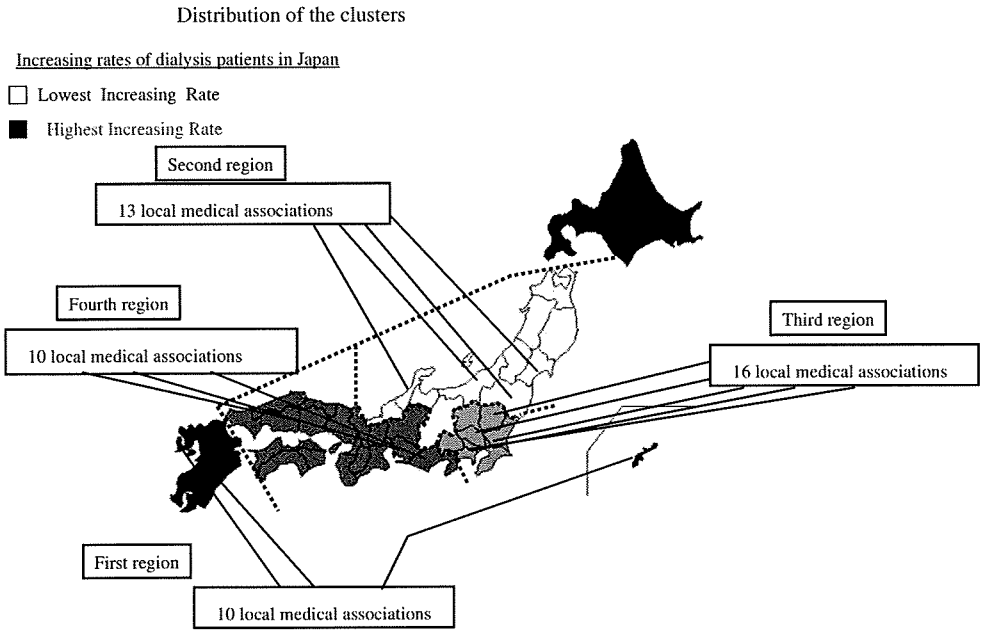

Fig. 1 Distribution of the clusters. We have recruited 49 local medical associations (clusters) in 15 different prefectures, which were classified into four regions (strata) based on the level of increase in the rate of dialysis patients [17]

include at least one managing facility and two or more clusters. The primary intervention study duration is from October 2008 to March 2012.

Rationale for setting the number of patients

This project aims to examine whether or not intervention can reduce the incidence of dialysis patients by 15% over the next 5 years. Regarding the calculation, we estimated the annual decrease in GFR as 0.59 ml/min/year (standard deviation (SD) 0.04 ml/min/year), based on changes in renal function among healthy Japanese people who underwent health checkups [17, 18] and the rate of renal deterioration in patients in CKD stage 3 with diabetes or hypertension [mean serum creatinine = 1.69 mg/dl (SD = 0.57 mg/dl), annual decrease rate = 5.93 ml/min/year (SD 4.321 ml/min/year), $n = 569$] [18, 19]. The required study size was calculated as 2,038 when the unknown intracluster correlation coefficient was assumed to be 0.5. We determined the required number as 2,264 for groups A and B, assuming that 10% would withdraw. We applied the simple number of 2,500 (1,250 for each group) as the target number of patients to perform this study.

Eligible patients

Each registered general physician obtained written informed consent for the study from eligible patients. They were formerly registered after the data center verified their eligibility. Inclusion criterion were: (1) age between 40 and 74 years; (2) in CKD stage 1, 2, 4, or 5; (3) in CKD stage 3 with proteinuria (ratio of urinary protein/urinary creatinine $\geq$0.3, or proteinuria $\geq$1+) and diabetes or hypertension.

Dialysis patients and those who did not consent were excluded from this study.

Assignment and randomization

This trial is a stratified open cluster-randomized study with two intervention groups: group A (weak intervention) and group B (strong intervention). We have recruited 49 local medical associations (clusters) in 15 different prefectures, which were classified into four regions (strata) based on the level of increase in the rate of dialysis patients (Fig. 1). Each local medical association recruited 10–58 general physicians by whom patients in this study has been treated. Local medical associations are randomized when the enrolment period is completed.

Intervention methods

Patients in group A clusters are instructed initially to undergo treatment in accordance with the current CKD treatment guide only, whereas patients in group B clusters are not only instructed in the same fashion but also receive consultations by dietitians visiting the local general practice offices. In addition, the data center closely monitors the treatment status and provides the group B general practice office with comments on the data.

Goals for the treatment of chronic kidney disease (groups A and B)

Participants in the study, or patients, will receive treatment according to the CKD Clinical Practice Guide [16]. Table 1 shows a summary of targets for CKD treatment applied to all patients. In patients with CKD, lifestyle modifications to avoid obesity and stop smoking are necessary. Strict blood pressure control (less than 130/80 mmHg), strict blood sugar control (HbA1c <6.5%), and low-density lipoprotein (LDL)-cholesterol control (LDL-C <120 mg/dl) are shown as targets for CKD treatment. The standards for referral from general physicians to nephrologists are as follows: (1) ratio of urinary protein/urinary creatinine $\geq$0.5, or proteinuria $\geq$1+; (2) estimated GFR (eGFR) <50 ml/min/1.73 m^2; (3) both proteinuria and hematuria positive ($\geq$1+); and (4) when family physicians judge that patients should consult a nephrologist. Estimated GFRs in this study are calculated using the following formula:

$$\mathrm{eGFR(ml/min/1.73\ m^2)} = 194 \times \mathrm{Age}^{-0.287} \times \mathrm{Cre}^{-1.094} (\times 0.739 \text{ in the case of women}).$$

Monitoring of treatment status by the data center (only group B)

The data center closely monitors the treatment status and provides the group B general practice office with comments on the data. In addition, the data center will provide information on the patients scheduled to visit the office, examinations, and treatment that patients should undergo on their next visit, patients who did not visit hospitals as scheduled, those who are going to receive lifestyle/dietary advice, and those who meet the conditions for referral to nephrologists. The center also monitors patients and their schedules: the next consultation date, required examinations, details of treatment and care provided, and advice on lifestyle and nutrition. The centers will contact patients by mail, telephone, or email a week before the consultation day and encourage those who have not consulted a physician for over 2 months to receive care, trying to prevent their withdrawal from treatment. To facilitate referrals to nephrologists, the centers send a list of patients who meet the criteria for referral to the physicians and clinical research coordinators (CRCs).

Table 1 CKD practice guide target in this study

CKD stages	Lifestyle	Diet	Blood pressure	Blood sugar	Lipid metabolism	Hemoglobin
Stage 1	Smoking cessation BMI <25 kg/m^2	Sodium chloride <6 g/day for hypertensives	<130/80 mmHg	HbA1c <6.5%	LDL-C <120 mg/dl	
Stage 2	Smoking cessation BMI <25 kg/m^2	Sodium chloride <6 g/day for hypertensives	<130/80 mmHg	HbA1c <6.5%	LDL-C <120 mg/dl	
Stage 3	Smoking cessation BMI <25 kg/m^2	Sodium chloride <6 g/day for hypertensives DPI: 0.6-0.8 g/kg/day	<130/80 mmHg	HbA1c <6.5%	LDL-C <120 mg/dl	Hb 10–12 g/dl
Stage 4	Smoking cessation BMI <25 kg/m^2	Sodium chloride <6 g/day for hypertensives DPI: 0.6–0.8 g/kg/day Potassium restriction	<130/80 mmHg	HbA1c <6.5%	LDL-C <120 mg/dl	Hb 10–12 g/dl
Stage 5	Smoking cessation BMI <25 kg/m^2	Sodium chloride <6 g/day for hypertensives DPI: 0.6–0.8 g/kg/day Potassium restriction	<130/80 mmHg	HbA1c <6.5%	LDL-C <120 mg/dl	Hb 10–12 g/dl
Others			<125/75 mmHg If proteinuria >1 g/day			

BMI body mass index, *DPI* dietary protein intake

Nutrition and lifestyle improvement (only group B)

Registered dietitians provide support according to the instructions and advice from family physicians. They help patients achieve their CKD treatment goals, explaining to patients about examination results, achievements in CKD care, and their implications. Registered dietitians receive training so that they will be able to provide integrated and consistent advice.

Data collection

At each consultation, physicians will measure patients' blood pressure, and check their blood pressure conditions at home. Examinations or surveys will be performed every 6 months regarding body weight, abdominal circumference, smoking status, fasting serum creatinine, blood urea nitrogen (BUN), potassium, hemoglobin (Hb), high-density lipoprotein cholesterol (HDL-C), total cholesterol (TC), triglyceride (TG), uric acid, total protein, albumin, fasting blood glucose, HbA1c (only in the case of diabetes), urinary creatinine levels, amount of urinary proteins, eGFR, number of patients referred by nephrologists, number of new dialysis patients, and incidence of cardiovascular events.

Parameters for assessment

Primary parameters for assessment are: (1) the rate of continuous clinic visits of CKD patients, (2) the proportion of patients under cotreatment between general physicians and nephrologists, and (3) annual changes in CKD stage.

Secondary parameters are: (1) the proportion of adherence to the complete CKD treatment guide, (2) the rate of achievement of blood pressure goals, (3) the number of subjects with 50% reduction in urinary protein, (4) the number of subjects with a doubling of serum creatinine or 50% reduction in eGFR, (5) yearly changes in the number of patients starting renal replacement therapy, and (6) the incidence of cardiovascular events.

Statistical analysis

Statistical analyses will be performed using an intent-to-treat approach. Differences in primary endpoints between intervention groups are described by their 95% confidence intervals. The declining velocity of eGFR is tested by analysis of variance, using the efficacy of interventions as fixed effects and cluster effects as random effects. We employ a generalized linear model with age, gender, complications, and previous GFR as covariates where appropriate. The significance level on both sides in hypothesis testing is set at 0.05.

For secondary endpoints, we will use analysis of variance with a generalized linear model.

Ethical considerations

This study is being conducted in accordance with the Ethical Guidelines for Clinical Studies (revised on December 28, 2004, of the Ministry of Health, Labor, and Welfare) and the Ethical Guidelines for Epidemiological Studies (revised on August 16, 2007, of the Ministries of Education, Culture, Sports, Science, and Technology/ Health, Labor, and Welfare). All medical professionals involved in this study must comply with these ethical standards. This study is a Central Institutional Review Board (Central IRB) program, and the Committee on Ethics in Strategic Research of the Kidney Foundation, Japan, will examine and approve implementation plans and their revision.

Discussion

The purpose of this study is to enhance cooperation between nephrologists and general physicians, improve lifestyle and dietary advice provided by registered dietitians at general physicians' offices, and offer measures to control blood pressure and other critical parameters in practice, thereby filling the evidence-practice gap, which will slow the progression of kidney disease.

Recently, the concept of chronic kidney disease has been announced not only in Japan, but also throughout the world [9, 10]. There are more than ten million CKD patients in Japan [4], and so CKD is regarded as a public health problem.

CKD guidelines for general physicians or patients have been published in European countries [9, 20–22]. The USA is also preparing similar measures for CKD [23, 24]. In Japan, annual urinalysis for early detection of renal disease started in the 1970s [11, 25], and a serum creatinine test was included in health examinations as early as 1989 to detect kidney failure among adults aged 40 years or older [26]. However, the number of dialysis patients is increasing by approximately 4% each year. It is necessary to implement more appropriate measures to reduce the rate of new dialysis patients in Japan as soon as possible.

In 2007, the Japanese Society of Nephrology established the CKD Clinical Practice Guide to help family physicians provide care for CKD patients. The guide suggests that lifestyle and dietary advice on obesity prevention [27], smoking cessation [28], and a sodium-restricted diet, and treatment for metabolic disorders [29, 30], hypertension [31], and hyperlipidemia [32] are effective to prevent progression of CKD. However, most people are not making sufficient efforts to manage their own health condition [13]. It is necessary to show the effect on the progression of CKD of treatment as part of the Clinical Practice Guide. Our challenge is to obtain sufficient evidence regarding the efficacy of filling the evidence-practice gap in preventing deterioration of renal function among Japanese patients.

We set the following conditions for patient eligibility in this study: CKD patients aged between 40 and 74 years; patients in CKD stage 1, 2, 4 or 5; and patients in CKD stage 3 with a high level of urinary protein and diabetes or hypertension. Proteinuria is known as the strongest predictor of decreasing renal function [13, 33], and the aggressive management of blood pressure and glucose [29, 31] and administration of RAS inhibitors [34–36] prevent the deterioration of renal function. The reason for the condition regarding urinary proteins in stage 3 patients is that we need to register patients showing significant deterioration in renal function [37].

Regarding lifestyle and dietary advice, we have prepared a list of instructions and advice for individual patients on a priority basis, so that registered dietitians can design a guidance schedule based on the priority list and provide consistent advice. In this study, we focus on preventing progression of CKD in the early stage by giving priority to Japanese CKD practice guide goals. We are preparing a long-term guidance method covering a wide range of health management items while seeking ways to reduce the evidence-practice gap as much as possible.

We predict significant positive effects in intervention group B (increased collaboration in clinical practice) in terms of increases in the rate of continued consultation and collaboration between nephrologists and other physicians, and reduced CKD stage progression as a result of instructions and advice from registered dietitians, compared with intervention group A. This study was designed to examine the effectiveness of a support system for collaborative CKD diagnosis and treatment by conducting a cluster-randomized controlled trial. We expect that this study will help improve clinical practices for CKD patients and provide high-quality clinical findings of global standard. Although the number of CKD patients in Japan is estimated to be more than ten million, there are only 3,000 nephrologists. If effective collaboration is established among nephrologists in CKD care, it will have a significant positive impact on renal care systems. In the area of renal care, few large-scale intervention studies have been performed on kidney care systems, except those aimed to assess the efficacy of drug interventions. Little progress has been made in the development of infrastructure for clinical studies and research environments in Japan. This study is expected not only to help develop the infrastructure required for clinical renal studies but also to generate valuable findings.

Progress of the study

Prior to the study, we selected 15 management facilities and 49 local medical associations, registered 491 family physicians (between April and June 2008), and registered 2,494 study participants on a provisional basis (between April and October 15, 2008), 2,413 of whom were randomly divided into intervention groups A (1,211) and B (1,202) in units of medical associations (or clusters) in September 2008. We started the intervention study on October 20, 2008.

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Therapeutic Apheresis and Dialysis

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An Overview of Regular Dialysis Treatment in Japan (As of 31 December 2007)

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Abstract: A nationwide statistical survey of 4098 dialysis facilities was conducted at the end of 2007, and 4052 facilities (98.88%) participated. The number of patients undergoing dialysis at the end of 2007 was determined to be 275 242, an increase of 10 769 patients (4.1%) compared with that at the end of 2006. The number of dialysis patients per million at the end of 2007 was 2154. The crude death rate of dialysis patients at the end of 2007 from the end of 2006 was 9.4%. The mean age of new patients begun on dialysis was 66.8 years and the mean age of the entire dialysis patient population was 64.9 years. For the primary diseases of new patients begun on dialysis, the percentages of patients with diabetic nephropathy and chronic glomerulonephritis were 43.4% and 23.8%, respectively. The percentages of facilities that achieved the control standard of endotoxin concentration in the dialysate solution of <0.05 EU/mL and those that achieved a bacterial count of <100 cfu/mL in the dialysate solution, as specified by the Japanese Society for Dialysis Therapy, were 93.6% and 97.4%, respectively. The percentage of patients positive for the hepatitis C virus antibody among the entire dialysis population significantly decreased from 15.95% at the end of 1999 to 9.83% at the end of 2007. The mean hemoglobin concentration in all the dialysis patients at the end of 2007 was 10.27 (±1.32, SD) g/dL, which has scarcely changed over the last three years. The numbers of male and female patients with a history of hip fracture were 142.9 and 339.0 per 10 000 dialysis patients, respectively, showing an extremely high prevalence among female patients. A history of hip fracture correlates with a low body mass index, serum albumin concentration, and a history of diabetes. The serum creatinine level of patients upon introduction to dialysis was 8.34 (±3.55) mg/dL, and the estimated glomerular filtration rate was 5.43 (±3.43) mL/min/1.73 m^2 for the patients who were newly begun on dialysis in 2007. **Key Words:** Clinical condition, Dialysis patient population, Endotoxin concentration, History of fracture, Survey, Survival rate.

The Japanese Society for Dialysis Therapy has been conducting a yearly statistical survey of dialysis facilities across the country since 1968. A nationwide statistical survey of 4098 dialysis facilities was conducted at the end of 2007, and 4052 facilities (98.88%) responded. The number of patients undergoing dialysis at the end of 2007 determined on the basis of the survey results from dialysis facilities was 275 242, an increase of 10 769 patients (4.1%) from the number in 2006. The crude death rate of dialysis patients in 2007 was 9.4%, which is not significantly different from those over the last 10 years (1).

In the first part of this report, we summarize basic data on chronic dialysis patients in Japan at the end of 2007; in the second part, we summarize data obtained from the same survey on the following items: the current status of dialysate solution quality control, hepatitis virus infection, and renal anemia therapy; the patient history of hip fracture; and the clinical conditions of patients at the introduction of

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dialysis. Among them, the history of hip fracture has never been surveyed and is a new survey item.

We used the survey data that were available when this report was being prepared (in November 2008); therefore, the values tabulated in this report are slightly different from those reported in "An Overview of Regular Dialysis in Japan (As of 31 December 2007)" (2), which was published as a rapid report in June 2008.

METHODS

This survey is conducted every year by sending questionnaires to target dialysis facilities. The 4098 facilities surveyed in this study consisted of the member facilities of the Japanese Society for Dialysis Therapy as of 31 December 2007, and additional non-member facilities offering dialysis for patients with chronic kidney diseases. The number of facilities in the present survey increased by 47 (1.2%) from that in the preceding year's survey. The questionnaires were mainly sent and collected by mail; some were also faxed. Moreover, a floppy disk instead of the paper questionnaire was sent to the facilities that had earlier indicated a preference for it.

This survey consisted of two types. One was a facility survey, in which items related to the details of dialysis facilities, such as the number of patients, staff members, and patient stations at individual facilities, were investigated (using the questionnaire referred to as "sheet I"). The other was a patient survey, in which the epidemiological background, treatment conditions, and outcome of treatment of individual dialysis patients were investigated (using the questionnaires referred to as "sheets II, III, and IV").

The collection rate of the questionnaire (sheet I) at the end of 2007 was 98.88% (4052 facilities), which was higher than that for the 2006 survey (98.37%). The number of facilities from which both questionnaires (i.e. facility survey and patient survey) were collected was 3899 facilities (95.14%), which was also higher than that in the 2006 survey (93.98%). In addition, the number of facilities that responded via an electronic file on a floppy disk was 2935 facilities (75.28%), an increase of at least 6% from the 2006 survey.

I. Tabulation of basic data on chronic dialysis patients at the end of 2007

Data on the dialysis patient population dynamics for the year 2007 were tabulated mainly on the basis of the results of the facility survey. The data included the number of new patients begun on dialysis, the number of patients who died, the crude death rate for the year 2007, and the total number of dialysis patients at the end of 2007. The cumulative survival rate after introduction to dialysis was calculated using a life table method (2).

II. Tabulation of data on new items surveyed

The following items were investigated with the survey on the dialysis patient population dynamics: the current status of dialysate solution quality control, hepatitis virus infection, and renal anemia therapy; the history of hip fracture; and the clinical conditions of patients at introduction to dialysis.

RESULTS AND DISCUSSION

I. Tabulation of basic data on chronic dialysis patients at the end of 2007

1. Number of patients

Table 1 shows a summary of the dynamics of the dialysis patient population in Japan at the end of 2007 obtained from the present survey. Only the data on the durations of dialysis and the longest dialysis shown in this table were obtained from the patient survey, whereas the totals of other parameters were obtained from the facility survey.

The total number of dialysis patients in Japan at the end of 2007 was 275 242, as determined from the facility survey. The number of dialysis patients in Japan at the end of 2006 was 264 473, showing an increase of 4.1% (10 769 patients) from the end of 2006 to the end of 2007.

In the 2006 report, the change in the rate of annual increase in the number of dialysis patients at the end of each year (hereafter, the rate of annual increase in the dialysis patient population) was shown in a graph, and it was pointed out that the rate may reach 0% by around 2014. The rate shown in the 2006 report was calculated using the following equation:

Rate of annual increase in the dialysis patient population (%) = (Dialysis patient population at the end of the target year – Dialysis patient population at the end of the previous year) ÷ Dialysis patient population at the end of the previous year (%)

The dialysis patient population at the end of each year, the denominator of the above equation, increases every year by the difference in the patient population between the target and previous years; therefore, the rate of annual increase in the dialysis patient population decreases even if the annual increase in the number of dialysis patients is constant because the dialysis patient population, which is the denominator of the equation, increases every year. If

TABLE 1. *Current status of chronic dialysis therapy in Japan (as of 31 December 2007)*

Number of facilities		4 052	Increase of 67 (1.7%)			
Equipment	Number of patient station	108 583	Increase of 4201 (4.0%)			
Capacity	Simultaneous dialysis (patients)	107 466	Increase of 3893 (3.8%)			
	Maximum accommodation capacity (patients)	364 286	Increase of 13 343 (3.8%)			
Chronic dialysis patients†		275 242	Increase of 10 769 (4.1%)			
Daytime dialysis		223 953	(81.4%)			
Nighttime dialysis		41 742	(15.2%)			
Home dialysis		187	(0.1%)			
Peritoneal dialysis		9 362	(3.4%)			
Patients (per million)		2 154.2	Increase of 84.3			
Number of patients newly introduced to dialysis		36 934	Increase of 561 (1.5%)			
Number of deceased patients		25 253	Increase of 1219 (5.1%)			
Duration of dialysis‡ (years)		Male	Female	Unknown	Total	
0–4		83 516	47 173	19	130 708	(49.4%)
5–9		40 371	25 704	1	66 076	(25.0%)
10–14		18 803	13 467	0	32 270	(12.2%)
15–19		9 108	7 364	0	16 472	(6.2%)
20–24		5 241	4 362	0	9 603	(3.6%)
≥25		5 184	4 042	1	9 227	(3.5%)
Total		162 223	102 112	21	264 356	(100.0%)
Longest dialysis history		39 years, 8 months				

†The total number of chronic dialysis patients is the total of the column for the number of patients in sheet I, and does not necessarily agree with the total number of patients counted according to the method of treatment. ‡The number of dialysis patients was calculated from questionnaire sheets II to IV.

this is correct, the rate of annual increase approaches 0% with increasing dialysis patient population; however, it will never reach 0%.

To demonstrate the above prediction, the increases in the dialysis patient population at the end of each year were calculated. The annual trend is shown in Figure 1a. The annual increase in the dialysis patient population is approximately 10 000, and has tended to decrease over the past 10 years; however, it would still take a long time for the rate of annual increase in the dialysis patient population to reach 0%.

An estimated trend in the annual increase in the number of new patients begun on dialysis (hereafter, the annual increase in the number of new patients) is shown in Figure 1b. The annual increase in the number of new patients is approximately 1000, similarly showing a decreasing trend over the past 10 years.

The number of facilities that responded to the questionnaire at the end of 2007 was 4052, which increased by 67 (1.7%) from the previous year. The number of patient stations at the end of 2007 was 108 583, which increased by 4201 (4.0%) from the previous year. The rates of increase in the number of patient stations and dialysis patients were higher than that in the number of dialysis facilities. This finding indicates that the number of patients treated at one facility has been increasing. The total number of patients who can simultaneously receive dialysis was 107 466, and the maximum capacity of all the

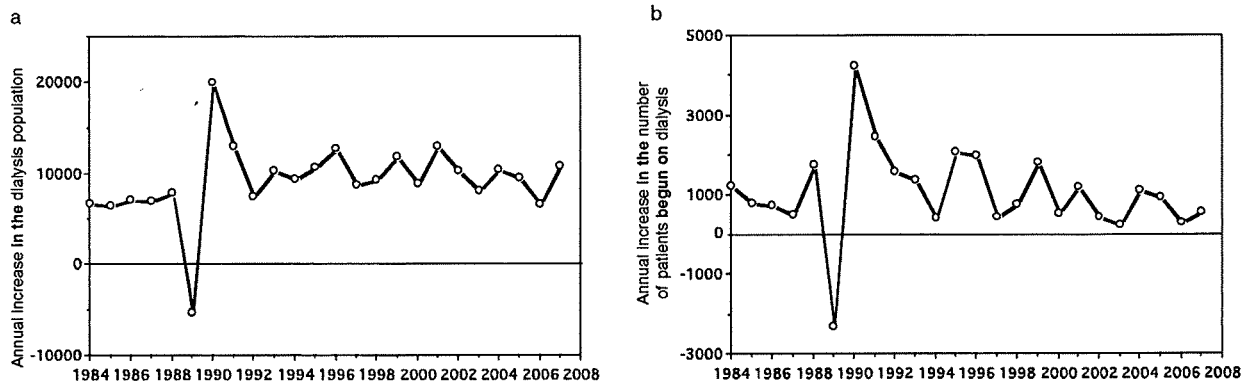

FIG. 1. Changes in the annual increase in (a) the dialysis population, and (b) the number of patients begun on dialysis.

facilities to provide dialysis was 364 286; both numbers increased in 2007.

The percentage of patients who received dialysis during the daytime further increased to 81.4%, whereas those receiving it during the nighttime decreased to 15.2%. The trends of the increasing number of daytime dialysis patients and the decreasing number of nighttime dialysis patients were the same as those in the 2006 survey.

The longest dialysis duration was 39 years and 8 months. The longest dialysis durations in the past 10 years were 31 years at the end of 1997, 32 years at the end of 1998, 33 years at the end of 1999, 34 years at the end of 2000, 35 years and 10 months at the end of 2001, 36 years and 8 months at the end of 2002, 37 years and 6 months at the end of 2003, 37 years and 3 months at the end of 2004, 38 years at the end of 2005, 39 years at the end of 2006, and 39 years and 8 months at the end of 2007. Thus, the longest dialysis duration has increased by approximately one year every survey up to the end of 2003, but the rate of increase in the longest dialysis duration has decreased since 2004. These long-term dialysis patients were begun on dialysis in the early stage of dialysis therapy in Japan; therefore, the above-described finding may indicate that 40 years have passed since these patients were begun on dialysis during this early stage of dialysis therapy and many of them have died of old age.

Table 2 shows the total number of dialysis patients in each prefecture of Japan determined from the facility survey. The number of dialysis patients per million at the end of 2007 was 2154.2 (Table 1). Table 3 shows changes in the number of dialysis patients per million.

2. Mean age

The dialysis patient population in Japan is aging yearly. The patient survey showed that the mean age of new patients begun on dialysis in 2007 was 66.8 years (±13.3, SD, here and throughout), and the mean age of the entire dialysis patient population in 2007 was 64.9 years (±12.7) (Table 4). The dialysis patient population aged by 7.2 years from the end of 1987 to the end of 1997, but aged by 5.6 years from the end of 1997 to the end of 2007. Thus, the rate of aging of the dialysis patient population has decreased. Similarly, the mean age of new patients begun on dialysis increased by 6.3 years from the end of 1987 to the end of 1997, but increased by only 4.6 years from the end of 1997 to the end of 2007. These findings show that the rate of aging of new patients begun on dialysis has also decreased.

Table 5 shows the gender and age distributions of new patients begun on dialysis in 2007. Table 6 shows the gender and age distributions of all dialysis patients in 2007. Tables 7 and 8 show the age distribution according to the primary disease. The data in these tables were obtained from the patient survey.

3. Primary disease of new patients begun on dialysis

Table 7 shows a summary of the primary diseases of new patients begun on dialysis in 2007. Table 8 shows a summary of the primary diseases of all the patients at the end of 2007.

Table 9 shows changes in the percentage of patients according to the main primary disease of renal failure for the new patients begun on dialysis each year. Since 1983, when the patient survey was first conducted, the number of new patients with diabetic nephropathy as the primary disease has continuously increased. In 1998 the number of patients with diabetic nephropathy as the primary disease became the highest among the new patients begun on dialysis, instead of the former top primary disease, chronic glomerulonephritis, and has been continuously increasing. Among the new patients begun on dialysis in 2007, the numbers of patients with diabetic nephropathy and those with chronic glomerulonephritis as the primary diseases were 43.4% and 23.8%, respectively. The number of patients with an "unspecified" primary disease newly begun on dialysis has increased yearly, and the percentage was 10.2% in 2007. Following these three diseases, the percentage of patients with nephrosclerosis as the primary disease has been increasing, accounting for 10.0%. This increase is considered to be related to the aging of the new dialysis patients. The number of patients with polycystic kidney disease, rapidly progressive glomerulonephritis, chronic pyelonephritis, and systemic lupus erythematosus (SLE) nephritis as the primary diseases were also observed, and the percentages of these patients were nearly the same as those in the previous years.

Table 10 shows changes in the percentage of patients according to the primary disease of renal failure for all the dialysis patients each year. Reflecting the trend among new patients begun on dialysis each year, the number of patients with chronic glomerulonephritis as the primary disease of renal failure has continuously decreased yearly. Instead, the number of patients with diabetic nephropathy as the primary disease has continuously increased (chronic glomerulonephritis, 40.4%; diabetic nephropathy, 33.4% in 2007). Assuming that the dynamics of the dialysis patient population in Japan continues to show this trend, the percentage of patients with

TABLE 2. *Numbers of chronic dialysis patients by prefecture*

Names of administrative divisions	Daytime	Nighttime	Home hemodialysis	Peritoneal dialysis	Total†
Hokkaido	11 535	1 438	5	450	13 429
Aomori Prefecture	2 676	221	0	121	3 018
Iwate Prefecture	2 269	360	0	144	2 773
Miyagi Prefecture	3 548	832	0	89	4 469
Akita Prefecture	1 639	145	0	63	1 847
Yamagata Prefecture	1 808	256	0	139	2 204
Fukushima Prefecture	3 641	497	1	230	4 368
Ibaraki Prefecture	5 335	854	1	154	6 344
Tochigi Prefecture	4 326	719	0	62	5 108
Gunma Prefecture	3 949	751	19	133	4 833
Saitama Prefecture	11 355	1 961	0	449	13 784
Chiba Prefecture	9 410	1 851	4	232	11 493
Tokyo	20 771	5 039	9	852	26 665
Kanagawa Prefecture	12 955	2 985	1	524	16 474
Niigata Prefecture	3 402	993	1	139	4 535
Toyama Prefecture	1 837	279	0	67	2 184
Ishikawa Prefecture	1 904	381	0	86	2 372
Fukui Prefecture	1 398	214	1	79	1 691
Yamanashi Prefecture	1 759	210	1	20	1 990
Nagano Prefecture	3 481	646	0	133	4 260
Gifu Prefecture	3 386	613	3	161	4 160
Shizuoka Prefecture	7259	1 355	52	290	8 908
Aichi Prefecture	11 200	3 108	3	573	14 931
Mie Prefecture	2 921	656	9	137	3 717
Shiga Prefecture	1 950	504	2	92	2 555
Kyoto Prefecture	4 091	957	2	170	5 220
Osaka Prefecture	16 707	2 741	9	657	20 154
Hyogo Prefecture	8 798	1 757	3	332	10 896
Nara Prefecture	2 507	222	1	113	2 845
Wakayama Prefecture	2 298	293	0	27	2 619
Tottori Prefecture	993	124	0	116	1 233
Shimane Prefecture	1 140	145	0	87	1 372
Okayama Prefecture	3 398	489	0	243	4 130
Hiroshima Prefecture	5 536	527	0	441	6 504
Yamaguchi Prefecture	2 660	359	0	133	3 152
Tokushima Prefecture	1 954	287	0	178	2 419
Kagawa Prefecture	1 919	247	7	239	2 412
Ehime Prefecture	2 661	439	1	166	3 267
Kochi Prefecture	1 806	202	0	45	2 052
Fukuoka Prefecture	9 729	2 218	1	336	12 283
Saga Prefecture	1 586	289	0	13	1 888
Nagasaki Prefecture	2 828	522	1	136	3 487
Kumamoto Prefecture	4 492	949	0	150	5 591
Oita Prefecture	3 045	361	1	120	3 527
Miyazaki Prefecture	2 804	537	0	55	3 396
Kagoshima Prefecture	4 147	529	2	115	4 792
Okinawa Prefecture	3 140	680	0	71	3 891
Total	223 953	41 742	187	9362	275 242

†The total number of chronic dialysis patients is the total of the column for the number of patients in sheet I, and does not necessarily agree with the total number of patients counted according to the method of treatment. The number of dialysis patients was calculated based on facility survey data.

chronic glomerulonephritis as the primary disease and that with diabetic nephropathy will reverse in a few years; it is considered that the percentage of patients with diabetic nephropathy as the primary disease will become the largest also for all the dialysis patients. Patients with an unspecified primary disease accounted for 7.4% of all the dialysis patients. Following these three diseases, nephrosclerosis had the fourth largest number of patients.

4. Causes of death

Table 11 shows the classification of the causes of death of new patients who were begun on dialysis in 2007 and who died by the end of 2007. Table 12 shows the classification of the causes of death of patients who died in 2007 in the entire dialysis patient population. Table 13 shows the changes in the percentages of the leading causes of death in the entire dialysis patient population. The classification of the causes of

TABLE 3. *Changes in the number of patients per million*

Year	Patients per million	Year	Patients per million
1983	443.7	1996	1328.4
1984	497.5	1997	1394.9
1985	547.8	1998	1472.5
1986	604.4	1999	1556.7
1987	658.8	2000	1624.1
1988	721.1	2001	1721.9
1989†	790.0	2002	1801.2
1990	835.7	2003	1862.7
1991	937.6	2004	1943.5
1992	995.8	2005	2017.6
1993	1076.4	2006	2069.9
1994	1149.4	2007	2154.2
1995	1229.7		

†The collection rate is corrected at 86%, that is, rounded off at the 100th order. The number of dialysis patients was calculated based on facility survey data.

death was changed on the basis of the tenth revision of the international statistical classification of diseases and related health problems (ICD-10) starting with the survey at the end of 2003.

The causes of death of new patients begun on dialysis in 2007 were infectious diseases (24.2%), cardiac failure (23.2%), malignant tumors (10.3%), cerebrovascular disorder (5.5%), and cardiac infarction (3.5%). The major cause of death of new patients begun on dialysis was cardiac failure until 2002. The percentage of dialysis patients who died of infectious diseases has increased and become as large as that of dialysis patients who died of cardiac failure since 2003; this trend has continued until 2007. The increases in the numbers of elderly patients and diabetic patients who easily develop infectious diseases are considered to account for the increasing percentage of patients who died of infectious diseases.

The leading cause of death among the entire dialysis patient population was cardiac failure, accounting for 24.0% of all the patients who died. The percentage of death from cardiac failure among all the patients who died decreased between 1990 and around 1996, and remained nearly constant afterwards. The second leading cause of death was infectious diseases, accounting for 18.9% of all the patients who died. The percentage of death from infectious diseases has tended to increase since 1990. These trends were similar to those observed for the causes of death of new patients begun on dialysis, which was mentioned above.

Following the causes of death mentioned above, the percentages of patients who died of cerebrovascular disorder and malignant tumors were high, at 8.9% and 9.2%, respectively. The percentage of patients who died of cerebrovascular disorder has tended to decrease since 1994; moreover, the percentage of patients who died of cardiac infarction has also tended to decrease since 2002.

5. Annual crude death rate

The annual crude death rate was calculated from the facility survey data. It shows the percentage of the number of patients who died in a given year with respect to the mean annual number of dialysis patients. The annual crude death rate in 2007 was 9.4%. Table 14 shows the trend of annual crude death rates from 1983, which have ranged between 9.2–9.7% since 1992. Despite the increase in the numbers of diabetic patients, who have a low life expectancy, and elderly patients, the annual crude death rate remains nearly constant, which suggests an improvement in dialysis control technology in Japan.

6. Cumulative survival rate of new patients begun on dialysis each year

The cumulative survival rates of new patients begun on dialysis from 1983 are summarized by the year of introduction (Table 15). Moreover, the 1-, 5-, 10-, 15-, and 20-year survival rates of patients begun on dialysis are extracted from the table and plotted in

TABLE 4. *Changes in the mean age of new patients begun on dialysis and in that of patients at the end of each year*

	Mean age of patients newly begun on dialysis treatment		Mean age of patients at the end of each year	
Year	Mean	±SD	Mean	±SD
1983	51.9	15.5	48.3	13.8
1984	53.2	15.3	49.2	13.8
1985	54.4	15.4	50.3	13.7
1986	55.1	15.2	51.1	13.6
1987	55.9	14.9	52.1	13.7
1988	56.9	14.9	52.9	13.6
1989	57.4	14.7	53.8	13.5
1990	58.1	14.6	54.5	13.5
1991	58.1	14.6	55.3	13.5
1992	59.5	14.5	56.0	13.5
1993	59.8	14.4	56.6	13.5
1994	60.4	14.3	57.3	13.5
1995	61.0	14.2	58.0	13.4
1996	61.5	14.2	58.6	13.4
1997	62.2	14.0	59.2	13.4
1998	62.7	13.9	59.9	13.3
1999	63.4	13.9	60.6	13.3
2000	63.8	13.9	61.2	13.2
2001	64.2	13.7	61.6	13.1
2002	64.7	13.6	62.2	13.0
2003	65.4	13.5	62.8	12.9
2004	65.8	13.4	63.3	12.9
2005	66.2	13.4	63.9	12.8
2006	66.4	13.4	64.4	12.8
2007	66.8	13.3	64.9	12.7

TABLE 5. *Number of new patients begun on dialysis in 2007 according to age and gender*

Age of the patients when newly begun on dialysis (years)	Male	(%)†	Female	(%)†	Subtotal	(%)†	No information available	Total	(%)†
<5	9	(0.0)	10	(0.1)	19	(0.1)	0	19	(0.1)
5–9	6	(0.0)	4	(0.0)	10	(0.0)	0	10	(0.0)
10–14	12	(0.1)	6	(0.0)	18	(0.0)	0	18	(0.0)
15–19	20	(0.1)	12	(0.1)	32	(0.1)	0	32	(0.1)
20–24	71	(0.3)	34	(0.3)	105	(0.3)	0	105	(0.3)
25–29	120	(0.5)	69	(0.5)	189	(0.5)	0	189	(0.5)
30–34	247	(1.1)	123	(1.0)	370	(1.0)	0	370	(1.0)
35–39	464	(2.0)	215	(1.7)	679	(1.9)	0	679	(1.9)
40–44	671	(2.9)	253	(2.0)	924	(2.6)	0	924	(2.6)
45–49	989	(4.2)	419	(3.3)	1 408	(3.9)	0	1 408	(3.9)
50–54	1 458	(6.2)	611	(4.8)	2 069	(5.7)	0	2 069	(5.7)
55–59	2 819	(12.0)	1 187	(9.4)	4 006	(11.1)	1	4 007	(11.1)
60–64	2 852	(12.2)	1 272	(10.0)	4 124	(11.4)	3	4 127	(11.4)
65–69	3 281	(14.0)	1 639	(12.9)	4 920	(13.6)	7	4 927	(13.7)
70–74	3 775	(16.1)	1 947	(15.4)	5 722	(15.9)	2	5 724	(15.9)
75–79	3 372	(14.4)	2 067	(16.3)	5 439	(15.1)	1	5 440	(15.1)
80–84	2 221	(9.5)	1 671	(13.2)	3 892	(10.8)	0	3 892	(10.8)
85–89	832	(3.6)	890	(7.0)	1 722	(4.8)	1	1 723	(4.8)
90–94	152	(0.6)	216	(1.7)	368	(1.0)	0	368	(1.0)
≥95	26	(0.1)	24	(0.2)	50	(0.1)	0	50	(0.1)
Total	23 397	(100.0)	12 669	(100.0)	36 066	(100.0)	15	36 081	(100.0)
No information available	60		32		92			92	
Total	23 457		12 701		36 158		15	36 173	
Mean	65.84		68.60		66.81		67.73	66.81	
SD	13.07		13.55		13.31		7.40	13.30	

†The value in parentheses on the right-hand side of each number is the percentage of patients with respect to the total of the column.

TABLE 6. *Number of all dialysis patients in 2007 according to age and gender*

Age (years)	Male	(%)†	Female	(%)†	Subtotal	(%)†	No information available	Total	(%)†
<5	21	(0.0)	20	(0.0)	41	(0.0)	0	41	(0.0)
5–9	18	(0.0)	14	(0.0)	32	(0.0)	0	32	(0.0)
10–14	19	(0.0)	14	(0.0)	33	(0.0)	0	33	(0.0)
15–19	77	(0.0)	49	(0.0)	126	(0.0)	0	126	(0.0)
20–24	291	(0.2)	167	(0.2)	458	(0.2)	0	458	(0.2)
25–29	713	(0.4)	400	(0.4)	1 113	(0.4)	0	1 113	(0.4)
30–34	1 859	(1.1)	969	(0.9)	2 828	(1.1)	0	2 828	(1.1)
35–39	3 575	(2.2)	1 832	(1.8)	5 407	(2.0)	0	5 407	(2.0)
40–44	5 400	(3.3)	2 786	(2.7)	8 186	(3.1)	0	8 186	(3.1)
45–49	7 783	(4.8)	4 233	(4.1)	12 016	(4.5)	1	12 017	(4.5)
50–54	12 364	(7.6)	7 053	(6.9)	19 417	(7.3)	1	19 418	(7.3)
55–59	22 862	(14.1)	13 142	(12.9)	36 004	(13.6)	2	36 006	(13.6)
60–64	23 361	(14.4)	13 576	(13.3)	36 937	(14.0)	2	36 939	(14.0)
65–69	24 719	(15.2)	14 793	(14.5)	39 512	(14.9)	9	39 521	(15.0)
70–74	24 225	(14.9)	14 633	(14.3)	38 858	(14.7)	3	38 861	(14.7)
75–79	18 799	(11.6)	12 837	(12.6)	31 636	(12.0)	2	31 638	(12.0)
80–84	10 874	(6.7)	9 437	(9.2)	20 311	(7.7)	0	20 311	(7.7)
85–89	4 115	(2.5)	4 663	(4.6)	8 778	(3.3)	1	8 779	(3.3)
90–94	1 005	(0.6)	1 334	(1.3)	2 339	(0.9)	0	2 339	(0.9)
≥95	139	(0.1)	158	(0.2)	297	(0.1)	0	297	(0.1)
Total	162 219	(100.0)	102 110	(100.0)	264 329	(100.0)	21	264 350	(100.0)
No information available	4		2		6			6	
Total	162 223		102 112		264 335		21	264 356	
Mean	64.16		65.98		64.87		66.33	64.87	
SD	12.52		12.92		12.71		8.51	12.71	

†The value in parentheses on the right-hand side of each number is the percentage of patients with respect to the total of the column.

TABLE 7. *Number of new patients begun on dialysis in 2007 (and their mean ages) according to primary disease*

Primary disease	Number of patients	(%)†	No information available	(%)†	Total	(%)†	Mean age	SD
Chronic glomerulonephritis	8 561	(23.8)	41	(45.1)	8 602	(23.8)	66.45	14.31
Chronic pyelonephritis	278	(0.8)	2	(2.2)	280	(0.8)	64.42	15.06
Rapidly progressive glomerulonephritis	468	(1.3)	0	(0.0)	468	(1.3)	69.99	14.30
Nephropathy of pregnancy/pregnancy toxemia	68	(0.2)	0	(0.0)	68	(0.2)	57.56	13.60
Other nephritides that cannot be classified	148	(0.4)	0	(0.0)	148	(0.4)	61.32	20.35
Polycystic kidney	827	(2.3)	0	(0.0)	827	(2.3)	61.31	13.41
Nephrosclerosis	3 621	(10.1)	5	(5.5)	3 626	(10.0)	73.67	11.54
Malignant hypertension	248	(0.7)	0	(0.0)	248	(0.7)	61.10	16.56
Diabetic nephropathy	15 663	(43.5)	18	(19.8)	15 681	(43.4)	65.44	11.49
Systemic lupus erythematosus nephritis	302	(0.8)	4	(4.4)	306	(0.8)	60.50	15.67
Amyloidal kidney	170	(0.5)	0	(0.0)	170	(0.5)	68.20	9.28
Gouty kidney	107	(0.3)	1	(1.1)	108	(0.3)	65.82	12.60
Renal failure due to congenital abnormality of metabolism	33	(0.1)	0	(0.0)	33	(0.1)	47.24	21.85
Kidney and urinary tract tuberculosis	22	(0.1)	0	(0.0)	22	(0.1)	72.23	9.95
Kidney and urinary tract stone	67	(0.2)	0	(0.0)	67	(0.2)	68.36	12.52
Kidney and urinary tract tumor	162	(0.4)	1	(1.1)	163	(0.5)	70.96	11.82
Obstructive urinary tract disease	99	(0.3)	1	(1.1)	100	(0.3)	66.89	16.22
Myeloma	140	(0.4)		(0.0)	140	(0.4)	70.40	9.33
Hypoplastic kidney	59	(0.2)	1	(1.1)	60	(0.2)	35.14	27.81
Undetermined	3 664	(10.2)	9	(9.9)	3 673	(10.2)	69.84	13.43
Reintroduction after transplantation	273	(0.8)	4	(4.4)	277	(0.8)	56.67	17.28
Others	1 037	(2.9)	4	(4.4)	1 041	(2.9)	67.47	15.25
Total	36 017	(100.0)	91	(100.0)	36 108	(100.0)	66.80	13.31
No information available	64		1		65		70.53	11.65
Total	36 081		92		36 173		66.81	13.30

†The value in parentheses on the right-hand side of each number is the percentage of patients with respect to the total of the column.

Figure 2. The survival rates were calculated using a life table method (3).

The 1- to 10-year survival rates have been increasing since 1992 for patients begun on dialysis in 1992 or later. A significant change employed from around 1992 was the start of the clinical application of erythropoietin. This trend of increasing survival rate for the patients begun on dialysis after 1992 may be due to the improvement of anemia therapy using erythropoietin from the initial phase of dialysis.

The 15-year survival rate of patients begun on dialysis after 1992 is still unclear because only the data from the patients begun on dialysis before 1992 are used for calculating the 15-year survival rate. It will be interesting to determine whether the survival rates for 15 years and longer will also increase for the patients begun on dialysis after 1992.

II. Tabulation of data on new items surveyed

A. Current status of dialysate solution quality control

Following the previous survey, the surveyed items included the measurement frequency and endotoxin concentration in the dialysate solution, measurement frequency and bacterial count in the dialysate solution, the medium used for bacterial cultivation of dialysate solution, and the installation of endotoxin retentive filters (ETRFs). The amount of the sample for the measurement of bacterial count in the dialysate solution was also added to these items in the present survey.

1. Measurement of endotoxin concentration in dialysate solution

a. Measurement frequency. There were 3664 facilities that responded to questions regarding the measurement frequency of endotoxin concentration in the dialysate solution (Table 16). The endotoxin concentration in the dialysate solution was measured at 87.5% of the facilities that responded to the questionnaire, an increase of 5% from the percentage in the 2006 survey. According to the quality control standard by the Japanese Society for Dialysis Therapy, it is recommended that the endotoxin concentration in the dialysate solution be measured more than once a month; however, the percentage of facilities that carried out the measurement more than once a month was only 31.5%, indicating that compliance with the recommendation needs improvement.

TABLE 8. *Number of all dialysis patients in 2007 (and their mean ages) according to primary disease*

Primary disease	Number of patients	(%)†	No information available	(%)†	Total	(%)†	Mean age	SD
Chronic glomerulonephritis	106 702	(40.4)	2	(33.3)	106 704	(40.4)	63.50	12.84
Chronic pyelonephritis	3 138	(1.2)	0	(0.0)	3 138	(1.2)	62.83	14.26
Rapidly progressive glomerulonephritis	1 742	(0.7)	0	(0.0)	1 742	(0.7)	64.95	14.30
Nephropathy of pregnancy/pregnancy toxemia	1 775	(0.7)	0	(0.0)	1 775	(0.7)	59.71	9.96
Other nephritides that cannot be classified	1 214	(0.5)	0	(0.0)	1 214	(0.5)	58.05	17.03
Polycystic kidney	8 920	(3.4)	0	(0.0)	8 920	(3.4)	62.93	11.03
Nephrosclerosis	17 144	(6.5)	0	(0.0)	17 144	(6.5)	72.91	11.96
Malignant hypertension	1 956	(0.7)	0	(0.0)	1 956	(0.7)	62.55	14.41
Diabetic nephropathy	88 257	(33.4)	1	(16.7)	88 258	(33.4)	65.69	10.96
Systemic lupus erythematosus nephritis	2 261	(0.9)	0	(0.0)	2 261	(0.9)	56.85	13.77
Amyloidal kidney	513	(0.2)	0	(0.0)	513	(0.2)	65.47	11.26
Gouty kidney	1 256	(0.5)	1	(16.7)	1 257	(0.5)	65.56	11.61
Renal failure due to congenital abnormality of metabolism	262	(0.1)	0	(0.0)	262	(0.1)	47.31	17.90
Kidney and urinary tract tuberculosis	392	(0.1)	0	(0.0)	392	(0.1)	69.59	9.68
Kidney and urinary tract stone	552	(0.2)	0	(0.0)	552	(0.2)	68.23	11.43
Kidney and urinary tract tumor	644	(0.2)	0	(0.0)	644	(0.2)	69.18	12.08
Obstructive urinary tract disease	692	(0.3)	0	(0.0)	692	(0.3)	60.76	18.23
Myeloma	207	(0.1)	0	(0.0)	207	(0.1)	70.06	10.78
Hypoplastic kidney	548	(0.2)	0	(0.0)	548	(0.2)	39.73	19.41
Undetermined	19 451	(7.4)	2	(33.3)	19 453	(7.4)	67.14	13.42
Reintroduction after transplantation	1 894	(0.7)	0	(0.0)	1 894	(0.7)	52.98	12.79
Others	4 725	(1.8)	0	(0.0)	4 725	(1.8)	62.66	16.11
Total	264 245	(100.0)	6	(100.0)	264 251	(100.0)	64.87	12.71
No information available	105		0		105		68.05	12.39
Total	264 350		6		264 356		64.87	12.71

†The value in parentheses on the right-hand side of each number is the percentage of patients with respect to the total of the column.

b. Dialysate solution endotoxin concentration. Measured endotoxin concentrations in the dialysate solution were obtained from 3186 facilities (Table 17). The quality control standard of endotoxin concentration in the dialysate solution reported by the Japanese Society for Dialysis Therapy is <0.05 EU/mL. The percentage of facilities that satisfied this standard was 93.6%, an increase of approximately 5%

TABLE 9. *Changes in the percentage of new patients begun on dialysis each year in terms of primary disease*

Year	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995
Diabetic nephropathy	15.6	17.4	19.6	21.3	22.1	24.3	26.5	26.2	28.1	28.4	29.9	30.7	31.9
Chronic glomerulonephritis	60.5	58.7	56.0	54.8	54.2	49.9	47.4	46.1	44.2	42.2	41.4	40.5	39.4
Nephrosclerosis	3.0	3.3	3.5	3.7	3.9	3.9	4.1	5.4	5.5	5.9	6.2	6.1	6.3
Polycystic kidney	2.8	2.8	3.1	2.9	3.2	3.1	3.1	2.9	3.0	2.7	2.6	2.5	2.4
Chronic pyelonephritis	2.4	2.2	2.1	2.0	1.8	1.8	1.5	1.5	1.7	1.6	1.1	1.4	1.2
Rapidly progressive glomerulonephritis	0.9	0.7	0.9	1.0	0.8	0.9	0.8	0.7	0.6	0.7	0.8	0.8	0.8
Systemic lupus erythematosus nephritis	1.1	1.1	1.1	1.2	0.9	0.9	1.0	1.1	1.3	1.3	1.2	1.2	1.1
Undetermined	4.4	4.0	4.8	4.2	4.1	3.8	4.0	3.3	3.7	3.7	3.3	3.9	4.5

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Diabetic nephropathy	33.1	33.9	35.7	36.2	36.6	38.1	39.1	41.0	41.3	42.0	42.9	43.4
Chronic glomerulonephritis	38.9	36.6	35.0	33.6	32.5	32.4	31.9	29.1	28.1	27.4	25.6	23.8
Nephrosclerosis	6.4	6.8	6.7	7.0	7.6	7.6	7.8	8.5	8.8	9.0	9.4	10.0
Polycystic kidney	2.5	2.4	2.4	2.2	2.4	2.3	2.4	2.3	2.7	2.3	2.4	2.3
Chronic pyelonephritis	1.1	1.2	1.1	1.1	1.0	1.1	0.9	1.0	0.9	1.0	0.8	0.8
Rapidly progressive glomerulonephritis	0.8	1.1	0.9	0.9	1.0	1.0	1.1	1.2	1.1	1.1	1.2	1.3
Systemic lupus erythematosus nephritis	1.3	1.0	1.1	1.2	0.9	1.0	0.9	0.7	0.8	0.8	0.8	0.8
Undetermined	5.0	5.5	5.6	6.1	7.6	9.0	8.4	8.8	9.3	9.5	9.9	10.2

TABLE 10. *Changes in the percentage of patients at the end of each year in terms of primary disease*

Year	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995
Diabetic nephropathy	7.4	8.4	9.4	10.5	11.7	12.8	14.0	14.9	16.4	17.1	18.2	19.2	20.4
Chronic glomerulonephritis	74.5	72.1	72.3	70.6	69.4	67.9	65.9	64.1	61.7	60.4	58.8	57.7	56.6
Nephrosclerosis	1.5	1.7	1.9	2.0	2.1	2.1	2.3	2.6	2.9	3.1	3.4	3.6	3.8
Polycystic kidney	2.7	2.9	3.0	3.1	3.1	3.2	3.2	3.3	3.3	3.3	3.3	3.2	3.2
Chronic pyelonephritis	3.1	3.3	2.6	2.4	2.4	2.3	2.2	2.2	2.1	2.0	1.9	1.8	1.7
Rapidly progressive glomerulonephritis	0.5	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Systemic lupus erythematosus nephritis	0.8	0.8	0.9	0.9	0.9	0.9	0.9	1.0	1.1	1.1	1.1	1.1	1.1
Undetermined	2.2	2.3	2.3	2.5	2.6	2.5	2.6	2.6	2.9	2.9	2.9	3.1	3.2

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Diabetic nephropathy	21.6	22.7	24.0	25.1	26.0	27.2	28.1	29.2	30.2	31.4	32.3	33.4
Chronic glomerulonephritis	55.4	54.1	52.5	51.1	49.7	49.6	48.2	46.6	45.1	43.6	42.2	40.4
Nephrosclerosis	4.0	4.2	4.4	4.5	4.8	5.0	5.1	5.3	5.7	5.9	6.2	6.5
Polycystic kidney	3.2	3.2	3.2	3.2	3.2	3.3	3.3	3.3	3.4	3.3	3.4	3.4
Chronic pyelonephritis	1.6	1.6	1.5	1.5	1.4	1.4	1.3	1.3	1.3	1.2	1.2	1.2
Rapidly progressive glomerulonephritis	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.7
Systemic lupus erythematosus nephritis	1.1	1.1	1.1	1.1	1.0	1.0	1.0	0.9	0.9	0.9	0.9	0.9
Undetermined	3.6	3.9	4.2	4.4	5.0	5.6	5.9	6.3	6.4	6.6	7.0	7.4

from that in the 2006 survey. The percentage of facilities that satisfied the endotoxin concentration of <0.001 EU/mL, which is required for an ultrapure dialysate solution, was 53.0%, a marked increase from 29.8% in the 2006 survey, showing a considerable improvement in solution cleanliness.

2. *Bacterial test of dialysate solution*

a. Measurement frequency. There were 3441 facilities that responded to questions regarding the frequency of the bacterial test of the dialysate solution (Table 18). The test was carried out at 50.1% of these facilities, showing a marked increase from 37.1% at the end of 2006. In accordance with the quality control standard by the Japanese Society for Dialysis Therapy, it is recommended to measure the bacterial count in the dialysate solution more than once a month; however, the percentage of facilities that carried out the test more than once a month was only 16.9%, indicating the need to improve the practice of carrying out bacterial tests as a routine task.

TABLE 11. *Classification of the causes of death of new patients begun on dialysis in 2007*

Cause of death	Male	(%)	Female	(%)	Total	(%)	No information available	Total	(%)
Cardiac failure	460	(22.9)	260	(23.9)	720	(23.2)	0	720	(23.2)
Cerebrovascular disease	102	(5.1)	69	(6.3)	171	(5.5)	0	171	(5.5)
Infectious disease	479	(23.8)	270	(24.8)	749	(24.2)	0	749	(24.2)
Hemorrhage	59	(2.9)	26	(2.4)	85	(2.7)	0	85	(2.7)
Malignant tumor	239	(11.9)	80	(7.3)	319	(10.3)	0	319	(10.3)
Cachexia/uremia	62	(3.1)	51	(4.7)	113	(3.6)	0	113	(3.6)
Cardiac infarction	68	(3.4)	42	(3.9)	110	(3.5)	0	110	(3.5)
Potassium poisoning/moribund	55	(2.7)	30	(2.8)	85	(2.7)	0	85	(2.7)
Chronic hepatitis/cirrhosis	44	(2.2)	10	(0.9)	54	(1.7)	0	54	(1.7)
Encephalopathy	2	(0.1)	3	(0.3)	5	(0.2)	0	5	(0.2)
Suicide/refusal of treatment	23	(1.1)	6	(0.6)	29	(0.9)	0	29	(0.9)
Intestinal obstruction	9	(0.4)	13	(1.2)	22	(0.7)	0	22	(0.7)
Lung thrombus/pulmonary embolus	7	(0.3)	2	(0.2)	9	(0.3)	0	9	(0.3)
Death due to disaster	10	(0.5)	2	(0.2)	12	(0.4)	0	12	(0.4)
Others	229	(11.4)	117	(10.7)	346	(11.2)	0	346	(11.2)
Undetermined	162	(8.1)	108	(9.9)	270	(8.7)	0	270	(8.7)
Total	2010	(100.0)	1089	(100.0)	3099	(100.0)	0	3099	(100.0)
No information available			1		1		0	1	
Total	2010		1090		3100		0	3100	