TRANSPLANTATION AND HOME HEMODIALYSIS:

THEIR COST-EFFECTIVENESS IN THE TREATMENT OF END STAGE RENAL DISEASE

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ABSTRACT

Transplantation and home hemodialysis have been available to treat patients with end stage renal disease for several years but it is not clear which approach is most cost-effective and should be recommended when decisions about extending facilities are made. This study compared the costs of home hemodialysis and transplantation for comparable patients using the marginal cost methodology. Sixteen patients in a home program were matched with sixteen patients in a transplantation program with regard to sex, age, primary disease and other medical diseases. Questionnaires and a chart review allowed the accounting of all health services received in hospitals, offices or at home, and provided indicators of treatment effectiveness. The impact of the additional services generated by choosing one treatment over the other (difference between the two programs) was evaluated in terms of personnel, equipment and supply. Survival and rehabilitation were similar in the two groups. However, for each year of follow-up, transplantation was less expensive than home dialysis. When these results were translated in terms of supporting a transplantation program for seven years, the savings were considerable. These results suggest that transplantation would be the most cost-effective way to treat end stage renal failure, at least for the subgroup of patients equally eligible for either transplantation or home dialysis.

RESUME

L'évaluation du traitement de l'insuffisance rénale terminale ne peut se faire par l'attribution des traitements au hasard. Pour contourner ce problème, une étude analytique de deux traitements avec critères de sélection similaires, paraissait indiquée. Cette étude a identifié des patients comparables et a utilisé le concept du coût marginal pour comparer les coûts de l'hémodialyse à la maison et de la transplantation rénale. Seize patients sur hémodialyse à la maison furent couplés à seize patients avec transplantation rénale pour le sexe, l'âge, le diagnostic primaire, et autres maladies. Un questionnaire et une revue des dossiers a permis d'évaluer l'efficacité des traitements et d'énumérer tous les services reçus à l'hôpital, au bureau ou à la maison. L'impact des services additionnels occasionnés par le choix d'un des deux traitements (différence entre les deux programmes) a été évalué pour le personnel, les équipements et les approvisionnements. La survie et la réhabilitation étaient similaires dans les deux groupes. Cependant, pour chaque année sous observation, le programme de transplantation fut moins dispendieux et lorsque traduit en termes des implications pour supporter un programme de transplantation pour sept ans, les économies furent considérables. Ces résultats identifient la transplantation comme ayant le meilleur rendement pour le traitement de l'insuffisance rénale terminale, à tout le moins pour le sous groupe de patients éligibles pour la transplantation ou pour l'hémodialyse à la maison.

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CHAPTER 1 INTRODUCTION

In a period of constantly rising medical care costs[1,2,3], evaluation of the effectiveness and costs of specific programs is required to determine the most efficient allocation of resources[4,5]. This study compared the relative efficiency of transplantation and dialysis, the two most common programs used to treat end stage renal disease (ESRD). The aim was to provide a basis for deciding which program should be favored or expanded on a long term basis, given the probable necessity of increasing services for patients with ESRD[6,7].

Previous studies in the area have failed to provide a basis for this decision making because data were not obtained from comparable patients (exclusive alternatives)[8], and because cost estimates were not generated through the marginal costs methodology (as opposed to average cost) and did not include all the cost generating factors (direct, indirect and intangible costs)[9].

This study then was undertaken to provide a firm basis for health planning by generating the information required to identify the most efficient therapy for patients with end stage renal disease. First, to avoid biases in the choice of patients for specific modes of therapy[8], the selection of patients was made through a matching process that insured a greater degree of comparability between the groups than was achieved in previous studies. The process was facilitated by focusing our evaluation on the two modes of treatment for which clinicians were likely to apply similar selection criteria: home hemodialysis and

transplantation. Second, our cost estimates included all costs, while previous studies have looked only at hospital costs. Finally, since we were interested in measuring the impact of choosing one program rather than the other, the marginal cost methodology was adopted. This required costing only of the difference in services between programs (compared to the more conventional approach which would have costed all the services in each program and then computed the difference in costs). The marginal cost methodology has never been used before in the health field.

Chapter 2 of this thesis contains a literature review summarizing the work done in this field, stressing and detailing the strengths and the weaknesses of previous investigations. Chapter 3, "Subjects and Methods", describes the matching process employed to identify comparable patients, the measures taken to develop a comprehensive listing of all the services received by patients and the concepts underlying the marginal cost methodology. Matching for factors affecting health or cost outcomes, insured that the two groups studied were comparable except for the treatment received. Measurements of health status allowed the description of health outcomes in terms of both survival and quality of survival, and an exhaustive listing of all services permitted the description of costs (hospital and home costs, professional and non-professional costs, etc.). Finally, the marginal cost methodology[10,11] estimated accurately the impact on cost of choosing one of the two programs studied by calculating the additional number of services resulting from such a choice (difference between programs) and estimating the additional costs incurred by the institution to provide these additional services.

Chapter 4, Analysis and Results, describes the findings and their analysis: the survival and the rehabilitation were similar in the two groups and the costs incurred by the institution for personnel and equipment were very small because the size of the additional services did not require changes in either the staffing pattern or the equipment resources. As a result, our patients on transplantation almost invariably received services costing less to the institution than the services received by our patients on home hemodialysis even for the first year of treatment.

Finally, in Chapter 5, we discuss the strengths, weaknesses and possible applications of our findings.

CHAPTER 2 REVIEW OF THE LITERATURE

This review of the literature includes a definition of end stage renal disease and a description of the different diseases leading to the condition. The major focus is on the advantages and disadvantages of home hemodialysis and transplantation. Finally, the economic evaluation of these treatments is summarized.

END STAGE RENAL DISEASE

Patients with end stage renal disease (ESRD) are those in whom kidney dysfunction is severe enough to make survival for twelve months impossible without treatment[6]. They are a heterogeneous group insofar as a variety of diseases may underlie the kidney failure (the distribution of diseases is shown in Table 1.) Nevertheless, in all cases, supportive techniques are required to prevent death.

Since this definition is obviously retrospective, physicians usually classify patients with renal failure according to the level of serum creatinine or the rate of creatinine clearance. Because patients with serum creatinine levels of 10 mg/100 ml or more have been found to have a one year survival of only 5 to 25%[12,13], this level, or a creatinine clearance of less than 10 ml/min./m^2 of body surface, is generally accepted as indicating end stage renal failure.

Several diseases may lead to end stage renal failure and the distribution of patients with end stage renal failure among the different disease categories is summarized in Table 1. The main sources of

TABLE 1: DISEASES CAUSING END STAGE RENAL DISEASE (ESRD)

Underlying disease	Proportion of ESRD patients with each underlying disease
Glomerulonephritis	38.1 to 56%
Pyelonephritis	12.3 to 18%
Polycystic Kidney Disease	5.4 to 8.8%
Nephrosclerosis	4.9 to 6.7%
Diabetic Nephropathy	1.2 to 7%
Analgesic Nephropathy	1.3 to 2.5%
Others	36.8 to 1%

these data are the Canadian Renal Failure Registry[14], The American Renal Transplant Registry[15], The American National Registry of long term dialysis patients[16], and the European Dialysis and Transplant Association[17].

The glomerulonephritides found in the largest proportion of ESRD patients are a composite of different diseases with different etiologies. The common denominator is glomerular damage due to a hypersensitivity reaction involving antibodies, immune complexes, inflammation, fibrosis and/or cell proliferation. The natural history of the glomerulonephritides may involve slow (10 years) or rapid (few months) progression to end stage renal failure. This group of diseases does not include all the systemic diseases which have glomerulonephritis as one of their manifestations; rather it includes only diseases with glomerular involvement as their primary manifestation.

Pyelonephritis is defined as chronic interstitial inflammation of the kidneys resulting from bacterial infection. Although the association with bacterial infection would seem to make the diagnosis simple, the situation is more complex, since pyelonephritic pathologic lesions are often found in patients who either have a sterile kidney culture or lack a history of bacterial urinary infection. Furthermore, the pathologic lesions (active interstitial inflammation and tubular atrophy leaving most glomeruli normal) are at best suggestive, not pathognomonic. Nonetheless, patients with this type of lesion behave very similarly and progress slowly (years to decades) to end stage renal failure.

Analgesic nephropathy shares similar pathologic findings with pyelonephritis and affected patients often have superimposed bacterial infections of the kidney. However, unlike pyelonephritis, it is characteristically associated with papillary necrosis. The natural history of this disease is similar to pyelonephritis except that if analgesic abuse can be stopped early enough, the patient's chance of improvement is greater.

Polycystic kidney disease is a hereditary disorder in which multiple cysts of the renal parenchyma replace normal renal tissue. Sometimes associated with pyelonephritis, the pathologic process leads progressively to renal insufficiency in a slow and relentless way.

Nephrosclerosis or hypertensive nephropathy is the renal manifestation of long standing hypertension. Approximately 10% of hypertensive patients will develop marked renal insufficiency over the course of many years due to impaired circulation in the renal arteries. Occasionally, hypertension will be malignant and lead to renal failure within a year.

Diabetic nephropathy is more common in patients with juvenile (insulin dependent) than with adult onset diabetes. The most common renal manifestation is diffuse sclerosis of the glomeruli developing slowly over time.

Many investigators have estimated the incidence of end stage renal failure using data from death certificates[18,19,20,21], hospital records[21,22,23], or questionnaires[24,25]. The incidence figures reported range between 28 and 75 cases per million population per annum. The reliability of these figures is unknown, since the completeness and accuracy of the information used in their calculation was rarely verified. In one study[26], where validation was attempted, the age-specific incidence rate of all cases of end stage renal failure in need of treatment was 109.2 per million under 65 years of age per annum.

Further information can be obtained from the various patient registries. In 1977, The European Registry[17] enrolled 10,116 patients from a population of 541 million, an incidence rate of 18.7 per million population. However, this is probably an underestimate of the true incidence, since only 85% of the known centers provided information. Because of similar underreporting, the incidence rate in Canada for 1975 (30.3 per million population) is also likely to be an underestimate[14].

In the United States, there is no registry collecting information on all patients with end stage renal disease. The latest major source of information, therefore, is a report to the Congress in 1975[27] on patients referred for treatment. From a survey of all kidney centers in 12 states and two counties, an incidence rate of 36 per million population was found, with a range between jurisdictions of 14 to 68 cases per million. Because these numbers referred to patients undergoing treatment for ESRD, the variation in "incidence" was attributed

primarily to geographic variation in the referral of patients or the application of selection criteria that precluded the treatment of some referred patients and unevenness in the availability of treatment facilities throughout the country. While all these factors would lead to an underestimate of the incidence, it is of interest that this rate does not differ appreciably from the 40 per million (treatable patients) estimated almost one decade earlier from the number of deaths from uremia[16].

In summary, existing data reveal a wide range in the incidence estimates (18 to 109 per million) with the majority of reports suggesting an incidence of about 30 to 60 cases per million per year.

The prevalence of end stage renal failure depends on the survival of incident cases. This, in turn, will depend on the number of incident cases offered supportive treatment and the effectiveness of the different modes of therapy. By definition, patients with end stage renal failure should not survive more than a year if they do not receive treatment. As a result, the prevalence at the end of the year should not differ appreciably from the yearly incidence, approximately 30-60 cases per million population.

If a large proportion of incident cases is successfully treated, the prevalence will be appreciably higher than the incidence. Unfortunately, no population has been studied and treated long enough with both stable selection criteria and stable programs to enable the calculation of an accurate prevalence rate. Indeed, treatment for end stage

renal failure has been available on a large scale only for approximately ten years and during that period the different programs have grown steadily and changed their selection criteria markedly[28].

Nonetheless, one study has attempted to produce prevalence information through use of a physician survey and review of death certificates and laboratory results. McCormick and Navarro[29] identified 79 patients with end stage renal failure of whom 41 were eligible for treatment by the criteria used in 1969. This yielded a prevalence of 38 per million population. If we use the more relaxed selection criteria of today, most of the 38 excluded patients would be accepted for treatment and the prevalence would be 73 per million population. However, since the treatment programs had not been available on a large scale for a long time at the time of this study, even the latter figure is certainly an underestimate of the prevalence at stability in a fully treated population.

A recent study of the situation in the United States[7] not only demonstrates this underestimate (305 patients per million population on dialysis in 1979) but also suggests that social, cultural and economic factors (rather than medical and epidemiological factors) explain most of the variation between states and/or countries (6 to 983 patients per million population).

TREATMENT OF ESRD

The two basic modes of therapy for end stage renal failure are dialysis and kidney transplantation. Patients offered transplantation are highly selected in terms of age and associated medical diseases[17]. Since similar restrictions are placed on those offered home hemodialysis[30,31], these two modes of therapy are basically the exclusive alternatives for specific patients with end stage renal failure and may be compared for decision making purposes.

Hemodialysis. Dialysis is defined as "the process of separating crystalloids and colloids in solution by the difference in their rates of diffusion through a semipermeable membrane; crystalloids pass through readily, colloids very slowly or not at all"[32]. In the body, the kidneys normally provide this function, separating crystalloids, many of which are waste products of metabolism, from colloids, the blood in which these products are carried. When the kidneys do not function, the process of artificial dialysis can keep the level of waste products within a range compatible with comfortable survival.

Two techniques can be used for dialysis when the kidneys do not function: peritoneal dialysis uses the peritoneum as the semipermeable membrane and hemodialysis uses a synthetic semipermeable membrane in a machine. These techniques can be further distinguished according to the place where they are done (home, hospital, special centers) and to the professionnal support they require.

Peritoneal dialysis was made available for maintenance dialysis in 1968 when Teckhoff described a bacteriologically safe implanted access device[33]. Although this technique seemed promising for widespread application[34], it has remained a marginal mode of therapy. Indeed, in 1975, only 12.6% of all Canadians on dialysis received peritoneal dialysis and less than half of them were treated at home[14]. Recently, a continuous ambulatory variant of the technique was evaluated on 13 patients. While it had several desirable aspects (simple, practical, cheap, relatively efficacious), there were also many undesirable features (high risk of peritonitis, large protein losses, urea clearance less than that by hemodialysis)[35],[36]. The long term results of this technique remain to be evaluated[37]. In view of the problems and limited use of this technique, it was not included as a mode of treatment in this study.

The artificial kidney, which made hemodialysis possible, was designed in 1948 by Kolff[38] and the cannulation device to insure repeated access to blood was developed in 1960[39]. The first long-term intermittent hemodialysis program was started in Seattle in 1962[40] and a home program began a year later. Between 1970 and 1977, the number of patients on hemodialysis in Europe increased dramatically from 4500 to 28,500[28], while in the United States it rose from 1500 to 10,000 between 1969 and 1974[16],[27].

Hemodialysis can be carried out either in the hospital or at home. Usually, home dialysis candidates are younger, male[30] and less severely ill[31]. The limited care dialysis center is a relatively recent alternative where patients share facilities and either self-

dialyse under supervision or receive limited help from professionals. Although there is very little data on the characteristics of patients in this group, it is reasonable to think that they will be somewhere between the two extremes usually identified with home and hospital dialysis.

Hemodialysis is an imperfect technique insofar as it cannot correct completely many of the metabolic deficiencies caused by the diseased kidney[41]. Furthermore, dialysis may produce serious psychological problems (psychosis and depression) due to the dependency on a machine to survive[41,42,43]. Applying the technique at home adds to these problems an additional psychological stress both on the patient and the family[41,44,45,46].

Despite these limitations, hemodialysis remains the most important mode of treatment[47,48] for end stage renal failure and home treatment has very specific advantages since dialysis may be done more frequently and for longer periods of time. This flexibility facilitates autonomy and full rehabilitation and permits better control of metabolic deficiencies. Moreover, home therapy reduces the risk of infection with the hepatitis B virus both for patients and professionals. Finally, home dialysis is much less expensive than most other modes of therapy, especially hemodialysis in hospital[49].

The prognosis of patients on home hemodialysis can be considered in terms of their survival and their rehabilitation. However, since most studies have involved heterogeneous groups of patients relatively poorly described with regard to the many variables likely to influence

survival and rehabilitation, the available data must be viewed cautiously. Figure 1 describes the survival of 9,063 patients on home hemodialysis in 29 different European countries[17]. This is the largest and most recent group studied. In Europe, while the differences due to age are obvious, the overall survival at five years for home hemodialysis is 15% higher than hospital dialysis, 5-10% higher than live donor transplantation and 15-20% higher than cadaver donor transplantation[17]. Two earlier American studies[50,51], involving 125 and 628 patients had three-year survival rates of 72% and 62% compared to the 83% in the more recent study. The reasons for the differences are unknown but could be related to selection biases or to secular changes in the cases or therapies. However, since other sources describe better survival for transplanted patients[28], comparisons between treatments remain hazardous.

Rehabilitation has not been studied as extensively as survival and the only outcome measured on a large number of patients has been rehabilitation to work (activity). Table 2 summarizes the rehabilitation of patients given dialysis (home or hospital) or transplantation (living or cadaver donor). The figures in column 2 show that there is little difference in the ability of patients in home hemodialysis or in transplantation programs to return to work. Similarly, the actual rehabilitation of patients in home hemodialysis and cadaver transplant programs is about the same (columns 3 and 4). The similarity does not hold for patients whose transplants come from living donors, their actual rehabilitation being better.

FIGURE 1

SURVIVAL OF PATIENTS ON HOME HEMODIALYSIS (IN PERCENT)[17]

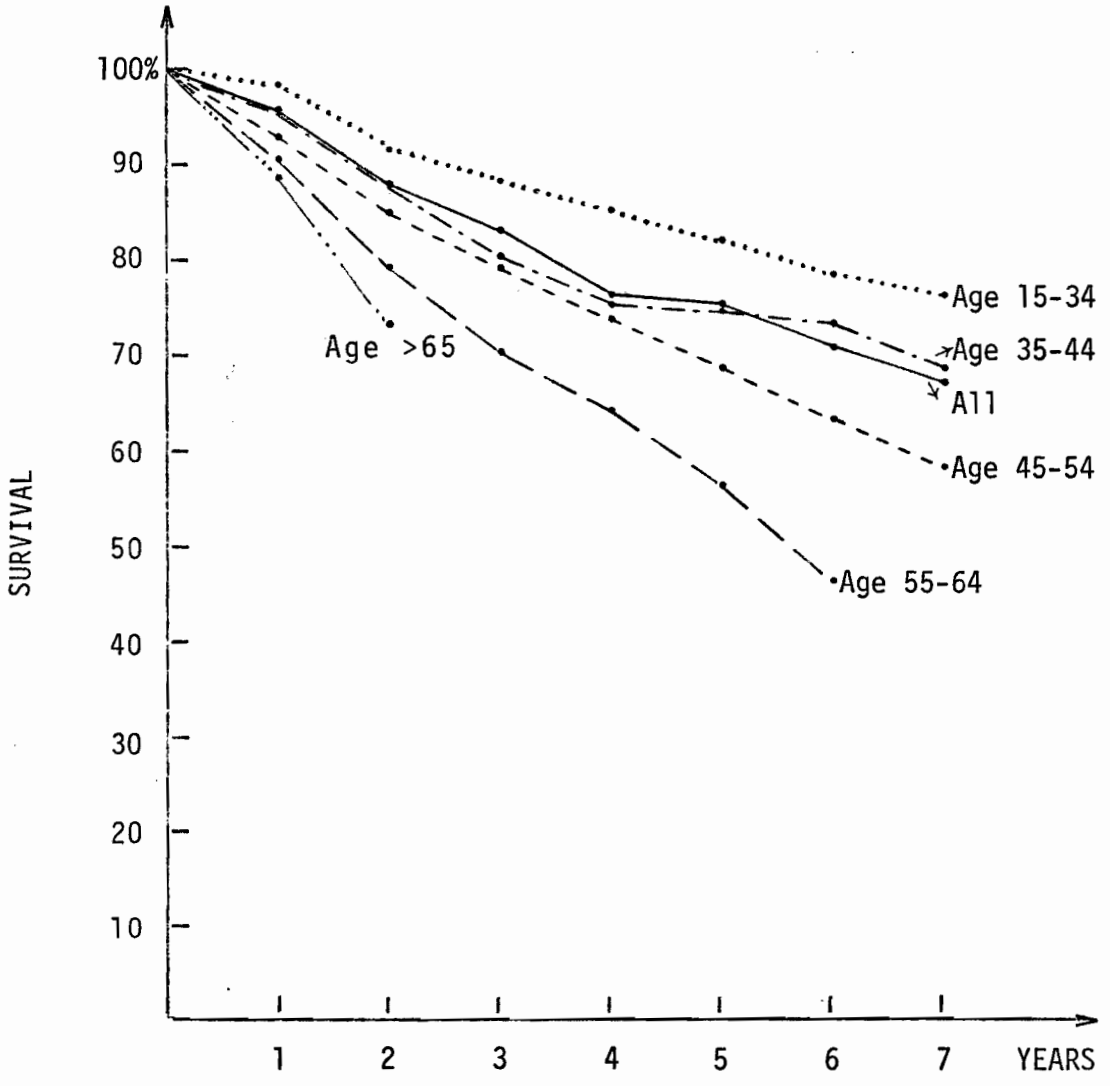


TABLE 2: REHABILITATION AFTER TREATMENT IN EUROPE[17]

	(1) Number of patients	(2) Percentage (of 1) considered able to resume full-time occupation by professionnals	(3) Did resume full-time occupation % of (2)	(4) Did resume part time occupation % of (2)
Home dialysis	4,335	93%	59%	16%
Hospital dialysis	18,473	81%	37%	20%
Transplantation living donors	734	98%	76%	11%
Transplantation cadaver donors	3677	96%	63%	16%

In two other studies for which data are available, 39% (12/31 patients)[46] and 36% (130/362 patients)[51] of cases on home hemodialysis actually returned to full-time occupation while 39% and 10% returned to work part-time. These results differ from the findings in Table 2 but we have no way to determine if patients in the different studies were actually comparable.

Kidney Transplantation. The second basic mode of therapy for ESRD, kidney transplantation, involves surgical replacement of the diseased kidneys by healthy ones. The first human kidney transplantations were reported in France in the late 1940s and in the United States in the early 1950s[52]. Once the surgical technique was established, efforts were concentrated on the development of immunosuppressive treatments to minimize the rejection caused by the immune reaction in the recipient. The latter development was first reported in 1962 by J.P. Merrill et al[53].

Since transplantation is a surgical technique, some of the complications with this mode of therapy result from technical failures that add considerably to morbidity[54]. Also, certain metabolic abnormalities associated with prolonged end stage renal failure are not always fully corrected by transplantation.

Perhaps the most important factor in the success or failure of transplantation is the immunosuppressive therapy given to prevent immunologic rejection of the graft. Corticosteroids and immunosuppressive drugs have been used with some success, but rejection still may

occur[41]. However, the drugs themselves may produce numerous and possibly serious side effects. Infections that could lead to death are the most common and serious complications attributed to immunosuppressive therapy, since suppression of the immune system increases the susceptibility of the recipient to microorganisms (bacteria, viruses, fungi)[52]. Other complications directly linked to corticosteroids or immunosuppressive medications, such as increasing the risks for other diseases[55],[56], add to the disadvantages of transplantation. However, since the early 1970s when the survival of the patient was given priority over the survival of the transplant, there has been less aggressive use of immunosuppressive agents[57]. This has been accompanied by marked improvement in patient survival without adversely affecting graft survival[58].

In addition, although living donors run a low risk of dying from nephrectomy, they have to pay a price: the perioperative complication rate may be as high as 28%[59], and in one study 19% of donors (12 of 64) were severely traumatized by the donation or the subsequent events[60]. The ultimate risks of live kidney donation are not precisely known[54].

The main advantages of transplantation are that it corrects many of the metabolic abnormalities associated with renal failure (anemia, abnormal nerve conduction, bone diseases) and it lacks the psychological stresses linked with dialysis. If the complications associated with surgery or immunosuppression are avoided and if there is prolonged graft survival with adequate function, transplanted patients should return to a long-lasting, autonomous life of good quality.

In considering the prognosis of transplanted patients, it is important to distinguish between those receiving a transplant from a living related donor and those receiving a cadaver transplant. This distinction has an intuitive basis in the fact that kidneys from related donors are less immunogenic than cadaver kidneys (unrelated donors) and less prone to immunologic rejection. Figures 2 and 3 describe the survival of 1,979 patients who received a transplant from a living related donor and of 12,670 patients who received a cadaver kidney[17]. The survival is obviously better in the former group (for example, 5 year survivals for age group 35-44 are respectively 65% and 58%). While the effect of age is in the same direction in both groups, it appears more pronounced in the recipients of cadaver kidneys as shown by the wider spread in Figure 3. Although similar results have been reported[15,50], other investigators found much better survival rates (80% three year survival for cadaver transplants)[28], and these differences are not easy to explain in view of the heterogeneity in the patients and in the different programs[28].

Another measure of the success of transplantation is the duration of graft survival. In general, there is also a recipient-age effect on graft survival, and kidneys from living donors function for a longer period. The survival curves for living donor and cadaver donor grafts resemble the survival curves for patients except that they are lower (by 12% for living donors; by 30% for cadaver donors) throughout the follow-up period. However, the one year graft survival (cadaver kidney) may vary from 15% to 75% from center to center[60].

FIGURE 2

SURVIVAL OF PATIENTS, FIRST LIVE DONOR GRAFT (1,979 PATIENTS[17])

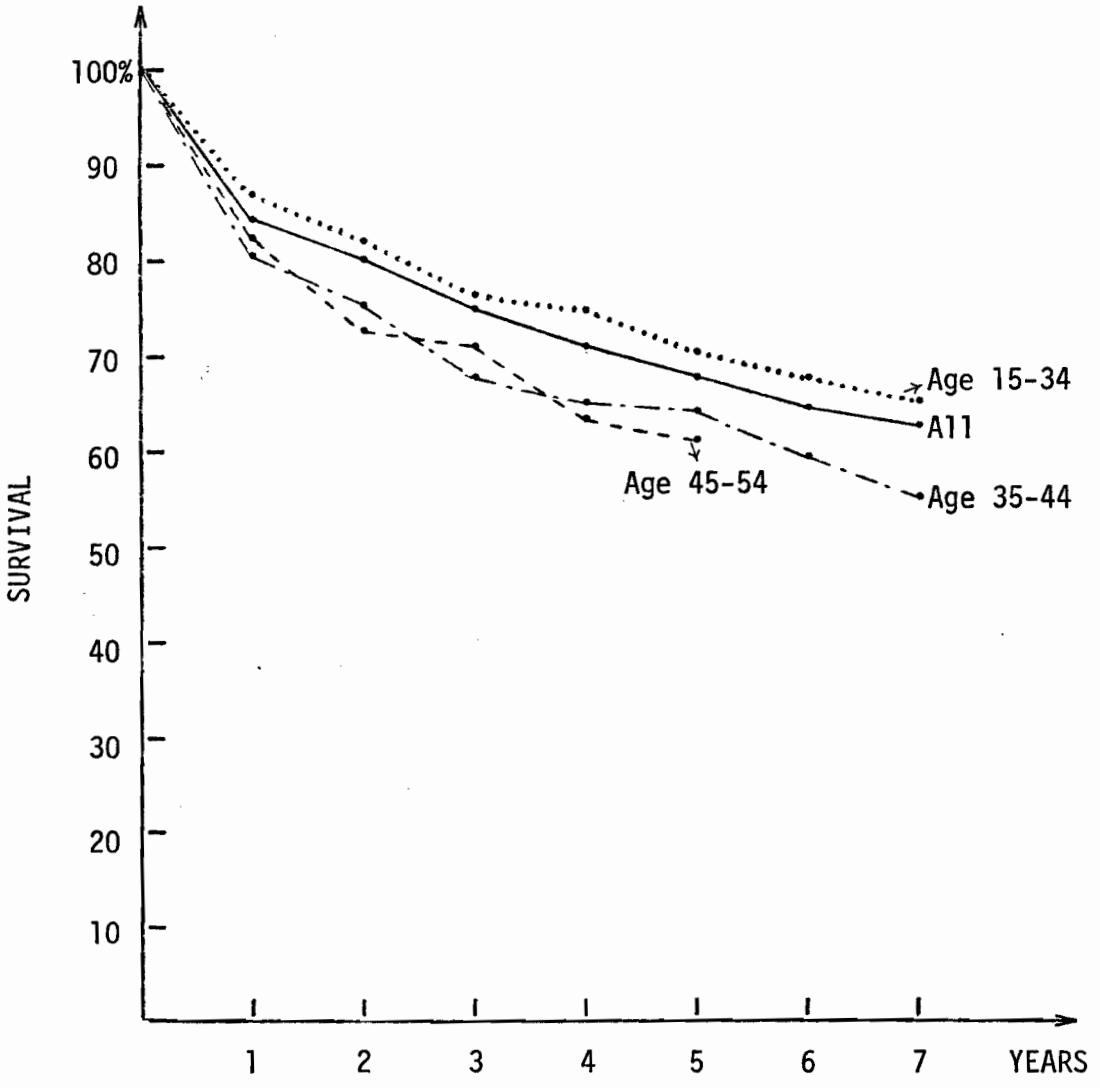
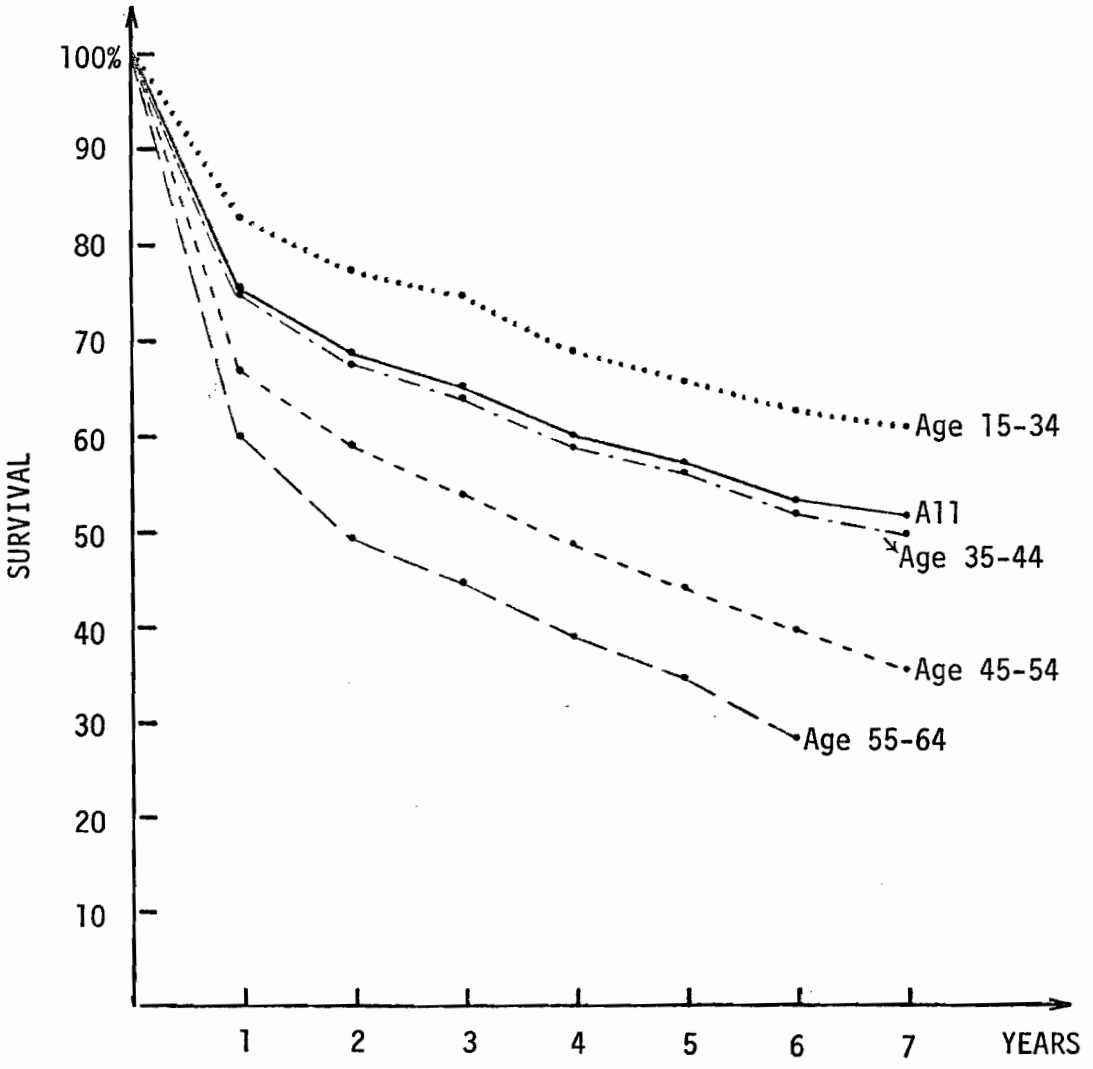


FIGURE 3

SURVIVAL OF PATIENTS, FIRST CADAVER GRAFT (12,670 PATIENTS[17])



There have been few studies of the morbidity, quality of life or rehabilitation of transplant patients. Krumlovsky et al[62] found that transplanted patients spent more of their survived days in hospital (16.6%) than hemodialysis patients (6.7%). However, the two groups may not have been comparable because their susceptibility to complications (morbidity) was not determined at the outset. Simmons and Schilling[63] reported that transplantation had a beneficial impact on the physical well-being, social-psychological adjustment, self-image, satisfaction with major role relationships, and vocational rehabilitation of 177 transplanted patients. Poznanski et al[64] described a similar effect in 18 children and adolescents although they document clearly the psychological problems associated with recurrent rejection or failure of the transplant.

Rehabilitation to work is the most commonly measured quality of life outcome and the results have been presented above (see Table 2).

EXTRAPOLATION AND NEEDS

Long term planning for treatment of end stage renal failure must rely on a number of assumptions regarding potential patient load. These include: 1) the incidence of end stage renal failure; 2) the distribution of patients among the different modes of therapy; 3) survival within each treatment; 4) the technological changes likely to influence either the distribution of patients among the different modes of treatment or the survival; 5) the changes in selection criteria likely to occur as treatment becomes more available.

The Burton report[16] was the first attempt to assess the implications of treating almost all patients dying from renal failure. Most of the assumptions used in this study were obtained from the literature available in 1967 and are summarized in Table 3. Comparison of these assumptions with those used in the more recent study by Barnes[65] (also shown in Table 3) illustrates the extent to which most parameters have changed in 10 years.

The estimates done by Barnes were also based on data available in the literature. The author acknowledged serious reservations about the interpretation of his results primarily because the cohorts of treated patients were relatively young and provided very little information on what would happen late in their natural history (10 years or more after starting treatment). Furthermore, it was practically impossible to predict the impact of technological changes and changes in selection criteria.

According to Barnes' estimate, at stability, the United States would support approximately 109,000 patients, a number still much larger than the 35,000 patients estimated to be under treatment in 1975 (22,000 patients on dialysis, 13,000 survivors of tranpslantation)[15].

Based on a twelve years' experience, on a constantly rising incidence of ESRD (5 to 72 patients per million population), and by treating 54% of their patients by center dialysis, 20% by home dialysis, 26% by transplantation, Cestero et al estimated that their program would reach equilibrium (stability) after 25 years and maintain 632 patients per million population under treatment[48].

TABLE 3: SUMMARY OF ASSUMPTIONS USED IN THE EXTRAPOLATION STUDIES

STUDIES	INCIDENCE	TREATMENTS	DISTRIBUTION OF PATIENTS AMONG TREATMENTS	DEATH RATE		TRANSPLANT FAILURE		OUTCOME
				FIRST YEAR	SUBSEQUENT YEARS	FIRST YEAR	SUBSEQUENT YEARS	
Burton Report 1968	200 patients per million per year	Hemodialysis	72%	50%	10%	-	-	900 patients per million population under treatment after 15 years
		Transplantation	28%	35%	-	30-35%		
Barnes Benjamin A. 1977	40 patients per million per year	Hemodialysis						*245 patients per million population under treatment after 10 years
		*Home	20%	8.8%	5.7%	-	-	
		*Hospital	50%	16.7%	9.6%	-	-	
		Transplantation						*515 patients per million population under treatment at stability
		*Living donor	10%	10.8%	4.9%	11%	15%	
		*Cadaver donor	20%	27%	8.8%	19%	18%	

For the province of Quebec, an annual incidence rate for ESRD of 20 per million population was estimated between 1971 and 1974[66]. This estimate was based on the number of patients reported to have begun treatment. According to the report this incidence rate necessitates a growth of 14% in the available resources between 1976 and 1981, while costs limitations require the reassignment of patients from hospital dialysis to self care or home hemodialysis, and to transplantation programs[65]. The details are summarized in Table 4.

ECONOMIC EVALUATION OF TREATMENT PROGRAMS

To evaluate a program in economic terms, the resources invested in the program have to be expressed in monetary terms (costs). When the outcomes of the program can also be expressed in monetary terms (benefits), the evaluation of the program means relating the benefits to the costs (two monetary values). This approach is called the cost-benefit analysis. By assigning a dollar value to designated program outcomes, this approach allows the comparison of benefits and costs within a specific program as well as between programs with similar or different outcomes. The first comparision is a response to the question "is the program financially rewarding" and the second is a response to the question "which of many alternatives is the most effective"?

However, it is not always possible to express outcomes in monetary terms, especially when they have no market counterpart. In this case, the outcomes (effectiveness) are difficult to value by their market price and they are expressed in units other than dollars (for example survival, quality of life). The evaluation process then relates the

TABLE 4: RESOURCES ALLOCATION FOR TREATMENT OF END STAGE RENAL FAILURE IN QUEBEC[66]

	1976 (actual)		1981 (projection)	
	Number of patients	Patients per million	Number of patients	Patients per million
center hemodialysis	240	40	144	24
self care hemodialysis	0	0	36	6
home hemodialysis	50	8	120	20
transplantation	123	16	138	23
all	413	64	438	73

magnitude of the effects to the financial costs of a specific program. This approach is defined as the cost-effectiveness analysis.

This part of the review focuses first on the cost-benefit analyses, and tries to determine if the treatment of ESRD is financially rewarding. That section describes the results and methodology of the studies, and identifies the weaknesses implicit in expressing benefits in monetary terms. The characteristics of the costing process in these studies are described in the next section with the cost-effectiveness studies.

In addition to describing the findings in the different cost-effectiveness studies, the next section underlines the main weaknesses especially with regard to the costing process. To facilitate the identification of these weaknesses, a short description of the potential pitfalls could be helpful.

The first potential pitfall has to do with the patients included in the different studies. A comparison between two treatments has meaning only if it can be shown that the treatment is the only difference between the groups of patients studied[8]. In other words the patients receiving different treatments should be comparable especially with regard to characteristics that could be related to cost or effectiveness.

Second, in addition to the obvious hospital cost, professional costs, home care costs and the value of time spent by family members to help the person on dialysis, should all be included in the calculation of costs.

Finally, since we are interested in finding the financial impact of choosing one program rather than the other, we have to accept the fact that patients are going to be treated whatever is the choice, and that whatever the treatment, the services provided to patients will be in large part, the same. Indeed, in the transplantation and the home dialysis programs, patients are going to be hospitalized, dialysed, operated on, investigated, etc. Measuring the impact of choosing one treatment should mean costing the differences in services between the two programs (marginal cost) and not costing all the services in each program before calculating the difference in cost (difference in total costs). The distinction is primordial as shown in the following example. Suppose that a transplantation program uses 100,000 laboratory tests in a year, while the home dialysis program uses 90,000. The marginal cost would be obtained by costing 10,000 tests while the difference in total costs would be obtained by costing first 100,000 tests and then 90,000 tests and finally generating the difference between these two costs. Costing 10,000 tests may not include any personnel or equipment costs (leaving only supply cost in the costing process) because it may represent only a minor change in the output of the program. In contrast, costing 100,000 tests (T) and 90,000 tests (D) would probably generate personnel and equipment costs, which, added to the supply cost, would lead to a high average cost per test. This high average cost per test would lead to the difference T minus D still much larger than the marginal cost of 10,000 tests. This inappropriate large difference in total costs of the two programs is the main reason why marginal cost is highly preferable[9,11].

Using the marginal cost approach introduces another issue: the size of the population studied. Since this approach deals with a difference in services, and since this difference is a function of the total number of patients in each program, as the number of patients increases, the impact on the institution may be larger, resulting in more costs (personnel and equipment costs may become pertinent). Consequently, an appropriate marginal cost study should try to involve the total number of patients that a program would have to support in reality and not an arbitrary number of patients.

Cost Benefit Analysis The first cost benefit study of treatment of end stage renal disease used the information available on survival, rate of rehabilitation, costs of treatment and average earnings (in 1968 dollars) to evaluate hemodialysis at home, hemodialysis in hospital and transplantation[67]. A summary of all the assumptions (or estimates) and of the results is shown in Table 5. The authors estimated the benefit/cost ratios of each treatment by the extension of a cohort analysis of 1000 individuals in each treatment. As seen in Table 5, all the benefit/cost ratios were smaller than one; only transplantation could achieve a ratio greater than one if the survival at 2 years were 90%.

Buxton and West[68] performed a similar analysis using more recent information on survival, rehabilitation costs and average earnings of patients receiving dialysis. Their assumptions (or estimates) and their results are summarized in Table 6. Their benefit-cost ratios are also smaller than one, and a sensitivity analysis in which one factor was varied at a time did not markedly change the outcome: benefits

TABLE 5: ASSUMPTIONS (ESTIMATES) USED IN COST BENEFIT STUDY BY LESOURD, ET AL[67]

TREATMENTS	DEATH RATE			REHABILITATION RATE (% OF PREMORBID EARNINGS)	COSTS PER YEAR***		BENEFIT* COST RATIO
	FIRST YEAR	TWO YEARS	SUBSEQUENT YEARS		FIRST YEAR	SUBSEQUENT YEARS	
HEMODIALYSIS							
•AT HOME	15%	-	10%	70%	$13,560	$4,160	0.65
•IN HOSPITAL	15%	-	10%	70%	$18,252	$18,252	0.25
TRANSPLANTATION							
•LIVING DONOR	→ 25%		-	60%	$18,500 - $20,720**		0.63 to 0.88
•CADAVER DONOR	→ 40%		-	60%	$18,500 - $20,720**		0.63 to 0.88

*Benefit calculated by using average earning between age 45 and 54: Male $6,075
Female $3,600

**Total costs of a transplantation, not a yearly cost•

***5-Year depreciation and 5% discount rate applied

TABLE 6

ASSUMPTIONS (ESTIMATES) USED IN COST BENEFIT STUDY BY BUXTON, ET AL

TREATMENTS	DEATH RATE AFTER 6 YEARS	REHABILITATION RATE (% OF PATIENTS ABLE TO WORK**)			COSTS PER YEAR***		BENEFIT COSTS RATIO §	I.S.V. §§
		YEAR 1	YEAR 2	YEAR 3 & AFTER	FIRST YEAR	SUBSEQUENT YEAR		
HOME HEMODIALYSIS	36.6%*	45%	65%	75%	£ 4690	£ 3390	0.31	£ 2600
HOSPITAL HEMODIALYSIS	50%	30%	52%	60%	£ 5600	£ 5600	0.16	£ 4720

*Taking into account six months on hospital dialysis before starting home dialysis

**Full-time equivalents' rates

***Taking into account: 1° Capital costs amortized over the appropriate number of years of utilization, 2° Direct running cost (including salaries of professionals) but excluding indirect costs, a discount rate of 10% per year was used

§Benefits calculated from average annual wages (1972): £1908 for men
£1066 for women

§§Implicit social value = $\frac{\text{total present value of costs - total present value of benefits}}{\text{discounted sum of life-years saved}}$

outweighed costs only when many cost factors decreased together toward estimates lower than best estimates and when benefits increased together toward higher estimates. The authors also calculated the implicit social value of each treatment. This represents the minimum social value of patients' life years saved implicit in the continuance or the expansion of these treatments. These two studies offer the best evaluation of ESRD treatments by the cost benefit approach. By contrast with them, the study by Longmore and Rehahn[69] concluded that treatment of renal failure was a cost to society only for the first two years. However, their methodology suffered from many weaknesses; many of their assumptions were at variance with other data in the literature and the differences (high survival, 100% complete rehabilitation, use of gross national products instead of average earnings, low dialysis costs) tended to overestimate benefits and underestimate costs[70,71].

In summary, all but one cost-benefit study suggest that treating patients with renal failure is generally not cost-beneficial. However, in all the studies, individuals are valued on the basis of their lifetime earnings (human capital approach), an approach that has serious shortcomings well summarized by Acton[72]. Arbitrary assumptions are used to solve problems of definition and measurement; for example, it is often assumed that a person's earnings are an adequate measure of social worth. Furthermore, this approach takes no account of the impact of disease on families and weighs differentially individuals or groups by accepting the unequal distribution of income. As a result, even the best of these cost benefit analyses cannot be considered sufficient for appropriate decision making.

Cost-effectiveness analysis. With their outcomes expressed in non-monetary terms, the cost-effectiveness studies usually have a limitation; they can be used only for comparing programs with similar outcomes[72]. However, short of using the market prices as a value index, the valuation process can be systematized through utility theory which assigns utility values between zero (utility value associated with death) and one (utility value associated with health) to the different health statuses of interest[73].

Only one study has applied utility theory to the field of chronic renal failure and found that the utility value for home dialysis was between 0.40 to 0.65 (depending on duration: for life or for 8 years). Kidney transplantation achieved a value of 0.58 (duration: 8 years) compared to hospital dialysis 0.56 (also duration 8 years)[74]. As a result, patients having the possibility to choose between transplantation (0.58) and home dialysis (0.65) for a duration of 8 years, would slightly prefer home dialysis to transplantation. This preference should be weighed against any difference in cost between the two treatments.

Most of the other cost effectiveness studies (Tables 7 & 8) related outcomes to costs and the outcomes were rarely measured in terms of quality of life. Thus, these cost-effectiveness studies were, in essence, cost studies concentrating their energy on cost estimation and only very crudely measuring effectiveness by reporting survival.

These studies are numerous and their results can be summarized by grouping them according to their scale. The first group, summarized in Table 7, includes studies that were performed with data from national or regional agencies[65,75,27,67,16,76,3]. The second group includes studies that usually describe either a single program or a small group of patients using more detailed information; these are summarized in Table 8[9,77,78,79,80,81,82,83].

In estimating the costs of a program of treatment for renal failure, the elements described by Douglas[9] should be taken into account. These elements, and the extent to which each study considered them in calculating costs, are shown in Table 9. The authors either specifically included the elements in their cost calculations (Y), they specified that they did not include them (N), they failed to mention the element so that it is impossible to know if it was included or not (N.S), or they clearly did not have to take it into account (N.A.: especially elements 4, 5 and 6 when a hemodialysis program was evaluated).

The different cost elements were rarely defined in the respective studies although they implicitly had similar meaning from one study to the other. Direct cost were usually costs which could be specifically allocated directly to a cost "centre"* or a cost "unit"**[11]. For example, direct costs with regard to fellowships or research would be the money spent in these cost centres when they pertained entirely to

* cost centre: location, person, item of equipment for which costs could be ascertained.

** cost unit: unit of product, service, or time in relation to which costs could be ascertained or expressed.

TABLE 7

COSTS OF TREATMENT IN END STAGE RENAL FAILURE

FROM NATIONAL OR REGIONAL DATA

SOURCE OF COSTS FIGURES	TREATMENT	C O S T S** FIRST YEAR	FOLLOWING YEARS	R E M A R K S	REFERENCES
National Surveys U.S.A.	Transplantation	$15,000	$ 1,500		65
American Hospital Association	Home Dialysis	8,000	6,000	Includes rental of machines	65
	Hosp. Dialysis	30,000	30,000		
Health Care Financing Administration, U.S.A.	Hosp. Dialysis	24,500	24,500		75
	Home Dialysis	17,000	15,400		
	Transplantation	25,000	1,500 - 3,000 9,000	If patient stable If patient unstable	
	Transpl. Rejection		10,000		
Department of Health Education and Welfare, U.S.A.	Hosp. Dialysis	30,100	30,100	*Range 15,800 to 39,600 depending on centers	27
	Home Dialysis	14,900	7,000		
	Center Dialysis	27,600	27,600	*Range 12,800 to 46,800 depending on centers	
	Transplantation	15,000	---	*Include hospital room, board, ancillary charge, professional fees	
Lesourd, D.A.	Hosp. Dialysis	18,252	18,252		67
	Home Dialysis	13,560	4,160	*Initial investment (machine and home alterations) charged the first year	

**U.S. Dollars

TABLE 7

COSTS OF TREATMENT IN END STAGE RENAL FAILURE

FROM NATIONAL OR REGIONAL DATA (CONTINUED)

SOURCE OF COSTS FIGURES	TREATMENT	C O S T S** FIRST YEAR	FOLLOWING YEARS	R E M A R K S	REFERENCES
Burton, B.T.	Hosp. Dialysis	$20,000	$20,000		16
	Transplantation	16,000	?	*Pre-transplant treatment and medication excluded	
Committee on Chronic Kidney Disease, Bureau of the Budget, U.S.A.	Hosp. Dialysis	14,000	?		76
	Home Dialysis	5,000	?		
	Transplantation	15,000	?		
Committee on Finance, United States Senate, 95th Congress	Hosp. Dialysis	24,800	24,800		3
	Home Dialysis	22,760	13,237	*Home modifications and equipment purchase accounted during first year	
	Transplantation				
	living related	20,700	500 - 1,500	Graft rejection $9,000	
	cadaver	34,400	1,500 - 3,000		

**U.S. Dollars

TABLE 8

COSTS OF TREATMENT IN END STAGE RENAL FAILURE

FROM PROGRAMS

SOURCE OF COSTS FIGURES	TREATMENT	C O S T S* FIRST YEAR	FOLLOWING YEARS	R E M A R K S	REFERENCES
Blagg, C.	Institutional Dialysis	$20,000 - 30,000	same	*Including doctors fees	9
	Home Dialysis	2,500 - 3,500	same		
Rae, A. et al	Home Dialysis	14,601	9,094	*If costs of equipment and home alteration are charged first year	77
		9,645	9,645	*If these costs are amortized over 10 years	
				*From prospective observation of 22 patients	
Johnson, W.J., et al	Home Dialysis	14,745 - 24,723	3,945 - 7,123	*Costs of quipment and home alterations charged entirely first year	78
	Community Hosp.	12,000 - 18,600	12,000 - 18,600	*From prospective observation of respectively 16, 7, and 22 patients	
Pearson, D.A.,	Hosp. Dialysis	14,000 - 25,000		*Questionnaires sent to 12 programs, reviews of hospital financial and billing documents, interviews with staff and blue cross	79
	Home Dialysis	5,616			
Schippers, H.M.A., et al	Hosp. Dialysis	DFL 68,712		*From tariffs used in Dutch Public Health Insurance Companies and in Committee on Hospital tariffs in the Dutch Government	80
		17,000			
	Transplantation	DFL 40,767		*Average number of procedures obtained from review of charts of respectively 25 and 96 patients	
		11,500			

* U.S. Dollars if not otherwise specified

TABLE 9: ELEMENTS OF COSTS CONSIDERED IN THE LITERATURE

IMPORTANT ELEMENTS OF COSTS (At Home or in Hospital)	BARNES, B.A.	STANGE, P.V.	REPORT TO CONGRESS	LESOURD, D.A.	BURTON, B.T.	KLARMAN, H.E.	DOUGLAS, R.A.	RAE, A. et al	JOHNSON, N.J. et al	PEARSON, D.A. et al	SCHIPPERS, H.M.A. et al	STEWART, J.H. et al	BILINSKI, R.T. et al	DIETHELM, A.G. et al	ROBERTS, S.D. et al
-Direct costs with regard to:															
a) personnel	NS*	Y	NS	Y	NS	NS	NS	Y	Y	Y	Y	Y	Y	Y	Y
b) fellowships	NS	NS	NS	Y	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
c) supplies	NS	Y	NS	Y	NS	Y	NS	Y	Y	Y	Y	Y	Y	Y	Y
d) equipment	Y	Y	NS	Y	NS	NS	NS	Y	Y	N	Y	Y	Y	Y	Y
e) depreciation	NS	NS	NS	Y	NS	NS	NS	NS	NS	NS	Y	NS	Y	NS	N
f) travel	NS	NS	NS	Y	NS	NS	NS	NS	NS	NS	Y	NS	Y	NS	N
g) research	NS	NS	NS	Y	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS	N
-Overhead costs	NS	NS	NS	Y	NS	NS	NS	NS	Y	Y	Y	Y	Y	NS	NS
-Professional fees	NS	Y	NS	NS	NS	NS	Y	Y	NS	NS	Y	Y	Y	N	Y
-Pre transplant treatment during waiting period in transplant costs	NS	NS	NS	NS	NS	NS	NA	NA	NA	NA	NS	Y	NA	Y	Y
-Post transplant dialysis in transplant costs	NS	NS	NS	NS	NS	Y	NA	NA	NA	NA	NS	NS	NA	NS	NS
-Expenses of living donors in transplant costs	NS	NS	NS	NS	NS	NS	NA	NA	NA	NA	NS	NS	NA	NS	NS
-Marginal costs methodology	NS	N	NS	NS	NS	NS	NS	NS	NS	N	NS	N	NS	NS	NS

*Y: Yes, included in the costs calculation
N: No, not included
NS: Not specified
NA: Not applicable

the programs studied (dialysis, transplantation). Overhead costs were the costs that could not be directly associated with the production of a cost unit or with the activity of a cost centre but had to be apportioned on a suitable basis[11]. For example, the cost of heating a space (where the program studied is located) which is a small part of a larger institution came from apportioning the cost of heating the large institution. Professional fees were costs related to professional interventions that were not taken into account in the costs of personnel.

This table shows clearly that many elements were not specified in each study. This introduces uncertainty in the cost estimates. Even in the study of Lesourd et al, it is not clear if the treatment and dialysis costs during the waiting period for transplant were included in the costs of transplantation. Furthermore, it is not clear if professional fees were included in the cost calculations or if the expenses incurred by living related donors are included in the transplantation costs. It seems that no study took this factor into account.

Many of these studies appear to have used an average costs methodology, and none employed the marginal cost methodology for an accurate cost estimation. This methodology is considered the best costing approach for decision making, since it estimates the effect on costs and benefits of undertaking a specific course of action and eliminates the residual costs which are the same no matter which alternative is chosen[11].

However, previous cost benefit or cost-effectiveness studies remain inconclusive not only because they did not use proper costing methodology, but also because they did not study patients who were convincingly comparable. Any program assessment must control for differences in patients (other than treatment) which influence program costs and outcomes. For instance, age, sex, diagnosis and residual renal function are known to be related to service utilization and costs[84,85,86]. Similarly, age, diagnosis[87,28], level of activity, associated medical diseases[87], personality characteristics[88,89,44] and occupation[90] are associated with rehabilitation or prognosis. The comparability of patients in two groups would be insured if, and only if, most of these factors are shown to play a similar role in the two groups. This similarity was never ascertained in any of the studies reviewed.

Furthermore, the questionable quality of the information available is also suggested by the large variations in the estimates summarized in Tables 7 and 8: 1) the costs of home dialysis for the first year vary from $2,500 to $24,723; 2) the costs of hospital dialysis for the first year vary from $7,500 to $30,000; 3) the costs of transplantation for the first year also vary from $8,900 to $25,000. Nevertheless, the available data (Tables 7 and 8) suggest that transplantation would be more expensive than home hemodialysis for the first year of the program, while the reverse would be true for the remaining period under treatment. According to longitudinal extrapolation studies, over time, transplantation would appear less costly[76].

In summary, hemodialysis at home and transplantation appear as alternative modes of treatment for end stage renal failure, with each mode having its advantages and disadvantages. Proper choice between these two treatments requires detailed study of all the costs and benefits of each. However, the poor comparability of patients between groups and the weaknesses in the costing methodology noticed in the studies reviewed, jeopardize the usefulness of these studies for making decisions about the desirability of different treatment approaches for end stage renal disease.

Given the uncertainty remaining despite previous studies, we have taken another look at the issue taking into consideration the prognosis of the groups studied and assessing all the cost factors with the marginal cost methodology.

CHAPTER 3 MATERIAL AND METHODS

This study sought to compare the costs of treatment for two groups of comparable patients, one receiving home hemodialysis, the other transplantation. These two methods of treatment had been available in Montreal for more than ten years when the study was undertaken, suggesting that a retrospective look at patients treated during that period could generate the information sought.

SUBJECTS:

In Montreal, hospital A treats patients with end stage renal failure primarily by home hemodialysis while hospital B provides transplantation. They have followed these respective policies for over 10 years. As a result, patients with ESRD have been treated differently only because they have been cared for in different hospitals.

All patients considered as candidates for home hemodialysis or transplantation at hospitals A and B, respectively, since 1970 were eligible for the study. However, only those subjects who could be matched on variables influencing survival, costs, and on eligibility for transplantation, were actually selected as subjects.

The charts of 151 patients (17 home hemodialysis, 134 transplantation, the total number of patients treated in each program from 1970 to 1978) were reviewed to identify the following characteristics: age, sex, primary renal disease, other medical diseases, occupation,

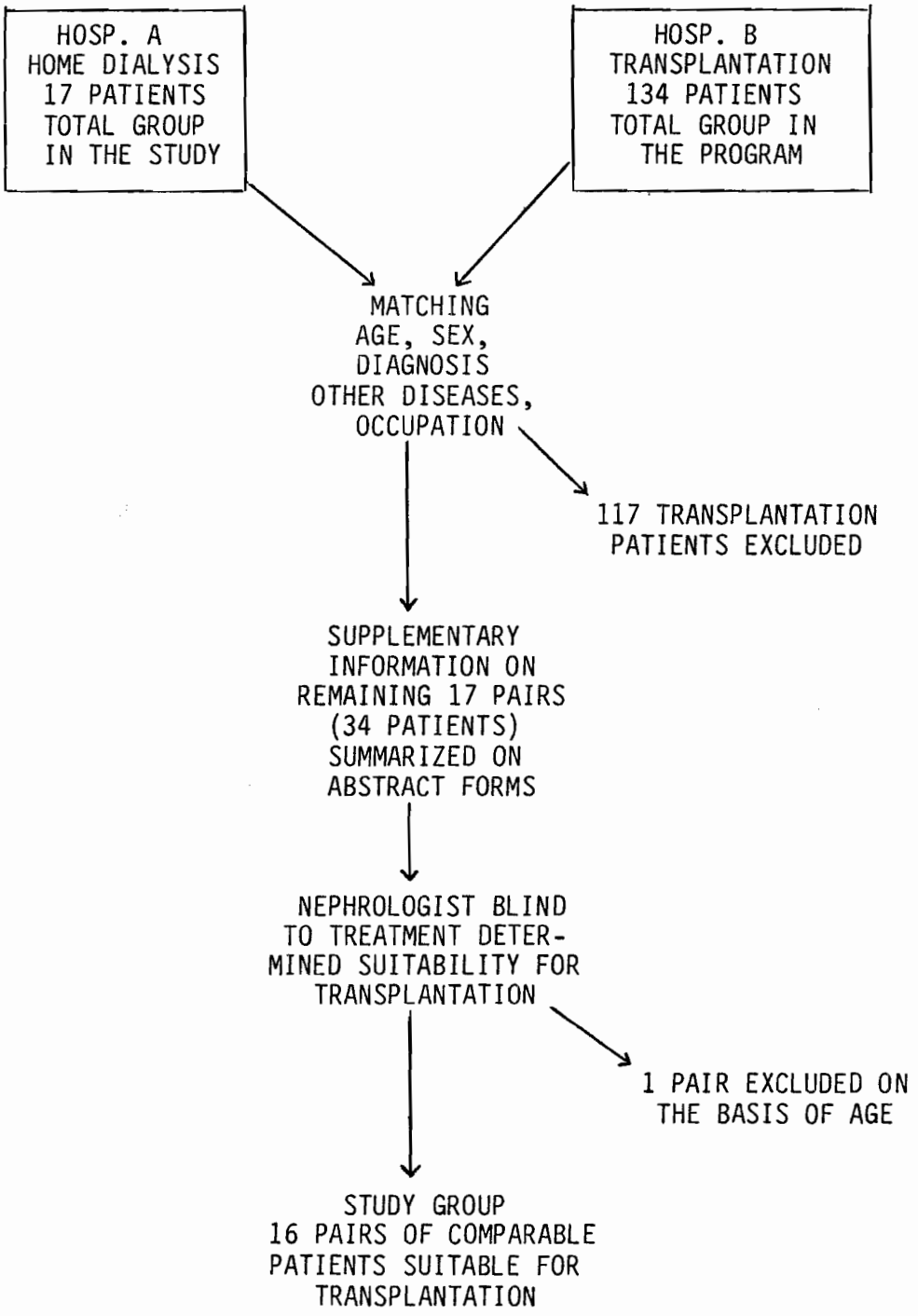
residual renal function and premorbid (one year before evaluation*) level of activity (work, housework or study) (see Figure 4). This information was then used to assemble matched pairs of patients in order to ensure that subsequent cost assessments were related to differences in treatment and not to differences in the patients in each program.

Information on age and sex was always available and clearly stated in the chart. Information on primary disease was also available for each patient; any case where the diagnosis was not clearly stated was eliminated to avoid possible selection bias. The presence of associated medical disease was judged either by direct mention in the chart or by pre-established criteria. Patients were considered to have hypertension if antihypertensive medications were being administered or if the blood pressure was above 150/90 mm hg on three successive readings at least one week apart shortly before or during evaluation. The diagnosis of diabetes was made if the patient was on insulin or an oral hypoglycemic agent, if he was prescribed a diabetic diet or if blood sugar determinations were in a diabetic range (2 hours after meal - more than 120 mg per 100 ml).

An attempt was then made to match the 17 hemodialysis patients with the transplantation cases on three primary characteristics: sex, primary renal disease, and associated medical disease. All but one

* Evaluation refers to the first encounter (in hospital or not) when the patient was identified as a candidate for either home hemodialysis or transplantation and was put on one of the program lists.

FIGURE 4: COLLECTION OF DATA



hemodialysis patient could be perfectly matched. This patient had glomerulonephritis that differed in type (hence a different name from his partner). However, the two patients in this pair were matched for associated disease, including hypertension, the major source of prognostic differences between the two primary diseases. For this reason, the difference between these patients was not considered significant (see details in Appendix A, Table A-1).

Once the three primary characteristics were matched, age matching was attempted. Ten pairs could be matched within 5 years of age, and three pairs within 10 years; four pairs differed by more than 10 years. The summation of the differences by pair (transplantation minus home hemodialysis) led to a total difference between the two groups of 22 years (see details in Appendix A, Table A-2). However, one pair was excluded at a later stage (patients 9 and 32) and the summed difference between pairs decreased to one year.

Matching on occupation could not be done in view of incomplete or imprecise information in the charts. For example, some patients were classified as retired at the time of evaluation but there was no mention of the length of or reason for retirement, or of their occupation before retiring. A summary of the available information on occupation can be found in Appendix A, Table A-3.

Since the best index of kidney funtion, endogenous creatinine clearance, was unavailable for several patients (six in each group), matching on this variable was not performed. However, we compared the

information available stressing the clinical difference between the two groups rather than the statistical difference. Table 10 describes the distribution of patients for whom information was available according to levels of residual renal function that were suggested as clinically significant by Bonomini et al[85]. This table, as well as the available raw data (Appendix A, Table A-4) suggest that the two groups were clinically similar (an unpaired t-test on the raw data was used in view of the importance of missing data; the p value was 0.1*). Moreover, in the six patients per group for whom the endogenous creatinine clearance was unavailable, the serum creatinine levels were similar: the average serum creatinine was 12.5 mg/dl (range 9-16.5) for transplantation patients and 12.8 mg/dl (range 9.4-14) for dialysis patients.

Of the many metabolic deficiencies associated with renal failure, anemia has been definitely correlated with the severity of disease[91]. Since anemia develops only slowly, its severity is an indicator of the long term effects of renal failure. Comparison of the two groups with regard to anemia (hemoglobin in gm/dl) showed convincingly that they were similar: 7.7 gm/dl average for transplantation patients versus 7.3 gm/dl for dialysis patients with ranges of 6.0-10.0 and 4.7-10.4. Data are detailed in Appendix A, Table A-5. An unpaired t-test gave a p value of 0.35** and a paired t-test on the 12 pairs for whom information was available gave a p greater than 0.7.

* The test had a power greater than 95% for detecting a difference of 5 cc/min/m^2 between groups.

** The test had a power of 95% for detecting a difference of 1 gm/dl between the groups.

TABLE 10: ENDOGENOUS CREATININE CLEARANCE

A) In the pairs of patients with available information

HOME DIALYSIS \ TRANSPLANTATION	0 - 5*	6 - 15*	
0 - 5	2	2	
6 - 15	1	1	
			6 pairs

B) For patients whose matched partner lacked information

	TRANSPLANTATION	HOME HEMODIALYSIS	
0 - 5*	2	2	
6 - 15*	3	2	
			9

Finally, because information on premorbid level of activity was not available, matching on this variable was impossible. Nonetheless, the information was subsequently obtained from questionnaires administered to the patients selected for the study and an "a posteriori" comparison was performed (Table 11). Statistical analysis was done on a two-by-two table grouping full-time and part-time activity together. The McNemar test with continuity correction gave a $p = 0.1336$ suggesting that the two groups were similar. However the power to detect a 10% difference between the two groups is very low (51%).

The matching process led to the identification of 17 pairs of patients. Both the "a priori" comparisons (sex, primary disease, associated medical disease, age) and "a posteriori" comparisons (occupation, residual renal function, premorbid level of activity) suggested that the two groups of patients were comparable prior to treatment.

These 17 pairs were then put through a second selection step (see figure 4) to determine their eligibility for transplantation. Information from patients' charts at the time of evaluation for treatment was summarized according to predetermined criteria on standardized forms* (see Appendix B) and submitted to a transplantation specialist blind to treatment. This expert accepted all but one patient for transplantation. The exception was a male patient over 55 years of age. When he and his paired partner (patients 32 and 9) were excluded, 16 pairs of comparable patients all eligible for transplantation were left for study.

* Electrocardiograms and radiological tests were reread by a cardiologist and a radiologist blind to treatment.

TABLE 11: LEVEL OF ACTIVITY ONE YEAR BEFORE EVALUATION

		TRANSPLANTATION			
		FULL-TIME* ACTIVITY	PART-TIME ACTIVITY	NO ACTIVITY	TOTAL
HOME HEMODIALYSIS	FULL-TIME ACTIVITY*	7	2	4	13
	PART-TIME ACTIVITY	1	0	0	1
	NO ACTIVITY	0	0	0	0
		8	2	4	14**

* Patients spending 30 hours per week performing usual activity

** Two patients and their families could not be reached (one in each program), consequently two pairs could not be included in this table. Also one patient was excluded at a later stage because he was not suitable for transplantation.

SOURCES OF INFORMATION

There were three main sources of information. First, charts in the two hospitals studied were reviewed extensively to obtain information on the hospital services received by each individual (all items of information obtained from this source are summarized in Table 12). Although the accuracy of charts may be questioned particularly for certain types of information (e.g. health status), most of the services important for costing purposes are likely to be recorded correctly. Furthermore, any inaccuracies in the charts probably reflect the under-reporting rather than the over-reporting of events, and there is no reason to think this under-reporting would differ systematically between hospitals or programs.

Second, hospital records (pharmacy and supplies) were used to estimate the cost of supplies for treatment at home. This information was probably quite precise and valid, although it was not available for all patients for the total duration of treatment. However, many patients obtained their supplies for home treatment from the hospital, and this information was kept on records.

Third, questionnaires* were sent to patients (families and/or physicians were interviewed by telephone if the patient had died) to obtain information on the costs of treatment at home or at other

* This instrument comprised questions formulated for this study as well as items selected from the literature. It was pre-tested on five patients receiving hospital hemodialysis. The information obtained on their past medical experience (previous periods of dialysis treatments, previous transplantation services received at other centers) and on their level of activity or health status perception was identical to the information in their charts and/or known to the treating physician.

TABLE 12: SUMMARY OF SOURCES OF INFORMATION

SOURCES OF INFORMATION	VARIABLES					
	PATIENT VARIABLES				COST VARIABLES	
	SURVIVAL	LEVEL OF ACTIVITY	HEALTH STATUS	MAJOR MEDICAL EVENTS	HOSPITAL SERVICES	HOME SERVICES
Patients' charts	Deaths often occurred in hospital			Transplantations Transplant failures Return to hospital dialysis	Information on all hospital services listed in Table 15	
Hospital records	Deaths that occurred outside the hospital were known to the programs					Information on supplies provided monthly to patients on home hemodialysis mostly from pharmacy and central supply depts.
Questionnaires		Level of activity before and after treatment	Health perception and physical capacity at the time of study	Transplantation, transplant failure, and return to hospital dialysis in other medical centers	Services received in other centers or by other physicians	Number of hemodialyses Number of artificial kidneys; Liters of dialysate per month, etc. alterations in home equipment Transportation Help from member of family and loss of income for that reason

medical centers, and on the patients themselves (level of activity, health perceptions, physical capacity) (see Table 12). While this reliance on memory, especially when the respondent was a member of the family, may have underestimated the services provided by other centers, there is no reason to believe that there would be any systematic recall biases based on type of treatment received.

MEASURES OF EFFECTIVENESS AND COST

The retrospective approach of this study made it difficult to measure effectiveness in great detail; it was impossible to construct health status indices for the patients studied. Nonetheless, the information from the questionnaire on the level of activity and health perceptions of patients served as indicators of health status.

All the important events such as transplantations, transplant failures, transfers from one mode of treatment to another, losses to follow-up and deaths were noted and grouped into a summary of events describing the follow-up period of each set of patients.

Assessing the cost of treatment involved a comprehensive description and counting of all services received by each patient either in hospital or at home (including losses of income by family members) and a good estimate of the impact of these services as direct, indirect or intangible costs. The services described and counted for each patient are listed in Table 13. The assignment of costs to each of these services is described in detail in Chapter 4.

TABLE 13: TYPES OF SERVICE COST ACCOUNTED*

Hospital services	1. Number of treatments of hemodialysis in hospital
	2. Number of treatments of peritoneal dialysis
	3. Number of each type of intervention**
	4. Laboratory services
	5. Social service visits
	6. Physical medicine visits
	7. Visits in office or clinics
	8. Anesthesia
	9. Number of days in hospital
	10. Number of days of intensive care
	11. Number of each type of consultation in hospital
	12. Medications
Home services	13. Transportation
	14. Number of remunerated hours lost by persons helping patients at home
	15. Number of hemodialysis treatments at home

* When the transplant came from a living donor, services received by the donor were counted as having been received by the transplanted patient.

** Diagnostic or therapeutic interventions such as biopsies, operations, etc.

If one assumes that, for each of the seven years for which we have information, a group of 16 patients similar to our initial group began treatment, one could estimate the costs during the 7th year of supporting all the survivors treated over these seven years. This estimate could be obtained by adding the marginal costs (impact) of the program for each of the seven years. This approach in fact translates data obtained from one cohort over seven years into data obtained from seven similar cohorts (each in a different year of its follow-up) during the seventh year of the program; as a result, it measures the impact of running the program during its seventh year, and this impact is the basis for the application of the marginal cost methodology. Since the costs of interest are the costs incurred for one year, discounting and adjustment for inflation were not indicated[92]. Our results are in constant 1977 dollars.

Another issue to be considered in estimating the cost of services in this study is the fact that some patients changed programs during the follow-up period. This required a decision as to which program would be assigned the costs of the services received after the switch was made. Since institutions offering transplantation programs must also have available a dialysis program for patients awaiting transplantation and for patients who reject their transplant, dialysis support was considered an integral part of the transplantation program and all the dialysis costs incurred by patients after their acceptance for transplantation (including costs both before and after the transplant) were counted under this latter program.

In contrast, an institution choosing to offer home hemodialysis does not necessarily require a transplantation program. Consequently, transplantation need not be considered part of the dialysis program, and the costs of the hemodialysis program need not include transplantation costs when patients elect to be transplanted after they have been treated on home hemodialysis for a certain time. However, it may also be argued that, in a real life situation, transplantation will most likely be available and inevitably a certain number of patients will switch from home hemodialysis to transplantation. In this case, it would be suitable to keep the transplantation costs within the home hemodialysis program to have a better estimate of the costs. To allow for both positions, two estimates of the costs of hemodialysis were done: the first excluding transplantation costs (home dialysis), the second including them (mixed home dialysis).

CHAPTER 4 ANALYSIS AND RESULTS

The ultimate goal of analysis was to describe and analyse the differences in effectiveness and costs between the two programs. After having summarized the events in each group, statistical methods for qualitative data were used to assess the significance of the differences in effectiveness. To analyse the difference in costs, more complex methods were required. They included the following five procedures: 1) computation of an adjusted life table; 2) calculation of the difference in number of services between the two programs; 3) calculation of the costs impact of the service differences; 4) generation of the total difference in costs between the two programs; 5) generation of the total costs per patient (individual costs) and their statistical analysis.

SUMMARY OF EVENTS IN HEMODIALYSIS AND TRANSPLANT PROGRAMS

Tables 14 and 15 present the most important and pertinent events in the follow-up period for patients in each program. Since this information is primarily descriptive, statistical analyses were not pertinent.

As can be seen in Table 14, the number of patients under observation at the beginning of each year did not differ markedly between the two groups but the number of patient-years under observation differed markedly for the third year (much less for all other years). Major losses to follow-up occured during this third year in the two groups but for different reasons (five patients in the transplantation group

TABLE 14: SUMMARY OF EVENTS

	TRANSPLANTATION							HOME DIALYSIS*						
YEAR	1	2	3	4	5	6	7	1	2	3	4	5	6	7
Patients under observation at beginning of year	16	16	14	8	6	5	4	16	16	15	9	8	6	4
Patient-Years observed**	16	14.83	9.67	7.25	5.42	4.42	3.67	16	15.33	13	8.83	6.42	5.0	4.08
Patients lost to follow-up due to late entry in treatment group	-	-	5	1	1	1	2	-	-	-	1	-	1	3
Patients transferred from home dialysis to transplantation	-	-	-	-	-	-	-	-	1	5	-	1	-	-
Transplantation Operation	14	4	-	-	-	-	-	-	-	-	-	-	-	-
Transplant Failure	4	1	-	-	-	-	-	-	-	-	-	-	-	-
Death	-	2	1	1	-	-	-	-	-	1	-	1	1	-
Patients who returned on hemodialysis in hospital	2	1	-	-	1	-	-	-	-	2	1	-	-	-

* Patients transplanted were excluded at the time of transplantation

** Each patient under follow-up at the beginning of each year was weighted by the proportion of the year during which he was observed

TABLE 15: SUMMARY OF EVENTS

	TRANSPLANTATION							MIXED HOME DIALYSIS*						
YEAR	1	2	3	4	5	6	7	1	2	3	4	5	6	7
Patients under observation at beginning of year	16	16	14	8	6	5	4	16	16	16	14	10	8	6
Patient-Years observed**	16	14.83	9.67	7.25	5.42	4.42	3.67	16	16	15.5	11.5	8.67	7.6	4.08
Patient lost to follow-up due to late entry in treatment group	-	-	5	1	1	1	2	-	-	1	2	-	1	4
Transplantation Operation	14	4	-	-	-	-	-	-	1	6	1	1	-	-
Transplant Failure	4	1	-	-	-	-	-	-	1	2	1	-	-	-
Death	-	2	1	1	-	-	-	-	-	1	2	2	1	-
Patients who returned on hemodialysis in hospital	2	1	-	-	1	-	-	-	-	2	1	-	-	1
Patients who returned on hemodialysis at home	-	-	-	-	-	-	-	-	-	1	1	-	-	-

* Patients transplanted remained in the program

** Each patient under follow-up at the beginning of each year was weighted by the proportion of the year during which he was observed.

were lost to follow-up because they entered late, while five patients in the dialysis program switched to transplantation). Eighteen transplantions were performed in the transplantation program (two patients had two transplantations each) and five transplants failed in the first two years. The number of deaths and the number of patients who returned to hemodialysis in hospital did not differ markedly between the two groups but these events tended to happen later in the home dialysis program. A total of seven patients in the home dialysis program eventually received a transplant.

Table 15 compares the transplantation to the mixed home dialysis program (patients in the home dialysis program were retained in this program even after they received a transplant). There was a large difference both in the number of patients under observation at the beginning of each year after the third year and in the number of patient-years after the second year. The large difference in the number of patients lost to follow-up due to late entry, especially for the third year, suggests that the patients in the transplantation group entered in their program chronologically later than the patients in the home dialysis group. Finally, although there were half as many transplantations in the mixed home dialysis program, the total number of transplant failures was similar in the transplantation group.

The differences between Tables 14 and 15 are related to the differences between "home dialysis" and "mixed home dialysis". The former group excludes patients as soon as they are transplanted while the latter keeps them under observation.

EFFECTIVENESS OF THE PROGRAMS

The information on survival for each program was organized in life tables (Appendix A, Table A-6) and in survival curves (Figure 5) and the statistical significance of the difference was estimated by calculating the 95 percent confidence limit associated with the life table of the transplantation group. As can be seen, the probabilities of survival at the end of the seventh year are grossly similar to each other and to the results reported in the literature (Figures 1,2,3). The 7 years survival of dialysis patients is well within the 95% confidence limit applied to the transplantation program. However, the small number of patients produced wide confidence limits and decreased to 50% (power) the probability of detecting a difference of 10% between the groups.

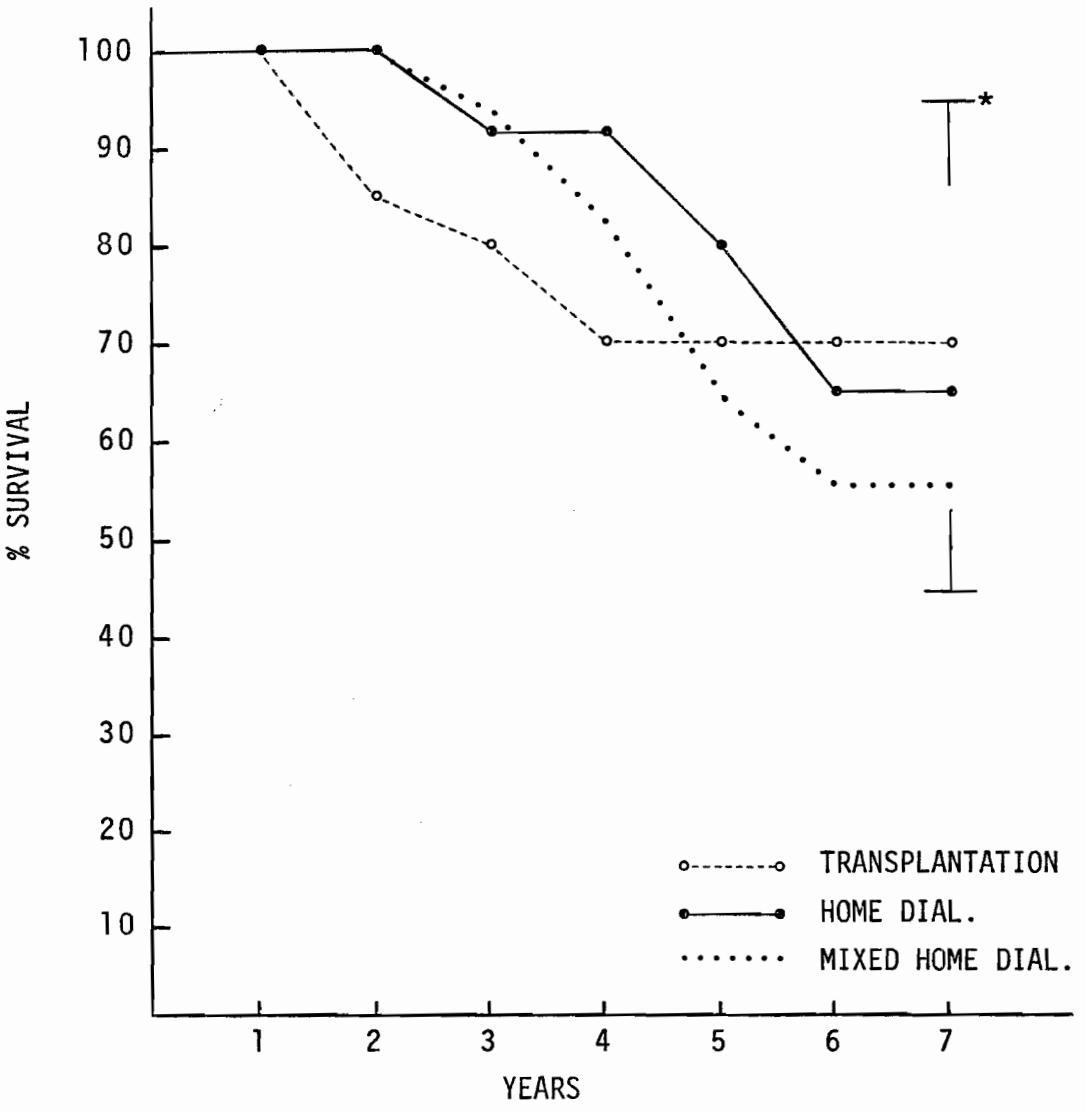
The curves also demonstrate that transplanted patients tend to die earlier but this difference does not reach statistical significance.

As the best measure of quality of survival available, information on level of activity one year after treatment is summarized in Table 16. It indicates the patients' perceptions of their ability to work one year after treatment relative to their ability to work one year before treatment.

For seven pairs, therapy made no difference. Among the remainder, the transplanted patient did better in four (3 + 1 below the diagonal) and worse in three (1 + 2 above the diagonal) pairs. These data were analyzed in the format of a 2 x 2 table by grouping "improved" and

FIGURE 5

SURVIVAL CURVES



*95% CONFIDENCE LIMITS

TABLE 16: REHABILITATION TO WORK ONE YEAR AFTER TREATMENT

		TRANSPLANTATION			
		Improved	Same	Deteriorated	Total
HOME DIALYSIS	Improved	0	1	0	1
	Same	3	5	2	10
	Deteriorated	0	1	2	3
	Total	3	7	4	14*

* No information on 2 patients as explained in Table 11

"same" together. The McNemar test with the continuity correction gave a probability of 1.0 and the test without correction gave a probability of 0.5630. Neither value is significant, suggesting that this measure of the outcomes of the two treatments did not differ one year after treatment. However, this test had only a 50% chance to detect a 10% difference between the two groups (power).

Similar information was collected about work activity at the time of study or, for those who had died, two weeks prior to their death (Table 17). The results were remarkably similar, again suggesting no treatment effect.

Data on the patients' overall health perceptions and physical capacity at the time of study are summarized in Tables 18 and 19. They suggest similarity between the two groups except for a very fine distinction between "very good health" and "pretty good health" (transplantation: 8 very good, 2 pretty good; home hemodialysis: 3 very good, 6 pretty good).

COMPUTATION OF AN ADJUSTED LIFE TABLE

Patients in this study were followed for varying periods of time due to death, short follow-up because of late entry in either program, or loss to follow-up because of transfer from home dialysis to transplantation. Thus, to avoid underestimating either the total number of services received or the impact of the two programs on their institutions, the costs generated by patients not followed for reasons other than death had to be taken into account. To do so, we computed an

TABLE 17: REHABILITATION TO WORK AT THE TIME OF STUDY OR TWO WEEKS BEFORE DEATH IF DECEASED

		TRANSPLANTATION			
		Improved	Same	Deteriorated	Total
HOME DIALYSIS	Improved	0	1	0	1
	Same	2	4	4	10
	Deteriorated	0	2	1	3
	Total	2	7	5	14

TABLE 18: OVERALL PERCEPTION OF HEALTH AND MOOD AT TIME OF STUDY

		VERY GOOD	PRETTY GOOD	NOT TOO GOOD	TOTAL
HEALTH	TRANSPLANTATION	8	2	2	12
	HOME DIALYSIS	3	6	1	10
MOOD	TRANSPLANTATION	7	4	1	12
	HOME DIALYSIS	5	4	1	10

TABLE 19: DIFFICULTY WITH ACTIVITIES

		YES	NO	NOT APPLICABLE	TOTAL
WALKING AS FAR AS A MILE	TRANSPLANTATION	3	8	1	12
	DIALYSIS	4	5	0	9
CLIMBING UP 2 FLIGHTS OF STAIRS	TRANSPLANTATION	4	8	0	12
	DIALYSIS	5	5	0	10
GETTING DRESSED	TRANSPLANTATION	2	10	0	12
	DIALYSIS	1	9	0	10
SHOPPING	TRANSPLANTATION	3	7	2	12
	DIALYSIS	1	8	1	10
CLEANING FLOORS	TRANSPLANTATION	1	7	4	12
	DIALYSIS	0	6	3	10

adjusted survival table which compensated for the effect of short follow-up due to late entry or transfer from home dialysis to transplantation. The computation involved extrapolating the observed death-rate to patients "lost to follow-up" and using the survivors among the patients to generate costs for the cohort.

Since the survival curves of the two groups were not statistically different, they were combined to generate an average survival table (Table 20). The adjusted life table (Table 21) was then prepared through the procedures described at the bottom of this same table. This computation produced an estimate of the survival experience of 16 patients in each group, if they had all entered at the same time in the study and if the survivors had all been followed-up for 7 years. The process appeared conceptually acceptable since the reason for short follow-up or loss to follow-up did not seem to imply that these patients would have received more or less services than the patients kept under observation. The last column of Table 21 gives the best estimate of the number of patients under observation during each year.

CALCULATION OF COST DIFFERENCE

Difference in services. The marginal costs methodology chosen for this study requires that the impact of the difference in number of services used by each of the two treatment programs be calculated. A detailed listing of the services received by all patients is presented in Appendix A, Table A-7. Those services having a major impact on the institution (and on costs) are summarized in Table 22 for each program

TABLE 20: AVERAGE SURVIVAL TABLE

Transplantation and Home Dialysis

Year	Alive at Beginning of interval	Withdrawn Alive	Death During interval	Exposed to risk of dying	Probability of dying	Probability of surviving	Cumulative probability of surviving
x	$O_x = O_{x-1} \overset{-(W_{x-1})}{-(d_{x-1})}$	W_x	d_x	$O'_x = O_x - \frac{W_x}{2}$	$q_x = d_x / O'_x$	$p_x = 1 - q_x$	$P_x = P_{x-1} \times p_x$
1	16	0	0	16	0	1	1
2	16	0.5	1	15.75	0.0635	0.9365	0.9365
3	14.5	5	1	12	0.0833	0.9167	0.8585
4	8.5	1	0.5	8	0.0625	0.9375	0.8048
5	7	1	0.5	6.5	0.0769	0.9231	0.7429
6	5.5	1	0.5	5	0.1000	0.9000	0.6686
7	4	2.5	0	2.75	0	1	0.6686

TABLE 21: COMBINED SURVIVAL TABLE

(with adjustments)*

Year	Alive at Beginning of interval	Death During interval	Probability of dying	Probability of surviving	Cumulative probability of surviving	Patients under observation during the year
x	$O_x = O_{x-1} - d_x$	d_x	$q_x = d_x/O'_x$	$p_x = 1-q_x$	$P_x = P_{x-1} \times p_x$	$O_x - d_x/2$
1	16	0	0	1	1	16
2	16	1.02	0.0635	0.9365	0.9365	15.49
3	14.98	1.25	0.0833	0.9167	0.8585	14.36
4	13.74	0.86	0.0625	0.9375	0.8048	13.31
5	12.88	0.99	0.0769	0.9231	0.7429	12.39
6	11.89	1.19	0.100	0.9	0.6686	11.3
7	10.70	0	0	1	0.6686	10.7

* Adjustments: 1) probability of dying obtained from Table 20

2) deaths calculated from that probability assuming no loss to follow-up

3) new probability of surviving obtained

TABLE 22: NUMBER OF SERVICES IN EACH PROGRAM

	TRANSPLANTATION								HEMODIALYSIS							
YEAR	1	2	3	4	5	6	7	Total	1	2	3	4	5	6	7	Total
Patients years under observation	16	14.83	9.67	7.25	5.42	4.42	3.67		16	15.33	13	8.83	6.42	5.0	4.08	
Hemodial. in hospital (treatments)	459	218	7	5	119	130	105	1043	583	101	263	131	37	16	-	1131
Interventions	86	19	13	4	2	2	-	126	47	21	9	6	9	5	-	97
Biochemistry (units)	79682	31863	18321	3985	3651	212	713	140307	32290	14314	16146	4205	5037	2707	1047	75796
Immunology (units)	11195	4823	3114	775	1301	719	460	14887	2517	1219	1047	903	920	490	307	7703
Days in hospital	1155	490	108	76	112	39	49	1935	595	250	158	23	67	33	-	1126

and for each year*. To compute the difference between programs in the number of services received, the procedure shown in Table 23 (example: biochemistry services for the third year) was followed. In this example, the difference of 9,390 units measures the impact of choosing transplantation rather than hemodialysis on the biochemistry laboratory. As a result, if a hospital currently operating a dialysis program instead operated a transplant program with 16 new entrants each year, the 14 patients surviving in their third year would generate 9390 more units of biochemistry services. When these computations are made for the other major hospital services, the result is the same (see Table 24): transplantation requires more hospital services than dialysis.

Impact of the service differences. Although transplantation uses more hospital services than home hemodialysis, the additional services resulting from transplanting rather than dialyzing would only add a few more services to the total provided by the hospital (see Table 25). For example, the additional 73,562 biochemistry units would increase the total biochemistry units by less than 2 percent (for details see Table A-11, Appendix A).

The impact of these extra services on the hospital was assessed by asking the director of each involved department the following question: "If your department decreased (or increased) its output by (example: 73,562 biochemistry units) in a year, would you need to make adjustments in your personnel, equipment, or supplies?" No adjustments in

* For all the remaining cost calculations in the text or the associated tables, only the services in Table 22 will be mentioned. The details regarding all the other services will appear in Appendix A.

TABLE 23: HANDLING OF DATA TO GENERATE DIFFERENCE IN NUMBER OF SERVICES: BIOCHEMISTRY SERVICES FOR THE THIRD YEAR

1. Number of units in biochemistry per study group for the third year
   (transp: 18,321*; dial. 16,146*)

2. Average biochemistry units per patient year observed for each study group
   (transp: 18,321/9.67*= 1,895 units per patient-year)
   (dial: 16,146/13* = 1,242 units per patient-year)

3. Difference in units per patient year between the two programs
   (1,895 - 1,242 = 653 units units per patient-year)

4. Total difference in number of units between the two programs given 14.38 patients under treatment by adjusted life table
   (653 x 14.38** = 9,390 units)

*obtained from table 22

**obtained from table A-10

TABLE 24: DIFFERENCE: TRANSPLANTATION MINUS HOME DIALYSIS
(NUMBER OF SERVICES ADJUSTED FOR LIFE TABLE)

YEAR	1	2	3	4	5	6	7	Total
Patient years under observation (adjusted life table)	16	15.49	14.36	13.31	12.39	11.30	10.70	
Hemodialysis in hospital (treatments)	-123	125	-280	-192	210	330	318	388
Interventions	39	-2	10	-1	-13	-7	-	26
Biochemistry (units)	47392	18820	9390	973	-1440	-820	-753	73562
Immunology (units)	8678	3500	3465	68	1258	807	607	18383
Days in hospital	560	259	-69	38	132	27	163	1110

TABLE 25: IMPACT OF TRANSPLANTATION ON THE INSTITUTION DURING THE SEVENTH YEAR OF THE PROGRAM

	Number of services offered by the hospital in 1977 (1)	Total difference transplantation minus hemodialysis in number of services for adjusted life table (2)	Percentage of column (1) represented by column (2)
Hemodialysis in hospital (treatments)	3,879	+388	10%
Interventions	21,492	+39	0.12%
Biochemistry (units)	3,976,767	+73,562	1.85%
Immunology (units)	194,749	+18,383	9.44%
Days in hospital (patient days)	236,996	+1110	0.47%

personnel or equipment were necessary for any of the services; adjustments in supply were required, however, making this the only cost-generating factor in the calculation of the cost per unit of non-professional hospital services.

It should be noted, though, that while the demands listed in Table 25 did not require staff changes in any department, they certainly represented an additional load for the workers in these units. This additional workload is very difficult to quantify in terms of dollars since it reflects such intangibles as the quality of life at work. In an attempt to estimate this cost, recognizing that it would be a gross overestimate, we multiplied the differences reported in Table 25 by the average salary per service unit for each work center. This gave the maximum possible dollar impact of the differences (Table 26). Although these costs were not used in the cost calculations because they are so crude, they will be compared to the total difference in costs between the two treatments to see if they can change the conclusion.

A distinction between professional and non-professional services was necessary because professional services (mostly physician services) were remunerated on a fee for service basis by a provincial agency and could not be estimated using hospital expenditure data. These services were cost accounted by counting (from charts) how many of each type of professional services were given to each patient and then multiplying these by the assigned fee*.

* Fee scale in "Manuel de Médecins Specialistes, Régime D'Assurance Maladie", Québec.

TABLE 26: ESTIMATE OF LABOUR COST INVOLVING THE MAIN TYPES OF SERVICES

	Difference in number of services	Salaries and wages of personnel in centers per unit of service	"Intangible costs" overestimate
Hemodialysis in hospital (treatments)	388	$45.89	$17,805
Interventions	39	32.05	1,250
Biochemistry (units)	73,562	0.16	11,770
Immunology (units)	18,383	1.19	21,875
Days in Hospital	1110	56.00	62,160
Total			$114,086

A distinction between hospital and home services was also indicated (see Table 13). Most of the services offered at home were concentrated in the home hemodialysis treatment and had no counterpart in the transplantation program. In other words, the resources used to offer the services at home (equipment, personnel) could not be used by any other hospital patient concurrently, and would not be used for any patient on a transplantation program. Consequently, the costs of home services did include all the costs for equipment, personnel and supplies (Table 28).

A summary of all costs per unit (non-professional, professional, home) for each type of service is detailed in Tables 27 and 28. The information in Table 27 was obtained in large part from patients' charts or financial records in hospital, was easily accessible, and allowed easy computations (only services specifically recorded were costed). The information in Table 28 came from different sources according to the type of service offered. The bulk of this information came from questionnaires although not all the cost generating items were reported by the patients or their families*. Nonetheless, 69% of the cost-related questions were answered and could be used for computations. As indicated in Table 28, for patients with missing cost data, the costs were generated from averages or medians (where averages were influenced by high values) of the costs reported by other patients.

* Many of the costs per unit of services could be obtained from institutions (equipment, supplies, salaries) but some of them had to come from the patient (alterations, salary paid to helpers, salary foregone by helpers, transportation).

TABLE 27: CALCULATION OF COSTS PER UNIT FOR HOSPITAL SERVICES

TYPE OF SERVICE	SUPPLY COSTS FOR 1976 OR 1977	NUMBER OF UNITS OF SERVICE	SUPPLY COSTS PER UNIT	PROFESSIONAL COSTS PER UNIT*	TOTAL COSTS PER UNIT
HEMODIALYSIS IN HOSPITAL	$150,854	3,879	$39.00	$105 First post transplant dialysis $35 Other dialysis	$144.00 $74.00
DAYS IN HOSPITAL	$2,092,183**	236,996	$8.83	$19 Complete examination $5 per day, first 15 days $15 per week after first week $150 for immunosuppression	
VISITS	$70,000	155,396	$0.45	$11 per visit	
INTERVENTIONS	$1,574,241	21,492	$73.00 $36.50***	Fees varied for each operation	
ANESTHESIA	$168,822	14,511	$12.00	Fees varied for each operation and with the duration of anesthesia	
CONSULTATIONS	-	-	-	Fees varied with the specialty consulted	
BIOCHEMISTRY	$143,115	4,184,866	$0.03	$0.16	$0.19

*Manuel des Médecins Spécialists, Régime D'Assurance-Maladie, Assurance Maladie, Québec

**Includes dietary and laundry costs, costs for linens, medical and surgical supplies (operating rooms, laboratories considered separately) but excludes housekeeping, security, maintenance, medical records, and administration

***For minor operations not performed in the operating room and/or without general anesthesia, a description of the material used suggested that $73 was a gross overestimate; to minimize this effect we arbitrarily divided by 2

TABLE 27: CALCULATION OF COSTS PER UNIT FOR HOSPITAL SERVICES (CONTINUED)

TYPE OF SERVICE	SUPPLY COSTS FOR 1976 OR 1977	NUMBER OF UNITS OF SERVICE	SUPPLY COSTS PER UNIT	PROFESSIONAL COSTS PER UNIT*	TOTAL COSTS PER UNIT
MICROBIOLOGY	$942,141	2,552,071	$0.37	$0.08	$0.45
HEMATOLOGY	$198,845	5,019,278	$0.04	$0.01/unit (surveillance) Interpretation fee varied with test	
IMMUNOLOGY	$48,411	902,184	$0.05	Differed from tests to tests	
ENDOCRINOLOGY	$92,776	1,742,032	$0.05	-	$0.05
PATHOLOGY - CYTOLOGY	$506,923	2,597,979	$0.24	Varied between $1.65 and $10.80	
RESPIRATORY LABORATORY	$16,634	915,938	$0.02	Pulmonary Function Tests $59.40 Blood Gas $26.34	
NUCLEAR MEDICINE	$8,474	9,738	$0.87	Varied from $2.50 to $20.00	
RADIOLOGY	$951,865	102,854	$9.25	Varied from $2.10 to $88.25	
ELECTROMYOGRAM	$7,777	139	$56.00	$31.00	$87.00
ELECTROENCEPHALOGRAM	$6,412	1,101	$5.82	$11.00	$16.82
ELECTROCARDIOGRAMS	$15,368	33,062	$0.46	$3.50	$3.96
PHYSIOTHERAPY	$8,559	68,900 (visits)	$0.12	-	$0.12
SOCIAL SERVICES	$2,940	12,657 (visits)	$0.23	-	$0.23
MEDICATIONS	-	-	Varied for each drug	-	-

*Manuel des Médecins Spécialistes, Régime D'Assurance-Maladie, Assurance Maladie, Québec

TABLE 28: CALCULATION OF COSTS PER UNIT FOR HOME SERVICES (1977 DOLLARS)

COST FACTORS / TYPE OF SERVICE	ALTERATIONS* IN HOUSE:	EQUIPMENT**	SUPPLY	PERSONNEL (NURSING, SUPPORT AT HOME)	PROFESSIONAL FEES***	COMMENTS
TRANSPORTATION	-	-	-	-	-	Patients did not provide enough information in questionnaires
NUMBER OF REMUNERATED HOURS LOST BY PERSONS HELPING PATIENTS AT HOME	-	-	-	·Salary (or minimum wages $3.00/hour) foregone to help patient	-	Minimum wages used when salary foregone not provided in questionnaires
HEMODIALYSIS TREATMENT AT HOME	Information obtained from questionnaires.° Space: $1800 (Med.) Electricity: $200 (Med.) Water Supply: $50 (Med.) Drain: $110 (Average)	Information obtained from hospital. Machine: $5950 Scale: $135 Dialysate Meter: $165 Deionizer: $795 Water Softener: $404 Single Needle: $795 Cylinders: $2080	Information obtained from hospital and questionnaire. Cylinder (c̄ deionizer): $27/Month Dialysate: $2.45/Gallon Pharmacy supply: $70-115/Month Artificial kidney: ≈ $100/Month	·Notwithstanding training, costs of nursing in Hemodialysis Unit has been averaged to $210/patient/year (from a yearly salary of $12,000).°° ·Training = hemodialysis in hospital (see hospital services)	$110/Month/ Patient	

*Amortized over the duration of therapy
**Amortized over ten years
***Manuel des Médecins Spécialistes, Régime D'Assurance-Maladie, Assurance Maladie, Québec
°When patients described specific alterations, and when they did not provide the costs, the average costs (median when average influenced by high values) estimated by four to five responders were attributed to the patient
°°Costs of additional nursing support (private nurse) were added to average costs

Difference between programs. The calculation of the total difference in costs between the two programs from the total difference in services utilization (impact) was obtained by multiplying the total difference between the two programs for each type of service by the cost per unit (Tables 25, A-11, 27 and 28) and adding this to the difference in the professional costs incurred by the patients of the two programs. These differences in costs adjusted with the adjusted life table are shown in Table 29.

For each year, the home hemodialysis and the mixed dialysis program generated a substantial additional cost compared to transplantation. For example, in the first year of treatment, the cohort on transplantation saved $72,075 compared to a similar cohort on home hemodialysis. However, the total differences in costs shown at the bottom of Table 29 are the most meaningful figures since they correspond to the marginal costs of a program during the seventh year. That is, they describe for a hospital the financial impact of running a transplantation program instead of a home hemodialysis program for the seventh year of the program.

Figure 6 describes the relative contribution of hospital and home services to the excess costs between the two programs. For example, with regard to hospital and ambulatory services taken separately, transplantation cost more than dialysis for the first year, but cost nearly $30,000 less during the third year. However, even for the first year, this small excess cost for transplantation remains very small compared to the enormous excess cost ($115,000) related to home services. In general, the transplantation program was usually slightly

TABLE 29: ADDITION COSTS PER YEAR OF FOLLOW-UP FOR TREATING ONE GROUP OF 16 PATIENTS FOR SEVEN YEARS (1977 DOLLARS)

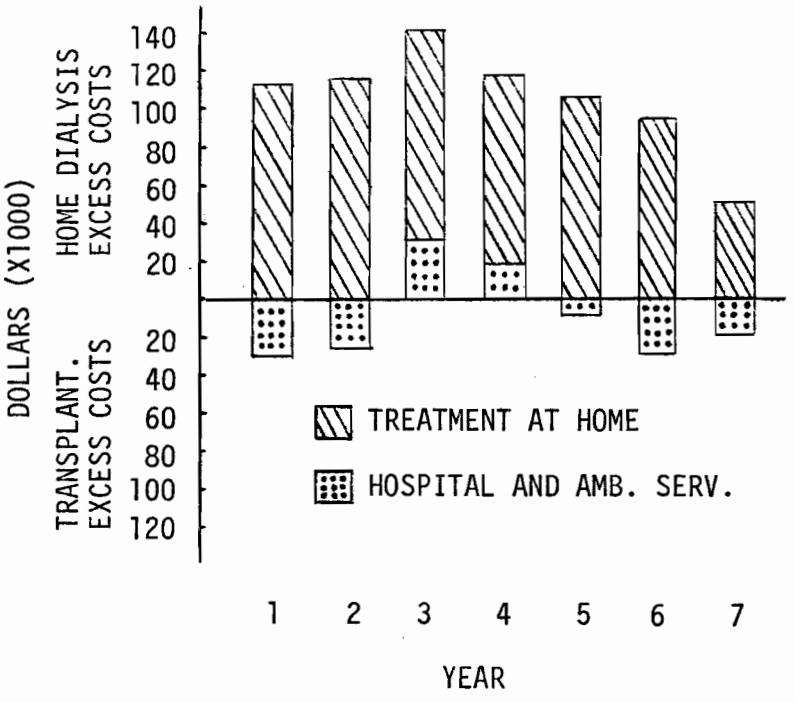
Year	Difference* between transplantation and home hemodialysis	Difference* between transplantation and mixed dialysis
1	$ - 72,075	$ - 72,075
2	- 86,258	- 83,931
3	-143,423	-134,122
4	-122,179	-113,593
5	-104,017	- 76,333
6	- 70,252	- 41,188
7	- 31,190	- 34,129
Total	$ - 629,394	$ - 555,371

* Adjusted with adjusted life table

FIGURE 6

EXCESS COSTS BY CATEGORY OF SERVICES

TOTAL FOR STUDY GROUPS



more demanding on hospital services but the very large costs of home services more than compensated for this small difference. The importance of home costs is easily understood when some of the costs per unit of services in Table 28 are applied to the average experience of a patient on treatment for a year: alterations $508, equipment $699, supplies $4192, for a total of $5,399 (personnel and professional costs not included). Supply costs explain most of the costs incurred at home. For both programs and for hospital and home services, professional costs represented, on average, 25 to 32 percent of the total costs.

In summary, by running a transplantation program instead of a home hemodialysis program, during the seventh year of the program, the total savings were approximately $629,394 or $6,600 for each of the 94 survivors under treatment.

INDIVIDUAL COSTS

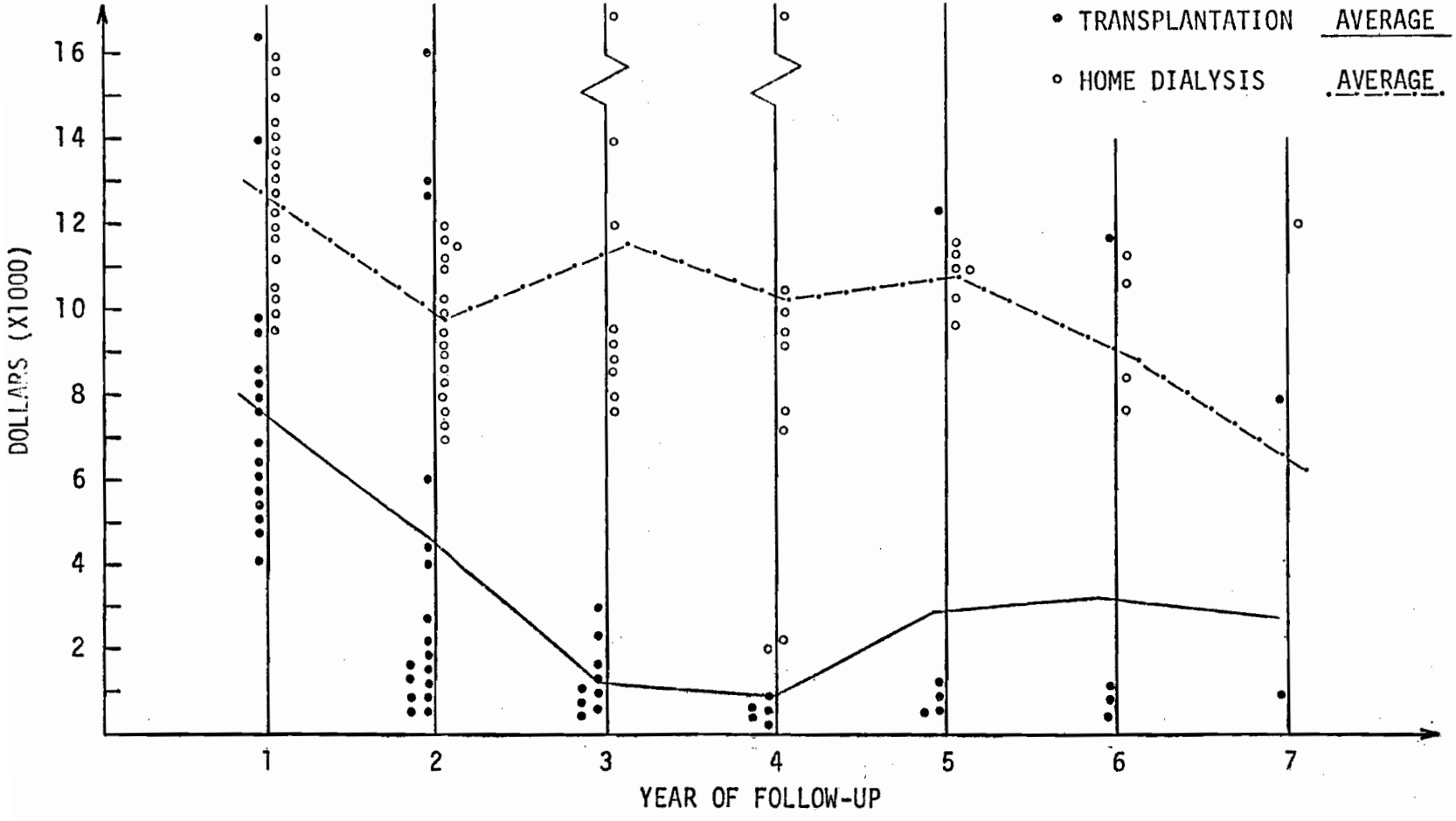
To insure that the higher costs of home dialysis apply to the large majority of patients taken individually and to avoid the possibility that a few patients receiving very expensive treatments elevate inappropriately the average costs, the relative values of services rendered to each patient were generated. This formulation (relative values of services rendered to each patient) is conceptually similar to what would be total costs for each patient if we were not dealing with marginal costs.

Knowing the number of services received by each patient for each year and the costs of each service, it was possible to generate the relative values of services rendered to each patient. The data are summarized in Figure 7 and detailed in Table A-12.

The difference between the two groups appears very large for the full period of follow-up with home dialysis always higher on average (first year: home dialysis $12,479, transplantation $7,975; second year: $9,929, $4,361). Although the year-specific values varied more in the transplantation group than in the dialysis group, this can be explained by the expensive hospitalization and/or dialysis treatments related to transplant rejection and transplant failure. It is striking that only two patients in the home dialysis program had a total value below $10,000 (first year) while all but two patients in the transplantation group had their total below $10,000.

The individual values were analyzed by a three way analysis of variance (ANOVA) organized in a factorial design, considering value (cost) as the outcome variable (a quantitative continuous variable) and years, treatments, and patients as classification variables (categorical variables). By making the three factors (classification variables) crossed between each other, we took into account the pairing between the patients in the two programs and the repeated measures over years of follow-up. "Year" and "treatment" were treated as having fixed effect and "patient" as having a random effect (see Table 30). This latter effect postulated the patients as being randomly selected from a general population of such patients.

FIGURE 7 : RELATIVE VALUES OF SERVICES RENDERED TO EACH PATIENT



N.B.: Only patients followed for the full twelve months of each year are presented in the figure; for each year costs information were also obtained from patients not followed for the full year and this information is included in the calculation of averages.

TABLE 30: DESCRIPTION OF THE ANALYSIS

$$Y_{ijk} = u... + A_i + B_j + C_k + AB_{ij} + AC_{ik} + BC_{jk} + ABC_{ijk}$$

Where: Y_{ijk}: value per patient, per treatment, per year

u: mean value over patients, treatments, and years

Factor		Levels	Model	Crossed or Nested
A:	Patient	i=i..p=1 to 16	Random	Crossed
B:	Treatment	j=i..q=1 to 2	Fixed	Crossed
C:	Year	k=i..r=1 to 2	Fixed	Crossed

Expected mean squares

Factor	Degree of freedom	Expected mean square
A_j	p -1 = 15	$4\ \sigma^2$
B_j	q -1 = 1	$2\ \sigma^2\ ab + 32\ \sigma^2 b$
C_k	r -1 = 1	$2\ \sigma^2\ ac + 32\ \sigma^2 c$
AB_{ij}	(p - 1) (q - 1) = 15	$2\ \sigma^2 ab$
AC_{ik}	(p - 1) (r - 1) = 15	$2\ \sigma^2 ac$
BC_{jk}	(q - 1) (r - 1) = 1	$2\ \sigma^2 + 16\ \sigma^2 bc$
ABC_{ijk}	(p - 1) (q - 1) (r - 1) = 15	σ^2

*σ^2= variance

Missing data (due to death or late entry in either program) represented a serious problem as early as the third year (only 8 pairs had complete information). Since substitution of estimates for the missing data does not recover the information lost[93] and since these substitutions destroy the symmetry and simplicity of the analysis[94], we elected to analyse only the first two years of follow-up. During these two years, there were no missing data, and data on the two patients (one in each program) not followed for the full twelve months of the second year could be adjusted by extrapolating the actual cost data for the months observed (ten and four months) respectively to the full twelve months. In neither of these two cases was there reason to suspect that treatment would have been markedly different had observation continued until the end of the second year (one patient entered late in his program and one patient changed treatment electively).

Table 31 summarizes the results of the analysis of variance. The probabilities obtained suggest that the differences between treatments and between years are statistically significant, while the interaction "treatment-year" is not significant.

TABLE 31: RESULTS OF THE ANALYSIS OF VARIANCE

Source of variance	F value	Degrees of freedom	Probability
Treatment	22.9627	1, 15	$p < 0.005$
Year	21.5175	1, 15	$p < 0.005$
Treatment-Year	0.4998	1, 15	$p > 0.05$

CHAPTER 5 DISCUSSION

This study has shown for the first time that the survival and rehabilitation of comparable patients with ESRD do not differ whether they receive transplantation or home hemodialysis. Furthermore, although patients receiving transplantation used more hospital services, it was almost invariably less expensive to treat them than the home hemodialysis patients, since home services were very costly. When translated in terms of the impact of running a treatment program for ESRD, these differences meant huge savings for the institution choosing transplantation.

To put these findings into perspective, some issues need to be considered. These include the limited number of patients and the short follow-up; a review of all the possible biases that might influence the conclusions; the effect of size (program or institution) on estimates derived from the marginal cost methodology; and finally the generalization of this study.

The limited number of patients in this study carries certain limitations in that some statistical tests will have low power and the interpretation of findings may be made more difficult by large variations. The low statistical power was obvious in the measures of pre- and post-treatment levels of activity and in the survival of patients. Consequently, the sensitivity of these tests was low and the similarity of patients for these characteristics is not fully insured. However, especially for post-treatment survival and level of activity, our

findings are congruent with those reported in the literature. Moreover, the absence of statistical significance between the two survival curves is only of relative value: if a much larger group of patients had been studied, the small differences found might have been statistically significant. The consequences of falsely assuming similar survival would be twofold: first, the differential effectiveness would be wrongly excluded from consideration with the differential costs in the decision-making process, and second, since home hemodialysis was more expensive, the difference in costs between the two programs would be underestimated (since the literature suggests that any difference in survival would favor patients in the home dialysis program). The impact of the first consequence is difficult to estimate because it would involve puting values on survival and the quality of life. The second consequence has no impact on the conclusion but only on the size of the difference found. By contrast with the effectiveness data, the statistical and clinical significance of the difference in costs was impressive: $629,394 for 94 patients during the seventh year, or $6,600 per patient treated for that year.

The second limitation linked to the small number of patients is the variation in the differences in costs found over years (Table 29). Indeed, the differences in cost between the two programs increase to reach very high values in the third and fourth years, but then decrease progressively over the last three years. A look at Table 14 explains a large part of this variation. In the transplantation program, three patients had to return to hospital dialysis (a very expensive treatment) during the first two years, none during the third and the fourth year, and one during the fifth year (this patient was on

treatment for the remaining three years). In the home dialysis program, the pattern is exactly the reverse: the three patients who returned to hospital dialysis did so during the third and fourth years. Table 24 translates these changes into the difference in number of dialyses in hospital between the two programs, and by referring to the cost per dialysis in Table 27 ($74.00), we can estimate the impact of these changes over years. It becomes clear that a change of -280 (third year) to +330 (sixth year) yields a cost difference of $45,140 (610 x 74). This amount explains about 60% of the total difference between year three and year six (143,423 - 70,252 = 73,171). This example demonstrates the importance of hospital dialysis cost, but also suggests that, had our group been larger, the movement of patients between treatment modalities would have been averaged in a smoother continuum, preventing large variation in the total differences.

The short follow-up period (seven years) in this study has the same limitation as it did in previous studies, since the long-term effects of treatment remain to be described. This unknown long-term outlook of patients, combined with decreasing cost differences after the third year (Table 29), suggest that if we could follow the patients long enough, the transplantation program might become more expensive than the home hemodialysis program. However, we have seen that much of the variation observed in the differences can be explained by the inevitable large variation associated with the small numbers of patients. This large variation makes the trends observed (differences over years) less reliable, and would suggest that taking the different values as variation around a mean would be more appropriate. If we

accept this, the negative differences (transplantation minus home hemodialysis, Table 29) for the seven years of observations make a future reversal in the differences (negative to positive) rather unlikely.

In interpreting these results, it is important to rule out the possibility that factors other than treatment could explain the differences between the groups. The confounding effect of such factors or biases as decribed by Feinstein[96] is highly unlikely. Indeed, almost all the factors known to be associated with quality of life or use of services were controlled to insure their equivalence in the two groups either by successful matching or a posteriori statistical comparison. Furthermore, the influence of biases in interpreting diagnostic interventions and in deciding suitability for transplantation was essentially eliminated by having these interpretations and decisions repeated for both groups by the same professionals blind to treatment. All this made a "susceptibility" bias very unlikely.

Since the main interventions (transplantation and home hemodialysis) were associated with a host of diagnostic and therapeutic services and since the outcome depended on accurately costing all these services, the completeness of information was very important. The review of charts was extensive and comprehensive, done by the investigator, and supplemented by a questionnaire covering services that could have been received from other centers. This, combined with the fact that most patients never received any services from other centers, suggests that the counting of services was similar in both groups.

One possible source of error could have occurred if services were ascribed to the hemodialysis group for patients actually awaiting transplantation: all the pretransplant immunologic evaluations might have been counted under the home dialysis programs when they were not really part of that program. However, we have reason to believe that this did not occur: 1) the bulk of the immunologic investigations ascertained from the charts were routine diagnostic tests likely to be used in both groups (protein electrophoresis, rheumatoid factor, L.E. cells, antinuclear antibody); 2) the highly specialized tests (tissue typing) associated with pre-transplant evaluation were not reported in the charts; their costs were estimated for the average patient and added at the time of transplantation. Systematic distortion in the identification of treatment or change of treatments is thus hardly possible.

Another issue to consider concerns the extent to which the cost estimates used in this study can be applied to other programs or other institutions. This relates to the method of generating costs used in this study. The marginal costs approach focused on the additional services resulting from choosing one program over the other and estimated the impact of these additional services by comparing them to the total number of services provided by the institution. A low ratio of additional services to total services generated a low cost per unit of service because no change in personnel and equipment was required. However, the same number of additional services in a smaller institution with a smaller total service load, or an increased number of additional services in a similar institution might very well require changes in personnel and equipment and generate higher costs per unit.

This would lead to more expensive additional services. Since these considerations apply mostly to hospital services, and since transplantation makes a larger use of these services, enlarging the program in a stable institution could theoretically lead to a situation where transplantation would be more expensive than dialysis. A sensitivity study of this phenomenon would provide information as to the likelihood of such a change. However, in view of the large difference between the two programs, this change is unlikely, especially when we find that the gross overestimate of intangible costs ($114,086) remains small compared to this large difference ($629,394).

In practical terms, the transplantation programs in Quebec (all in institutions of size similar to the institutions studied) performed an average of 21 transplants in 1974 (range 8 to 30), and the institution studied performed a yearly average of 25 transplants. In the United States, seventy-five percent of institutions reported an average of 20 or fewer transplants per year. It is important to note that these numbers are in terms of transplants and many patients receive more than one transplant. We should then assume that all these centers treated each year a smaller number of patients than the number of transplants reported. For example, in our study, although 16 patients were followed, 18 transplants were performed. All this suggests that the cost estimates based on 16 patients could very well apply to other institutions.

To determine the extent to which our findings can be used in choosing treatment for future patients with ESRD, we must consider the representativeness of the patients studied. In this study, subjects

were not chosen randomly. Rather the total group of home hemodialysis patients (less one) was investigated and the transplantation patients were selected by matching. As a result, neither group can be considered a random sample of any population. However, it would be justifiable to consider observed variability in this finite population as if it came from a large hypothetical sample of an ESRD population with the same random variation[95]. This means postulating random selection of our patients, and random, unsystematic variation of the observations.

This postulate can be partly validated by comparing our small groups to a known large group. The hypothetical population for our study would be all patients in Canada with ESRD and eligible either for transplantation or for home hemodialysis. Unfortunately, very little information is available for this group of patients. Three other comparison groups may be considered: 1) all patients with ESRD in Canada; 2) the total transplantation population from which 16 patients were selected; 3) transplanted patients in Canada.

For each population, the information available allows us to compare diagnoses (Table 32), ages (Table 33) and sex (Table 34). According to these data, glomerulonephritis was more frequent in the transplantation and study groups, and patients in these groups also tended to be younger (very few patients over 50 years) although 75% of the study group's patients were between 30 and 49 years of age. In addition, the male-female ratio was larger in the transplantation group (7:3) than in the ESRD group (3:2). This ratio was 3:1 in the study groups. Although showing some differences, these comparisons certainly do not strongly undermine our postulate and allow us to treat our study groups as samples.

TABLE 32: PERCENTAGE OF PATIENTS WITH EACH DIAGNOSIS

	Canada, End Stage Renal Failure (N = 690)	Transplantation Program in the institution studied. (N = 134)	Study Group (N = 16)
Glomerulonephritis	38%	55%	56%
Pyelonephrites	12%	12%	12%
Polycystic disease	8%	10%	0%
Diabetic nephropathy	7%	1%	6%
Hypertensive nephrpathy	6%	2%	6%
Analgesic nephropathy	2%	1%	6%
Hereditary nephritis	2%	1%	0%
Others	22%	18%	14%

TABLE 33: PERCENTAGE OF PATIENTS WITHIN EACH AGE GROUP

	Canada transplantation[14] (N = 285)	Canada, End Stage renal failure[14] (N = 690)	Transplantation Program in the institution studied. (N = 134)	Study Group (N = 16)
0 to 9	2.4%	0.9	0.%	0%
10 to 19	11.9%	7.5%	10.5%	6.3%
20 to 29	26.5%	15.8%	24.6%	12.5%
30 to 39	20.7%	14.5%	20.7%	43.7%
40 to 49	20.4%	19.4%	23.18	31.2%
50 to 59	10.5%	18.8%	17.1%	6.3%
60 to 69	1.7%	16.8%	-	-
70 and more	0.3%	3.5%	-	-
Not known	5.4%	2.7%	-	-

TABLE 34: PERCENTAGE OF PATIENTS: MALE AND FEMALE

	Canada End stage renal failure[14] (N = 690)	Transplantation Program in the institution studied (N = 134)	Study Group (N = 16)
Male	59%	69%	75%
Female	41%	31%	25%

One practical limitation is often raised when expansion of transplantation is considered: the number of donors (mostly cadaver) does not always meet the demand, and the discrepancy would worsen if demand increased[27]. However, in the United States, one survey has shown that only 2.5 to 35% of potential donors acually donate their kidneys, the variation being a function of the centers or the criteria for identifying potential donors. Since a surveillance system could produce a 9-fold increase in the number of kidneys donated[97], thus improving the efficiency of the donor system, a shortage of transplants is not a necessary deterrent to our recommendations.

In summary, it appears justifiable to extrapolate the results of this study to numerous programs of similar size in institutions of similar size and, on the basis of a partially validated postulate, to use them to orient future patients to appropriate treatments. The applicability of the results could probably be tested further by a sensitivity analysis of the effects of changes in size of programs and institutions. Nevertheless, given our findings, we suggest that patients with ESRD eligible for transplantation and home hemodialysis should be treated by transplantation to maximize the efficiency of treatment.

STATEMENT OF ORIGINALITY

This study compared home hemodialysis and transplantation by evaluating the costs and effectiveness of treatment in two groups of patients made comparable by matching. Prior investigations never insured this comparability before their evaluation.

This work also included most factors which directly or indirectly, would influence the benefits or the costs of each program. A similar level of comprehensivenss was never achieved in previous studies. Due to the marginal cost approach, our results provided a more accurate estimate of what would be the impact of choosing one of the studied programs in an institution similar to the two studied. This approach has been used for the first time in this study, and our costs figures did not suffer from the overestimation implicit in the average costs aproach used in previous studies.

APPENDIX A

DETAILED TABLES

TABLE A-1: DIAGNOSIS

NO	DIALYSIS	B I O P S Y		TRANSPLANTATION	NO
30	C.G.N.[a]	---	---	C.G.N.	7
1	DIABETIC NEPHROPATHY	---	---	DIABETIC NEPHROPATHY	23
4	R.P.G.N.[b]	YES	YES	R.P.G.N.	6
33	C.G.N.	---	---	C.G.N.	13
26	CHRONIC PYELO.[c]	---	YES	CHRONIC PYELO.	31
5	PYELO. & PHEN.[d] NEPHROPATHY	---	YES	ANALGESIC NEPHROPATHY	12
15	R.P.G.N.	YES	YES	R.P.G.N.	27
20	OBSTRUCTIVE UROPATHY	---	YES	HYDRONEPHROSIS	25
29	CHRONIC PYELO.	---	---	CHRONIC PYELO & OBSTR URO[g]	17
24	M.P.G.N.[e]	YES	YES	M.P.G.N.	34
10	C.G.N.	---	---	C.G.N.	28
3	PROLIFERATIVE G.N.	YES	YES	M.P.G.N.	8
18	R.P.G.N.	YES	YES	EPIMEMBRANEOUS G.N.	21
16	C.G.N.	---	---	C.G.N.	22
17	MALIGNANT HYPERTENSION	YES	YES	MALIGNANT HYPERTENSION	11
2	S.L.E.[f]	YES	YES	S.L.E.	19

a Chronic glomerulonephritis
b Rapidly progressive glomerulonephritis
c Chronic pyenonephritis
d Phenacetin
e Membraneo-proliferative glomerulonephritis
f Systemic lupus erythematosus
g Obstructive uropathy

TABLE A-2: AGE OF PATIENTS IN THE STUDY

Case No.	Transplantation Age	Case No.	Dialysis Age	d
9*	40	32*	63	-23
7	37	30	42	-5
23	31	1	32	-5
6	30	4	23	+7
13	48	33	49	-1
31	38	26	34	+4
12	41	5	45	-4
27	34	15	20	+14
25	25	20	15	+10
17	44	29	54	-10
34	19	24	20	-1
28	50	10	52	-2
8	35	3	19	+16
21	26	18	50	-24
22	42	16	42	0
11	48	14	45	+3
19	30	2	31	-1
				-22

* These two cases were excluded from all calculations because one of them was not eligible for transplantation.

TABLE A-3: SUMMARY OF OCCUPATIONS AVAILABLE IN THE CHARTS FOR MATCHED PAIRS

Patient Number	Home Hemodialysis Program	Transplantation Program	Patient Number
32	Retired	Physician	9
30	Highway Foreman	Pediatrician	7
1	Lawyer	Unemployed Supervisor	23
4	Teacher	At home	6
33	Policeman	Accountant	13
26	Public Relations Councelor	Clerk	31
5	Nurse	At home	12
15	Unemployed Clerk	Unemployed Truck Driver	27
20	Student	Clerk	25
29	Retired	Welder	17
24	Student	Unemployed Security Agent	34
10	At home	At home	28
3	Unemployed	Unemp.Cook	8
18	Executive	Vice-Pres. Marketing Company	21
16	Operator	Mechanic	22
17	Technician	Unemployed Plumber	11
2	At home	At home	19

TABLE A-4: CREATININE CLEARANCE OF MATCHED PAIRS

Case No.	Transplantation cc/min/m^2	Case No.	Dialysis cc/min/m^2
9*	0.88	32*	-
7	-	30	6.5
23	7.9	1	2.76
6	2.1	4	-
13	-	33	-
31	-	26	-
12	-	5	1.7
27	11.2	15	2.0
25	4.9	20	6.1
17	5.5	29	-
34	-	24	7.0
28	-	10	3.0
8	10.2	3	-
21	7.6	18	-
22	3.5	16	2
11	3.0	14	0
19	7.4	2	8
	6.3		4.0

* These two cases were excluded from all calculations because one of them was not eligible for transplantation.

TABLE A-5: HEMOGLOBIN LEVELS OF MATCHED PAIRS

Case No.	Transplantation values	Case No.	Dialysis values
9*	-	32*	-
7	6.7	30	8.3
23	8.4	1	8.8
6	7.2	4	7.5
13	8.5	33	6.9
31	6.9	26	7
12	10	5	6.3
27	9.8	15	10.4
25	6.9	20	5.7
17	9.2	29	-
34	-	24	5.3
28	-	10	8.2
8	7.8	3	-
21	8.2	18	10.4
22	6	16	5.6
11	6.8	14	7.7
19	5.8	2	4.7
	7.7		7.3

* these two cases were excluded from all the calculations because one of them was not eligible for transplantation.

TABLE A-6

SURVIVORSHIP TABLE

	YEAR x	ALIVE AT BEGINNING OF INTERVAL $O_x = O_{x-1}\{^{-W_{x-1}}_{-d_{x-1}}$	WITHDRAW ALIVE W_x	DEATH DURING INTERVAL d_x	EXPOSED TO RISK OF DYING $O'_x = Q_x - W_x/2$	PROBABILITY OF DYING $q_x = d_x/O'_x$	PROBABILITY OF SURVIVING $p_x = 1 - q_x$	CUMULATIVE PROBABILITY OF SURVIVING $P_x = P_{x-1}'p_x$	95% CONFIDENCE LIMIT
TRANSPLANT	1	16	0	0	16	0	1	1	
	2	16	0	2	16	0.1250	0.8750	0.8750	
	3	14	5	1	11.5	0.0870	0.9130	0.7989	
	4	8	1	1	7.5	0.1333	0.8667	0.6924	
	5	6	1	0	5.5	0	1	0.6924	
	6	5	1	0	4.5	0	1	0.6924	
	7	4	2	0	3	0	1	0.6924	± 0.2474
HOME DIALYSIS	1	16	0	0	16	0	1	1	
	2	16	1	0	15.5	0	1	1	
	3	15	5	1	12.5	0.0800	0.92	0.92	
	4	9	1	0	8.5	0	1	0.92	
	5	8	1	1	7.5	0.1333	0.8667	0.7973	
	6	6	1	1	5.5	0.1818	0.8182	0.6523	
	7	4	3	0	2.5	0	1	0.6523	
MIXED HOME DIALYSIS	1	16	0	0	16	0	1	1	
	2	16	0	0	16	0	1	1	
	3	16	1	1	15.5	0.0645	0.9355	0.9355	
	4	14	2	2	13	0.1538	0.8462	0.7916	
	5	10	0	2	10	0.2000	0.8000	0.6333	
	6	8	1	1	7.5	0.1333	0.8667	0.5489	
	7	6	4	0	4	0	1	0.5489	

TABLE A-7

TOTAL NUMBER OF SERVICES IN EACH PROGRAM

	TRANSPLANTATION								HOME DIALYSIS								MIXED HOME DIALYSIS							
YEAR UNDER OBSERVATION	1	2	3	4	5	6	7	TOTAL	1	2	3	4	5	6	7	TOTAL	1	2	3	4	5	6	7	TOTAL
PATIENT YEARS UNDER OBSERVATION	16	14.83	9.67	7.25	5.42	4.42	3.67		16	15.23	12	8.82	6.42	5.0	4.08		16	16	15.5	11.5	8.67	7.0	4.08	
HOSPITALIZATIONS	73	25	13	9	13	11	6	150	41	20	9	3	6	3	1	83	41	23	18	8	8	4	1	103
DAYS IN HOSPITAL	1155	490	108	76	112	39	49	2029	595	250	158	23	67	33		1126	595	294	453	120	107	33	6	1544
VISITS	86	127	51	33	46	17	9	369	29	43	30	15	16	8	3	144	29	46	31	15	17	9	7	54
HEMODIALYSIS IN HOSPITAL	459	218	7	5	119	130	105	1043	583	101	263	131	37	16	-	1131	583	105	404	148	59	16	129	1444
INTERVENTIONS	86	19	13	4	2	2	-	126	47	21	9	6	9	5	-	97	47	23	25	8	11	7	5	126
CONSULTATIONS	71	32	27	8	9	9	1	157	44	13	7	1	2	3	-	70	44	13	10	4	4	3	1	79
ANESTHESIA	50	10	1	2	1	-	-	64	40	22	13	2	6	4	-	87	40	23	26	5	7	4	-	105
BIOCHEMISTRY (UNITS)	79682	31863	18321	3975	3651	2102	713	140307	32290	14314	16146	4205	5037	2707	1047	75746	32240	17041	24772	10337	8504	2884	1358	98192
HEMATOLOGY (UNITS)	18796	13576	7148	1991	3020	1180	1450	47161	6505	1876	1423	810	537	517	60	11728	6505	2449	4293	2609	1187	531	156	17730
MICROBIOLOGY (UNITS)	5549	4115	3008	562	539	508	147	14428	1585	278	544	21	170	-	-	2598	1585	1360	1922	814	614	-	30	6316
RADIOLOGY	227	112	95	51	50	29	32	596	129	50	49	21	28	11	2	290	129	62	78	48	38	12	5	372
IMMUNOLOGY (UNITS)	11195	4823	3114	775	1301	719	460	14887	2517	1219	1047	903	920	490	307	7703	2517	2109	4245	915	1648	490	337	8264
ENDOCRINOLOGY (UNITS)	209	83	202	9	568	12	-	1083	28	40	10	24	-	-	-	104	28	40	12	24	-	-	-	104
NUCLEAR MEDICINE	73	35	14	2	-	-	4	126	15	12	10	4	5	3	3	52	15	29	68	59	24	3	5	203
PHYSIOTHERAPY	91	14	19	2	1	-	-	128	26	25	25	2	1	-	-	79	26	29	39	10	1	-	-	105
SOCIAL SERVICE	22	21	18	18	8	8	4	99	16	6	1	-	-	1	-	24	16	6	1	-	-	1	-	24
CARDIOVASCULAR	35	22	28	9	14	7	4	119	38	19	20	6	19	5	-	107	38	19	26	8	20	5	-	116
RESPIRATORY (UNITS)	593	171	639	231	230	94	77	2035	340	51	357	85	136	17	-	986	340	51	442	238	391	17	-	1473
CYTOLOGY (UNITS)	21	5	5	-	5	5	5	46	61	-	-	-	-	-	-	61	61	-	-	14	-	-	-	75
PATHOLOGY	39	25	9	1	-	-	-	74	15	10	7	1	7	2	-	42	15	10	7	4	7	2	-	45
ELECTRO-ENCEPHALOGRAM	-	-	-	-	-	-	-	-	5	2	1	1	1	-	-	10	5	2	1	1	1	-	-	10
ELECTROMYOGRAM	3	2	1	-	-	-	-	6	9	8	5	-	2	2	2	28	9	8	5	-	2	2	2	28
DRUGS (DOLLARS)	17759	12980	2394	1782	3151	4093	836	42995	13340	11806	9263	7242	6802	4685	2010	55148	13340	12140	12871	8260	7781	5521	2821	62734

TABLE A-8

NUMBER OF SERVICES PER PATIENT YEAR

	TRANSPLANTATION								HOME DIALYSIS								MIXED HOME DIALYSIS							
YEAR UNDER OBSERVATION	1	2	3	4	5	6	7	TOTAL	1	2	3	4	5	6	7	TOTAL	1	2	3	4	5	6	7	TOTAL
PATIENT YEARS UNDER OBSERVATION	16	14.83	9.67	7.25	5.42	4.42	3.67		16	15.33	13	8.83	6.42	5.0	4.08		16	16	15.5	11.5	8.67	7.0	4.68	
HOSPITALIZATIONS	4.6	1.7	1.3	1.2	2.4	2.5	1.6	15.3	2.6	1.3	0.7	0.3	0.9	0.6	0.3	6.7	2.6	1.4	1.1	0.7	0.9	0.6	0.3	7.5
DAYS IN HOSPITAL	72.2	33.0	7.3	5.4	20.7	8.8	13.4	160.8	37.2	16.3	12.2	2.6	10.4	6.6	-	85.3	37.2	18.4	29.2	10.4	12.2	4.7	1.5	113.7
VISITS	5.4	8.6	5.3	4.6	8.5	3.9	2.4	38.6	1.8	2.8	2.3	1.7	2.5	1.6	0.7	13.4	1.8	2.9	2.0	1.3	2.0	1.3	1.7	13
HEMODIALYSIS IN HOSPITAL	28.7	14.7	0.7	0.7	22.0	29.4	28.6	123.8	36.4	6.6	20.2	14.8	5.8	3.2	-	82.9	36.4	6.6	29.9	12.8	6.8	2.3	31.6	126.4
INTERVENTIONS	5.4	1.3	1.2	0.6	0.4	0.5	-	9.4	2.9	1.4	0.7	0.7	1.4	1	-	8.1	2.9	1.4	1.6	0.7	1.3	1	1.2	10.3
CONSULTATIONS	4.4	2.2	2.8	1.1	1.7	2.0	0.3	14.5	2.8	0.9	0.5	0.1	0.3	0.6	-	5.2	2.8	0.8	0.7	0.4	0.5	0.4	0.3	5.7
ANESTHESIA	3.1	0.7	0.1	2.8	0.2	-	-	6.8	2.5	1.4	1	0.2	0.9	0.8	-	6.9	2.5	1.4	1.7	0.4	0.8	0.6	-	7.4
BIOCHEMISTRY (UNITS)	4980	2149	1895	548	674	476	194	10915	2018	934	1242	476	785	541	257	6253	2018	1065	1598	899	981	412	333	7206
HEMATOLOGY (UNITS)	1175	915	739	275	557	267	395	4323	407	122	109	92	84	103	15	932	407	153	277	227	137	76	38	1305
MICROBIOLOGY (UNITS)	347	277	311	78	99	115	40	1267	99	18	42	2	26	-	-	188	99	85	124	71	71	-	7	457
RADIOLOGY	14.2	7.6	9.8	7.0	9.2	6.6	8.7	63	8.1	3.3	3.8	2.4	4.4	2.2	0.5	24.5	8.1	3.9	5.0	4.2	4.4	1.7	1.2	28.5
IMMUNOLOGY (UNITS)	700	325	322	107	240	163	125	1982	157	99	81	102	143	98	75	756	157	132	274	80	190	70	82	1402
ENDOCRINOLOGY (UNITS)	13.1	5.6	20.9	1.2	104.8	2.7		148.3	1.8	2.6	0.9	2.7	-	-	-	8.0	1.7	2.5	0.8	2.1				7.1
NUCLEAR MEDICINE	4.6	2.4	1.5	0.3	-	-	1.1	9.9	0.9	0.8	0.8	0.5	0.8	0.6	0.7	5.1	0.9	1.8	4.4	5.1	2.8	0.4	1.2	16.6
PHYSIOTHERAPY	5.7	0.9	2.0	2.8	0.2	-	-	11.5	1.6	1.6	1.9	0.2	0.2	-	-	5.6	1.6	1.8	2.5	0.9	0.1	-	-	7.0
SOCIAL SERVICE	1.4	1.4	1.9	2.5	1.5	1.8	1.1	11.5	1	0.4	0.1	-	-	0.2	-	1.7	1	0.4	0.1	-	-	0.1	-	1.6
CARDIOVASCULAR	2.2	1.5	2.9	1.2	2.6	1.6	1.1	13.1	2.4	1.2	1.5	0.7	3.0	1.1	-	9.8	2.4	1.2	1.7	0.7	2.3	0.7	-	9.0
RESPIRATORY (UNITS)	37	11	66	32	42	21	30	239	21	3	27	10	21	3	-	85	21	3	29	21	45	2	-	121
CYTOLOGY (UNITS)	1.4	0.3	0.5	-	0.9	1.1	1.3	5.7	3.8	-	-	-	-	-	-	3.8	3.8	-	-	1.2	-	-	-	5.0
PATHOLOGY	2.4	1.7	0.9	0.1	-	-	-	5.2	0.9	0.7	0.5	0.1	1.1	0.4	-	3.7	0.9	0.6	0.5	0.4	0.8	0.3	-	3.5
ELECTRO-ENCEPHALOGRAM	-	-	-	-	-	-	-	-	0.3	0.1	0.1	0.1	0.2	-	-	0.8	0.3	0.1	0.1	0.1	0.1	-	-	0.7
ELECTROMYOGRAM	0.2	0.1	0.1	-	-	-	-	0.4	0.8	0.5	0.4	-	0.3	0.4	0.5	2.7	0.6	0.5	0.3	-	0.2	0.3	0.5	2.4
DRUGS (DOLLARS)	1110	875	248	246	581	926	228	4214	834	770	713	820	1060	937	493	5627	834	759	830	718	897	789	691	5518

TABLE A-9

DIFFERENCE BETWEEN THE TWO PROGRAMS IN NUMBER OF SERVICE PER PATIENT YEAR

	TRANSPLANTATION MINUS HOME DIALYSIS								TRANSPLANTATION MINUS MIXED HOME DIALYSIS							
YEAR UNDER OBSERVATION	1	2	3	4	5	6	7	TOTAL	1	2	3	4	5	6	7	TOTAL
PATIENTS UNDER OBSERVATION																
HOSPITALIZATIONS	2	0.4	0.7	0.9	1.5	2.4	1.4	9.3	2	0.3	0.2	0.6	1.5	1.9	1.4	7.9
DAYS IN HOSPITAL	35	16.7	-4.8	2.8	10.2	2.2	13.4	75.5	35	14.7	-21.9	-5.1	8.3	4.1	11.9	47
VISITS	2.6	5.8	3.0	2.9	6	2.3	1.7	24.3	3.6	5.7	3.3	3.3	6.5	2.6	0.7	25.7
HEMODIALYSIS IN HOSPITAL	-7.7	8.1	-19.5	-14.2	16.2	26.6	26.2	35.7	-7.7	8.1	-29.2	-12.2	15.2	26.3	-3.0	-5.4
INTERVENTIONS	2.4	-0.1	0.7	-0.1	-0.1	-0.6		1.3	2.4	-0.2	-0.3	-0.2	-0.9	-0.6	-1.2	-1.0
CONSULTATIONS	1.7	1.3	2.3	1.0	1.4	2.0	0.3	10.0	1.7	1.4	2.1	0.8	1.2	1.6		8.8
ANESTHESIA	0.6	-0.8	-0.9	2.5	-0.8	-0.8		-0.2	0.6	-0.8	-1.6	2.3	-0.6	-0.6		-0.7
BIOCHEMISTRY (UNITS)	2962	1215	653	72	-111	-66	-62	4663	2962	1083	296	-351	-307	64	-139	3608
HEMATOLOGY (UNITS)	768	793	630	183	474	164	380	3392	768	762	462	48	420	191	357	3008
MICROBIOLOGY (UNITS)	248	259	269	75	73	115	40	1079	248	192	187	7	29	115	33	811
RADIOLOGY	6.1	4.3	6.1	4.7	4.9	4.4	8.2	38.7	6.1	3.7	4.8	2.9	4.9	4.9	7.5	34.8
IMMUNOLOGY (UNITS)	542	226	241	5	97	65	50	1226	542	194	48	27	50	93	43	997
ENDOCRINOLOGY (UNITS)	11.3	3.0	20.0	-0.5	104.8	2.7		141.3	11.3	3.1	20.1	-0.9	104.8	2.7		141.1
NUCLEAR MEDICINE	3.6	1.6	0.7	-0.2	-0.8	-0.6	0.4	4.7	3.6	0.6	-2.9	-4.9	-2.8	-0.4	-0.1	-6.9
PHYSIOTHERAPY	4.1	0.7	0.0	2.5				7.3	4.1	-0.9	-0.6	1.9	0.1			4.6
SOCIAL SERVICES	0.4	1.0	1.8	2.5	1.5	1.6	1.1	9.9	0.4	1.0	1.8	2.5	1.5	1.7	1.1	10.0
CARDIOVASCULAR	-0.2	0.2	1.4	0.6	-0.4	0.6	1.1	3.3	-0.2	0.3	1.2	0.6	0.3	0.9	1.1	4.2
RESPIRATORY (UNITS)	16	8	39	22	21	18	21	145	16	8	38	11	-3	19	21	110
CYTOLOGY	-2.4	0.3	0.5		0.9	1.1	1.4	1.8	-2.4	0.3	0.5	-1.2	0.9	1.1	1.4	0.6
PATHOLOGY	1.5	1.0	0.4	0.1	-1.1	-0.4		1.5	1.5	1.1	0.5	-0.2	-0.8	-0.3		1.8
ELECTROENCEPHALOGRAM	-0.3	-0.1	-0.1	-0.1	-0.2			-0.8	-0.3	-0.1	-0.1	-0.1	-0.1			-0.7
ELECTROMYOGRAM	-0.4	-0.4	-0.3		-0.3	-0.4	-0.5	-2.3	-0.4	-0.4	-0.2		-0.2	-0.3	-0.5	-2.0
DRUGS (DOLLARS)	276	105	-465	-574	-478	-11	-265	-1412	276	117	-583	-473	-316	137	-464	-1306

TABLE A-10

DIFFERENCE BETWEEN THE TWO PROGRAMS BASED ON THE ADJUSTED LIFE TABLE

	TRANSPLANTATION MINUS HOME HEMODIALYSIS								TRANSPLANTATION MINUS MIXED DIALYSIS							
YEAR UNDER OBSERVATION	1	2	3	4	5	6	7	TOTAL	1	2	3	4	5	6	7	TOTAL
PATIENT YEARS (ADJUSTED LIFE TABLE)	16	15.49	14.36	13.31	12.39	11.3	10.7		16	15.49	14.36	13.31	12.39	11.3	10.7	
HOSPITALIZATIONS	32	6	10	12	19	30	17	126	32	37	3	8	13	24	17	134
DAYS IN HOSPITAL	560	259	-69	38	132	27	163	1110	560	228	-315	-69	108	51	145	708
VISITS	57	90	43	39	78	29	21	357	57	88	47	45	84	33	9	363
HEMODIALYSIS IN HOSPITAL	-123	125	-280	-192	210	330	318	388	-123	125	-420	-165	197	327	-36	-95
INTERVENTIONS	39	-2	10	-1	-13	-7	-	26	39	-3	-4	-3	-12	-7	-15	-5
CONSULTATIONS	27	20	99	14	18	25	6	209	27	22	30	11	16	20	-	126
ANESTHESIA	10	-12	-13	34	-10	-10	-	-1	10	-2	-23	31	-8	7	-	15
BIOCHEMISTRY (UNITS)	47392	18820	9390	973	-1440	-820	-753	73562	47392	16776	4256	-4742	-3982	796	-1689	58807
HEMATOLOGY (UNITS)	12291	12283	9059	2472	6148	2039	4617	48909	12291	11803	6644	648	5447	2374	4338	43545
MICROBIOLOGY (UNITS)	3964	4012	3868	1013	947	1429	486	15719	3964	2974	2689	95	376	1429	401	11928
RADIOLOGY	98	67	88	63	64	55	100	535	98	57	69	39	64	61	91	479
IMMUNOLOGY (UNITS)	8678	3500	3465	68	1258	807	607	18383	8678	3005	690	364	649	1156	522	15064
ENDOCRINOLOGY (UNITS)	181	46	288	-7	1362	34	-	1904	181	48	288	-12	1359	34	-	1898
NUCLEAR MEDICINE	58	25	10	-3	-10	-7	5	78	58	9	-42	67	-36	-5	-1	50
PHYSIOTHERAPY	65	11	0	34	-	-	-	110	65	-14	-9	26	1	-	-	69
SOCIAL SERVICE	6	15	26	34	19	20	13	133	6	15	26	34	19	21	13	134
CARDIOVASCULAR	-3	3	20	8	-5	7	13	43	-3	5	17	8	4	11	13	55
RESPIRATORY (UNITS)	253	124	561	297	272	224	255	1986	253	124	43	149	-39	236	255	1021
CYTOLOGY	-39	5	7	-	12	14	17	16	-39	5	7	16	12	14	17	32
PATHOLOGY	24	15	6	1	-14	-5	-	27	24	17	7	3	-10	-4	-	37
ELECTROENCEPHALOGRAM	-5	2	1	-1	-3	-	-	-6	-5	-2	1	1	-1	-	-	-6
ELECTROMYOGRAM	-6	-6	-4	-	-4	-5	-6	-31	-6	6	3	-	-2	-4	6	3
DRUGS (DOLLARS)	4419	1626	-6686	7822	-6200	-137	-3220	-2376	4419	1812	-8383	-6390	-4098	1703	-5638	-16575

TABLE A-11: IMPACT OF TRANSPLANTATION ON THE INSTITUTION DURING THE SEVENTH YEAR OF THE PROGRAM (COMPARED TO HEMODIALYSIS)

	Number of services offered by the hospital in 1977 (1)	Total difference: transplantation minus home dialysis in number of services for adjusted life table (2)	Percentage of column (2) with regard to column (1)
Patient days in hosp.	236,966	+1110	0.47%
Visits	155,396	+357	0.23%
Hemodialysis in hosp.	3,879	+388	10.00%
Interventions	21,492	+26	0.12%
Consultations	-	+209	-
Anesthesia	14,511	-1	0.01%
Biochemistry*	3,976,767	+73,562	1.85%
Hematology*	5,019,278	+48,909	0.97%
Microbiology*	2,552,071	+15,719	0.61%
Radiology	106,711	+535	0.48%
Immunology*	194,749	+18,383	9.44%
Endocrinology*	1,724,032	+1,904	0.1%
Nuclear Med. tests	9,738	+78	0.8%
Social Service visits	12,657	+133	1.8%
Cardiovascular tests	33,062	+43	0.13%
Respiratory tests	915,938	+1,986	0.21%
Cytology tests	162,859	+16	0.01%
Pathology tests	112,492	+27	0.03%
EEG	1,101	-11	1.0%
EMG	-	-31	-
Physical Medicine	68,900	+110	0.16%

* in units

TABLE A-12: RELATIVE VALUES OF SERVICES RENDERED TO EACH PATIENT

	TRANSPLANTATION								HOME DIALYSIS						
PT #/YEAR	1	2	3	4	5	6	7	PT #/YEAR	1	2	3	4	5	6	7
7	4023	474	150	150				30	15975	11659	13275	10042	10895	10949	2399
23	4791	1981	1006	150				1	12550	9714	13937*				
6	6472	1137	901	643	89			4	10355	8823	8788	2753	36		
13	6260	12786						33	11437	8089	7810	7681	5503		
31	8899	3770	742	557	665	1077	526	26	9849	7785	7537	7745	9970	7308	404
12	5235	576	779	825	699	623	565	5	13369	10104	9830	9459	11131	10485	11425
27	5549	2240	2252	983	1312	148		15	14191	11821	9832*				
25	7125	1018	388					20	12442	9227	9127	9169	10265	8877	7798
17	9531	4203	775					29	10755	11465	24611	21791	11088		
34	16638	1603	1088	665	554	564	833	24	11265	6771	3883*				
28	14191	12974	1404	2279	11994	11069	8472	10	12810	8207	6880				
8	7956	2814	15					3	9171	8649	194*				
21	5114	664						18	15646	10791	7104*				
22	9927	1393**						16	14425	9605	11247	10575	10807	5890	15
11	7643	16544	8					14	13719	11543***					
19	8248	799	89					2	11718	7970	8506	8508	*		
TOTAL	127602	64676	9597	6460	15313	13481	10396	TOTAL	199677	152223	142561	87723	69625	43509	22031

* Transplanted during that year
** 10 months extrapolated to 12 months
*** 4 months extrapolated to 12 months and transplanted during that year

APPENDIX B

QUESTIONNAIRES

IDENTITY NO: _____

COST-EFFECTIVENESS STUDY

Please answer each question by putting a check (✓) in the appropriate box or by filling in the blank.

1. How would you describe your usual daily activity <u>one year before</u> you began hemodialysis or had your transplantation:

   Remunerated work ☐

   Non remunerated work ☐

   Housework ☐

   Other ☐

   Please specify: _____

2. <u>One year before</u> you began hemodialysis or had your transplantation, in a typical week were you able to perform your usual daily activity:

   Most of the time (30 hours or more per week) ☐

   Part of the time (less than 30 hours per week) ☐

   Other ☐

   Please specify: _____

3. <u>One year after</u> you began hemodialysis at home, in a typical week were you able to perform the same usual daily activity described in Question 1:

   Most of the time (30 hours or more per week) ☐

   Part of the time (less than 30 hours per week) ☐

   Not at all ☐

   N.B.: If you answered "Not at all", were you performing another type of activity:

   NO ☐

   YES ☐ ; please specify: _____

   Most of the time (30 hours or more per week) ☐

   Part of the time (less than 30 hours per week) ☐

4. Last week, were you able to perform the usual daily activity described in Question 1:

Most of the time
(30 hours or more per week) ☐

Part of the time
(less than 30 hours per week) ☐

Not at all ☐

N.B. If you answered "Not at all", were you performing another type of activity

NO ☐

YES ☐ ; please specify: _____

Most of the time
(30 hours or more per week) ☐

Part of the time
(less than 30 hours per week) ☐

5. How would you say your health is these days? Would you say your health is:

Very good ☐

Pretty good ☐

Not too good ☐

6. Taking all things together, how would you say things are these days? Would you say you are:

Very happy ☐

Pretty happy ☐

Not too happy ☐

7. Today, do you have any physical difficulty with:

	NOT APPLICABLE	NO	YES	If yes, how long have you had this difficulty?
Walking as far as a mile?	☐	☐	☐ →	_____
Climbing up two flights of stairs (16 steps)	☐	☐	☐ →	_____
Getting dressed	☐	☐	☐ →	_____
Doing your shopping	☐	☐	☐ →	_____
Cleaning floors	☐	☐	☐ →	_____

8. For each physician (specialist or not) who has treated you since you were first treated for your kidney disease by either hemodialysis or transplantation, would you please give the following information.

Name of physician	City	Number of visits per year	Cost of transportation per visit
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

9. Since the beginning of your treatment for kidney disease by either hemodialysis or transplantation, would you please give the following information for each stay in hospital of at least 24 hours (please include the initial hospitalization):

Name of hospital	City	Approximate date of admission
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

10. For each period of time during which you have been treated by hemodialysis on a regular basis (several times a week), please give the following information.

PLACE				TREATMENTS			MACHINE		
Was treatment received at home or in hospital		Name of hospital or centre SUPERVISING treatment	City in which this hospital or centre is located	Frequency of treatment per week	Duration of each treatment in hours	Number of months during which you were treated	Cost per month of service and maintenance*	Trade mark of machine	Model of machine
home	hospital								
☐	☐								
☐	☐								
☐	☐								
☐	☐								
☐	☐								

*Not including cost of artificial kidneys and reagents (dialysate).

11. Did you have to make any alterations in your home when you started your home dialysis?

NO ☐

YES ☐ ; please indicate all alterations and estimate the approximate cost:

		COST
Space.....	☐ :	$_____
Electrical power outlet.....	☐ :	$_____
Water supply.....	☐ :	$_____
Drain.....	☐ :	$_____
Water softener.....	☐ :	$_____
Deionizer.....	☐ :	$_____
Other:.....	☐ :	$_____

Please specify _____

12. For your last month on home dialysis, who helped you during your treatment at home?

A member of your family ☐

An attendant ☐

A nurse ☐

Other, please specify _____ ☐

No one, I do not have any help ☐ Go to Question 15

13. Did you have to pay for the help you were getting?

NO ☐

YES ☐ ; How much for each treatment? $_____

14. Did the person helping you have to take time off from other payed employment?

NO ☐

YES ☐ ; a) How many hours did he or she take off from work each week? _____

b) What is the occupation of this person?

_____

15. For your last month on home dialysis, what were the regular supplies used for your treatment?

	NUMBER		COST	
Dialysate	_____	litres/month	$_____	per litre
Artificial kidney	_____	per month	$_____	per unit

16. Have you ever had a kidney transplantation?

NO ☐

YES ☐ ; When did you first have it:

_____ _____
month year

17. Aside from your hospitalization and physician cost, has any of the cost of your treatment (hemodialysis and/or medication) been met by someone other than yourself?

NO ☐

YES ☐ ; a) Hemodialysis

NO ☐

YES ☐ ; by Medicare ☐

Insurance company ☐

Other ☐

Please specify_____

b) Medication

NO ☐

YES ☐ ; by Medicare ☐

Insurance company ☐

Other ☐

Please specify_____

Thank you for completing this questionnaire. Please return it to us in the stamped envelope provided. If you have questions regarding this study, do not hesitate to communicate with us, we will be happy to give you any additional information.

If any of the questions in the questionnaire were unclear to you or if you have any additional comments, please indicate this on the back of this page.

Numéro D'identification: _____

Analyse Coûts-Bénéfices

S'il vous plaît, veuillez répondre aux questions en cochant (√) le carré approprié ou en écrivant dans l'espace disponible.

1. Comment décririez-vous votre activité quotidienne principale un an avant votre traitement par hemodialyse ou transplantation?

   Travail rémunéré ☐

   Travail non rémunéré ☐

   Travail de maison ☐

   Autres ☐

   Spécifiez _____

2. Un an avant votre traitement par hémodialyse ou transplantation, au cours d'une semaine typique, pouviez-vous vous consacrer à votre activité quotidienne principale:

   La plupart de votre temps (30 heures ou plus par semaine) ☐

   Une partie de votre temps (moins de 30 heures par semaine) ☐

   Autres ☐

   Spécifiez _____

3. Un an aprés le début de votre traitement par hémodialyse à la maison, au cours d'une semaine typique, pouviez-vous vous consacrer à votre activité quotidienne principale décrite à la question 1:

   La plupart du temps (30 heures ou plus par semaine) ☐

   Une partie du temps (moins de 30 heures par semaine) ☐

   Pas du tout ☐

   N.B.: Si vous avez répondu "Pas du tout", pouviez-vous vous consacrer à une autre activité?

   NON ☐

   OUI ☐ ; s'il vous plaît spécifiez _____

   La plupart du temps (30 heures ou plus par semaine) ☐

   Une partie du temps (moins de 30 heures par semaine) ☐

4. La semaine dernière, pouviez-vous vous consacrer à votre activité quotidienne principale décrite à la question 1:

La plupart du temps
(30 heures ou plus par semaine) ☐

Une partie du temps
(moins de 30 heures par semaine) ☐

Pas du tout ☐

N.B.: Si vous avez répondu "Pas du tout", pouviez-vous vous consacrer à une autre activité?

NON ☐

OUI ☐ ; s'il vous plaît spécifiez _____

La plupart du temps
(30 heures ou plus par semaine) ☐

Une partie du temps
(moins de 30 heures par semaine) ☐

5. Comment va votre santé actuellement? Diriez-vous que votre santé est:

Très bonne ☐

Bonne ☐

Mauvaise ☐

6. A tout considérer, comment vont les choses actuellement? Diriez-vous que vous êtes:

Très heureux (se) ☐

Heureux (se) ☐

Malheureux (se) ☐

7. Aujourd'hui, éprouvez-vous quelque difficulté physique que ce soit quand:

	Ne s'applique pas	NON	OUI	Si oui, depuis quand avez-vous cette difficulté?
Vous marchez jusqu'à un mille	☐	☐	☐ →	_____
Vous montez deux étages (16 marches)	☐	☐	☐ →	_____
Vous vous habillez	☐	☐	☐ →	_____
Vous allez magasiner	☐	☐	☐ →	_____
Vous nettoyez vos planchers	☐	☐	☐ →	_____

8. Pour chaque médecin (spécialiste ou non) qui vous a traité(e) depuis que vous avez commencé votre traitement pour défaillance rénale par hémodialyse ou transplantation, pourriez-vous s'il vous plaît donner l'information suivante:

Nom du médecin	Ville	Nombres de visites par année	Prix du transport par visite
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

9. Depuis que vous avez commencé votre traitement pour défaillance rénale par hémodialyse ou transplantation, pourriez-vous s'il vous plaît donner l'information suivante sur chaque hospitalisation de plus de 24 heures (inclure l'hospitalisation initiale):

Nom de l'hôpital	Ville	Date approximative de l'admission
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Pour chaque période où vous avez été traité(e) par hémodialyse de façon régulière (plusieurs fois par semaine) pourriez-vous s'il vous plaît donner l'information suivante:

ENDROIT			TRAITEMENT			MACHINE		
z-vous été ité(e) à maison ou 'hôpital	Nom de l'hôpital ou centre SUPERVISANT le traitement	Ville où se situe cet hôpital ou ce centre	Fréquence des traitements par semaine	Durée de chaque traitement en heures	Nombre de mois durant lesquels vous avez été traité(e)	Coût par mois du service et de l'entretien*	Marque de la machine	Modèl de la machi
☐ hôpital								
☐								
☐								
☐								
☐								

* Ne pas inclure le coût du rein artificiel ou du dialysat

11. Avez-vous eu à faire des transformations dans votre maison quand vous avez commencé votre dialyse à domicile?

NON ☐

OUI ☐ ; s'il vous plaît identifiez chaque transformation et évaluez-en le coût approximatif:

		Coût
Aménagement d'espace.....	☐ :	$_____
Entrée d'électricité.....	☐ :	$_____
Entrée d'eau.....	☐ :	$_____
Egout.....	☐ :	$_____
Appareil pour adoucir l'eau..... (Water Softener)	☐ :	$_____
Appareil pour éliminer les ions..... (Deionizer)	☐ :	$_____
Autres.....	☐ :	$_____

S'il vous plaît spécifiez _____

12. Pour votre dernier mois de traitement par hémodialyse à la maison, qui vous a aidé(e) durant vos traitements à la maison?

Un membre de la famille ☐

Un(e) assistant(e) ☐

Une infirmière ☐

Autre, ☐
spécifiez _____

Personne, je ne reçois aucune aide ☐ ; allez immédiatement à la question 15.

13. Avez-vous eu à payer pour l'aide obtenue?

NON ☐

OUI ☐ ; combien alors pour chaque traitement? $_____

14. Est-ce que la personne qui vous a aidé(e), a dû se libérer d'un travail rémunérateur pour ce faire?

NON ☐

OUI ☐ ; a) Elle s'est libérée pour combien d'heures par semaine? _____

b) Quelle est l'occupation de cette personne?

_____

15. Pour votre dernier mois de traitement par hémodialyse à la maison, quels furent les approvisionnements nécessaires pour le traitement?

	Nombre	Coût
Dialysat	_____ litres/mois	$_____ par litre
Reins artificiels	_____ par mois	$_____ par unité

16. Avez-vous déjà eu une transplantation rénale?

NON ☐

OUI ☐ ; quand l'avez-vous eue:

_____ _____
mois année

(si plusieurs, inscrivez la première)

17. Outre les coûts des soins hospitaliers et des soins offerts par les médecins, y a-t-il une partie du coût de votre traitement (hémodialyse et/ou médicaments) qui est ou à ètè defrayée par quelqu-un d'autre que vous même (ex: une compagnie d'assurances)?

NON ☐

OUI ☐ ; a) hémodialyse

NON ☐

OUI ☐ ; par Assurance-maladie ☐

Compagnie d'assurances ☐

Autres ☐

Spécifiez _____

b) médicaments

NON ☐

OUI ☐ ; par Assurance-maladie ☐

Compagnie d'assurances ☐

Autres ☐

Spécifiez _____

Merci d'avoir complété ce questionnaire. S'il vous plaît, veuillez nous le retourner dans l'enveloppe affranchie ci-incluse. Si vous avez des questions au sujet de cette étude, n'hésitez pas à communiquer avec nous, ce sera un plaisir de vous donner ces informations additionnelles. Si une ou plusieurs des questions du questionnaire n'est ou ne sont pas claire(s) ou si vous avez des commentaires (additionnels), nous vous invitons à nous en faire part dans l'espace prévu ci dessous.

IDENTITY NO: _____

COST-EFFECTIVENESS STUDY

Please answer each question by putting a check (✓) in the appropriate box or by filling in the blank.

1. How would you describe your usual daily activity one year before you began hemodialysis or had your transplantation:

   Remunerated work ☐

   Non remunerated work ☐

   Housework ☐

   Other ☐

   Please specify: _____

2. One year before you began hemodialysis or had your transplantation, in a typical week were you able to perform your usual daily activity:

   Most of the time (30 hours or more per week) ☐

   Part of the time (less than 30 hours per week) ☐

   Other ☐

   Please specify: _____

3. One year after you had transplantation, in a typical week were you able to perform the same usual daily activity described in Question 1:

   Most of the time (30 hours or more per week) ☐

   Part of the time (less than 30 hours per week) ☐

   Not at all ☐

   N.B.: If you answered "Not at all", were you performing another type of activity:

   NO ☐

   YES ☐ ; please specify: _____

   Most of the time (30 hours or more per week) ☐

   Part of the time (less than 30 hours per week) ☐

4. Last week, were you able to perform the usual daily activity described in Question 1:

Most of the time
(30 hours or more per week) ☐

Part of the time
(less than 30 hours per week) ☐

Not at all ☐

N.B. If you answered "Not at all", were you performing another type of activity

NO ☐

YES ☐ ; please specify: _____

Most of the time
(30 hours or more per week) ☐

Part of the time
(less than 30 hours per week) ☐

5. How would you say your health is these days? Would you say your health is:

Very good ☐

Pretty good ☐

Not too good ☐

6. Taking all things together, how would you say things are these days? Would you say you are:

Very happy ☐

Pretty happy ☐

Not too happy ☐

7. Today, do you have any physical difficulty with:

	NOT APPLICABLE	NO	YES	If yes, how long have you had this difficulty?
Walking as far as a mile?	☐	☐	☐ →	_____
Climbing up two flights of stairs (16 steps)	☐	☐	☐ →	_____
Getting dressed	☐	☐	☐ →	_____
Doing your shopping	☐	☐	☐ →	_____
Cleaning floors	☐	☐	☐ →	_____

8. For each physician (specialist or not) who has treated you since you were first treated for your kidney disease by either hemodialysis or transplantation, would you please give the following information.

Name of physician	City	Number of visits per year	Cost of transportation per visit
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

9. Since the beginning of your treatment for kidney disease by either hemodialysis or transplantation, would you please give the following information for each stay in hospital of at least 24 hours (please include the initial hospitalization):

Name of hospital	City	Approximate date of admission
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

10. Aside from your hospitalization and physician cost, has any of the cost of your treatment (medication) been met by someone other than yourself (eg. insurance company)?

NO ☐

YES ☐ ; by Medicare ☐

Insurance Company ☐

Other ☐

Please specify: _____

11. Have you ever been on hemodialysis as a regular treatment (several times every week)?

NO ☐

YES ☐ ; Please answer the following question

12. For each period of time during which you have been treated by hemodialysis on a regular basis, would you please give the duration of treatment (in months), the name of the hospital or the centre supervising the treatment and the city in which this hospital or centre is located:

Duration	Name of hospital or centre	City

Thank you for completing this questionnaire. Please return it to us in the stamped envelope provided. If you have questions regarding this study, do not hesitate to communicate with us, we will be happy to give you any additional information.

If any of the questions in the questionnaire were unclear to you or if you have any additional comments, please indicate this on the back of this page.

Numéro D'identification: _____

Analyse Coûts-Bénéfices

S'il vous plaît, veuillez répondre aux questions en cochant (✓) le carré approprié ou en écrivant dans l'espace disponible.

1. Comment décririez-vous votre activité quotidienne principale un an avant votre traitement par hémodialyse ou transplantation?

   - Travail rémunéré ☐
   - Travail non rémunéré ☐
   - Travail de maison ☐
   - Autres ☐

   Spécifiez _____

2. Un an avant votre traitement par hémodialyse ou transplantation, au cours d'une semaine typique, pouviez-vous vous consacrer à votre activité quotidienne principale:

   - La plupart de votre temps (30 heures ou plus par semaine) ☐
   - Une partie de votre temps (moins de 30 heures par semaine) ☐
   - Autres ☐

   Spécifiez _____

3. Un an après votre transplantation, au cours d'une semaine typique, pouviez-vous vous consacrer à votre activité quotidienne principale décrite à la question.1:

   - La plupart du temps (30 heures ou plus par semaine) ☐
   - Une partie du temps (moins de 30 heures par semaine) ☐
   - Pas du tout ☐

   N.B.: Si vous avez répondu "Pas du tout", pouviez-vous vous consacrer à une autre activité?

   NON ☐

   OUI ☐ ; s'il vous plaît spécifiez _____

   - La plupart du temps (30 heures ou plus par semaine) ☐
   - Une partie du temps (moins de 30 heures par semaine) ☐

4. La semaine dernière, pouviez-vous vous consacrer à votre activité quotidienne principale décrite à la question 1:

La plupart du temps
(30 heures ou plus par semaine) ☐

Une partie du temps
(moins de 30 heures par semaine) ☐

Pas du tout ☐

N.B.: Si vous avez répondu "Pas du tout", pouviez-vous vous consacrer à une autre activité?

NON ☐

OUI ☐ ; s'il vous plaît spécifiez _____

La plupart du temps
(30 heures ou plus par semaine) ☐

Une partie du temps
(moins de 30 heures par semaine) ☐

5. Comment va votre santé actuellement? Diriez-vous que votre santé est:

Très bonne ☐

Bonne ☐

Mauvaise ☐

6. A tout considérer, comment vont les choses actuellement? Diriez-vous que vous êtes:

Très heureux (se) ☐

Heureux (se) ☐

Malheureux (se) ☐

7. Aujourd'hui, éprouvez-vous quelque difficulté physique que ce soit quand:

	Ne s'applique pas	NON	OUI	Si oui, depuis quand avez-vous cette difficulté?
Vous marchez jusqu'à un mille	☐	☐	☐ →	_____
Vous montez deux étages (16 marches)	☐	☐	☐ →	_____
Vous vous habillez	☐	☐	☐ →	_____
Vous allez magasiner	☐	☐	☐ →	_____
Vous nettoyez vos planchers	☐	☐	☐ →	_____

8. Pour chaque médecin (spécialiste ou non) qui vous a traité(e) depuis que vous avez commencé votre traitement pour défaillance rénale par hémodialyse ou transplantation, pourriez-vous s'il vous plaît donner l'information suivante:

Nom du médecin	Ville	Nombres de visites par année	Prix du transport par visite
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

9. Depuis que vous avez commencé votre traitement pour défaillance rénale par hémodialyse ou transplantation, pourriez-vous s'il vous plaît donner l'information suivante sur chaque hospitalisation de plus de 24 heures (inclure l'hospitalisation initiale):

Nom de l'hôpital	Ville	Date approximative de l'admission
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

10. Outre les coûts des soins hospitaliers et des soins offerts par les médecins, y a-t-il une partie du coût de votre traitement (médicaments qui est défrayée par quelqu'un d'autre que vous même (ex: une compagnie d'assurances)?

NON ☐

OUI ☐ ; par Assurance maladie ☐

Compagnie d'assurances ☐

Autres ☐

Spécifiez _____

11. Avez-vous déjà été traité(e) par hémodialyse de façon régulière (plusieurs fois par semaine)?

NON ☐

OUI ☐ ; si oui, répondez à la question suivante:

12. Pour chaque période où vous avez été traité(e) par hémodialyse de façon régulière, pourriez-vous donner la durée du traitement (en mois), le nom de l'hopital ou du centre supervisant le traitement et la ville dans laquelle se trouve cet hôpital ou ce centre?

Durée	Nom de l'hôpital ou du centre	Ville

Merci d'avoir complété ce questionnaire. S'il vous plaît, veuillez nous le retourner dans l'enveloppe affranchie ci-inclus. Si vous avez des questions au sujet de cette étude, n'hésitez pas à communiquer avec nous, il nous fera plaisir de vous donner ces informations additionnelles. Si une ou plusieurs des questions du questionnaire n'est ou ne sont pas claire(s) ou si vous avez des commentaires, nous vous invitons à nous en faire part à l'endos de cette page.

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