The organization and financing of end-stage renal disease treatment in Japan

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Abstract

End-stage renal disease (ESRD) affects 230,000 Japanese, with about 36,000 cases diagnosed each year. Recent increases in ESRD incidence are attributed mainly to increases in diabetes and a rapidly aging population. Renal transplantation is rare in Japan. In private dialysis clinics, the majority of treatment costs are paid as fixed fees per session and the rest are fee for service. Payments for hospital-based dialysis are either fee-for-service or diagnosis-related. Dialysis is widely available, but reimbursement rates have recently been reduced. Clinical outcomes of dialysis are better in Japan than in other countries, but this may change given recent ESRD cost containment policies.

ISHCOF
International Study of Health Care Organization and Financing

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Introduction

People in Japan have one of the longest life expectancies in the world (WHO, 2006). Yet the level of health care spending is among the lowest in developed countries, and Japan spends about half of what the United States spends for health care. Japan started to move toward national health insurance with wide coverage in 1947. From the beginning, payment for medical care has been provided by not-for-profit insurance institutions. (All health insurance institutions are non-profit institutions because for-profit health insurance firms and for-profit hospitals are generally prohibited.) There are currently more than 5,000 non-profit insurance institutions. These firms are typically large industry unions, public service unions, or small business associations.

The fraction of citizens covered by health insurance gradually expanded until, by 1952, virtually all citizens were covered. Citizens pay monthly premiums determined by their employment arrangement and income levels. Usually, employers pay about half of the premium for their employees. The unemployed, retirees, and some government employees are insured by community health insurance funded by sliding scale premiums and a substantial government subsidy. Insurance firms do not contract with individual providers. As long as the health care provider is certified as being "national insurance registered," the insurance institution is obligated to pay the claim. As a result, all citizens may choose any physician or hospital that they wish. Copayments of 10%–30% are usual. Out-of-pocket payment is capped at approximately US $600 per month (higher depending on income level). Health insurance reimburses all out-of-pocket payments over this cap.

The Japanese national health insurance uses a universal fee schedule that specifies the payment amount for each of more than 3,000 listed health services, including physician fees, hospital fees, and medications. The Central Social Insurance Medical Council revises this fee schedule biannually through negotiation among the government, payers such as health insurance unions, and the Japanese Medical Association. The fees for the same services are frequently revised downward, especially for procedures and drugs billed frequently in the preceding period. This mechanism financially discourages the provision of high-cost procedures. In a sense, revision of the fee schedule is part of the cost containment process for Japanese medical care. Although individual insurance institutions play virtually no formal role in systematic cost containment, these central processes have assisted the policy objective of keeping health spending low (Ikegami, 1991; Ikegami & Campbell, 1995; Iglehart, 1988).

In 2003, the government began offering the option of a prospective payment system (PPS) for hospital care—the diagnosis procedure combination (DPC). This system is similar to the diagnosis-related group–based PPS in the United States but has several differences; for example, the DPC classification determines only the per-day fee, not the per-admission fee. Initially, only highly specialized tertiary-care hospitals, including most university hospitals and large public hospitals, accepted the DPC option. Over time, however, an increasing number of hospitals have been enrolling in this newer payment option, partly because the government created financial incentives to encourage acceptance. These incentives used an inflation factor to guarantee the total amount of reimbursement paid in the pre-enrollment year if these hospitals cared for the same diagnosis set of patients. As of 2006, 360 of 9,000 hospitals (including long-term-care facilities) had enrolled for the DPC scheme.

Physicians are largely divided into two groups based on their practice style: those who own their own offices (office practitioners) and those employed by hospitals (hospital physicians). Office practitioners are typically in solo practice and have offices that function as small hospitals, providing a wide range of preventive, diagnostic, and treatment services. Many of these offices are equipped with advanced diagnostic and therapeutic equipment, such as x-ray machines, ultrasound scans, and even computed tomography scans and magnetic resonance imaging. Hospital physicians are almost universally employed by university hospitals or public or private hospitals. Insurance payments do not separate physician fees from hospital fees, and the entire sum is paid to facilities (hospitals or offices). Office practitioners usually do not attend hospitalized patients or conduct procedures in hospitals. When their patients need hospital care beyond that offered in their practice and clinic, the patient is referred to a hospital physician. The hospital physician initially determines whether hospitalization is appropriate and also provides the hospital physician services. On average, office practitioners earn considerably higher incomes than hospital physicians. Many hospital physicians compensate their low salaries by moonlighting.

Hospitals are divided into large-scale public hospitals (e.g., national hospitals, municipal hospitals, or semipublic entities such as the Red Cross Society) and smaller, private (nonprofit) facilities. Two-fifths of the hospitals are small (fewer than 100 beds) and are effectively extensions of clinics run by individual physicians. Hospitals receive a modest per diem bed fee, which covers hotel costs and basic nursing fees for the stay. Per diem fees vary depending on each ward's staff-to-patient ratio, ranging from 9,000 yen to 15,000 yen (US$68 to $123; PPP 2004) for a general ward (intensive care units and other specialized wards have different arrangements). Other services provided during the hospital stay are paid for according to the national fee schedule in addition to the reimbursement (per diem) for the hospital stay itself.

About 80% of maintenance hemodialysis (HD) is provided in private sector units (mostly solo-practice tax-paying clinics), and the rest is provided in large hospitals (JSDT, 2006).

Methods

This paper is part of the International Study of Health Care Organization and Financing (ISHCOF), a substudy of the Dialysis Outcomes and Practice Patterns Study (DOPPS). The DOPPS is a multi-faceted, multi-year international study of the variations in practice patterns and treatment of end-stage renal disease (ESRD) patients on HD and their impact on clinical and other outcomes. The ISHCOF aims to characterize economic structures and their impact on the delivery of dialysis care. The study is based primarily on one-time commissioned surveys (2004–2005) and subsequent papers by authors from each of the 12 DOPPS countries. Details of the methods are described in Dor, Pauly, Eichleay, and Held (2007).

In general, the reported statistics and data are based on secondary data sources, including the Japanese Society for Dialysis Therapy, the Ministry of Health, Labour and Welfare (MHLW), and cited published journal articles. Hospital charges were estimated from two sources: the Survey of Medical Care Activities in Public Health Insurance, which is conducted every June on

sampled facilities (MHLW, 2002a), and the National Medical Care Expenditure (MHLW, 2004).[1] HD costs were based on those reported in the *Journal of the Japanese Society for Dialysis Therapy* (JSDT, 2006), with an additional amount added for night care and outpatient surgery procedures. Transplant estimates were based on an estimate of the number of transplant patients from the Japanese Organ Transplantation Network and a cost estimate from the Second Nagoya Red Cross Hospital (Japan Renal Transplantation Society, 2003). The total hospitalization charge for all health care was multiplied by the fraction of charges for renal failure, the fraction of renal failure charges for actual procedures, and the fraction receiving artificial kidney use as a procedure (see the tables in Appendix A).

For international comparisons in this paper, the prevalence and incidence of dialysis in Japan are used synonymously with the prevalence and incidence of end-stage renal disease (ESRD) because the number of transplant patients in Japan is negligible (<0.5%).

All monetary estimates were provided in national currency units and converted to US dollars with Organization for Economic Cooperation and Development purchasing power parities (PPP) for the year of each estimate (OECD, 2006). Because of the small number of economic investigators and countries in this study, international comparisons reported here are informal and qualitative, unless otherwise noted.

The gross epidemiology of kidney disease and provision of care in Japan

With its population of 127 million and 2 million foreign residents in 2006, Japan has seen a substantial increase in both the prevalence and incidence of ESRD in recent years. The number of HD patients has increased almost exponentially, from 215 in 1968 to 32,331 in 1979 and 257,765 in 2005 (Fig. 1). Over the past decade (1995–2005), ESRD prevalence grew at an average of 5.7% per year (JSDT, 2007). In 2005, the prevalence of ESRD in Japan was 2017 per million population (pmp) and it had increased 17% in the five years since 2001 (JSDT, 2007). The incidence of ESRD was 282 pmp in 2005, and it had increased 8% since 2001 (2.0% per year) (JSDT, 2007).

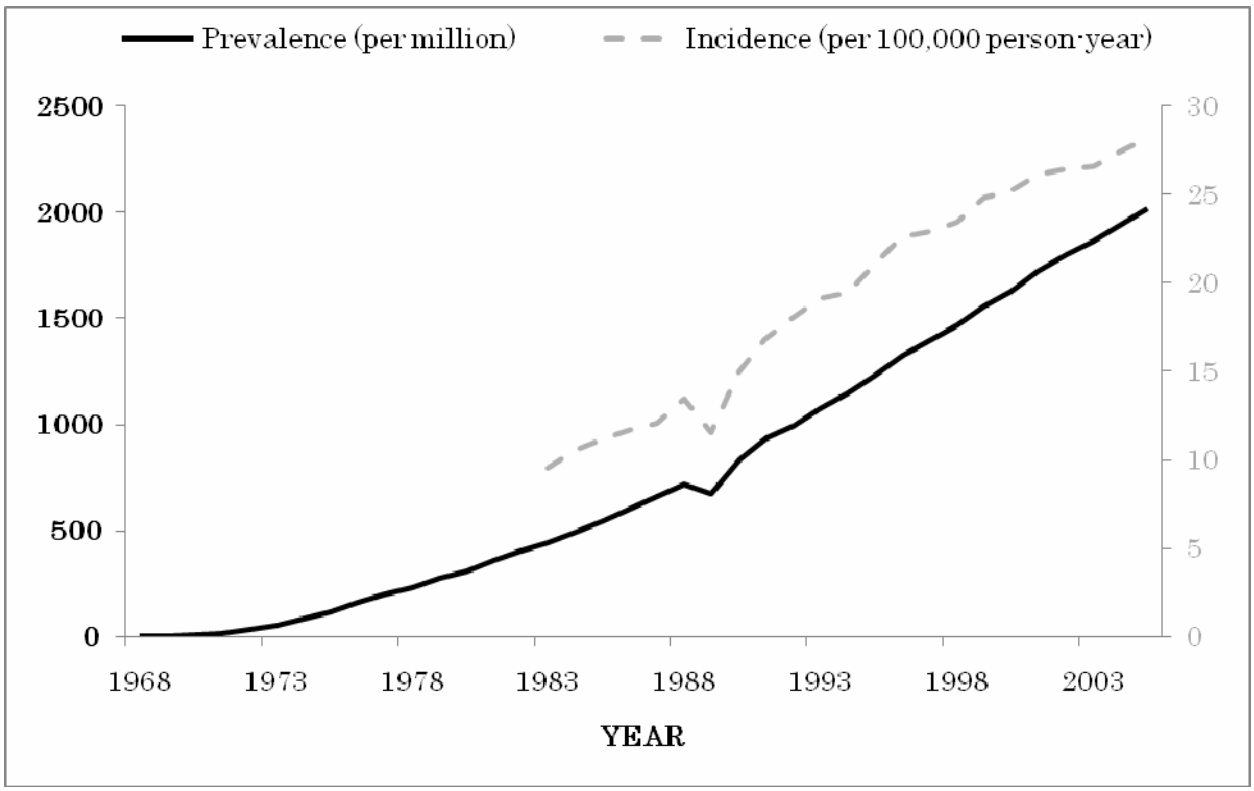
The reason for this rise in ESRD incidence has been discussed extensively by specialists in Japan. The predominant theory is that the growing incidence of type 2 diabetes mellitus (DM) is driving the increase in the number of diabetic nephropathy and ESRD patients. Actually, DM is a national epidemic (it is estimated that 8 million people have type 2 DM and 8 million have glucose intolerance) (MHLW, 2002b). Diabetic nephropathy affects a significant proportion of the ESRD patients in Japan—35% of the prevalent HD patients and more than 40% of the incident HD patients (JSDT, 1999). These data have led to a recently proposed strategy to prevent the development of DM nephropathy under the global chronic kidney disease campaign.

[1] The Survey of Medical Care Activities in Public Health Insurance and the National Medical Care Expenditure produce statistics from insurance claim databases. The data used to calculate hospitalizations for this estimate are those for which renal failure was indicated as the primary diagnosis. Other nondialysis-related hospitalizations by ESRD patients (for whom renal failure could be a secondary diagnosis) may be, therefore, not be included in this estimate. For this reason, we expect our estimate is biased low.

Another explanation for this increase in ESRD is the rapid aging of the Japanese population (Oliver, Ikegami, & Ikeda, 1997). Although DM clearly increases with age, the elderly are reaching ESRD for other reasons, such as renal sclerosis and chronic glomerulonephritis. The role of DM as the primary cause of ESRD appears to be declining among older patients, as DM is sometimes seen as a comorbid condition with other basic causes of ESRD.

The proportion of older people in Japan is expected to peak in about 2040 and decline after that. In the meantime, under current conditions, the number of HD patients is expected to increase, although the increased rate will slow because of shorter life expectancy in older patients. In 2040, people aged 65 years and older are expected to number 36 million, or 33% of the entire population (NIPSSR, 2002). Given these trends, where the number of aged Japanese is very high and growing rapidly, a strategy to prevent or manage hypertension or arteriosclerosis may be a realistic and efficient way to reduce the growth in ESRD patients.

Figure 1. Incidence and prevalence of end-stage renal disease in Japan (1985–2005).



Source: JSDT, 2007

Although the rate of kidney transplantation in Japan is quite low by international standards, its prevalence and incidence have increased considerably over the past five years. The prevalence has increased 29% and the incidence 27%. This increase in transplantation is mainly due to an increase in living donor transplantation (from 79% to 84% between 2001 and 2005 (Japanese Society for Transplantation, 2006)), particularly among family members, which has been facilitated by recent advances in immunosuppressive treatment (Suzuki, Sugisaki, Yoshida, & Yamazaki, 2002). However, despite this rapid increase in transplantation rates, the absolute

number of operations remains very low; fewer than 1,000 patients (less than 2% of total HD patients) receive kidney transplants per year (see transplant section below).

In 2002, Japan had 871 publicly owned dialysis facilities and 2,741 privately owned facilities. These privately owned facilities are typically "not-for-profit," solo practice, tax-paying institutions. Japan's laws do not allow health care institutions to operate for profit. Publicly owned facilities tend to be smaller, treating an average of 51 patients, whereas private facilities treated an average of 68 patients each (Suzuki, Sugisaki, Yoshida, & Yamazaki, 2002).

All dialysis facilities tend to operate during the day and evening, but very few operate around the clock. As the HD population ages and has a greater proportion of retired patients, the demand for night-time dialysis falls. Night-time dialysis (from 6 pm to 9 pm) receives a higher price (3,000 yen or approximately $US23), but anecdotal opinion is that it is not sufficient given the added requirements of providing night-time dialysis. Furthermore, night-time dialysis requires considerably more human resources compared to the nominal increase in reimbursement received.

Human resources to support HD care in Japan

Japan does not limit the number of physicians specializing in nephrology. Among the members of the Japanese Society of Nephrology are 7,273 specialists, 2,442 of whom are board certified. There are 3,800 physicians who are members of the Japan Society of Transplantation. In addition, Japan has nearly 1 million registered nurses and more than 780,000 clinical technicians certified by the government. A Japanese Association of Dialysis Physicians survey reported an average of 1.4 registered nurses and 0.3 technicians per 10 HD patients in outpatient facilities. Registered nurses make up over 80% of the patient care staff in Japanese dialysis facilities (JSDT, 2002).

Most of the office physicians in Japan typically provide primary care (such as internal medicine, pediatrics, dermatology, orthopedics, and obstetrics and gynecology) and are organized as small privately owned solo practices. Whether the physician who provides dialysis care also provides nondialysis medical care is uncertain. Because there is little organized structure regarding who should treat what conditions, patients treated in public and private hospitals are most likely referred to other specialists for much of their nondialysis care. Patients who receive their dialysis in small clinics, on the other hand, may receive much of their nondialysis medical care in the same clinic. But the clinic may make some referrals to other specialists, depending on the types of care required and the access to other specialists. For example, Japan has 8 million type 2 diabetes patients. Endocrinologists see only a small fraction of these patients; the rest are seen mostly by other specialists or office physicians, including generalists, dialysis clinic physicians, gynecologists, and orthopedic surgeons.

Owners of these small private practices earn a higher income than salaried, hospital-employed specialists (anecdotally an average of three times higher, with wide variation). Likewise, nephrologists, if they are employed by a university or a large public hospital, have a fixed salary that ranges from 6 to 12 million yen (US$45,113 to $90,226; PPP 2004) per year. A significant

proportion of physicians also moonlight, and their additional income is estimated to range from 3 to 8 million yen (US$22,556 to $60,150; PPP 2004) per year.

Expenditures

In 2002, Japan's total health expenditure was 7.9% of the gross domestic product (GDP), which was lower than that of most other ISHCOF nations (World Bank, 2005). In contrast, the United States spent 14.6% of GDP on health care in 2002, more than any other ISHCOF country (World Bank, 2005). Per capita health expenditures in the general population are also lower in Japan than in the United States, US$2,139 and US$5,635, respectively (OECD, 2005). Two reasons for this difference in per capita health spending are that surgery is less common in Japan than in the United States and hospitalization rates are also much lower (Ikegami, 1991).

Japan has no comprehensive database on total ESRD expenditures. Based on several data sources for the various treatment modalities (see the Methods section, above), the annual expenditure per ESRD patient in Japan is estimated to be 6 million yen (US$41,681; PPP 2003). This estimate suggests that ESRD expenditures comprised 3.7% of Japan's total health expenditures in 2003 (OECD, 2007). In contrast, the United States spent only 1.8% of total health expenditures on ESRD in 2003 (Hirth, 2007).

Hospitalization

In addition to regular dialysis visits, Japanese HD patients incur about 0.65 hospitalizations per patient year (Pisoni et al., 2004). Admission rates for Japanese HD patients are low by DOPPS standards, but length of stay in Japan tends to be long, partly as a result of so-called "hospitalization for social reasons," when hospitals function as nursing homes providing HD care. However, there is a movement in policy circles to differentiate between acute and chronic care hospitals in Japan.

Although vascular access failure is much less common in Japan compared to other DOPPS countries (unpublished DOPPS data), the relatively lower admission rate is partly due to the waiting list for surgery and procedures in large hospitals. This results in more patients remaining in the hospital and receiving dialysis with a catheter while waiting for access surgery. In small hospitals, on the other hand, vascular access operations are usually performed within one day.

The total hospital charges for HD patients in 2003 (see the Methods section, above) were estimated at 176 billion yen per year (US $1.3 billion; PPP 2003), or roughly 767,270 yen per patient annually (US$5,519; PPP 2003).

Historical development of an egalitarian HD care system in Japan

HD was introduced in Japan about 40 years ago. In 1967, public health care insurance first covered HD care. Though insurance fully covered medical care charges, dependents of the insured had to make a 50% copayment. The price of HD care at that time was so high that many families with ESRD could not afford to make the copayment and patients died without treatment.

In 1972, the MHLW created an out-of-pocket cap that lessened the burden for patients with high cost outlays. This cap system was initially applied only to patients with ESRD and hemophiliacs (it currently also includes AIDS patients). Under this system, the HD patient copayment was only 10,000 yen (US$75; PPP 2004) per month. In addition, the government started certifying HD patients as "disabled," which exempted even this minimal patient copayment for all except the very wealthy. These new policies made HD treatment practically free for almost all HD patients, thereby substantially improving access to HD care. (This system to support patients with expensive medical fees was soon expanded to any type of medical care, but the ceiling was higher, approximately 50,000 to 60,000 yen [US$375 to $450; PPP 2004] per month).

These policies helped introduce and extend HD care to almost all ESRD patients in Japan at a very low cost to patients. Coincident with these finance changes, the government encouraged providers to meet this rapidly emerging demand for HD care. At that time, there were only a small number of nephrologists and most of them worked in large hospitals or university hospitals. To remedy the shortage, the MHLW invited physicians in the private sector to provide dialysis and other medical care to the kidney failure population. As part of these supply inducements, the ministry offered strong profit opportunities to private sector physicians who were willing to provide the appropriate services. For example, the insurers reimbursed dialyzers at the "purchase price" that HD practitioners claimed. Office physicians made significant profit from the difference between the reimbursement and the wholesale price. The average reimbursement price was about 12,000 yen (US$90; PPP 2004), whereas the wholesale price was about 8,000 yen (US$60; PPP 2004). Currently, the reimbursement for a dialyzer is about 3,000 yen (US$23; PPP 2004). Under MHLW's promotion policy, many internists, surgeons, urologists, and others entered this new arena of HD care.

These policy changes produced a situation in which almost all ESRD patients could obtain high-quality HD care without any waiting period and with minimal out-of-pocket charges. The number of HD patients increased by more than five times within 15 years (11.3% compounded growth per year).

Recent changes and current reimbursement system for HD treatment

Total health care spending in Japan increased 8.6% in the five years between 1998 and 2002. However, ESRD expenditures increased at an even higher rate of 14.2% for the same five-year period (1998–2002) (MLHW, 2000, 2004). This is likely a reflection of the increase in the total number of HD patients; prevalence of ESRD has increased by 22% and incidence by 12% for this same interval (JSDT, 2007).

Since its introduction into the Japanese public health insurance system 40 years ago, dialysis has experienced certain financial resource limitations. As discussed above, the reimbursement rate for dialysis was originally set quite high to encourage physicians and clinics to offer these services. However, a PPS payment style was introduced first for HD laboratory services in 1988 and then for dialysis treatment in 1994. The government has been using these prospective prices to reduce the overall payments for ESRD care.

Currently, the reimbursement system for outpatient dialysis has both a PPS component and a fee-for-service (FFS) component. The prospective payment is applied to the technical fee for HD treatment (including payments for staff, physician supervision, dialysate fluid, anticoagulants, saline for fluid replacement, and routine laboratory tests). FFS payments apply to dialyzers (four types with different prices), drugs (including erythropoietin, or EPO), special measurements (such as diagnostic imaging), and biological tests. A survey by the Japanese Association of Dialysis Physicians of 8,000 HD facilities in the private sector showed that, on average, 79% of reimbursements were PPS and 21% were FFS (Sugisaki, 2007). On the other hand, all inpatient dialysis treatments were covered by FFS payment until DPC was introduced. As described above, hospitals choosing the DPC option are small in number and, as a result, the overwhelming majority of hospitals still are paid for inpatient dialysis under FFS according to the master fee schedule.

The recent cost containment policy has led physicians and clinics to cut costs — for example, through a reduction in the number of dialysis facility staff and the use of lab tests. The current policy prohibits dialyzer reuse, but it is possible that this practice may be approved in the future as an additional method of cost reduction. All of these cutbacks have yet to occur to any appreciable extent, but there is considerable fear on the part of physicians that they may ultimately reduce the quality of care once afforded to ESRD patients.

On the other hand, some incentives for high-quality ESRD care still remain because of the relatively high unit price and profit margin for HD compared with treatments for other illnesses. Competition among dialysis facilities also ensures that patients receive good care, as does pressure from the Hemodialysis Patients' Association, whose membership exceeds 50% of HD patients and whose members are well informed of recent technological advancements and policy changes. At least in urban areas, any facility that tries to restrict quality in a way that patients or other physicians could detect would find itself losing patients to other facilities that had not made such practice changes. For example, the patients' association resisted attempts to abolish higher reimbursement rates for longer dialysis times because it was aware that the Japanese Society for Dialysis Therapy (JSDT) and the DOPPS show that longer dialysis time is associated with longevity (Saran, 2006).

In the 1970s and 1980s, 60% of Japanese HD patients under age 60 remained employed after beginning dialysis treatments; this percentage increased to 80% in 1997 (Hidai, 2000). Compared with other DOPPS countries, this employment rate among the HD population is exceptionally high (Fukuhara et al., 2003). Possible explanations for this observation include the increasing prevalence of disability legislation in the workplace, a cultural value that promotes being an active member of society rather than depending on public aid, and the high quality of dialysis care promoted by the government's incentive structure (i.e., higher reimbursement for longer dialysis times) (Hidai, 2000).

Specific aspects of treatment and financing

Prescription drugs

As mentioned above, national health insurance sets the price (payment rate) of prescription drugs through a price list that functions as a formulary of approved drugs. While patients make certain copayments for regular medications, no copayment exists for those related to ESRD treatment. Before the 2006 change in EPO reimbursements, EPO was included in the ESRD medications that did not require a copayment. Each insurance institution has an insurance claims review committee that reviews claims from medical facilities and sometimes refuses to reimburse for what are judged to be "excess" medications or medical care. High-priced drugs, such as EPO, have been frequent targets for the review. Although not officially announced, the insurance claims review committee in each prefecture is anecdotally said to have different allowances for the prescription of EPO. The reimbursement of low-priced drugs, such as iron and vitamins, is rarely refused.

As mentioned above, Japan revises its national fee schedule every two years. In the revision of April 2006, the government imposed price and policy changes to achieve a target reduction of 4% in overall HD expenditures. To achieve this target, payment for the use of EPO was changed from a dose-based payment per patient to a fixed-amount payment per session, regardless of dosage. Other medications were not brought under this amendment. The prospective price for EPO is now 2,900 yen (US$25; PPP 2006) per session, irrespective of the use or dose of EPO. DOPPS II showed that the typical dose of EPO for Japanese HD patients was 5,297 international units per week (Pisoni et al., 2004). Given that the official list price of EPO in Japan is 2,800 yen (US$22; PPP 2005) per thousand units, the average weekly price for a Japanese HD patient's EPO is 11,060 yen (US$86; PPP 2005). At the revised prospective price (8,700 yen (US$67; PPP 2005) for three dialysis sessions per week), the break-even dosage would be approximately 4,167 units per week or a reduction of approximately 21% compared with prior usage.

This 21% reduction applies to patients using EPO; however, facilities receive the prospective payment for EPO (8,700 yen per week) even for patients who do not use the medication. Assuming that these extra funds are used for patients who do receive EPO, the actual impact of this policy is not a 21% reduction in dose for the 85% of EPO-using patients, but a 7% reduction.

It is presumed that the facilities that used relatively low doses of EPO can treat anemia by optimizing their use of iron and are not therefore damaged by this amendment. The advantages of this amendment are that it (1) financially rewards facilities with better quality of care and cost-effective care for anemia and (2) protects quality of care by *not* being bundled into the unit price of dialysis care itself (cost cutting may have led to further cutting of qualified staff, for example).

The committee and the dialysis community expect that this EPO policy change may improve the quality of HD care because HD facilities, it is expected, will make more effort to investigate the underlying cause of anemia, such as gastrointestinal bleeding, and to appropriately use other options, such as iron supplements. Of course, physicians may simply prescribe less EPO, even to patients for whom it is actually indicated, which would leave those patients with higher anemia levels. The DOPPS will track these changes at the level of both processes and outcomes.

Transplantation

From 1964 to 2001, 11,463 kidney transplants were performed in Japan (Japan Renal Transplantation Society, 2003). Relative to the 230,000 Japanese ESRD patients, this is an extraordinarily low transplant level by DOPPS standards, but the current five-year incidence trend for transplantation is comparatively high. Most kidney transplants in Japan are from living donors who are family members of the patient.

Experts from various fields have hypothesized why organ transplant rates are so low in Japan and why so few are from donation after brain death (DBD) donors. Several of their theories stem from spiritual beliefs. For example, some Japanese still subscribe to ancient Chinese beliefs that prohibit people from injuring their own body (even piercing their ears). Others, including members of congress and some physician groups, believe that a DBD donor still contains a spirit. Under this belief system, removing organs from a DBD donor is equivalent to murder. Even today, physicians who perform organ transplantation are sometimes sued for their actions. Other explanations for the low levels of transplantation in Japan relate to more cultural behaviors, such as a lack of volunteerism and a low level of self-determination (Asai, Fukuhara, & Lo 1995).

The government currently does not aggressively or explicitly promote transplantation from DBD donors, probably because of a judgment that a national consensus on brain death has not been reached. This policy holds sway despite a law adopted in 1997 whose intent was to approve brain death as a legal procedure (Japanese Diet, 1997). In addition, the current national health insurance system does not provide reasonable economic incentives to the institutions that identify the consenting DBD donors and that resect kidneys from these donors. For example, health insurance reimburses only 350,000 yen (US$2,630; PPP 2004) for identification of consenting DBD donors and another 350,000 yen for the resection of the donor kidney. Without strong supporting policies, institutions lack incentives to convince families of DBD donors to donate their organs. They run the risk of antipathy from the donor's family members and lawsuits for murder by certain groups who still do not believe in brain death.

All these factors help explain why the absolute number of kidney transplantations in Japan is low. However, there is a movement in Japan to support market-driven policies for health care. In the case of the treatment of dialysis patients, kidney transplantation is certainly a cost-effective alternative that should be considered.

Some have proposed that future transplantations should be limited to those patients who are younger than 50 years of age, i.e., 15.3% of the ESRD population. Currently, kidneys are rationed according to a network for deceased donor transplantation, which places children as the highest priority. Patients who are positive for hepatitis C virus are matched with kidneys that are positive for hepatitis C virus. Priority is then given to recipients who are in the same region as the donor or who may have been waiting a long time for a kidney.

Almost all kidney transplantations are performed in large university hospitals. Only 176 of the 9,239 hospitals in Japan perform kidney transplantation. The average length of stay in the hospital following the operation is 30–45 days. As reported above, there is a waiting list for

surgery in public and university hospitals, i.e., those hospitals performing transplantations. While waiting for the surgery, patients receive preoperative tests. After surgery, surgical practice is to keep patients under observation for a long time. Organs are so scarce in Japan that physicians want to be sure the procedure is successful for the few patients who do receive transplants (Tsuji-Hayashi, 1999).

Patients are not required to share in any costs of transplantation, including costs of medication.

Dialysis

Most ESRD patients receive dialysis at a dialysis facility; 96.1% of these patients receive HD or hemodiafiltration (17.2% receive evening HD care), and 3.7% receive continuous ambulatory peritoneal dialysis (JSDT, 2005), a very low rate among DOPPS countries (Dor, Pauly, Eichleay, & Held, 2007). A very small number (0.04%) receive home HD (JSDT, 2005).

Japan has no national standard for dialysis dose (Kt/V) level or for treatment time. There are also no informal limits or guidelines for adequacy of dose or types of dialyzers used (although reuse of dialyzers is not allowed). Data from both DOPPS I and II show that the average duration of a dialysis treatment is 244 minutes (s.d. 32) (Saran, 2006). According to DOPPS II data, 69.3% of Japanese HD patients have a Kt/V greater than or equal to 1.2 (Dor et al., 2007).[2]

Patients missing or shortening dialysis sessions has been a problem in Japan, although it is much less common than the rest of the DOPPS countries. Even during the big earthquake accidents, patients were transferred to the adjacent prefecture, where other facilities gave rescue HD treatments. This shows that physicians and patients are well aware of the importance of not skipping an HD session. The main reasons for missed sessions are patient boredom with waiting through a long treatment and physical exhaustion. Yet high awareness as described above and current generous reimbursement, with almost no copayment for dialysis sessions for most patients and free transportation to sessions if needed, are not deterrents to missing or shortening sessions.

Trends and outcomes

With MHLW's cost-containment policy, the average price of dialysis in 1979 (about 16 million yen per patient per year) had decreased by two-thirds (5.9 million yen per patient per year) by 1994. Despite this drastic cost-cutting policy over 20 years (1980–2000), Japanese HD care has achieved some of the best outcomes in the world, such as for mortality (crude death rate of 8%-9% and five-year survival of 60%) and high employment rates (Fukuhara et al., 2003). This success is thought to be at least partly due to well-planned reimbursement policies giving financial incentives to facilities for higher quality of HD care, evening HD care, diet instruction, and strict water purification and sterilization (Hidai, 2000).

[2] Among 1,805 DOPPS II prevalent hemodialysis patients. This percentage is weighted to account for varying dialysis unit size.

However, the most striking reimbursement cuts occurred in 2002. With these changes to the reimbursement prices, the government reduced the prices of all items, including physician fees, laboratory examinations, drug costs, dialyzer costs, and patient meals. In total, these fee reductions decreased reimbursements by 8%. This policy change also abolished the system, unique in Japan, of reimbursing higher fees for dialysis sessions lasting more than four hours. Subsequently, the DOPPS showed that longer dialysis time is associated with better patient outcomes (Saran, 2006). The abolition of this reimbursement to promote longer HD time discouraged a practice that many conscientious physicians supported. A JSDT survey demonstrated that the proportion of patients receiving less than four hours of HD treatment has increased from 15% to 22% since the policy change. However, there were fewer instances in which HD treatment time was shortened from four to three hours than from five to four hours (JSDT, 2005).

Just after implementation of the substantial price changes in 2002, the Japanese Association of Dialysis Physicians consulted the think tank of the Japan Medical Association to predict the state of Japanese HD care in 15 years in order to construct a design for HD care (Sugisaki et al., 2004). According to their analysis, at so-called "complex HD facilities" (which have general inpatient wards and HD facilities for both induction and maintenance therapy), the cost-to-charge ratio was already 99.6% in 2001 and 103.1% in 2002. This result indicates that in 2002 some of the complex HD facilities were unable to cover costs for HD care. On the other hand, the cost-to-charge ratio among free-standing HD clinics, which care for relatively less complex patients, was 81.7% in 2002. However, the analysis projected that the margins of even free-standing HD clinics will continue to decline and that their cost-to-charge ratio will continue to rise. This trend certainly does not suggest a financial incentive for practitioners to continue their practice in the community. This report also concluded that in the worst-case scenario, many facilities will stop HD business in the near future if the government continues reducing the payment for HD care. Although free-standing clinics still have some reserves below the break-even point, clinic owners have significant concerns for the future. For example, many non-profit general hospitals are now under pressure, either from the local government or their governing bodies, to be financially independent. Until recently, local governments or founding bodies subsidized their financial deficit, but with the trend that even national hospitals should be financially independent, public hospitals are held financially responsible. In the past, large hospitals used to restrict their HD practice to new and acute care patients, but now they are retaining patients for regular HD maintenance therapy. Free-standing HD clinics, which used to receive all the non-acute and already initiated HD patients, no longer expect the same inflow of HD patients from these larger hospitals.

In October 2006, the government made more reductions in national insurance reimbursement rates, including the payment for HD. According to this amendment, those whose monthly household income exceeds 530,000 yen (US$4,109; PPP 2005) have a copayment of 20,000 yen (US$155; PPP 2005) per month. For those in lower income brackets, the copayment varies between zero and 10,000 yen (US$0 - $78; PPP 2005). The copayment exemption for ESRD patients will soon be terminated and all patients will be responsible for some copayment. It is not clear how far the government will reduce the payment level for HD treatment.

Conclusion

With its population of 127,435,000, Japan has experienced a substantial increase in both the prevalence and incidence of ESRD in recent years. Major factors contributing to this increase are the rapid aging of the Japanese population and the increasing number of patients with diabetic nephropathy.

Under strong initiatives established by the government more than 40 years ago, an egalitarian health care system for HD patients was successfully established and widely diffused across Japan. These strong government initiatives were also successful in bringing private sector physicians of all specialties into the care of ESRD patients. One effect of government initiatives is a community of vibrant private dialysis facilities that currently provide about 80% of HD care in Japan.

In the 1980s, the exponential increase of HD patients and higher medical costs became such an economic concern that the government succeeded in cutting the cost to one-third its previous value over 15 years. Despite this drastic cost-cutting policy, Japanese HD care has retained health care outcomes for ESRD patients that are considered some of the best in the world. Major government actions have included using and manipulating strong reimbursement policies to determine and enforce effective prices for health care services, including care for ESRD patients.

In 2002, the government not only cut overall reimbursement rates drastically but also cut reimbursement incentives for higher quality of care, for example, with the abolishment of policies paying for dialysis treatments of longer duration. As a result, the economic status of private HD facilities has declined to the extent that some facilities have started losing money.

The future of HD care in Japan remains unclear, but health care provider groups and the payers (government and insurers) must work together to reestablish a cost-effective HD care system in Japan, without sacrificing the excellent quality of care that was achieved in the 1980s and 1990s.

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Appendix A: Estimation methods for annual expenditure per ESRD patient

Japan has no available comprehensive data on ESRD expenditures. For this reason, the following methods were taken to obtain an annual expenditure per ESRD patient by estimating dialysis treatment costs, physician office visits, and hospitalization expenditures.

In 2003, the reimbursement was estimated at 4,992,000 yen per HD patient per year (US$35,914; PPP 2003) and 5,825,000 yen per peritoneal dialysis patient per year (US$41,910; PPP 2003) (JSDT, 2006). These reimbursements, shown in the first row of Table A1 include dialysis treatment, physician supervision, EPO, and all other drugs.

To better understand the cost of free-for-service EPO and other drugs, we separated them from the above described payment estimate. Using DOPPS data on the average EPO dose (5,297 units per patient per week), the percentage of DOPPS patients taking EPO in Japan (85%) (Pisoni et al., 2004), and the official list price for EPO in Japan (2,088 yen per 1,000 units), the annual expenditure on EPO per HD patient was US$4,000. At 6% of the total expenditure per HD patient (Lee et al., 2002), drugs other than EPO cost roughly US$3,200 per HD patient per year. These last two calculations do not appear in Table A1.

Hospitalizations for the primary diagnosis of renal disease cost insurance agencies about 767,111 yen (US$5,519; PPP 2003) per patient per year (MHLW, 2004). This estimate includes any fees for physicians in the inpatient setting.

Physicians other than those supervising dialysis treatments or treating inpatients were estimated to cost US$665 per year (OECD, 2006). This is the OECD estimate for physician office visits in the general Japanese population, and we assume that it also applies to the dialysis population.

Table A2 combines the various modality-specific expenditure estimates to derive an average cost across all ESRD modalities. The patient counts are used to derive the weight each modality would contribute to the overall mean. These weights are then multiplied by the cost for each modality and summed to obtain the annual expenditure per ESRD patient in Japan.

Table A1. Estimated annual expenditure for dialysis patients in Japan (2003)

	Expenditure per patient	
Component	**Hemodialysis (US$ PPP)**	**Peritoneal dialysis (US$ PPP)**
Dialysis	35,914	41,910
Hospitalization	5,519	6,640
Other physicians	665	665
Total	42,098	49,215

Table A2. Estimated annual expenditures for Japanese ESRD patients (2003)

Modality	Patient count	Weight	Expenditure per patient (US$; PPP)
Hemodialysis	229,385	0.93	42,098
Peritoneal dialysis	10,300	0.04	49,215
Transplant	8,330	0.03	18,705
Total ESRD	248,015	1.00	41,681

References

Asai, A., Fukuhara, S., & Lo, B. (1995). Attitude of Japanese and Japanese American physicians toward life sustaining treatment. *Lancet, 346*, 356–359.

Dor, A., Pauly, M. V., Eichleay, M. A., & Held, P. J. (2007). End stage renal disease and economic incentives: The International Study of Health Care Organization and Financing (ISHCOF). *International Journal of Health Financing and Economics*, DOI: 10.1007/s10754-007-9024-9

Fukuhara, S., Lopes, A. A., Bragg-Gresham, J. L., Kurokawa, K., Mapes, D. L., Akizawa, T., Bommer, J., Canaud, B. J., Port, F. K., & Held, P. J. (2003). Health-related quality of life among dialysis patients on three continents: the Dialysis Outcomes and Practice Patterns Study. *Kidney International, 64*, 1903– 1910.

Hidai, H. (2000). Need for an incentive-based reimbursement policy toward quality of care for dialysis care for dialysis patient management. *Kidney International, 58*, 363–373.

Hirth, R. A. (2007). The organization and financing of dialysis and kidney transplant care in the United States of America. *International Journal of Health Care Finance and Economics*. DOI: 10.1007/s10754-007-9019-6.

Iglehart, J. K. (1988). Japan's medical care system—part two. *New England Journal of Medicine, 319*, 1166– 1172.

Ikegami, N. (1991). Japanese health care: low cost through regulated fees. *Health Affairs, 10*(3), 87–109. Ikegami, N., & Campbell, J. C. (1995). Medical care in Japan. *New England Journal of Medicine, 333,* 1295–1299.

Japanese Diet (1997). *Organ Transplantation Act* [in Japanese]. July 16, 1997.

Japan Renal Transplantation Society (2003). Renal transplantation: A clinical registration count report 2003 (a follow-up survey) [in Japanese]. *Transplant, 4*(4), 362–368.

Japanese Society for Dialysis Therapy (JSDT) (1999). *An overview of regular dialysis treatment in Japan (as of December 31, 1997)* [in Japanese]. Tokyo: Japanese Society for Dialysis Therapy.

Japanese Society for Dialysis Therapy (JSDT) (2002). *An overview of regular dialysis treatment in Japan (as of December 31, 2000)* [in Japanese]. Tokyo: Japanese Society for Dialysis Therapy.

Japanese Society for Dialysis Therapy (JSDT) (2005). *An overview of regular dialysis treatment in Japan (as of December 31, 2003)* [in Japanese]. Tokyo: Japanese Society for Dialysis Therapy.

Japanese Society for Dialysis Therapy (JSDT) (2006). *An overview of regular dialysis treatment in Japan (as of December 31, 2004)*[in Japanese]. Tokyo: Japanese Society for Dialysis Therapy [CD Rom].

Japanese Society for Dialysis Therapy (JSDT) (2007). *An overview of regular dialysis treatment in Japan (as of December 31, 2005)* [in Japanese]. Tokyo: Japanese Society for Dialysis Therapy. Retrieved March 9, 2007, at http://www.jsdt.or.jp/overview/index.html

Japanese Society for Transplantation (2006). Factbook of organ transplantation in Japan, 2006 [in Japanese]. Retrieved May 22, 2007, at http://www.asas.or.jp/jst/factbook/2006/fact06_03.html

Lee, H., Manns, B. J., Taub, K., Ghali, W., Dean, S., Johnson, D., & Donaldson, C. (2002). Cost analysis of ongoing care of patients with end-stage renal disease: The impact of dialysis modality and dialysis access. *American Journal of Kidney Diseases, 40*, 611–622.

Ministry of Health, Labour and Welfare (MHLW) (2000). *National medical care expenditure 1998* [in Japanese]. Tokyo: Welfare Statistics Association.

MHLW (1993, 1996, 1999, 2002a). *Patient Survey* [in Japanese]. Tokyo: Welfare Statistics Association.

MHLW(2002b). National Diabetes Survey [in Japanese]. Retrieved May 22, 2007, at http://www.mhlw.go.jp.

MHLW(2004). *National medical care expenditure 2002* [in Japanese]. Tokyo: Welfare Statistics Association.

National Institute of Population and Social Security Research (NIPSSR). (2002). *Population projections for Japan: 2001–2050*. Tokyo: National Institute of Population and Social Security Research.

Oliver, A.J., Ikegami, N., & Ikeda, S. (1997). Japan's aging population; implication for health care. *Pharmacoeconomics, 11*, 306–318.

OECD (2005). *OECD health data 2005*. Paris: Organization for Economic Co-operation and Development.

OECD (2006). *Purchasing power parities (PPPs) for OECD Countries 1980–2005.* Paris: Organization for Economic Cooperation and Development. Retrieved April 28, 2006, at http://www.oecd.org/dataoecd/ 61/56/1876133.xls

OECD (2007). OECD statistical profile for Japan – 2006. OECD Statistics v.4.3. Retrieved May 21, 2007, at http://stats.oecd.org/wbos/viewhtml.aspx?query name=321&querytype=view&lang=en

Pisoni, R. L., Bragg-Gresham, J., Young, E.W., Akizawa, T., Asano, Y., Locatelli, F., Bommer, J., Cruz, J. M., Kerr, P. G., Mendelssohn, D. C., Held, P. J., & Port, F. K. (2004). Anemia management and outcomes from 12 countries in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American Journal of Kidney Diseases, 44*, 94–111.

Saran, R., Bragg-Gresham, J.L., Wizemann, V., Twardowski, Z., Saito, A., Levi, N.W., Kimata, N., Gillespie, B. W., Combe, C., Bommer, J., Akiba, T., Young, E. W., & Port, F. K. (2006). Longer treatment time and slower ultrafiltration in hemodialysis: associations with reduced mortality in the DOPPS. *Kidney International, 69*, 1222–1228.

Sugisaki, H., Suzuki, M., Yoshida, T., & Yamazaki, C. (2004). Ground-design in hemodialysis therapy [in Japanese]. *Journal Japanese Association Dialysis Physicians, 19*(3), 468–479.

Sugisaki, H., Ohta, Y., Ohira, S., Onoyama, T., Kuma, H., Suzuku, M., Yamakawa, T., Yoshida, T., Ono, T., Tozawa, S., Miyamoto, T., & Yamazaki, C. (2007). The 10t dialysis practice survey [in Japanese]. *Journal of the Japanese Association of Dialysis Physicians*, *21*(2) (in press).

Suzuki, M., Sugisaki, H., Yoshida, T., & Yamazaki, C. (2002). The 5t dialysis practice survey [in Japanese]. *Journal of the Japanese Association of Dialysis Physicians*, *17*(2), 183–226.

Tsuji-Hayashi Y. Fukuhara, S., Oshima, S., Uchida, K., Green, J., Takai, I., & Maeda K. (1999). Health-related quality of life among renal transplant patients in Japan. *Transplantation, 68*, 1331–1335.

World Bank (2005). 2005 World development indicators. Washington, D.C.: The World Bank Group.

World Health Organization (WHO) (2006). Annex table 1: basic indicators for all member states. In *The World Health Report 2006: Working Together for Health*. Geneva, Switzerland: World Health Organization. Retrieved September 18, 2006 at http://www.who.int/whr/2006/annex/en.