

International Study of Health Care Organization and Financing for renal replacement therapy in Italy: an evolving reality

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Abstract

The Italian national health system funds universal health care through general taxation, but health services are provided by local institutions. This study examines the epidemiology, provision, and funding of renal replacement therapy (RRT) in Italy. In 2001, prevalence and incidence of RRT in Italy were 0.083% and 0.014%, respectively. A 1999 donation law markedly increased renal transplantation rates. Italy spends 8.3% of its GDP on health care; 1.8% is for end-stage renal disease (ESRD) patients, who represent 0.083% of the general population. The reorganization of the NHS requires attention from the health community so that economic and geographic health disparities are not exacerbated.



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Introduction

The characteristics of national health care organizations are inextricably associated with each country's history and traditions, culture and social organization. In the world's most industrialized countries, three main models of health care can be distinguished by the source of their funding (Lameire, Joffe, & Wiedemann, 1999). The first is the public or "Beveridge" model, which is funded by taxation and has a centrally organized national health system (NHS) that relies mainly on public health care providers: the budget for health care expenditure is centrally fixed and competes with the state's other spending priorities. The second model is the "mixed" (or Bismarck) model, which is financed by compulsory premium-based social insurance and leads to a mixture of public and private providers, and more flexible funding. The third, the "private" model, is based on premiums paid by citizens to private insurance companies and leads to a system of mainly private providers in which the law of supply and demand governs health care expenditure; it is almost always constrained by regulation and affected by subsidies.

The NHS of Italy, like systems in many other Western countries (e.g. the United Kingdom, Spain, and Canada), developed from the Beveridge model. However, in Italy, many public offices and services are assigned to local legislative and administrative institutions, i.e. the country's 20 regions, characterized by wide autonomy in managing and purchasing health services. Furthermore, the region-directed funding system is transitioning to one of fiscal federalism (Legislative Decree number 56, February 18th 2000). Under this system, the central government will no longer distribute funds according to the size or demographic structure (e.g., age) of the regional population; fiscal revenues will be shared among regions in proportion to their fiscal capacity and health requirements. By 2013, when the fiscal federalism system is expected to be completely operational, the regions will not be subject to the central government's allocation restrictions. The aim of the reform is to make the regions increasingly responsible for the funding of their own expenditures, which make up the main component of their budget. Although a national equalizing fund is foreseen, the fiscal federalism could appreciably decrease the guarantees of health assistance in those regions that are economically weaker and do not have a strong tax base, particularly those in the south.

Many non-clinical factors influence the organization and management of end-stage renal disease (ESRD) treatment, including patients' education and attitudes, social behavior, doctors' personal beliefs, financial and organizational resources, and national health care policies concerning dialysis and transplantation. Financial factors, particularly the amount of reimbursement for treatment, play a major role in directing and leading the organizational model of renal replacement therapy (RRT); only in countries where the differences in reimbursement relative to cost for the various RRT modalities are inconsequential do other non-clinical factors become prominent in influencing the choice of RRT modality (Nissenson et al., 1993).

In this study, aimed at characterizing the current RRT reimbursement situation in Italy and its likely developments, we analyzed the organization of RRT by examining kidney disease epidemiology, the distribution of ESRD patients by treatment modality and provision, and the funding of RRT modalities.

Methods

This paper is part of the International Study of Health Care Organization and Financing (ISHCOF), a sub-study 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 ESRD patients on hemodialysis and their impact on clinical and other outcomes. The design of the DOPPS has been described previously (Pisoni et al., 2004, Young et al., 2000). 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 published articles, government documents, government web sites, and local medical institutions. When possible, independent validation of the ISHCOF data was performed with external data sources such as national kidney failure registries, World Health Organization reports, the Organization for Economic Cooperation and Development (OECD) database, and published articles. All monetary estimates were provided in national currency units and converted to U.S. dollars with OECD purchasing power parities (PPP) from the year of each figure (OECD, 2006). Due to the small number of investigators and countries in this study, all international comparisons reported here are informal and qualitative, unless otherwise noted.

To estimate the total expenditure per ESRD patient in Italy, several assumptions were made. An average of 139 treatments per patient per year was used to account for incident and deceased patients not completing an entire year of dialysis. The cost for drugs other than erythropoietin (EPO) was assumed to be 55% of the cost of EPO, as reported in a study of the Canadian dialysis cost system (Lee et al., 2002). Estimates for the cost of EPO were determined by multiplying the average DOPPS II dose by the percentage of Italian DOPPS patients taking EPO and the government listed price for EPO (€18.33 per 1000 units). For the estimate of hospitalization costs for non-acute dialysis patients, the number of patients was multiplied by the hospitalization rate reported for DOPPS I patients in Italy (Rayner et al., 2004) and the NHS reimbursement rate per hospital stay of €3,626. Hospitalization costs for transplant patients were included in the transplantation estimates, which assume that a patient in the year of transplantation costs five times more than a patient in the years after transplantation.

Data from De Negri, Formica, and Cavagnino (1997) were used to determine the cost per outpatient maintenance hemodialysis session (including fixed capital, administrative overhead, essential drugs and lab tests, staff time, and supplies, but excluding physician costs and drugs such as EPO, iron and vitamin D).

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

The prevalence and incidence of ESRD in Italy were 0.083% and 0.014%, respectively in 2001, and both have been increasing at a relatively slow rate. Italy has seen one of the slowest increases in its ESRD population among the countries participating in ISHCOF (Dor et al.,

2007), with an average annual change of 2.48% in prevalence between 1997 and 2001 (Conte, 2004). Over the same 5 years, the incidence of ESRD increased at an average annual rate of 4.40% (Conte, 2004), which was about average for ISHCOF countries (Dor et al., 2007). In the 6 years between 1996 and 2001, ESRD incidence increased by 22% and prevalence increased by 19% (Conte, 2004). Among the factors that may have influenced this relatively slow increase in ESRD are a reported Italian focus on chronic kidney disease (CKD), having nephrologists care for patients directly, a practice of using low protein diets, and the use of ACE inhibitors. In addition, it should be noted that the Italian ESRD patients have a relatively low frequency of diabetes both in the incident (17.8%) and in the prevalent (10.3%) population compared to other European countries (ERA-EDTA, 2003). Moreover, like other countries in southern Europe, Italy is characterized by a relatively low incidence of cardiovascular diseases (Locatelli et al., 2000a). The Italian Registry of Dialysis and Transplant (Registro Italiano di Dialisi e Trapianto, RIDT) reports a greater life expectancy for Italian dialysis patients compared to the European average: the probability of survival at 2 years for incident RIDT patients is 77%, whereas it is 68% for ERA-EDTA patients (Postorino, Salomone, & Rosati, 2005). These epidemiological data may partially account for the peculiar trend of the Italian ESRD population, but political and socioeconomic factors such as the ones mentioned above (direct care of CKD patients by nephrologists, the health system organization, dialysis provision and funding, education, and ethical issues) could also be of importance. Finally, the epidemiology of the dialysis treatment is mainly based on renal registry data that do not cover the entire national population in some cases, above all in Europe, and can have problems of data homogeneity and collection that can be source of appraisal errors, particularly when treatment in different nations is evaluated.

It is worth noting that the 2001 prevalence of kidney transplantation in Italy for those with ESRD is the second lowest, after Japan, among ISHCOF countries (0.0207%), even though the Italian transplantation system has dramatically improved over the last decade. Indeed, the incidence of transplantation increased 20% between 2001 and 2004 (from 0.0025% to 0.0030%) (Ministero della Salute, 2004, Postorino et al., 2005). The prevalence of kidney transplantation also made a remarkable increase from 0.0207% in 2001 to 0.0229% in 2004 (Ministero della Salute, 2004, Postorino et al., 2005).

ESRD dialysis patients are treated at both freestanding and hospital-based facilities. While freestanding centers only treat outpatients, hospital facilities also treat inpatients, can have satellite units and are referral centers for the freestanding units, which are usually private. Given Italy's geography and high population density, it is difficult to designate Italian facilities as urban or rural. Overall, in Italy there are 928 facilities, 270 of which are satellite units. The majority of satellite units have limited medical assistance (the Centro ad Assistenza Limitata, or CAL). They are in close relationship with the dialysis centers of public hospitals, but treatment is administered only by nursing staff. In these centers nephrologists supervise by phone or personally whenever needed, but they are not necessarily on site. CALs treat about 14% of all dialysis patients and are located mostly in the northern part of the country. Although there is a relatively high number of satellite units, most patients (53%) are treated at hospital-based centers with an average of 50 patients per hospital-based facility and 19 per satellite unit. Typically, dialysis facilities operate only during the day. Most (630) are public and the remainder (298) are private. Private centers are generally for-profit, but the health system does not discriminate between public and for-profit facilities when making payments. Private centers treat 25% of all

Italian dialysis patients. This occurs mainly in central and southern Italy. Interestingly, regions with a higher prevalence of “private” centers also have a larger number of dialysis centers per million population (pmp) and a lower prevalence of peritoneal dialysis; in most of these regions, peritoneal dialysis is not permitted in private facilities (Conte et al., 1998, Locatelli, Pontoriero, Del Vecchio, & Conte, 2000b, Nissenson et al., 1993).

Italy has 54,303 primary care physicians (PCPs). With a mean of 1,062 patients per citizen, Italy is about average internationally (data not shown). Only in the last 15 years has the Italian government limited the number of students entering academic courses of medicine or attending specialization schools. This is why Italy has about 2,700 nephrologists who see, on average, only 15 ESRD patients each (in addition to caring for nephrology, hypertension and transplant patients and performing vascular access procedures). Approximately 150 surgeons are available to perform transplants. On the other hand, there are only 10,600 dialysis nurses, with a ratio of one nurse for every five ESRD patients. In the general population, the number of nurses *per capita* has been quite stable in Italy since 1993 (5.3 per 1,000 population on average for the period 1993–2003), while it has increased at least slightly in most other ISHCOF countries (OECD, 2005). Moreover, in Italy the rate of nurses per thousand people is much lower than the average of 8.2 observed in the 30 OECD (Organization for Economic Cooperation and Development) countries (OECD, 2005). The situation is likely to worsen because of a recent change in the university system prolonging nursing school and, consequently, reducing the number of graduating young nurses. This is occurring especially in the northern regions. Given this limitation in nurses, the numbers of overall available ESRD staff are barely sufficient. This low ratio does not limit the admittance of patients to dialysis, but it likely hurts patients’ ability to move to other centers (e.g., when traveling). The only waiting lists that exist for care related to ESRD are for transplantation, and, as in all ISHCOF countries, this wait is due to the lack of available organs.

PCPs, nephrologists, and nurses earn relatively low salaries in Italy. The gross annual earning of PCPs, before any deduction for income tax and social security contributions, was about €78,700¹ (US\$92,618; PPP 2005) in 2005. At €71,500 (US\$84,118; PPP 2005), average gross annual income, Italian nephrologists earn only about 34% compared with nephrologists in Canada and the U.S., who are the highest paid in ISHCOF countries (Dor et al., 2007). Of the 12 ISHCOF countries, only Spain and Sweden have lower annual incomes for nephrologists (Dor et al., 2007). PCPs and nephrologists may practice free profession within defined limitations. The average gross annual earning for nurses is about €29,900 (US\$35,638; PPP 2005).

In general, incomes of salaried workers are not that high in Italy; physicians and nurses are not exceptions. According to the 2005 Eurostat report (Eurostat, 2005), the Italian gross domestic product (GDP) *per capita* Purchasing Power Standard (PPS) is 4.8% lower than the mean of the 15 state members of the European Union (EU-15), though in 2000 it was equal to the mean of the EU-15. Moreover, the Italian GDP *per capita* PPS is 24.6% lower than in Canada and 52.1% lower than in the US. So the salaries are low even when the lower GDP is taken into account.

PCPs may attend a maximum of 1,500 patients and they receive a basic capitation rate of €38.62 (US\$45; PPP 2004) per year by the NHS per patient. Moreover, PCPs receive a further

¹ PCP with more than 20 years of service and the maximum number of patients allowed.

compensation computed according to different parameters including number of patients older than 75 years, length of service, and achievement of goals established by the regional and national health authorities. Physicians who work in Italian public facilities are paid a salary that is fixed by a national contract and independent of the number of attended patients; only a small portion of this salary is related to the achievement of goals fixed by the hospital management during budget negotiations. It is of note that in the last 4 years the contracts of physicians working for the NHS have not been updated and have lost value compared to the relative cost of living, although this represents a widespread perception among Italian workers since the introduction of the Euro in 2002. Even nephrologists working in private dialysis facilities are usually salaried.

Expenditures

In 2001, Italy spent 8.3% of its gross domestic product on health care expenditures, which was €1,749 (US\$2,136; PPP 2001) per person per year (OECD, 2004). These expenditures increased by 15% between 1997 and 2001. Of this expenditure, 1.8% was used for ESRD care, with an expenditure of €31,472 (US\$38,427; PPP 2001) per ESRD patient per year and €6,234 (US\$44,242; PPP 2001) per dialysis patient per year. As in many other Western countries, in Italy important improvements have been obtained in the general well-being of the population. However, there are many concerns about the adequacy of available resources and how best to use them. In recent years, overall public health expenditures and those for dialysis have increased at the same rate, and their ratio has largely remained constant. It is worth noting that ESRD patients make up only 0.083% of the Italian population but consume 1.8% of overall health expenditures because ESRD patients are sicker than average and, above all, because treatment is very expensive. Any uncontrolled growth of such spending could eventually represent a significant risk to the stability and sustainability of public finances.

In Italy, 75% of health care is paid for by public funds and 25% by private funds, a division similar to that seen in many other ISHCOF countries (data not shown). More than 90% of the private funds are out-of-pocket payments, whereas only a small portion is paid by private health insurance. Part of these private funds is directed to a subsidiary contribution (the so-called “ticket”) that the patient pays for specialized services or for outpatient diagnostic procedures given by the NHS. Another portion of these funds is used to buy drugs not given by the NHS because they are believed to be of marginal efficacy. In some regions, patients have to pay a fixed amount of money for every drug package they buy, even if these are provided by the NHS. Finally, a part of the funds is directed towards health procedures from private institutions or independent professionals not covered by the NHS (dental or thermal therapies, for instance), for the reduction of waiting times for NHS non-urgent care and services (like surgeon visits and operations, cardiologist visits), or for treatment from a certain physician. A number of rules define who is exempt from copayments for specialized or diagnostic services. People older than 65, children younger than 6, people who are disabled or have a low income, and those affected by chronic diseases (such as ESRD) can be exempt from copayment for drugs and outpatient procedures related to their disease.

The entire population is covered by a single government insurance that is funded through general taxation. While private insurance can be purchased, this does not necessarily cover ESRD care. It covers what could be termed “small risks” or ancillary and supplementary services, such as optical treatments, choice of private provider and treating doctor, upgraded hospital accommodation and luxury services not covered or only partly reimbursed by public systems. Citizens covered by private insurance are few and are generally the wealthy. Nonetheless, all aspects of ESRD care are covered by public health insurance, including acute and chronic dialysis, drugs, and other sickness benefits. Similar to other outpatient services, reimbursement for dialysis treatments is provided by the NHS and is fixed by law (Ministerial Decree of 22 July 1996). Each center is reimbursed according to the outpatient services performed. The payment rates for dialysis differ according to the type and location of treatment (hospitals, CALs, home) (Table 1). In determining payment, the NHS considers the whole service, including the cost of the drugs given during dialysis and the laboratory tests needed for the session. Erythropoietin (EPO) cost is also included in treatment reimbursement. However, some regions reimburse EPO separately from the dialysis session. In any case, the rates appear inadequate considering costs both direct (personnel, materials, maintenance, amortization) and indirect (hotel services and general costs) (De Negri et al., 1997). Moreover, values are progressively eroded by inflation; since the introduction of this system in 1997, only a few regions have updated their dialysis reimbursement rates. Obviously, this is a critical point, since the erosion of profit margins, or even financial losses, especially in private facilities, could lead to a worsening in the quality of dialysis treatment. From this viewpoint, the rates of peritoneal dialysis are particularly low, suggesting that this treatment modality is used below its potential even though it could lead to a reduction in costs.

Table 1. Reimbursement Rates by Dialysis Mode and Facility Type, 2001

Modality	Reimbursement Rates (€) ^a		
	Hospital	CAL ^b	Home
Hemodialysis	155	129	103
Hemodialysis with biocompatible membranes	165	129	103
Hemodiafiltration	232	207	-
Hemodiafiltration with biocompatible membranes	258	207	-
Hemofiltration	258	-	-
CAPD	-	-	46
APD	-	-	55

^a Euros per session of extracorporeal dialysis and Euros per day of peritoneal dialysis.

^b Limited care facility (Centro ad Assistenza Limitata).

Public health insurance can be used to purchase ESRD care in the private sector. As described above, in Italy the system of dialysis providers is mixed; patients are free to receive dialysis in both private and public facilities. However, even if their choice is formally unconstrained, it is greatly influenced by the availability of facilities near their homes. Yet even in regions where private facilities prevail, public facilities provide other services that the private centers often cannot: emergencies, hospitalizations, clinical complications, preparation or revision of the vascular access, diagnostic and therapeutic procedures. The considerable expansion of private freestanding dialysis centers in some areas could not have been possible without the backup support of public hospital centers.

Dialysis patients are not required to share any cost of their treatment; instead, public insurance reimburses caregivers. Primary care physicians are reimbursed mainly through capitation, with a set amount paid in advance according to the number of charged patients and without regard to the nature of treatment given. On the other hand, specialist physicians and dialysis providers are paid entirely through a bundled fee-for-service (bundled payment per treatment) at the time of treatment. These fees cover direct care and ancillary services, as well as prescription drugs.

Hospitals are reimbursed for inpatient expenses entirely through prospective payments, which are fixed for ESRD patients based on underlying diagnosis classifications (DRGs). Direct care, ancillary services and medications are all covered through this method of payment. This system may affect the quality of dialysis care because the payment for associated DRGs in internal medicine and nephrology is quite low relative to costs. The DRG-based reimbursement is particularly insufficient in the case of hospitalized patients on dialysis, since it does not include any additional payment for dialysis treatment performed during hospitalization (Manno & Schena, 1996).

The fact that the cost of EPO is included in the dialysis fee may represent a further problem for the standard of ESRD care. When dialysis rates are limited and increasingly eroded by inflation, the scarcity of resources may induce physicians to reduce their efforts in reaching the recommended hemoglobin targets. This problem would not exist if EPO were reimbursed proportionally to the need of the single patient and separately from the dialysis session.

The rules for the accreditation of both public and private dialysis centers require that each nurse must take care of no more than three patients during the dialysis session. However, dialysis centers face a shortage of nursing staff. Thus, nurses often take care of a larger number of patients (usually four) than that fixed by the accreditation rules. In other instances, because of the shortage of hemodialysis stations, dialysis centers perform three dialysis shifts, sometimes maximizing the efficiency of treatment to reduce the length of the session. This makes it possible to increase the number of patients that can be treated under the same conditions of nursing staff: three shifts of patients are treated by only two shifts of nurses. All these strategies, aimed at saving human resources, can reduce the quality of dialysis, both in terms of both care and safety of the patients and in terms of their clinical outcomes. Indeed, a short dialysis time may be associated with increased morbidity and mortality in dialysis patients, especially if we consider that the dialysis population is getting older and sicker (Saran et al., 2006). In recent years, data from the Lombardy Registry of Dialysis and Transplant (Registro Lombardo di Dialisi e Trapianto, RLDT) demonstrated a trend towards a reduction in dialysis time (Locatelli, Marcelli, & Conte, 1995); this was confirmed by data from the DOPPS showing that in Italy, the mean duration of dialysis session is one of the lowest in Europe (even if partially justified by the lower average body mass index of the Italian population) (Hecking et al., 2004). These possible risks to the quality of dialysis could be reduced if reimbursement policies favoring the extension of treatment time and dialysis centers were encouraged to employ a motivated medical and nursing staff of an adequate size.

Specific aspects of treatment and financing

Prescription drugs

Medications dispensed for ESRD care are controlled by formularies in both the public and private sector and dispensed through pharmacies or directly by dialysis facilities. Physicians alone determine the need for pharmacological therapies. There is no fixed protocol governing the use of medications. All medications, including both EPO and antirejection drugs for transplant patients, are covered entirely by public health insurance. Iron and vitamin D are also covered through insurance, but there is a patient co-payment for multivitamins. The national drug formulary includes compounds of proven therapeutic efficacy (class A), which are provided by the NHS at no charge, and others that are sold over the counter without medical prescription or are of marginal or unclear efficacy (class C). Class C medications, including multivitamins, are paid for entirely by the patient.

The cost of EPO is bundled in the dialysis fee and therefore is covered entirely by insurance and the drug can be obtained through both private and public sources. However, its prescription has a number of restrictions in the pre-dialysis setting. The Agenzia Italiana del Farmaco (AIFA), which determines drug reimbursement rules for the NHS, established that for patients with chronic kidney disease, EPO can be prescribed only after a diagnosis of anemia (hemoglobin less than 11 g/dl) and reduced only when hemoglobin levels exceed 12 g/dl. Predialysis patients need a prescription from a facility approved by a regional health authority to receive EPO.

There are no restrictions regarding the use of iron and vitamin D. The only informal policies pertaining to the use of these drugs are the guidelines of the Italian Society of Nephrology (Fuiano & Zoccali, 2003a,b), but the AIFA is increasingly regulating the use of expensive drugs like calcimimetics, vitamin D analogs and new phosphate binders (e.g. sevelamer and lanthanum carbonate).

Hospitalization

In addition to their routine dialysis sessions, many ESRD patients require inpatient and outpatient hospital visits each year. In 2001, inpatient hospital admissions totaled about 30,000, 16% of which were for problems related to vascular access, according to DOPPS II data. A typical length of stay for a hospital admission is 10 days. According to the DOPPS, an HD patient makes, on average, about six outpatient visits per year for reasons other than dialysis. A specialist physician is primarily responsible for both inpatients and outpatients. Italy has one of the lowest hospitalization rates among the European DOPPS I countries, but this low rate is not accompanied by a lower mortality rate (Rayner et al., 2004). The hospitalization rate is influenced not only by comorbidities but also by other social and organizational factors, such as bed availability, adequacy of medical and nursing staff, family support, diagnostic and therapeutic protocols, and arrangements of financial reimbursement.

Transplantation

As mentioned previously, Italy has the lowest prevalence of kidney transplantation among the ISHCOF countries. There is no rationing of kidneys that become available, and racial, socioeconomic, and demographic differences do not seem to influence the incidence of transplantation. Before the end of the 1990s, the rate of organ donation varied greatly from the north to the south of Italy. In 1998, the mean Italian donation rate was of 12.3 pmp. However, in the north of Italy the donation level (20 pmp) largely exceeded the mean value of other European countries (14.8 pmp); in the south the donation rate was at the bottom of the list (only 5.1 pmp). In order to address this imbalance, in 1999 a national law set a new organization model across the whole country, largely based on the Spanish model (in view of Spain's relatively high donation rate). This model, in conjunction with structural improvements of intensive care units, qualified training courses for transplant coordinators, new rules for donors' expression of will, and national campaigns of sensitization, has allowed an increase in the donation rate across the country, thereby reducing the imbalance between the north and south. The Italian organizational retrieval and transplant system is articulated on four levels: local, regional, inter-regional and national.

In Italy, kidney transplantation activity has produced excellent results in terms of quality (in 2000–2002, overall 1-year survival was 92.4% for the graft and 97% for the patients) and number of transplants per year. During the last few years, a constant increase of organ donations and transplants from deceased donors has occurred in Italy. Indeed, the 10.1 donors pmp of 1995 became 21.1 donors pmp in 2004, thus leading Italy to place below Spain only (34.6 donors pmp) among the largest European countries, such as France (20.7 donors pmp), Germany (13.8 donors pmp), Poland (13.7 donors pmp) and the United Kingdom (12.0 donors pmp) (Ministero della Salute, 2004). In the same period (1995–2004), the number of kidney transplants per year increased from 1,061 to 1,745 and the number of all transplants per year rose from 1,888 to 3,216 (Ministero della Salute, 2004). No remarkable differences in 1-year graft survival have been observed among the Italian kidney transplant centers. However, the number of patients on the waiting list (approximately 6,500) and the waiting time (3.04 years, with a mortality rate of 1.18% per year) call for further action to increase the number of available organs (Ciancio, Venettoni, Mattucci, & Nanni Costa, 2005).

Forty of the 1,300 hospitals in Italy perform transplants. Formal data about the overall mean length of hospitalization for transplantation are lacking. The average hospitalization for a patient after a new kidney transplant is 15 days under normal conditions; when a complication occurs, the mean hospitalization can reach 25 days. Transplant recipients are not required to share in the cost of transplantation in any way. Diagnostic examinations and specialist visits required for being admitted and remaining on the transplant waiting list are completely covered by the NHS, together with the costs of the hospitalization for the transplantation, anti-rejection drugs and post-transplant follow-up visits. The NHS also fully covers the costs for the donor in the case of living transplantation. The Italian law² allows the donation of one organ for transplantation if

² The Italian law (Art. 5 “Codice Civile”) puts some limitations to citizens in freely disposing of their own body. In particular, actions that can lead to a permanent mutilation and/or reduction of body integrity are forbidden. As exception to this norm, the decision of giving a kidney for living transplant is admitted on the conditions of being free, unconditional, and not for profit.

this decision is free, unconditional, reversible, and, above all, not for the sake of profit. For this reason, living transplants are preferentially performed among members of a family even if not consanguineous.

Dialysis

In addition to the typical 15 visits per year made to a PCP by each ESRD patient, an average of 139 visits for hemodialysis are made, totaling a relatively high 5,300,000 visits, taking in account that patients new to dialysis and those who died or are transplanted were treated only for a part of the year. In hospital-based facilities, at each hemodialysis session the nephrologists will visit patients, if needed, update the dialysis schedule and the pharmacological therapy, and prescribe drugs. Patients on peritoneal dialysis and hemodialysis patients treated at CALs or at home are usually visited monthly, unless clinical complications arise. By far, most hemodialysis occurs at an outpatient dialysis unit; 89.6% of dialysis patients receive treatment this way. Almost no peritoneal dialysis occurs at the unit, but 10% of patients receive this type of dialysis at home. The remaining 0.4% of patients receive hemodialysis at home.

On average, each outpatient hemodialysis treatment costs €202 (US\$247; PPP 2001). In public dialysis centers, direct (personnel, materials, maintenance, depreciation) and indirect costs (indirect personnel, hotel services, and general costs) compose nearly 75% and 20% of the estimated price for dialysis, respectively. In particular, the cost for personnel represents 44% and dialysis materials 27% of the total (De Negri et al., 1997). Compared to public centers, private centers can save on general costs secondary to hotel and general services by reducing waste due to excessive bureaucracy that typically affects public management. Moreover, they can acquire materials, equipment, and services from the market without any tender or formality—in some cases directly from their own production, as some chains produce products and services for dialysis.

The Italian national standard for Kt/V level is greater than 1.3 spKt/V and DOPPS II data show a national average of 1.32. These levels are obtained by means of relatively short dialysis times (220 min), not particularly high blood flows (QB 307 ml/min), and dialyzers with an average surface of 1.5m², these being synthetic and/or high-flux in 28% and 42% of cases, respectively (Hecking et al., 2004). While the acceptable range of treatment time is similar to other ISHCOF countries (minimum 180 min, maximum 300 min), the average length of treatment time is one of the lowest of the ISHCOF countries (220 min)(data not shown). This shorter time may be related to the nursing shortage and its consequences mentioned earlier. The DOPPS data also show that Italian patients have lower body mass and thus lower urea distribution volume compared to the average patient in the European DOPPS I countries (Hecking et al., 2004). As a consequence, despite the short duration of dialysis treatment, the depurative indices are on average satisfying and similar to those of other European countries. Despite this, it must be emphasized that in Italy, as well as in the rest of Europe, one-third of patients display Kt/V levels lower than those recommended by the K/DOQI guidelines, and this trend has worsened over time (1998–2000 interval) (Hecking et al., 2004). This finding must be interpreted cautiously, as it could reflect the inability to prolong the duration of dialysis according to the needs of the patients (larger patients, low vascular access blood flow, frequent intradialytic hypotension) due to the limited availability of nurses or dialysis stations.

There are no limits regarding the type of dialyzers used, but Italian law does not allow dialyzer reuse. The majority of extracorporeal dialysis patients are treated with standard hemodialysis (83%); 14% and only 2% of the patients are treated with hemodiafiltration and hemofiltration, respectively. Since convective treatments are more expensive than standard hemodialysis, health care authorities in some regions have limited the diffusion of these techniques by establishing a maximum number of patients per center.

In Italy, compliance with prescribed dialysis treatments is not considered a problem. Indeed, it is unusual for patients to not attend dialysis or end the session before the predefined time and against the advice of the physician. In general, patients trust the dialysis staff; they tend to share a cultural background (ethical and religious values, solidarity, volunteerism, and the family nucleus), which facilitates patient management and adherence to the prescribed therapy.

Trends and outcomes

Certain demographic differences are strongly associated with the incidence of ESRD. Patients age 45–64 years old make up 30% of the ESRD population and those 65–74 make up 31% (Conte, 2004). About 59% of the ESRD population is male (Conte, 2004). The average age for incident ESRD patients (considering all RRT modalities) is 62 years, whereas the mean age of prevalent patients is 68 years (Postorino, 2005). These data are very similar to those of the other European countries in this study, documenting that the Italian dialysis population is, on average, the oldest in Europe (Rayner et al., 2004). The growing proportion of elderly patients mainly accounts for the increase in the number of patients who started renal replacement therapy in Italy. In fact, data from RLDT show that the frequency of incident ESRD patients aged 65 years is significantly and constantly increasing (Locatelli et al., 2004).

Between 1997 and 2001, the percentage of Italian dialysis patients treated in private facilities rose from 10% to 23%. This increase of private activity is associated not only with a reduction of patients treated in public facilities, either hospital-based (from 60% to 53%) or limited care (CALs, from 16% to 14%), but also with a lower use of peritoneal dialysis (from 14% to 10%). In particular, there was a sensible reduction of continuous ambulatory peritoneal dialysis (CAPD) partially offset by the increase of the more expensive automated peritoneal dialysis (APD) that currently accounts for about one-third of peritoneal dialysis treatments. (Conte, 2004).

According to the DOPPS data the gross mortality of hemodialysis patients is 15.4% (Rayner et al., 2004), and is not apparently influenced by race, socioeconomic status, or demographic differences. This finding is similar to that reported by the RIDT: in 2002 the gross mortality of hemodialysis patients was 14.3%, whereas mortality of the whole ESRD population (including transplanted patients) was 10.8%. The most recent RIDT data show a 12.5% gross mortality for dialysis patients, but this datum needs confirmation (Postorino et al., 2005). According to the DOPPS data the adjusted risk of mortality in France, Germany, and Spain did not significantly differ from that in Italy, though was higher in the UK (Rayner et al., 2004).

Discussion

Prevention could play an important role in reducing the need for RRT and, over the last few years, considerable progress has been made in the prevention and treatment of glomerulonephritis (Pozzi et al., 1999) and different stages of chronic kidney disease (Locatelli & Del Vecchio, 1999). However, the changing characteristics of the patients, especially the aging of the population, are not encouraging for the real possibility of reducing the incidence of ESRD. The Italian dialysis population grows by about 4% every year, a rate that (although lower than that of all other ISHCOF countries (Dor et al., 2007)) does not seem to decrease, as also documented by longer-term analyses performed by the RLDT (Locatelli et al., 2004). Furthermore, dialysis patients are also increasingly older and suffering from more comorbidities.

A progressive increase in costs assigned to ESRD treatment represents a direct consequence of this increasing number of patients, arousing much concern as to the adequacy of available resources. Although patients with ESRD represent only 0.083% of the overall national population, they consume 1.8% of the overall health care expenditure. Expenditures for RRT are a burden on public finances, given that RRT patients are exempted from co-payment of outpatient services related to their disease, and, even in those regions where a copayment for drugs exists, many patients are exempted for age and income reasons. This high and growing expense therefore raises problems for the national health budget.

Keeping a check on expenditures for ESRD should involve promoting the dialytic modalities with the lowest cost and social impact, such as hemodialysis performed in limited care centers and peritoneal dialysis. These two treatment modalities, although on average well represented at a national level, are poorly represented in southern-central Italy, where private centers, which find it more difficult to apply these techniques also because of regional laws, are more prevalent.

On the whole, survival after solid organ transplant in Italy ranks among the best for both donation and transplantation. The quality of transplants carried out is above European standards (Venettoni et al., 2004). Nevertheless, the elevated number of patients on the waiting list, often for rather long times, gives rise to the problem of a further improvement in both the procurement process and the use of available organs in order to bridge the gap between offer and demand and reduce the cost of ESRD treatment. As previously reported, efforts are under way to rectify this situation by increasing the number of kidney donors. Italy currently ranks second, after Spain, for organ procurement in Europe (Ministero della Salute, 2004).

While the NHS is the sole payer for ESRD and dialysis in Italy, private HD treatment covers 25% of the demand for RRT in the country. Thus, when it comes to RRT provision, Italy's "public" NHS model is actually a "mixed" public-private sector model. An international evaluation of the relationships between health care systems and RRT found that countries in which dialysis is mainly delivered by public facilities differed from those with "mixed" or private provision because they had lower RRT acceptance rates and ESRD treatment prevalence rates, greater use of home treatments, and a larger proportion of renal transplants (Horl, De Alvaro & Williams, 1999). An adequate portion of privately provided RRT may help demand and thus better satisfy the demand for RRT. However, when health services are entrusted to private companies (especially in a system with low reimbursement rates aimed at containing

costs), there is concern that their incentive to generate income may drive them to cut the cost, hence also the quality, of their services. In order to prevent this risk, some private dialysis networks operating in Italy have applied systems of quality assurance and promoted the application of the most commonly accepted guidelines for dialysis. Although Italy has observed a progressive expansion of private dialysis treatment, data comparing the probability of kidney transplant and clinical outcomes between public and private centers are, unfortunately, lacking.

Reimbursements for dialysis and nephrology related DRGs appear to be seriously inadequate when compared to costs. This insufficiency may result in overuse of dialytic modalities with a better reimbursement/cost ratio (generally those at higher cost), inappropriate charging of services collateral to dialysis, and reduced availability of dialysis resources (materials, drugs, and, possibly, staff), with possible negative reflections on quality of dialysis service and patient outcomes. Establishing shared rules for detection and reimbursement of outpatient services in charge to the NHS is therefore needed. The recent project known as “bricks of the NHS” seeks to address this need; it was launched in 2003 by the Italian government together with regional governments, with the aim of developing the measures needed to balance quality and costs.

The Italian Constitution, at article 32, recognizes health as a basic right of the individual and an interest of the community, to be promoted and protected. On the basis of this warrant, the Italian NHS has managed to join high standards of quality and universally available services (WHO, 2000) with a relatively restrained consumption of resources by paying relatively low prices for some inputs. But the challenge of balancing needs and resources requires increased attention to controlling expenditures and the progressive transfer of competencies and functions from the central government to the regions. Transition toward a more decentralized health care system nonetheless could exacerbate current disparities in the delivery of welfare services between those regions with the highest and the lowest income levels. Such differences might be particularly marked in those sectors either demanding a lot of resources, such as dialysis, or needing coordinating strategies at an over-regional level, such as transplantation. The qualified health care authorities and the nephrology community must pay attention so that this further imbalance will not occur.

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