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Continuum of Therapy in Progressive Renal Diseases (From Predialysis to Transplantation): Analysis of a New Organizational Model

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In the aging of Western populations, decreased mortality is counterbalanced by an increase in morbidity, particularly involving chronic diseases such as most renal diseases. The price of the successful care of chronic conditions, such as cardiovascular diseases or diabetes, is a continuous increase in new dialysis patients. However, the increased survival of patients on chronic renal replacement therapies poses new challenges to nephrologists and calls for new models of care. Since its split from internal medicine, nephrology has seen a progressive trend toward superspecialization and the differentiation into at least 3 major branches (nephrology, dialysis, and transplantation), following a path common to several other fields of internal medicine. The success in the care of chronic patients is owed not only to a careful technical prescription, but also to the ability to teach self-care and attain compliance; this requires good medical practice and a sound patient-physician relationship. In this context, the usual models of care may fail to provide adequate coordination and, despite valuable single elements, could end up as an orchestra without a conductor. We propose an integrated model of care oriented to the type of patient (tested in our area especially for diabetic patients): the patient is followed-up by the same team from the first signs of renal disease to eventual dialysis or transplantation. This model offers an interesting alternative both for patients, who usually seek continuity of care, and for nephrologists who prefer a holistic and integrated patient-physician approach.
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Successful therapy, especially for chronic diseases, is the result of 2 elements: correct diagnosis and prescription, and patient compliance. This apparently trivial sentence summarizes the link among good medical practice, education, compliance, and the patient-physician relationship.[1-9]

The result of increased life expectancy, mainly owing to the decrease in cardiovascular mortality, has been an overall increase of morbidity in the general population.[10] Chronic kidney diseases (CKD) can be considered as paradigmatic of what has been called, in the case of chronic health failure, a medical hydra—a mythologic monster whose heads (3 to 7 according to the legend) regrow and multiply once cut.[11] As expressed in a recent editorial, the price to be paid for the extraordinary success of renal replacement therapy (RRT) is its development up to a threshold that economically endangers its further development, with the risk of going back to rationing dialysis.[12,13] Conversely, the solution of technical problems linked to the management of dialysis sessions and to chronic support therapy has raised new problems, the first of which is noncompliance. The problem of

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Table 1 Features of the Main Patient-Physician Interaction Models and Their Most Important Practical and Organizational Consequences

Interaction Model	Type of Relationship	Features	Communication	Example of Organization
Hippocrates	Paternalistic, static The focus is on the doctor The doctor prescribes the best care based on his opinion of the patient	Holistic The physician takes care of the patient in a setting of mutual trust; the patient transfers the weight of his disease to the physician	Aimed at making the patient trust the physician and accept the care; in the nature of the relationship the best choice of the doctor is implicit	The physician explains the aims and reassures the patient of the feasibility of care; he reschedules the patient in a short time to stress the importance of the best care
Moses Maimonides	Paternalistic, dynamic The focus is on the doctor The doctor prescribes the best care, as far as he knows, and suggests eventual alternatives	Holistic The physician takes care of the patient in a setting of mutual trust; the patient transfers the weight of his disease to the physician	Aimed at making the patient trust the physician and accept the care; the alternative options of care are explained to the patient, who has to understand the different possibilities of care	The physician explains the aims and reassures the patient on the feasibility of care; the different options are clarified and the choice of the patient to follow a line of care has to be confirmed over time; he reschedules the patient in a short time
Medicine as office	Self-determination of the patient The focus is on the patient The doctor prescribes the best care	Technical The patient is free to choose what to do with his/her own life; the weight of the choice is on the patient, the patient decides and asks for a specific act of care Continuity of care is not part of the model	Aimed at understanding what to do and how to do it; reasons and reassurances are not part of the relationship; the patient meets the doctor, seeking care and choosing the referral person	The physician explains several details of the aspects of care. Because the choice to follow the care is up to the patient, the doctor is not interested in further follow-up evaluation and the patient autonomously chooses to continue the care
Therapeutic alliance	Alliance between different individuals of comparable value The focus is on the relationship Patient and doctor tailor the best feasible care according to the opinions of both parties	Holistic and tailored The physician and patient interact to get the best possible results in the specific case; the trust is mutual but the weight of the choice is mainly on the patient Continuity is the hallmark of the model	Aimed at identifying the optimum pragmatic balance between the best care, as far as the physician knows, and the specific needs and quality of life of the patient; it is a mutual exchange of information and suggestions	Both parties tailor the care to the individual needs: the alliance may require a significant initial time investment, with frequent contacts in the first period, to modulate the care according to the patient's needs Progressive autonomy may be gained by the patient

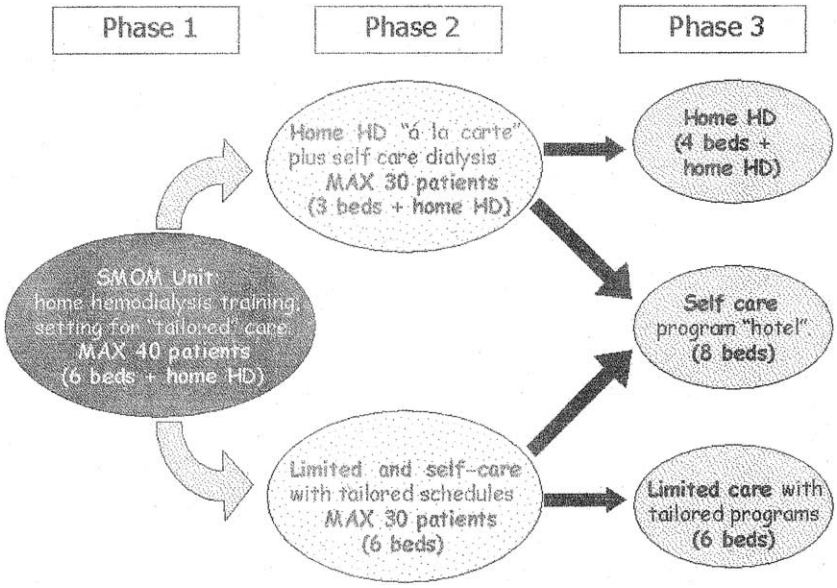

Figure 1 Evolution of the SMOM unit. Phase 2 started in May 2001, phase 3 will start in September 2004.

noncompliance, shared by most fields of internal medicine involved in the care of chronic diseases (from human immunodeficiency virus to diabetes or hypertension), has shown that correct prescription is not synonymous with efficacious care. In the latest edition of Harrison's Principles of Internal Medicine,[14] the internist's bible, an ever greater number of pages is dedicated to compliance, a fundamental part of therapy.[15-17]

Noncompliance has been studied extensively in nephrology as a cause of the failure of chronic therapies (in particular, diet in the case of predialysis follow-up evaluation), as a reason for frustration in trying to achieve adequate dialysis, and as a main cause of renal graft failure.[18,20] The importance of noncompliance casts light on the relationship between patient and physician, a significant factor in optimizing therapy and improving the quality of life.[21,22] This is the reason why an increasing amount of space is being given to discussions of the global care of patients in important internal medicine books and journals.[1-9,14-17]

Attention to the models of patient-physician interactions is not only an interesting philosophic complement to the education of a humane doctor, but is also the basis of the organization of the health care system, as discussed later.

Models Of Patient-Physician Interactions As The Basis For Health Care Policies

There have been remarkably few models of patient-physician interactions in the history of medicine. In the European tradition, 4 models summarize the history since Hippocrates. In biology, the preservation of protein structure over time testifies to its biologic importance. Similarly, in behavioral science, the preservation of a role testifies to its importance in the vital texture of society.[23] The most important features of the 4 main models are reported in Table 1 together with some practical consequences, for example, in the case of choice of diet in CKD.

A holistic model, as opposed to a model of patient self-determination, requires different hospital structures and medical approaches. Self-determination, in which each medical act is discussed singularly by an expert or bought by a patient, requires hospitals as offices. Continuity of care is not a hallmark of this model, in which chronic therapies are seen mostly as a series of separate acts, each requested by the patient.

The hospital as health factory has a counterpart in the hospital as home or monastery, where soul and body are cared for together within an individual and unique patient-physician relationship; this probably is easier to find in a Mediterranean country where the long-lasting tradition of medicine as a mission has not been forgotten completely.[24,25] Continuity of care is a crucial point in such a model: a complex relationship between patient and caregiver is an important part of the therapy that is seen as a history more than as the sum of single elements.

The models are not necessarily antithetical and they may coexist in the care of a single patient (eg, a patient who needs to begin dialysis and whose vascular access is created by an expert but who is followed-up throughout all phases by the usual caregivers). This provides the possibility for each patient and each physician to look for the best interaction.

From Theory To Practice: A Project Of Continuum Of Therapy In Progressive Renal Diseases

The Nephrology Center of the University of Turin (Ospedale Molinette) consists of several units: nephrology (ward, day

Table 2 The Outpatient Units: Main Characteristics of Treated Patients

SMOM Unit	Via Chiabrera Unit
Usual caregivers: nephrologists (with nephrologists in training)	Usual caregivers: nephrologists in training (with supervision)
Time per control: 30-45 minutes	Time per control: 15-30 min
Point of care in center	Link to the hospital for tests
Results of urgent tests arrive at the unit by fax in 4-6 hours, daily medical supervision of urgent tests	—
Day-service in center	Link to day-service
Diet revision in center	Prescription of diet, performed in another setting
Nursing staff in center	No nursing staff
Maternage for dialysis choice: nurses take patients to the SMOM dialysis ward and to the PD unit	Transfer to the SMOM unit for severe ESRD
Vascular access care	—
Diabetic patients, types 1 and 2	Elderly patients; diabetic patients, mainly type 2
Patients with severe kidney failure, work-up for pancreas, kidney, and kidney-pancreas transplantation	Patients with mild to moderate kidney failure
Immunologic diseases	—
Pregnancies	—
Usual frequency of controls: from once/y (stable patients, no renal function impairment) to once/wk (predialysis phase; last month of pregnancy)	Usual frequency of controls: from once/y (stable patients, no renal function impairment) to every other mo; higher frequency for specific problems
Point of discussion of critical cases	Point of discussion of critical cases
Organization of the pretransplant pathway (pre-emptive kidney-pancreas and pancreas)	Transfer to the SMOM unit for the start of the transplantation pathway
Open every morning, nurses: 8 AM to 4 PM, dialysis nurses respond until 11 PM	Open 3 afternoons/wk: 2 PM to 6 PM
389 controls from January to June 30, 2003*	454 controls from January to June 30, 2003*
Open 12 mo/y	Closed in August
266 patients (with clinical charts)	478 patients (with clinical charts)

NOTE. exceptions to the indications of the type of patients treated are possible, mainly for logistic reasons, the 2 units are situated in distant parts of the city.
Abbreviations: ESRD, end-stage renal disease.
*Assessment according to the agendas.

hospital, day service, outpatient units), kidney transplantation (about 100 transplants per year, with ward, day hospital, and outpatient unit), and dialysis (hospital hemodialysis, 2 satellite units for limited care and self-limited care, home hemodialysis, peritoneal dialysis). The number of chronic patients ranges from 195 to 210.

The present study focuses on an out-of-hospital dialysis unit named for the Sovereign Military Order of Malta (SMOM). SMOM, in 1971, donated a building for the first self-care dialysis in an out-of-hospital setting in Italy and, as far as we know, in Europe, as well as for training for the first Italian home hemodialysis program.[26,27]

After 2 decades of activity, home hemodialysis was abandoned almost completely in the early 1990s. Self-dialysis was moved to a larger area where, also owing to aging of the treated population, it progressively lost its initial approach, becoming a treatment with limited medical care and with progressively limited patient involvement. Consequently, in October 1998, the SMOM unit had only 15 patients, 6 at home and 9 in the center; in the previous 2 years, 2 patients had been trained for home hemodialysis and the unit survived only because it was flexible enough to offer some space for unconventional out-of-hospital dialysis.

The initial idea to restart a home hemodialysis program (while also improving the peritoneal dialysis program) was based on its positive clinical and rehabilitation history and the need to reduce overcrowding of the hospital wards; in fact, patients and physicians in our area were almost faced with the earlier-mentioned risk for going back to rationing dialysis.[12,13] The final result was the reorganization of a whole network of care, oriented toward a continuum of follow-up of single patients more than toward specific care of a single disease or disease phase. The continuum of care project started from this direct, on the spot experience and developed in a stepwise fashion:

1. The restart of home hemodialysis was preceded by a marketing analysis. Because our conventional program did not attract patient interest, we decided to offer a very flexible tailored program that also was open to patients willing to be treated at home but with clinical and psychologic conditions usually considered as contraindications for home dialysis.
2. The presence of a dedicated physician was considered an important factor for the safe implementation of the chosen policy. However, the small number of patients

Table 3 Consultant Network (Common to All 3 Phases of Care, From Predialysis to Transplantation)

	Reasons and Frequency	Type of Interaction
Common visits, with nephrologist and consultant		
Urology	All urologic and andrologic problems from renal failure to transplantation; once monthly	Common outpatient service, with urologist and nephrologist, one referral urologist
Diabetology	All metabolic problems of diabetic patients; strict cooperation for long-term problems; common decisions for counseling on the transplant pathway; nephrologist in training once weekly in the diabetic care unit to take on new patients, other frequencies on demand	Common visits; discussion of cases; direct referral; 2 main referral diabetologists (one for diabetic foot)
Endocrinology	All endocrinologic problems from renal failure to transplantation; every 2-3 months for nonurgent cases; scheduling in endocrinology for urgent problems	Visits in the SMOM unit; one referral endocrinologist
One referral consultant; common visits on demand		
Neurology	All neurologic problems from renal failure to transplantation	On demand; common consultations when required; case discussions
Gynecology	All gynecologic problems from renal failure to transplantation; pretransplant evaluation	On demand; common consultations when required; case discussions
Dermatology	All dermatologic problems from renal failure to transplantation; pretransplant evaluation; Routine: one patient/wk	On demand; common consultations when required; case discussions
Vascular surgery	Mainly for peripheral vascular diseases, from renal failure to transplantation; vascular access surgery is performed by the nephrologists	On demand; common consultations when required; case discussions
Referral to a unit or service: dedicated waiting lists		
Cardiology	Standard surveillance (once or twice yearly, pretransplant work-up); urgent controls on demand; routine: one patient/wk	Visits, EKG, and echocardiography in the same setting.
Myocardial scintiscan	Once yearly to every 2 years for dialysis patients; at start of dialysis in all cases; urgent controls on demand; routine: one patient/wk	Common discussion of cases on demand or every 4-6 mo
Radiology	Basic package: abdomen, thorax, and bones; abdominal and thyroid ultrasounds; routine: one patient/wk	Common discussion of cases on demand
Nuclear medicine	Radioisotopic clearance in dialysis patients with residual function; survey after graft; frequency of controls on demand	Preferential waiting list; discussion of cases once monthly on average

NOTE. Other consultations are organized on demand, favoring a stable consultant or small team whenever possible.
Abbreviation: EKG, electrocardiogram.

Table 4 Predialysis Care: General Schedule of Biochemical and Imaging Tests

Urea and creatinine clearance + proteinuria (assessed on 24 hours urine; Cockroft or MDRD formulae if urinary collection is not possible; radioisotopic clearances in selected cases)	Every other month; monthly in the case of low-protein diets (urea urinary excretion) or nephrotic syndrome; every 15 days in case of severe renal failure (GFR <15 mL/min); weekly during the start of dialysis
Urinalysis + urinary sediment (microscopic urinalysis is performed in the nephrology laboratory by nephrologists in training, under supervision)	Monthly; higher frequency in case of relapses of immunologic diseases or pyelonephritis
Urine culture	Every other month; higher frequency in case of urinary symptoms or pyelonephritis
Abdominal ultrasound (plus renal arteries color Doppler ultrasound)	Once yearly or according to symptoms (renal artery Doppler in case of worsening of renal function)
Vascular Doppler ultrasound (carotid arteries, abdominal arteries, peripheral arteries)	At least once in the follow-up period, frequency depending on the clinical situation (eg, aortic aneurysm, hypertension, stroke, severe dyslipidemia, and so forth)
MAG3 renal scintigraphy	At the start of follow-up evaluation; every 1-3 years or in case of sudden worsening of renal failure, pyelonephritis, or renal vascular events
DMSA renal scintigraphy	
Cardiologic evaluation (including cardiologic visit, EKG, echocardiography, thorax radiography)	Once yearly; more frequent in patients ≥60 years old or with cardiovascular events or on demand (symptoms or indications from the cardiologist consultant)
Myocardial perfusion SPECT	Once in follow-up period in the predialysis phase or as a part of pretransplant work-up; otherwise on demand
Other blood tests	Monthly: Na, K, HCO_3^-, Ca, P, complete blood cell count (weekly in the late predialysis phase); Every other month: serum albumin, ferritin; HbA1c (diabetics), uric acid, hepatic enzymes Twice yearly: serum protein electrophoresis, CRP, sedimentation rate, iPTH (higher frequency < 200 ng/mL), total cholesterol + HDL, triglycerides (higher frequency in dyslipidemia), vitamin B_{12} folic acid, homocysteine, PSA (men >50 y) Once yearly: TSH On demand: hormonal profile: plasma renin activity, aldosterone, gonadal steroids, prolactin in specific cases

NOTE. Serum creatinine ≥ 3 mg/dL, creatinine clearance < 25 mL/min. The basic schedule is modified depending on the clinical situation and patient preferences.

Abbreviations: MDRD, modification of diet in renal disease; GFR, glomerular filtration rate; EKG, electrocardiography; SPECT, single-photon emission computed tomography; CRP, C-reactive protein; iPTH, intact parathyroid hormone; HDL, high-density lipoprotein; PSA, prostate-specific antigen; TSH, thyroid-stimulating hormone.

did not justify such an investment. Therefore, the outpatient activity for diabetic and predialysis patients, run by the nephrologist in charge of the ongoing program, was transferred from the hospital to the SMOM. The policy was widened progressively to early referral of patients with CKD.

3. The close relationship with the predialysis phase helped to increase the pool of dialysis patients quickly (presently 50-55), with rapid transfer to the transplantation pool.
4. The progressive development of tailored dialysis schedules also interested patients who theoretically were suitable but did not have the ability to perform this kind of treatment. Thus, a new, very flexible, and tailored program of self-care dialysis was designed (Fig 1).
5. The growth of our outpatient care unit, mainly dedicated to diabetic patients, led to a close relationship with one of the most active Italian pancreas and pancreas-kidney transplantation centers (Pisa).[28] This in turn gave new impetus to the outpatient care unit for diabetic patients, where the tests required for the waiting list were organized.
6. The growing pool of dialysis patients and of patients wait-listed for pancreas-kidney or pancreas grafts led to the organization of posttransplant care, so as to continue the follow-up evaluation after the graft.

Table 5 Data of the 27 Patients Followed-Up in the SMOM Outpatient Unit Who Started RRT During January 2002 to June 2003 (Ordered According to Referral Time)

Patient	Age	Sex	Nephrology Referral	End-Stage Renal Disease	Start of RRT	Type of RRT	Comorbidities	Reasons for Choice
1	52	F	30/6/77	PNC	28/3/02	HHD	None; severe hypertension corrected by dialysis	Tailored treatment at home; wish for self-care
2	59	M	15/6/83	Vasc-Int	3/2/03	SMOM HD	None	Continue therapy in the previous setting; tailored programs
3	38	F	3/10/89	Diab	23/7/03	SPK graft	Type 1 diabetes	Preemptive transplantation
4	72	M	15/6/91	Diab + NAS	2/5/02	PD	Type 2 diabetes, hypertension, vasculopathy, Bowen disease, ischemic cardiopathy	Soft treatment at home; wish to continue self-care with the help of his-wife
5	46	F	15/5/92	FSGS	20/5/02	Self-care HD	Asthma, morbid obesity, hypothyroidism, severe nephrotic syndrome	Continue therapy in the previous setting
6	67	F	11/5/94	Diab + NAS	25/1/03	PD	Type 2 diabetes, obesity, hypertension, vasculopathy, ischemic cardiopathy	Soft treatment at home; not accepting hospital care
7	70	F	20/6/94	NAS	21/8/03	SMOM-HD	Hypertension, hyperthyroidism	Continue therapy in the previous setting
8	81	F	16/12/94	Diab + NAS	1/7/02	PD	Type 2 diabetes, hypertension, vasculopathy	Soft treatment at home; wish to continue self-care
9	41	M	15/6/95	Diab + NAS	15/7/02	Pancreas graft	Type 1 diabetes, blindness	Prevention of long-term diabetes complications
10	81	M	22/8/95	Diab + NAS	1/1/02	PD	Diabetes, vasculopathy, ischemic cardiopathy	Soft treatment at home with the help of his wife
11	72	M	15/5/96	Diab	16/8/02	Hospital HD other center	Type 2 diabetes, obesity, hypertension, vasculopathy, prostate carcinoma	Standard hospital treatment
12	46	F	4/6/96	Diab	21/4/03	Pancreas graft	Type 1 diabetes, HCV-positive hepatopathy	Prevention of long-term diabetes complications
13	81	F	15/1/97	NAS	Planned Sept-2003	Hospital HD in other center	Vasculopathy, hypertension, stroke reliquates	Standard hospital treatment, presently: late predialysis phase
14	48	M	15/6/97	Diab	23/4/03	Pre-emptive kidney graft	Type 2 diabetes, ischemic cardiopathy, hypertension, severe nephrotic syndrome	Kidney graft performed in a stepwise approach to pancreas-kidney transplant
15	67	F	30/6/97	Diab	15/10/02	PD	Type 2 diabetes, hypertension, vasculopathy	Soft treatment at home; wish to continue self-care

16	50	M	30/6/97	Diab	20/12/02	Hospital HD	Type 1 diabetes, hypertension, vasculopathy, severe nephrotic syndrome	Standard hospital treatment, refusing transplantation or self-care, low compliance
17	55	M	15/8/97	Diab + NAS	20/7/02	SMOM-HD	Diabetes (pancreasectomy), hypertension, vasculopathy, neuropathy	Continue therapy in the previous setting, tailored programs; Waiting-list for kidney pancreas graft
18	61	M	15/6/98	Diab	30/7/02	Self-care HD	Type 2 diabetes, vasculopathy, ischemic + valvular cardiopathy	Initial choice of HHD; partner not available, shift to self-HD
19	66	M	15/1/99	Diab	25/5/03	Hospital HD in other center	Type 2 diabetes, morbid obesity, hypertension, ischemic cardiopathy, respiratory insufficiency	Standard hospital treatment
20	42	F	7/6/99	Diab	5/2/03	Preemptive SPK graft	Type 1 diabetes	Preemptive transplantation
21	57	M	1/10/99	Diab + NAS	9/5/03	Hospital HD	Type 2 diabetes, hypertension, vasculopathy, ischemic cardiopathy, pancreas neoplasia	Standard hospital treatment
22	36	M	15/6/00	IgA-GN	7/11/02	Self-care HD	None; severe hypertension corrected by dialysis	Initial choice of HHD; partner not available, shift to self-HD
23	67	F	15/9/00	Diab + NAS	1/5/02	Hospital HD other center	Tuberculosis, type 2 diabetes, hypertension, HCV positive	Standard hospital treatment
24	75	F	1/2/01	Diab + NAS	27/7/03	PD	Type 2 diabetes, hypertension, vasculopathy, ischemic cardiopathy	Soft treatment at home; wish to continue self-care
25	64	M	7/2/01	NAS	Planned Sept–2003	Hospital HD	Type 2 diabetes, hypertension, vasculopathy, HCV positive	Standard hospital treatment; no interest in self-care, low compliance
26	41	M	12/2/02	Diab	15/04/03	SPK graft	Type 1 diabetes, hypertension, neuropathy	Preemptive transplantation
27	49	F	15/10/02	Diab	6/5/2003	Pancreas graft	Type 1 diabetes, systemic vasculitis	Prevention of long-term diabetes complications

Abbreviations: F, female; PNC, chronic pyelonephritis/interstitial nephritis; HHD, home hemodialysis; M, male; Vasc-Int, vascular interstitial; HD, in-hospital dialysis; Diab, diabetic nephropathy; SPK, simultaneous pancreas-kidney; NAS, nephroangiosclerosis/ischemic renal disease; FSGS, focal segmental glomerulosclerosis; HCV, hepatitis C virus; GN, glomerulonephritis.

Table 6 Main Clinical and Referral Data of the 24 Patients Being Treated in the SMOM Unit in August 2003 (According to Age)

Patient	Sex	Age	RRT* (y)	End-Stage Renal Disease	Referral; Notes	Dialysis Schedule (h or sessions/wk)	Type of Dialysis	Kt/V	Residual Renal Function†	EKRc mL/min[55]	Comorbidities
1	M	25	4.6	SLE	Hospital ward; integrated care home dialysis and SMOM	2 h–5/w 3 sessions at home, 2 in the SMOM unit	BHD	0.69	—	13.5	SLE, hypertension, cardiopathy
2	F	33	25.1	MPGN	Previously on home hemodialysis; in SMOM unit after failure of second kidney graft (grafts: 12/2/81–15/10/87)	3 h 45 min–3/w	BHD	2.04	—	20.5	HCV + long follow-up period
3	M	33	5.5	PNC	Hospital ward	4 h 45 min–3/w	HDF	1.62	—	16	None
4	F	35	1.9	GN	SMOM outpatient unit	3 h–2/w	BHD	1.15	3.4	9	None
5	M	37	5.8	DIAB	SMOM outpatient unit	2 h 30 min–6/w	BHD	0.81	—	18.5	Type 1 diabetes, neuropathy, severe visual impairment
6	M	39	21.1	FSGS	Patient's request after he dropped out of transplantation; previous dialysis in other self-care unit; 3 previous kidney grafts (1985-1989-21/5/97)	3 h–4/w	HDF	1.19	2	17	Long follow-up period, vasculopathy, severe nephrotic syndrome
7	F	44	5.7	NN	Transfer from other center	4 h–3/w	BHD	1.14	—	12.5	None
8	M	44	3.0	PKD	Day hospital; SMOM outpatient unit	4 h–3/w	BHD	1.42	—	14.5	Thyroid neoplasia and 2 septic episodes after start of dialysis
9	F	46	15.4	SLE	Previous CAPD; in SMOM unit after failed graft (data)	3 h 45 min–3/w	BHD	1.57	—	16	Active SLE
10	F	47	4.6	MPGN	PD (functional failure)	4 h 45 min–3/w	BHD	1.63	—	16.5	Severe hypertension before optimization of treatment
11	M	49	22.0	MPGN	Hospital ward, came to the SMOM for daily dialysis; previous kidney graft (03/01/93)	2 h 30 min–6/w	BHD	1	—	22	Long follow-up period, vasculopathy, ischemic cardiopathy
12	F	51	3.4	IgAN	Day hospital	3 h 30 min–4/w	AFB	1.3	—	18	Neoplasia; metabolic encephalopathy after start of dialysis
13	M	52	20.7	MPGN	Hospital ward, came to the SMOM for daily dialysis; 2 previous kidney grafts (15/5/84–1/5/96)	2 h 30 min–6/w	BHD	0.92	—	20.5	Vasculopathy, long follow-up period, thyroid neoplasia
14	M	53	6.8	IN	PD (peritonitis); hospital ward	4 h 45 min–3/w	HDF	1.43	—	14.5	None

15	F	54	3.7	AA	Day hospital; SMOM outpatient unit	4 h 30 min–3/w	BHD	1.66	—	17	Systemic amyloidosis
16	M	55	1.1	DIAB	Day hospital; SMOM outpatient unit	4 h–3/w	BHD	1.42	1	14.5	Secondary diabetes, neuropathy, severe visual impairment, malnutrition
17	M	57	26.3	GN	Previously on home hemodialysis; referred after failed graft (12/06/87)	4 h–3/w	HDF	1.11	—	12	Long follow-up period; vasculopathy
18	M	58	9.8	IN in collagen disease	In-hospital dialysis; other limited care center	3 h 30 min–2/w	BHD	1.4	3	10	Systemic disease
19	M	59	0.6	GN-NAS	Day hospital, private care, SMOM outpatient unit	4 h–1/w	BHD	1.31	8	4.5	Cardiopathy
20	F	59	3.5	NAS	Patient's request (from Morocco)	3 h 30 min–5/w	HDF	1.3	—	23	Morbid obesity, vasculopathy
21	M	61	2.5	GN	Day hospital; private care	4 h–3/w	BHD	1.3	—	14	Vasculopathy, severe COPD
22	M	62	3.1	IN	Day hospital	4 h–3/w	AFB	1.28	—	14	Liver disease (HCV-related)
23	F	70	0.0	NAS	SMOM outpatient unit; start in hospital	2 h–1/w	BHD	NA	8	NA	Vasculopathy
24	F	81	5.0	NAS	Private care	2 h 30 min–5/w	BHD	1	—	18	Vasculopathy, old age

Abbreviations: Kt/V, Daugirdas eqKt/V; EKRc, equivalent renal clearance; M, male; SLE, systemic lupus erythematosus; BHD, bicarbonate hemodialysis; F, female; MPGN, membranous and proliferative glomerulonephritis; HCV, hepatitis C virus; PNC, chronic pyelonephritis/interstitial nephritis; HDF, hemo-diafiltration; GN, glomerulonephritis (unspecified); DIAB, diabetic nephropathy; FSGS, focal segmental glomerulosclerosis; NN, not known; PKD, polycystic kidney disease; IgA N, IgA nephropathy; AFB, acetate-free biofil-tration; IN, interstitial nephropathy; AA, AA amyloidosis; NAS, nephrosclerosis; COPD, continuous ambulatory peritoneal dialysis; NA, not assessed.

*Since August 2003.

†BUC + BCrC/2 mL/min.

The Outpatient Units

The outpatient SMOM unit initially was dedicated to diabetic patients with renal diseases and to patients with severe CKD, although the selection progressively widened. Access to the unit is mainly from university hospital diabetic care units or other nephrology units. Direct access from the patient's family physicians is welcome and our policy is to involve them as much as possible. A policy of early referral of CKD patients was developed progressively.

The SMOM unit works closely with a second unit active in another out-of-hospital setting, dedicated to elderly and diabetic outpatients with milder renal diseases. The referral policy is similar and diabetic patients usually are transferred to the SMOM unit in the presence of severe nephrotic syndrome or severe renal failure. The same nephrologist supervises both units to ensure a common clinical approach. The organization is integrated closely, with the development of specific chores (Table 2).

The most important point is the time dedicated to clinical controls, which increases according to the severity of the renal disease (15-45 min). The nursing team involvement depends on the clinical severity. To minimize discomfort in severe CKD, blood samplings are performed in the SMOM unit: the patient is given the results at the subsequent visit, while urgent tests (faxed $\leq$ 6 h) are controlled daily. A network of consultants ensures that the global care is performed under the supervision of the usual caregivers, allowing continuity of physician-physician relationships and ensuring common decisional lines (Table 3).

This complex organization of care is expensive and time consuming. Indeed, our choice was considered potentially noneconomical by the reviewers of one of our reports on this subject.[29] There is a sort of conflict of interest between the need to slow the progression of renal failure in a growing and increasingly demanding patient population and the economic constraints, common to the care of all chronic diseases in aging populations.[11,30] The balance between investing in preventive care and managing limited resources is difficult.[12,30] One of the risks for nephrologists struggling with reduced budgets is to be self-limiting in defining the needs of CKD patients.

CKDs are currently one of the most serious health care problems. As Hutchinson[12] wrote in his editorial, the present system seems to hold back resources until the final phases of diseases, when the care becomes life-saving; yet less is spent in the early phases when therapy could slow progression, reduce the costs, and improve the quality of life. Investing up to 45 minutes of a nephrologist's time per control probably is considered heresy by most readers of this article. The same probably is true for the detailed and broad set of basic controls, tailored according to the individual needs of global care (Table 4).

Of course, these are difficult choices. However, the cost comparison must not consider noncare, inexpensive by definition, but rather the cost of RRT. According to the data recorded in our center, each year gained by delaying the start of dialysis in one patient could pay for about 6 months of a nephrologist's salary.[29] Furthermore, early nephrologic care is correlated with lower morbidity and mortality on dialysis; however, the costs of these issues have yet to be assessed. Actually, the decrease in morbidity results in a decrease of the overall costs of care, but the decrease in mortality paradoxically increases the overall health expenditure by further increasing the patient pool.[31,32] In addition, the costs change according to the mode of RRT, and a way to optimize the health care expenditure as well as to increase patient benefits, is linked to the choice of RRT.[33,34] Peritoneal dialysis (PD) is considered to have a superior cost-benefit profile; according to several investigators its choice increases with early nephrologic referral.[35] In our setting, PD accounts for 25% to 30% of our total patient pool and it was chosen mainly by patients referred early to the nephrologists.[36]

The high index of choice of self-care modalities in 27 patients followed-up in the SMOM outpatient unit who started RRT or were transplanted may indicate the cost-saving potential of early investment in nephrologic care, also when dialysis is unavoidable and in cohorts with a high mean age (58.6 y) and a high prevalence of comorbidity (88.8%, diabetes 77.7%) (Table 5). Seven patients (25.9%) chose to remain in the home-limited care network, whereas PD was chosen in 22.2%, and only 25.9% were referred to hospital wards. Another 7 patients (25.9%) underwent preemptive kidney-pancreas or kidney graft or isolated pancreas transplantation. The economic advantages of preemptive transplantation are obvious, although this topic has yet to be studied.

Last but not least, the systematic use of low-protein diets should be mentioned. Although the potential benefits of low-protein diets in retarding the progression of CKD have been shown,[37] compliance remains crucial. According to our flexible-tailored approach, we offer the patients a varied menu: no diet; low-protein diets at 0.8 to 0.6 g/kg/day of proteins, with aproteic foods or vegetarian-supplemented with α-ketoanalogues[38]; a vegetarian diet at 0.3 g/kg/day of proteins, supplemented with α-ketoanalogues and using aproteic food, is offered in particular cases. Patients are monitored regularly (usually monthly). Compliance with the chosen diet generally is good, probably owing to the baseline Mediterranean diet, and it presumably is facilitated by the continuity of therapeutic support.[39] This was studied mainly for vegetarian-supplemented diets. Attention was focused on diabetic patients, classically considered as more difficult for both metabolic and compliance reasons.

In the period from November 1998 to January 2003, 62 diabetic patients, 10 type 1 (mean serum creatinine [Crs] = 2.6 $\pm$ 1.5 mg/dL) and 52 type 2 diabetic patients (mean Crs = 2.5 $\pm$ 1.3 mg/dL), underwent at least one trial of a vegetarian diet with α-ketoanalogues; 5 type 1 and 24 type 2 diabetic patients were on treatment on January 30, 2003. The main indications were: severe renal failure (12 patients), delay of progression (35 patients), nephrotic syndrome (15 patients). The main reasons for discontinuation were: for type 1 diabetics, noncompliance (3 patients), kidney-pancreas graft (1 patient), dialysis (1 patient); for type 2 diabetics, start of dialysis (17 patients), noncompliance (5 patients), gastric intolerance (4 patients), other (2 patients). Only 12 of 62

Table 7 Dialysis Care: General Schedule of Biochemical and Imaging Tests

Blood tests	Monthly: complete blood cell count, biochemical profile pre- and postdialysis (urea, Na, K, Ca, P, HCO_3, Mg, serum albumin, total proteins, glucose), hepatic enzymes Every other month: HbA1c (for diabetic patients), urea and creatinine clearances (residual renal function), CRP, sedimentation rate, ferritin Three times: iron, transferrin, folic acid, vitamin B_{12} homocysteine, serum protein electrophoresis, iPTH (up to once monthly in case of high levels), osteocalcin, total cholesterol + HDL, triglycerides (higher frequency in case of dyslipidemia), INR, aPTT; fibrinogen, antithrombin III, viral markers (HAV, HBV, HCV, HIV) Twice yearly: thyroid hormones, sexual hormones (men: testosterone, prolactin; women: LH, FSH, estradiol, progesterone, prolactin), serum aluminum levels Yearly: erythropoietin, β-2-microglobulin, other virologic tests (parvovirus B19, Rubella, CMV, EBV, HSV 1 + 2, HHV6, VZV); for HCV patients: Ab to C22, HCV RNA, genotyping Other blood tests are performed with different frequencies according to the clinical conditions (eg, immunologic tests in selected patients, and so forth)
Recirculation test (glucose infusion test)	Twice yearly; more frequent in specific cases or on demand
Kt/V and EKRc assessment	Monthly; because of the ample use of nonconventional schedules, data are obtained one month in a single random session and the following month in all sessions of one week
Abdominal + thyroid and parathyroid glands US	Once yearly or more frequently according to the clinical conditions; part of pretransplant evaluation
Cardiologic evaluation (including cardiologic visit, EKG, thorax radiography, echocardiography, myocardial perfusion SPECT)	Once yearly; more frequent in selected cases: eg, in patients ≥60 years old or with previous cardiovascular events or on demand (new onset or worsening of cardiac symptoms or indications from cardiologist consultant); part of pretransplant evaluation.
Abdominal radiography	Once yearly or more frequently according to the clinical conditions
Skeletal radiography	Every 2-5 years or according to the clinical conditions; part of pretransplant evaluation
Vascular Doppler ultrasound (carotid, abdominal, and peripheral arteries)	At least once at start of RRT, frequency depends on the clinical situation (eg, abdominal aortic aneurysm, hypertension, stroke or TIA, and so forth) part of pretransplant evaluation
Holter pressure monitoring	On demand
Other imaging tests	On demand or according to the indications of transplant centers

NOTE. The basic schedule is modified depending on the clinical situation and patient preferences.

Abbreviations: CRP, C-reactive protein; iPTH, intact parathyroid hormone; HDL, high-density lipoprotein; INR, international normalized ratio; aPTT, active partial thromboplastin time; HAV, Hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; LH, leutinizing hormone; FSH, follicle-stimulating hormone; CMV, cytom egalovirus; EBV, Epstein-Barr virus; HSV, herpes simplex virus; HHV6, Human herpes virus 6; VZV, varicella zoster virus; EKRc, equivalent renal clearance; EKG, electrocardio- gram; SPECT, single-photon emission computed tomography; TIA, transient ischemic attack.

(19.3%) patients had a follow-up period of 6 months or less, whereas 49 of 62 (79%) patients had a follow-up period of 1 year or more, and 23 of 62 (37%) patients had a follow-up period of 4 years or more.

Dialysis Care

The SMOM motto is flexibility. Applied to patient care and to the structural organization, it has given rise to 3 distinct

Table 8 Grafted Patients Followed-Up in the SMOM Unit

Patient	Age	Sex	End-Stage Renal Disease	Graft	Date of Graft	Comorbidities	Origin	Regimen August 2003	Serum Creatinine Level in August 2003 (mg/dL)	RRT Follow-Up (y Before Graft)
1	54	M	Diabetes	SPK	9/2/01	Type 1 diabetes, neuropathy	Dialysis SMOM	Prednisone 2.5/0 mg, Tacrolimus 4.5 mg, MMF 1 g	1.6	7.6
2	54	F	Diabetes	SPK	18/2/01	Type 1 diabetes, neuropathy	Dialysis SMOM	Tacrolimus 3 mg, MMF 1 g	0.9	2.3
3	54	F	IgA GN	K	26/2/01	Long follow-up period, vasculopathy, skin multiple neoplasia	Dialysis SMOM	Prednisone 5 mg, Tacrolimus 1 mg, MMF 1 g	2.7	26.7
4	51	M	PN	K*	27/5/02	None	Dialysis SMOM	Prednisone 2.5 mg, Tacrolimus 5 mg, MMF .75 g	1.8	2.9
5	33	F	IgA GN	K	27/8/02	None	HHD	Methylprednisolone 2 mg, Tacrolimus, 14.5 mg, MMF 1 g	1	1.6
6	26	F	SHP	K	11/10/02	Systemic disease	Dialysis SMOM	Methylprednisolone 2 mg, Tacrolimus 6 mg, MMF 1 g	1.7	1.5
7	41	M	Diabetes + NAS	Pancreas†	20/10/02	Type 1 diabetes, blindness	SMOM outpatient	Prednisone 5 mg, Tacrolimus 4.5 mg, MMF 1.5 g	1	Pancreas only
8	56	F	PN	K	3/1/03	Binephrectomized, chronic infection, transplant in emergency, bladder reconstruction	Dialysis SMOM	Prednisone 2.5 mg, Tacrolimus 4.5 mg, MMF ???	1.2	2.1
9	42	F	Diabetes	SPK‡	5/2/03	Type 1 diabetes, nephrotic syndrome	SMOM outpatient	Prednisone 5 mg, Tacrolimus 10 mg, MMF 1.25 g	1.3	Pre-emptive
10	28	M	GN	K	26/2/03	None	HHD	Sirolimus .5 mg, Tacrolimus 11.5 mg	1	2.7
11	41	M	Diabetes	SPK‡	19/4/03	Type 1 diabetes, neuropathy	SMOM outpatient	Prednisone 5 mg, Tacrolimus 5.5 mg, MMF 1 g	1.7	Pre-emptive
12	46	F	Diabetes	P‡	21/4/03	Type 1 diabetes, hepatitis C virus positive, liver disease	SMOM outpatient	Prednisone 5 mg, Tacrolimus 5.5 mg, MMF 1.5 g	0.7	Pancreas only
13	48	M	Diabetes	K‡	23/4/03	Type 2 diabetes, ischemic cardiopathy, severe nephrotic syndrome	SMOM outpatient	Prednisone 7.5 mg, Tacrolimus 3.5 mg, MMF 1.25 g	1.4	Pre-emptive
14	68	M	GN	K	29/4/03	Ischemic cardiopathy	Dialysis SMOM	Prednisone 5 mg, CyA A 150 mg, MMF 1 g	1.7	4.5

15	49	F	Diabetes	P‡	6/5/03	Type 1 diabetes, systemic vasculitis	SMOM outpatient	Prednisone 7.5 mg, Tacrolimus 9.5 mg, MMF 1.5 g	0.8	Pancreas only		
16	46	F	MPGN	K	22/8/03	Previous severe hypertension	Dialysis SMOM	Prednisone 16 mg, Tacrolimus 30 mg, MMF 1.5 g	1.7		4.6 y	

NOTE. Shown according to date of graft.
Abbreviations: M, male; Diabetes, diabetic nephropathy; SPK, simultaneous kidney- pancreas; MMF, mophetil mycphenolate; CyA, cyclosporine A; F, female; IgA GN, IgA nephropathy; K, kidney; PN, chronic pyelonephritis/interstitial nephritis; HHD, home hemodialysis; SHP, Shoenlein Henoch purpura; NAS, nephroangiosclerosis/ischemic renal disease; GN, chronic glomerulonephritis; MPGN, membrane proliferative GN.
*Grafted in Barcelona (Spain).
†Grafted in Pisa (Italy).
‡Followed-up for nephrologic care (coming from a different region).

programs. As previously mentioned, the SMOM unit was transformed progressively during the 1990s into a sort of atypical out-of-hospital dialysis center; this resulted from a decreasing pool of home hemodialysis patients and a few patients in limited care who had dropped out of home hemodialysis or transplantation, or were referred from the dialysis ward, usually because of psychologic or work-related problems. The spirit of keeping an area for patients with particular needs or wishing to perform some kind of self-care, with the same flexible attitude as home dialysis, led to the further development of tailored programs and schedules. Since the start of the SMOM program (in November of 1998), the number of patients has increased progressively from 15 to 50-55, a stable pool since the past year (Fig 1).

The stepwise growth of the program gave life to small units with dedicated teams of caregivers, so as to not lose the family-like personal relationships; this also respected the patients' preference for small units instead of a large center, as assessed by a series of semistructured questionnaires at the start of the program.[40] Therefore, when the SMOM unit became overcrowded, the flexible home dialysis program was moved to a hospital area where it became the initial nucleus of a self-care program, as described elsewhere.[41,42]

In total, 87 patients were treated in the whole dialysis network from November 1998 to August 2003. The median age at the start of dialysis in our units was 49.8 years (range, 20.7-76.6 y); the median RRT duration at referral was .5 years (range, 0.0-31.8 y). A total of 73.5% of the patients presented at least one comorbid condition at referral (multiple comorbidity in 47.1%); 4 patients developed comorbidities after the start of RRT. The main reasons for discontinuation of the program were death (9 patients) and kidney or kidney-pancreas transplantation (21 patients); 8 patients were transferred to hospital wards for clinical or logistic reasons.

The main clinical features and dialysis schedules of the patients being treated in the SMOM unit in August 2003 are reported in Table 6. The center follows an incremental dialysis policy, 1 to 6 sessions/wk, with strict metabolic control. Tailoring of dialysis allowed us to treat out-of-hospital patients with multiple comorbidities safely; the same was true for home dialysis patients, 59.5% of whom had at least one comorbid condition at the start of the program.

Once again, the holistic patient-physician relationship, within the context of a well-consolidated continuum of therapy, was the secret to obtaining very good compliance and the choice by the patients of demanding schedules, including daily dialysis.

As discussed for the outpatient care units, the choice of tailored schedules, with ample use of more frequent dialysis, and the careful and frequent monitoring (Table 7) may be seen as too expensive. This especially is true in the case of daily dialysis[43]; according to a cost analysis performed in our center with a logic bottom-up technique, the cost of a dialysis session ranges from 229,17 € for hospital hemodiafiltration to 80,68 € for automated PD with icodestrin (limited care BHD at SMOM: 131,25 €; SMOM daily bicarbonate hemodialysis (BHD): 98,76 €; home BHD: from 96,50 € to 133,48 €

for daily or conventional dialysis, respectively; hospital BHD: 170,15 €).

The cost of daily dialysis or more frequent techniques may be considered too high (weekly costs: 592,56 € in the SMOM unit, 572,46 € at home) if compared with a standard 4-hour bicarbonate dialysis session 3 times per week (weekly costs: 510,45 € in hospital, 400,44 € at home), but may be highly competitive with respect to the so-called high-tolerance in-hospital treatment (weekly cost of hemodiafiltration and acetate-free biofiltration: 687,51 €). Furthermore, the cost calculation does not take into account the amortization of hospital structures, which are necessary in a growing dialysis population: in our region the net increase is about 30 dialysis patients per year per million people.[44] In our area, as elsewhere in Europe, the nursing shortage is becoming crucial and the possibility to work safely with a reduced nursing team is very appealing.

In summary, in contrast to the trend in most Italian and European settings, our policies have allowed us to renew an active home hemodialysis program and to lay the groundwork to restart (phase 3) a self-care program in which patients conduct the dialysis sessions with minimum help from a small team of nurses who act as home hemodialysis partners (Fig 1).

Transplantation Follow-Up Care

The third phase of the follow-up of renal patients was started in 2001, when 3 patients (2 with pancreas-kidney graft) asked to continue their follow-up care in the SMOM unit. The patients previously on dialysis in the unit were joined by a small but growing cohort of diabetic patients who received a pancreas or kidney-pancreas graft in the Pisa transplant center (Table 8). The basic schedule of biochemical and imaging tests is reported in Table 9. Immunosuppressive therapy is tailored according to the policy of our transplant center (Table 9).[45]

The small size of the SMOM unit and the close cooperation between caregivers and patients has allowed some relatively new clinical experiences, in particular, early pre-emptive kidney-pancreas transplantation (Table 9). The positive experiences with the difficult choice of early pre-emptive transplantation stimulated further referrals of new patients, and there are currently 9 diabetic patients at different stages of the transplantation work-up.

Because of the rapid growth of the program (9 patients grafted from January to August 2003), in phase 3 the dedicated outpatient facility will be moved to a larger area.

Overall Data

By all these means, the whole network has allowed us to decrease the hospital load of chronic patients: the overall pool of patients treated was 193 in November 1998 and 211 in August 2003; the in-hospital dialysis population decreased from 85 patients (62.0% of the whole hemodialysis pool) to 64 patients (42.4% of the whole hemodialysis pool) ($P = .001$) whereas the number of home hemodialysis patients increased from 6 (4.4% of the whole hemodialysis pool) to 21 ($P = .001$) in parallel with the increase in self-limited care hemodialysis patients from 9 (6.6%) to 34 (22.5%) ($P = .001$); the PD pool and the number of patients on dialysis in the second limited-care center remained stable (November 1998: PD 56 (29.1%), other limited care unit 37 (19.2%); August 2003: PD 60 (28.4%), second limited-care center 32 (15.2%) ($P = .950$). In August 2003, 24 patients were on hemodialysis in the SMOM unit and 31 patients were treated in the home hemodialysis or self-care area.

Survival data have only an indicative value in such a selected population, with a high prevalence of comorbidity and highly heterogeneous with regard to dialysis follow-up, clinical history, and age. Moreover, the relatively small number of patients does not allow stratification by age or comorbidity. Nevertheless, we calculated the gross mortality to give a general idea of the results and to allow for discussion of the data in an international perspective.

From November 1998 to August 2003, 221.33 patient-years of RRT follow-up evaluation were recorded in the whole dialysis network (SMOM unit, self-care, home hemodialysis; the number increases to 257.83 if the grafted patients are considered); in this period, 9 deaths were recorded (1 after graft), all in patients with comorbidities, 3 in patients with over 20 years of RRT.

The median age of the 9 patients who died was 52 years (42-71 y); all were affected by comorbidities (multiple in 7 patients, diabetes in 2 patients, active systemic lupus erythematosus in 2 patients, neoplasia in 3 patients); the median RRT follow-up period was 44 months (minimum 14.2 mo in a patient with active systemic lupus erythematosus who died of sepsis, maximum 384.9 mo in a severely vasculopathic patient). The follow-up period was more than 120 months in 4 of 9 patients. The causes of death were sepsis in 2 patients (1 after renal graft), cerebral hemorrhage in 1 patient, neoplasia in 2 patients, intestinal infarction in 1 patient, acute cardiovascular accident in 3 patients; death occurred after transfer to hospital dialysis in 3 patients who were previously at home or in the SMOM unit; death occurred at home (2 patients) and during hospitalization (4 patients) after referral from home dialysis or the SMOM unit.

The total gross mortality rate was 4.06 per 100 patient-years of observation and 3.49 per 100 patient-years when the follow-up period after renal graft was taken into account; in the 49 home hemodialysis patients (intention to treat) the gross mortality was 3.51 per 100 patient-years (2.98 considering follow-up period after graft), in self-limited care patients it was 4.66 per 100 patient-years (4.04 considering follow-up period after graft). The lack of a substantial difference between home and self-limited care patients supports the policy of wide indications for home hemodialysis. This figure includes the follow-up evaluation and the deaths recorded after transfer to the hospital ward for clinical reasons, whereas patients transferred to different settings for logistic

Table 9 Transplantation: Basic Schedule of Biochemical and Imaging Tests

Basic tests: serum creatinine, urea, Na, K, Ca, P, HCO_3, glucose, complete blood cell count, amylases (in pancreas grafts), Tacrolimus or Cyclosporin level (other immunosuppressive agents if required)	Three times/wk in the first 2 mo of posttransplant follow-up evaluation
	Twice weekly in the subsequent 2 months
	Once weekly from the fifth month
Creatinine and urea clearances, proteinuria, hepatic enzymes, albumin, total proteins, Ca, P, uric acid; urinalysis + urinary sediment; urine culture	Weekly in the first 4 months of posttransplant follow-up evaluation
	Twice, monthly from the fifth month
Reticulocyte count (in patients treated with epo), ferritin, INR, aPTT, fibrinogen, antithrombin III, sedimentation rate, CRP, EA-CMV	Monthly (coagulation tests are performed weekly in patients on anticoagulation therapy)
HbA1c, C-peptide	Monthly in pancreas grafts, every other month in kidney grafts
Total cholesterol + HDL, triglycerides	Every other month
Serum immunoglobulins, folic acid, vitamin B_{12} homocysteine, serum protein electrophoresis, iPTH, viral markers (HBV, HCV, HIV), thyroid hormones, PSA, Ca 15-3, Ca 125, CEA, Ca 19-9, AFP, NSE	Twice yearly (serum immunoglobulin levels are assessed every 3 months in patients treated with mycophenolate mophetil); all tests are modulated depending on the clinical status
Abdominal ultrasound (plus renal and/or pancreas color Doppler ultrasound)	At the start of posttransplant follow-up evaluation, then yearly or more frequently on demand
MAG3 Renal scintigraphy	At the start of follow-up evaluation, then on demand (eg, in case of sudden worsening of renal failure); in case of pyelonephritis or renal vascular events
DMSA scintigraphy	
Cardiologic evaluation (including cardiologic visit, EKG, echocardiography, thorax radiography, myocardial perfusion SPECT)	Once yearly; more frequently in patients with previous cardiovascular events or on demand (new onset or worsening of cardiac symptoms or indications from the cardiologist consultant)
Bone densitometry	Once yearly in the first 2 years, then on demand
Gynecologic and odontostomatologic evaluation	Once yearly or more frequently on demand
Other biochemical or imaging tests or specialist evaluations (eg, fundus oculi, EEG, electromyography, and so forth)	Planned according to the clinical conditions and to the pretransplant history

NOTE. Data from the first year of follow-up evaluation. From the second year of follow-up evaluation the frequency of tests usually depends on the clinical conditions. The basic schedule may be modified according to the clinical situation.

Abbreviations: epo, erythropoietin; INR, international normalized ratio; aPTT, active partial thromboplastin time; CRP, C-reactive protein; EA-CMV, early antigen-cytomeyalovirus; HDL, high-density lipoprotein; iPTH, intact parathyroid hormone; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PSA, prostate-specific antigen; CEA, carcino embryonic antigen; AFP, alpha fetoprotein; NSE, neuronal specific enolase; EKG, electrocardiogram; SPECT, single-photon emission computed tomography; EEG, electroencephalogram.

reasons were considered lost to follow-up evaluation at the date of transfer.

In the SMOM network, the gross mortality rate is remarkably less than the national rate (in 1995 it was 11%),[46] although it was recorded in a small patient series, in cohorts with a median age less than that of the general dialysis population (50.4 y; range, 25-81 y; in 55 patients in the SMOM network in August 2003 versus 66 y; range, 2.2-101 y in the whole region, according to data from the Regional Registry of Dialysis and Transplantation of Piedmont—updated December 2000), but with a higher prevalence of comorbidity (at least 1 comorbidity in 78.2% of patients in the SMOM network in August 2003 versus 56.9% according to the Registry data—updated December 31, 2003). Our data are comparable with those recorded in the classic studies of the Tassin unit, in a population with a similar age (mean, 52.9 y) and with a lower prevalence of comorbidity (27.8% for causes of end-stage renal disease) and a 5-year survival of 87%.[47]

New Perspectives: A New Role For The Postgraduate Nephrology School

The role of the postgraduate nephrology school is crucial in the implementation of new strategies and treatment policies. The University of Turin school is the only one like it in the Region—4,300,000 inhabitants (5 y; 4-5 new students/y).

The University of Turin school has a policy of individualized curricula, oriented toward hospital work or clinical research (mainly in the University). The clinical approach involving a continuum of care is discussed repeatedly in theoretical lessons; the students have the option to spend part of the postgraduate years in the SMOM network, directly experiencing the continuum of care model. As a rule, the best postgraduate students are involved in teaching activities in their areas of interest. The students involved in clinical or research work in the SMOM area also are involved in the

Table 10 The Role of Patients in the Validation of the Different Stages of the Continuum of Care Organization

Treatment	Patient Role
"Old model"	
Home hemodialysis	Training in center; 3 assisted dialysis sessions; return to the training center for clinical problems
Limited care dialysis	Constant schedules (standard: 4 h 3 times/wk)
Change	
Predialysis care unit	Rapid start of activity: 30 visits/wk within 6 mon
Point of care in center	Patient's request to minimize the time requirement
Start dialysis in the unit	Patient's request to avoid hospital dialysis; request a continuum of care
Daily hemodialysis	Home: rapid start of the program in center; patient's request
Tailored schedules	Progressive modifications to satisfy the patient's needs
Pre-emptive transplantation (kidney-pancreas)	Organization of a joint venture with the transplant center of Pisa; patient's request
Posttransplant follow-up evaluation (kidney-pancreas and home-limited care dialysis)	Patient's request not to interrupt the continuity of care

teaching activities of the medical school concerning the continuum of care model and the patient-physician relationship.

The importance of the patient-physician relationship and the peculiarities of the continuum of care model are discussed in detail in a series of small-group interactive lessons. Student satisfaction has been high: in a study performed in the 2001-2002 academic year, the opinions were highly favorable toward the inclusion of dialysis care in the nephrology course and the questions on RRT obtained high scores at the final examinations.[48] In the past 4 academic years, 4 theses dealt with the preparation of teaching tools for patients or for teaching programs in schools (3 books and 1 movie).[49]

Although the long-term effect of including these issues in the academic education is difficult to assess, the high interest shown by the students supports further development of the program as a useful teaching tool for a new generation of holistic physicians.

New Perspectives: Working Together

The interactive model of therapeutic alliance involves close cooperation between patients and physicians in the pursuit of common goals. Although this relationship has been the basis of the development of nephrology and dialysis in our area,[50] the active help of our patients has been a valuable tool to improve the care, to test the new organizational models, and to develop common programs.[40] The role of the patients in validation of the continuum of care organization is summarized in Table 10; it was fundamental not only in confirming the chosen strategies, but also in suggesting new ones, such as for posttransplant follow-up evaluation.

The newest and probably most interesting experience is the teaching program dedicated to high school students in the Turin area, which has involved a growing number of schools (1 school in 2000-2001, 65 schools in 2002-2003). The main aspects of renal diseases, dialysis, and transplanta-

Table 11 Protocol of the Randomized Controlled Trial on the Efficacy of an Educational Intervention, Targeted at High School Students, Concerning Opinions on Renal Transplantation and Organ Donation

Aim: to evaluate the effect of an educational program dealing with dialysis, renal transplantation, and organ donation
Target: high school students (last 2 years of school)
Setting: 2 large Italian cities in northern and southern Italy
Design: randomized controlled trial
Randomization: from the official lists of high schools, 10 schools in each city are selected randomly and randomized further into interventions and controls using the opaque, sealed, envelopes system
Intervention: first questionnaire, first lesson in small groups (1–2 classes; 2 h), held by a suitably trained nephrology fellow (within the postgraduate nephrology school), second lesson (all classes together; lesson coordinated by anephrologist, with nephrologists in training, patients), second questionnaire
Control: only the 2 questionnaires, at 1–2 months apart; the questionnaires contain multiple-choice and open-ended questions; this educational program has been included in the activities of the Universities of Turin and Naples
Outcomes: to evaluate the efficacy of the program (the ultimate aim is to increase the number of organ donations), surrogate outcomes are used and the results of the study are expressed in terms of: increase in prevalence of favorable opinions (or decrease of negative opinions) on cadaver and living-related organ donation in the intervention group versus the control group; satisfaction with the program and request for its repetition in subsequent years

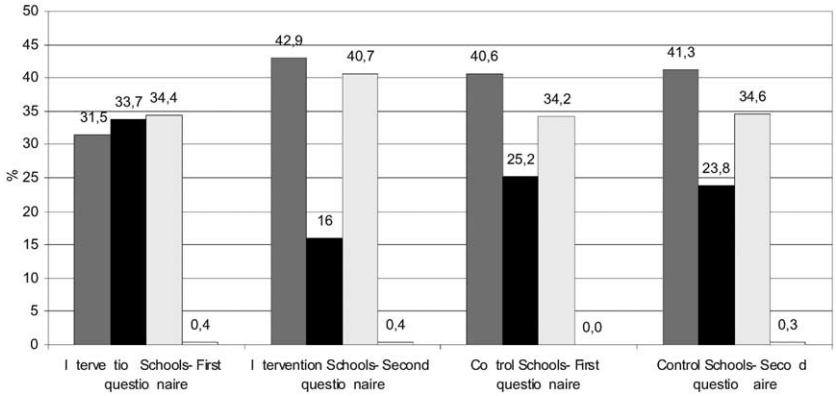

Figure 2 Opinions on cadaver donor renal transplantation at the first and second questionnaire: intervention and control schools (2001-2002: data on 14 schools). ■, Yes; ■, no; □, I do not know; ■, blank.

tion are discussed to increase interest in the clinical and ethical aspects and to improve attitudes toward organ donation. The success of the program, whose protocol is described in Table 11, mainly is owing to its working team. University teachers are flanked by postgraduate nephrology students, nurses, and patients, with different experiences of dialysis or renal transplantation. The results are encouraging despite a negative baseline situation, in which only 31.5% of the students were favorable to organ donation, the educational intervention was able to increase the positive responses and to sharply reduce the negative ones (Fig 2).

The opinions on living donation were very different: 76.8% of the students in the intervention schools and 80.0% of the students in the control schools were favorable. This positive attitude was considered important for the improvement and enhancement of our living donation programs, including pre-emptive transplantation, which should include the timely discussion of the choice of RRT.[51-53]

Conclusions

Continuum of care is not only an organizational, but also a philosophic, approach. It requires that we reconsider the overall care, favoring the holistic view of patients and underlining the need for a continuous patient-physician relationship as part of the therapy. This choice has the immediate consequence of differentiating between the caregivers involved in chronic care and in all stages of therapy, who should be selected because of their interest and skills in human relationships (patient-oriented care), and the caregivers involved as technical superexperts, consultants in specific phases of care (eg, in the immediate posttransplant period or for vascular access surgery), who should support the chronic caregivers in the resolution of particular problems (disease-oriented care).

Such a choice, giving space to the 2 souls of today's medicine (humane and technologic), may help us achieve a pragmatic compromise between the patients' preference for constant support and the need to keep up with the rapidly changing field of medicine. The development of all these concepts in the setting of academic medicine should be emphasized as a tool to defend our role, to cite Oreopulos,[54] as healers and teachers.

The stepwise history of our unit, in which the stimulus to give new life to home dialysis was the starting point for the organization of a network that follows-up patients, according to an early referral policy from the first signs of renal disease to dialysis and transplantation, underlines the importance of patient involvement in all aspects of their care, including the organizational ones.

The clinical and economic success of this program will need to be confirmed over time. However, the good compliance with hard treatments (vegetarian diets, daily dialysis), together with the high index of choice of home dialysis or self-care treatments, indicate the great potential of these choices. The promising result of a low gross mortality rate, despite a high prevalence of multiple comorbidities, further supports the clinical safety of this organizational model.

The interaction between patients and physicians in such a context could become as creative and innovative for the physicians as for the patients. This was shown by the successful involvement of almost all the high schools of the Turin area in an educational program dealing with RRTs, dialysis, and transplantation in which, for the first time in Italy, patients, postgraduate nephrologist trainees, and nephrology teachers were involved on an integrative basis.[53]

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