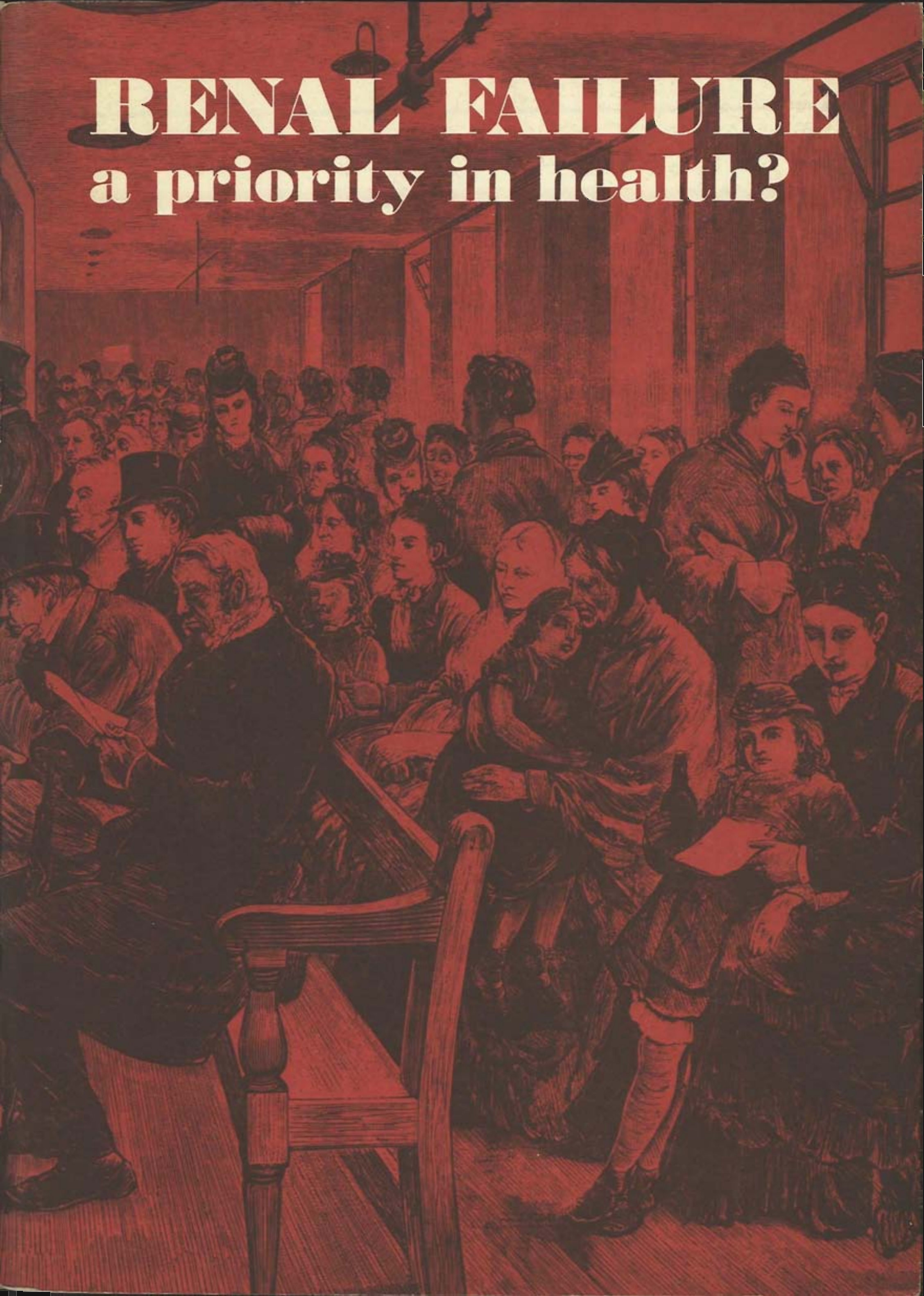
RENAL FAILURE
a priority in health?



Front cover:
The Queen's visit to the London Hospital. A sketch in the outpatients ward.
(The Mansell Collection).

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Introduction

The incidence of treatable chronic renal failure in Britain and other Western countries is very small indeed. The most commonly quoted figure is forty people (under sixty years old) per million total population per year.[1] Compared with conditions like coronary heart disease, cancer, bronchitis or arthritis, therefore, the magnitude of renal failure as a current health problem appears insignificant. What makes renal failure important, both in itself and as an illustration of the problems the NHS may have to face increasingly in the future, is the existence of an undoubtedly life-saving but at the same time highly expensive treatment in the form of dialysis and/or transplantation.

Up until the nineteen-thirties there were few areas where medical intervention could be claimed to be effective in saving life. Since the therapeutic revolution the capacity to intervene productively has increased enormously but in most cases prevention or treatment has involved chemotherapy. Usually this is relatively inexpensive, easy to procure (by prescription) and, in effect, freely available under the NHS. Dialysis and transplantation, on the other hand, like other forms of treatment requiring expensive hardware and ancillary staff, are relatively costly. It is also less easy to set up extra dialysis facilities than it is to make out another prescription or to perform a simple surgical operation. As a result, the availability of treatment for renal failure has been restricted and particularly difficult decisions have to be made by health service practitioners who come face to face with prospective patients.

Following the 1978 budget, in which provision was made for 400 extra dialysis machines, it may be anticipated that between twenty and twenty-five new patients per million population will be accepted for treatment in Britain. This implies that between

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[1] This represents only a small residue of the disease when compared with that experienced in the past. McKeown (1976) quotes death rates for a number of diseases, age standardised to the 1901 population. For 'nephritis' he quotes a rate of 46 deaths per million population in 1971 compared with an average of 615 per million per year over the years 1848–54. It is likely that death from kidney disease was even more common in earlier centuries. In many underdeveloped countries today, especially where malaria is endemic, kidney disease is a significant cause of death. Kibukamusake (1973) quotes data on hospital admissions in such countries. Although they are not good indicators of incidence, it is significant that about 2 per cent of all hospital admissions in countries where malaria is endemic are attributed to 'nephrotic syndrome'. Needless to say, not many of those admitted receive dialysis or a transplant. In Western countries such admissions now make up a negligible proportion of the total.

fifteen and twenty million, about 750 to 1,000 people (under 60 years old) will not be accepted and will, presumably, die.

There are, of course, other areas of the NHS, apart from dialysis and transplantation, where effective intervention is not available to all those likely to benefit. For example, a screening programme for high blood pressure among middle-aged men, followed by treatment, could significantly reduce mortality and incapacity from strokes. Another example is the replacement of arthritic joints. Patients may have to wait several years for treatment under the NHS.

So far, however, dialysis and transplantation is the only area of activity of the NHS (apart, perhaps, from accident and emergency services) where shortages of money and equipment (as well as kidneys for transplantation) prevent medical practitioners from extending routine life saving treatment to otherwise fit individuals who present with a terminal condition. It is for this reason that discussion of the subject is often so emotionally charged. Despite this, any sensible debate must accept, as a point of departure, that no service has an absolute claim on resources. If one service is given more money then, in principle, sacrifices have to be made elsewhere – either inside or outside the NHS.

History and future prospects

Haemodialysis

The introduction of life-saving haemodialysis was not the consummation of any large scale research programme. Rather, it was one of those new treatments which emerged from the activities of a few pioneering individuals who were able to utilise ideas, materials and methods from a number of diverse technologies. Effective procedures having been developed, however, these were inevitably taken up and refined by the medical community and its service industries.[2] It was only when long-term haemodialysis was emerging from the experimental stage that the moral and economic issues raised by an effective but highly expensive procedure became fully apparent to those responsible for allocating health service resources.

Living animals had been dialysed in experiments before the First World War. Extension to humans as a useful form of treatment was, however, limited by the materials available. Dialysis requires a semi-permeable membrane through which small

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[2] In Britain the health authorities themselves played an active part in the refinement of long-term dialysis, for example in the evaluation of equipment.

molecules (like urea) can pass from blood to a dialysate fluid. It also requires the prevention of blood clotting which is likely to occur when blood is re-routed outside the body. Though an anticoagulant was available (in the form of an extract from leeches) neither this nor the available membrane material was satisfactory.

The 1920s and 1930s saw significant advances in synthetic polymer chemistry and as a result cellulose acetate became available as a potential membrane material. In the mid-1930s purified heparin (an anticoagulant) also became available. These two developments set the stage for the next advance which took place in 1943 in occupied Holland. Although the circumstances were hardly conducive to this or any other sort of medical research, Kolff performed the first human dialysis with his rotating drum artificial kidney.

After the war Kolff's technique was widely used, particularly in Sweden and America. As a treatment for acute renal failure it proved an indispensable procedure for those whose kidney function had temporarily failed but whose kidneys could be expected to return to normal after the acute episode. In the Korean war it was widely used to replace kidney function temporarily among casualties.

However, long-term dialysis could not, at this time, be contemplated. The problem was technical. In order to get access to the patient's blood, some sort of tubing, a cannula, had to be placed in an artery. After passing through the dialyser the blood had then to be passed back into a vein through another cannula. After the dialysis the canulae had to be removed and the blood vessels tied off. Thus the barrier to long-term treatment was simply that repeated dialysis would eventually lead to exhaustion of blood vessels for access. What was required, therefore, was a means of taking a sufficiently large flow of blood out of the system without destroying a length of blood vessel every time.

The breakthrough came in 1960 in America when Quinton (an engineer) and Scribner (a physician) made use of two relatively new synthetic polymers, teflon and silastic, in the tubing used to re-route the blood outside the body. The Quinton-Scribner shunt consists of tubing made partly of teflon and mostly of silastic. It is connected permanently to the vascular system, leading blood out from a peripheral artery and in again to a nearby vein (usually in the leg). In between dialyses the blood simply runs in and out through the short length of tubing. When dialysis takes place the circuit is enlarged by opening a union in the middle of the tubing and joining both ends to the dialysis machine.

This advance depended on the properties of teflon, a rigid fluorinated hydrocarbon polymer and silastic, a silicon based rubber. Both materials are very inert and this property is associated with their low tendency to initiate blood clotting. Teflon is also rigid and, therefore, provides an ideal material for the point insertion of the tubing system into the blood vessels, which have to be kept open. Its rigidity prevents the collapse of the blood conducting channel at the most vulnerable point. Silastic, on the other hand, provides the ideal material for the rest of the circuit because it is flexible and because it acts as a shock absorber, minimising the transmission of vibration from tubing outside the skin to the blood vessels underneath the skin.

Such shunts do not last indefinitely. They occasionally require repair – on average about once a year. Each repair may take up another inch of blood vessels. Survival is, therefore, theoretically limited by the overall length of available vessels for access but it is clear that the potential for long-term survival with a Quinton-Scribner shunt is of an entirely different order to that which could be anticipated before 1960 when a repair had to be done at every dialysis session. Exhaustion of shunt sites is now a rare cause of death.[3]

In 1967 an alternative to the Quinton-Scribner shunt, the internal fistula, was described by two other American workers, Brescia and Cimino. If any peripheral artery in the arm is joined to a neighbouring large vein the veins of the arm enlarge because of increased blood flow and thicken because of increased blood pressure. Brescia and Cimino found that such an operation made it possible, for the first time, to obtain a sufficiently large flow of blood for dialysis by venepuncture. Furthermore, the clotting problem was minimised by the rapid flow of blood in the veins.

A large bore needle is used to take blood out of a vein in the arm. Flow through the dialyser may be assisted by a pump and the blood is then returned, via another large bore needle, into a vein further up the arm. One advantage of the internal fistula is that it can set people free from restrictions on bathing and exercise imposed by the existence of an extracorporeal circuit. Psychological problems described as the 'shunt syndrome' are also avoided. A third advantage of the internal fistula is that it obviates the problem of bleeding which occurs if the shunt falls apart.

The disadvantage is that venepuncture with large bore needles can be painful and the procedure may be more difficult for patients using dialysis to carry out for themselves. Also there is an increased risk of air embolism requiring more careful monitoring.

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[3] Of Scribner's three original patients who received shunts in 1960, one died in 1971 and another in 1973, both of myocardial infarction. The remaining one is still alive (at the time of printing) having received a transplant from his mother in 1968.

Nevertheless, the advantages are such that over 80 per cent of home and hospital dialysis patients in Europe currently use the Cimino-Brescia fistula as their usual method of access.

Long-term studies have shown that dialysis for six to eight hours three times a week or every two nights is a satisfactory regime. But recent experience in Italy and elsewhere, with the most up-to-date equipment, suggests that shorter dialysis periods (3–5 hours three times a week) can be adequate for many patients. Dialysis can take place at night while the patient is asleep but the regime inevitably restricts normal activity. Only in a minority of cases are there severe uncontrollable side-effects but a feeling of enervation is common after a dialysis session. The treatment requires a good deal of self-discipline and can impose considerable strain on patients and their families, especially with child patients.

Haemodialysis is based on the development of synthetic semi-permeable membranes which allow small or medium-sized molecules (depending on the size of the pores) to diffuse from a solution on one side of the membrane to a solution on the other. One of these solutions is blood and the other is the dialysate fluid. If the dialysate solution is made up with a zero concentration of toxic molecules then such molecules will, on balance, diffuse from blood to dialysate fluid. In quantitative terms, the most important substance to be taken out of the blood during dialysis is urea, the major nitrogenous waste product of metabolism. But urea is only mildly toxic, even in quite high concentrations. It is an equally important function of dialysis to reduce the concentrations of numerous other more toxic molecules, present in the blood in much smaller amounts, but about which relatively little is known.

About 98 per cent of people on dialysis in Europe are treated by haemodialysis in which the membrane is situated in the kidney machine. In about 2 per cent of cases, peritoneal dialysis is used. Here, the peritoneum, the lining of the cavity of the abdomen, is used as a natural semi-permeable membrane and dialysate fluid is introduced into the abdominal cavity. Toxic molecules can then pass from the blood vessels around the peritoneum into the dialysate fluid. The rate of clearance of toxic molecules, however, is low. Sometimes even non-stop peritoneal dialysis will not reduce hyperuraemia to acceptable levels.

Another recent development is haemofiltration (*BMJ* 1977). This involves the extraction of a solution containing toxic (and many other) molecules by filtration of the patient's blood, under pressure, against a cellulose nitrate filter. (Such filters are more permeable than dialysis membrances and this is the critical difference that allows filtration to take place). The remaining blood with red blood cells and proteins too large to pass through the filter can then be infused with a substitute fluid (modified Ringers) to make up for the volume of filtrate lost and finally passed back into the patient's vascular system.

Haemofiltration is more expensive than haemodialysis but it has been found that the minority of dialysis patients with uncontrollable high blood pressure can have it controlled by transfer to haemofiltration. This would probably reduce mortality among such people on long-term dialysis. In addition it has been found that blood lipid concentrations, usually raised in renal failure, can be reduced to normal levels. Perhaps, therefore, mortality from heart disease may be reduced. Finally, it is possible that haemofiltration may provide an answer for the small number of cases of dialysis dementia which some authorities have attributed to excess blood aluminium consequent upon the use of dialysis materials. But, despite these possible advantages, the inconvenience and discomfort of long sessions of artificial detoxification will remain.

Much research has gone into reducing the size of dialysis equipment with a view to giving the patient more flexibility and freedom. Portable haemodialysis equipment has been made possible by the use of sorbents, ion exchange resins and the urea splitting enzyme, urease, to regenerate the dialysate fluid for re-use.

It is possible that the clinical use of sorbents will become increasingly important in the future. They could, by the *in situ* regeneration of peritoneal dialysate, make peritoneal dialysis a preferred form of treatment in many more cases. It is also possible that swallowed sorbents could absorb toxins on passage through the intestines. The contents of the intestines come into intimate contact with blood vessels through natural semi-permeable membranes. It may be, in the future, that a combination of extracorporeal, peritoneal and gastro-intestinal treatments will reduce the rigours of treatment by dialysis.

Transplantation

The first kidney transplantation experiments among animals took place in the early years of this century, around the same time as the first dialysis experiments. The surgical techniques involved in the fusion of vessels, therefore, became available a long time before kidney grafting became an established operation in humans. The major barrier to transplantation as a means of prolonging human life was, and still is, the immune reaction which protects the body against incompatible foreign material. In 1955, nine kidney transplants were reported between genetically non-identical donors and recipients. Some of them functioned but, because of rejection, not for a prolonged period of time. During the post-war years, however, Medawar and his associates were laying the theoretical foundations of future organ transplantation work by their clarification of some of the mechanisms of the immune system. In 1956 a transplant between identical twins (who would not show any immune reaction against each other's tissue) resulted in prolonged survival for the first time. In 1959 whole body irradiation was used to damp a recipient's immune reaction, following a graft from a genetically non-identical donor, and prolonged survival was obtained in this type of case as well. Such operations, however, were relatively few and confined to cases where donor and recipient were related as in, for example, grafts between siblings. The event which allowed kidney transplantation to become an alternative to dialysis for the mass of patients with kidney failure was the introduction of the first immunosuppressive drug in 1960. Effective immunosuppressive drugs made possible the survival of at least a proportion of cadaver kidney transplants. This opened opportunities for people on dialysis to undergo transplantation, using the organs of dead people, without the ethical and emotional problems of using grafts from living relatives.

At first, the success rate of cadaver renal transplantation improved rapidly, with a significant proportion of grafts surviving for years rather than months. Early on, it was evident that blood group compatibility between donor and recipient was necessary, and that results using live, closely-related donors from the immediate family were much better. These observations raised hopes that, if grafts between unrelated people could be 'matched', then results using cadaver grafts might be improved to at least equal those between close relatives and possibly to equal those between twins.

The problem has been that the identification of tissue types has turned out to be much more complex than was evident ten years ago. At the moment, matching is possible between donor and recipient for two loci (parts) of the material controlling the tissue type: this is a complicated system of linked genes carried on a particular chromosome, chromosome 6. This area of genetic material determining tissue type is known as the HL-A system, and typing is routinely done for loci A and B of this system using white cells from the blood. A National Organ Matching Service was set up to ensure the best matches, its object being the attempt to ensure identity for the four antigens, two of which are coded for at each of the A and B loci, between the maximum number of donors and recipients.

The effect of matching HL-A A and B on live donors, within family grafts from brother to sister, or parent to child, is immediately evident. HL-A A and B identical grafts survive in 80–100 per cent of cases. The effect of matching on cadaver transplantation, if any, has been controversial, but the final consensus is that HL-A A and B matching, as at present performed, increases graft survival by about 15 per cent at two years following the graft, from 40 to 55 per cent when 'zero' matches are compared to 'full house' identical matches (NOMS, 1977). The effect is mainly dependent on identity of the HL-A B locus.

This disappointing conclusion has now been explained by the fact that two other loci have been identified in HL-A complex, HL-A C and HL-A D. The latter locus, D, seems much more important in determining graft survival than the A or B loci. Matching for this locus is technically more slow and complicated and is not yet routine. While it is possible that HL-A D matching will improve results, since 1970 the survival of cadaver grafts has remained essentially at the level shown in the European Dialysis and Transplant Association data with half the grafts failing within one year, and repeat transplants faring worse. Longer term results are even less encouraging, with an average five year cadaver graft survival of 32 per cent. Likewise, immunosuppressive regimes have not significantly changed in a decade.

There is, therefore, a great deal to be gained by improved control of immune reactions. This may come about by advances in understanding of the immune system itself or by the development of more selective immunosuppressive drugs, or both.

The possibilities for prevention

Table 1 gives a breakdown of the primary renal diseases that give rise to chronic renal failure in European countries. It shows that about half of patients accepted for treatment are classified as suffering from 'glomerulonephritis'.[4] The history of this slow progressive disease is not yet understood and the possibility of primary prevention in the future depends on elucidation of the extent to which its development is determined by infective, ischaemic or immunological factors.

The second largest reported cause of chronic renal failure is 'pyelonephritis' accounting for about a fifth of all diagnoses. This raises the possibility of primary prevention by treatment of early infections. However, in contrast to the situation in many underdeveloped countries, it is unlikely that the prevention of bacterial infection alone would have a significant impact on the number of people developing chronic renal failure from this cause in Britain.

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[4] According to Wing (1977), however, from whose article the data are reproduced, the classification in the table 'implies a greater diagnostic confidence than most physicians enjoy'.

Table 1 *Primary renal diseases of patients treated for end-stage renal failure in 27 European Countries and in Britain**

Diagnosis	*Europe (%) patients*	*Britain (%) patients*
'Glomerulonephritis'	46·6	46·9
Glomerulonephritis (Histologically examined)	(10·0)	(13·1)
'Pyelonephritis'	19·9	18·0
Drug-induced analgesic abuse	3·3	1·9
Cystic renal disease	8·4	9·9
Hereditary/congenital	3·2	3·1
Renal vascular disease	5·4	6·6
Other identified rare diseases	9·7	10·4
Aetiology uncertain	3·5	3·1
Total	100	100

Source Reproduced from Wing (1977).
*Data from all patients recorded on computer files of Registration Committee of the European Dialysis and Transplant Association.

It is accepted that screening for bacteruria is not justifiable except among pregnant women.

One means of primary prevention has been the removal of phenacetin from combined analgesic preparations. Analgesic abuse, however, has never accounted for a substantial proportion of cases of renal failure in Britain.[5] Yet in the future other substances may be implicated, thus widening the scope for prevention in this field.

Probably the most important preventive measure in the last ten or fifteen years has been the control of hypertension (either primary or secondary to renal damage) which can, uncontrolled, accelerate renal failure.

Figure 1 shows that the death rate from essential malignant hypertension in England and Wales decreased by 70 per cent between 1960 and 1973, a period during which potent drugs for the treatment of high blood pressure became available. There may be further possibilities for primary prevention of renal disease by the early detection and treatment of asymptomatic high blood pressure. This, however, could only be regarded as a spin off from a general screening programme for asymptomatic hypertension. Such a programme would in itself be expensive,

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[5] In Australia, on the other hand, it is reported that about a quarter of all cases of chronic renal failure are attributable to analgesics containing phenacetin. Active steps are being taken to deal with the problem.

Figure 1 *Deaths per million due to diseases likely to terminate in chronic renal failure. England and Wales 1960–73*

(Semi Log Scale)

though arguably worthwhile (OHE 1971), its main benefit being the prevention of strokes.[6]

To summarise, it may be said that the possibilities for prevention are, in the present state of knowledge, limited. Significant progress is likely to depend on unravelling the processes that lead to the slow degeneration of kidney tissue. Furthermore, even if a breakthrough enabled future renal failure to be eliminated the cost of treatment to the health services would drop only slowly as the existing stock of patients in renal failure received functioning transplants or died.

Incidence of renal failure and the level of provision

In the late nineteen-sixties, when dialysis units were still being set up, three studies were undertaken in Britain with a view to establishing the incidence of renal failure. The findings of these studies can be used to compare the level of provision of renal services with the number of people going into terminal renal failure each year and who could benefit from dialysis and/or transplantation. (Branch *et al* 1971, Pendreigh *et al* 1972, McGeown 1972).

The practice has grown up of quoting the number suitable for treatment in a given age group (eg 5–60 years) as a rate per million *total* population. Strictly speaking, the application of figures derived from these surveys should take account of the difference in the age/sex structure of populations then and now. However, this error will probably be small compared with that from other sources.

The three surveys took place in Scotland (the largest), Northern Ireland and an area of South Wales (the smallest). All of them used comparable criteria, for example defining uraemia as 100mg of urea per 100ml of blood, and the Scottish and Northern Irish researchers co-operated actively with each other in an effort to ensure comparability. Using a similar format to that of Pendreigh *et al* (1972), Table 2 summarises the relevant data.

The Irish and Welsh studies give very similar results, though, because of the small number of cases sampled, wide error intervals must be attributed to the Welsh results.

The Scottish survey suggests a higher incidence of treatable renal failure than the other two. This may be a consequence of an

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[6] A large scale controlled trial is now being undertaken under the aegis of the MRC to establish at what levels of blood pressure preventive treatment may be expected to be beneficial.

Table 2 *Incidence of chronic renal failure*

	Glamorganshire	*Whole of Scotland*	*Whole of Northern Ireland*
Incidence per million *total* population per annum of people with chronic uraemia judged suitable for dialysis and/or transplantation with estimate of standard error*	39±10·4* (under 60 years old) 28±8·9* (under 50 years old)	52±3·2* (under 65 years old) 38±2·7* (under 55 years old)	38±2·9* (5–59 years old) 33±2·9* (5–54 years old)
Number of cases sampled	14 (under 60 years old) 10 (under 50 years old)	270 (under 65 years old) 195 (under 55 years old)	176 (5–59 years old) 150 (5–54 years old)
Sources of data	Laboratory records, hospital admissions and notification by General Practitioners	Prospective notification by General Practitioner Principals and Hospital Consultants. Check from death certificates and further check from laboratory records	Prospective notification by General Practitioner Principals and Hospital Consultants. 92 per cent response from those consultants who might be expected to see patients with renal failure

Comments	Suitability for dialysis determined by examination examination of hospital case notes	Suitability for dialysis and/ or transplantation determined by examination by a renal physician in about quarter of cases and from hospital case notes in most other cases	Suitability for dialysis and/ or transplantation determined by examination by the author of study in over half of cases, in other cases suitability judged by information from other doctors or from case notes. Liaison with organisers of Scottish study with a view to making two studies as comparable as possible
Incidence per million *total* population per annum of chronic renal failure *including* cases with serious co-existing disease such as to be judged unsuitable for dialysis and/or transplantation with estimate of standard error		96 ± 4·3* (under 65 years old) 63 ± 3·8* (under 55 years old)	47 ± 3·1* (5–59 years old) 39 ± 2·9* (5–55 years old)

Source Branch *et al* (1971), Pendreigh *et al* (1972), McGeown (1972).

*These standard errors were not quoted by the authors of the studies. The estimates are the square roots of the number of cases sampled, on the assumption that the samples may be expected to follow a Poisson distribution.

apparent misinterpretation of the recorded data.[7] However, taking account of the statistical error estimates, and the different age groups concerned, the Scottish estimate of incidence is not, in fact, significantly different (at the 5 per cent level) from the others.

If it is assumed that British people as a whole are about as likely (now) as Northern Irish and Welsh people were (then) to develop primary renal disease, the table indicates that dialysis and transplantation services would have to take about 35–40 new patients per million total population per year in order to cope with all those people aged between 5–60 who could benefit from such treatment according to the selection criteria employed in the surveys.

This is the source of the often quoted incidence estimate of 40 per million population per annum. However, this excludes under 5 year olds and (much more important in terms of numbers) over 60 year olds. It would also exclude people with some other serious conditions such that they would have been judged 'unsuitable' for dialysis at the time of the surveys, the late nineteen-sixties.

But it is important to recognise that the criteria for acceptance have been continuously relaxing since the time that the very strict age and fitness selection criteria were originally suggested by Scribner's group (Lindholm *et al* 1963). It has been becoming increasingly clear that age and other serious disease (like diabetes) need no longer be contra-indications for long-term dialysis or for transplantation.

Table 3 shows the conditions which led to certain 5–60 year olds being considered unsuitable for treatment in McGeown's 1968–70 Northern Irish survey.

It may well be that the same sort of patients, for example those

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[7] The true Scottish incidence may have been over-estimated because the survey included people recorded as having 100mg urea per 100ml blood at *any time* during the survey period and judged to require treatment *within a year*. This would have meant, for example, that patients whose condition had reached a critical stage just at the beginning of the survey period would have been recorded as well as patients whose condition reached the same stage well after the end of the survey period. The error introduced depends on how rapidly people whose blood urea reaches 100mg per 100ml die. The more rapidly they die, and the longer the period of the survey, the closer would the number of cases recorded have approximated to the true incidence.

The essential point is that it is necessary to sample cases at a specific stage in the development of the condition in order to distinguish between the stock and flow of patients. This the Scottish study does not seem to have done. On the other hand, the Irish study whose 176 cases were those which reached terminal failure in the survey period and the Welsh study, whose 14 cases required immediate treatment, do seem to have done so.

Table 3 *Patients with terminal renal failure regarded as unsuitable for regular dialysis therapy, analysed by reason for unsuitability, among cases sampled by M. G. McGeown (1972). Chronic renal failure in Northern Ireland*

Disease	*No of Patients*
Malignant Disease	4
TB	3
Paraplegia	2
Other disabling CNS disease	3
Achalasia (severe)	1
Angina	1
Bronchiectasis (severe)	1
Mental disease (hospital inpatient)	5
Low IQ	3
Unco-operative Patient	9
Diabetes mellitus	14
Total	46
Total *without* other serious disease	222

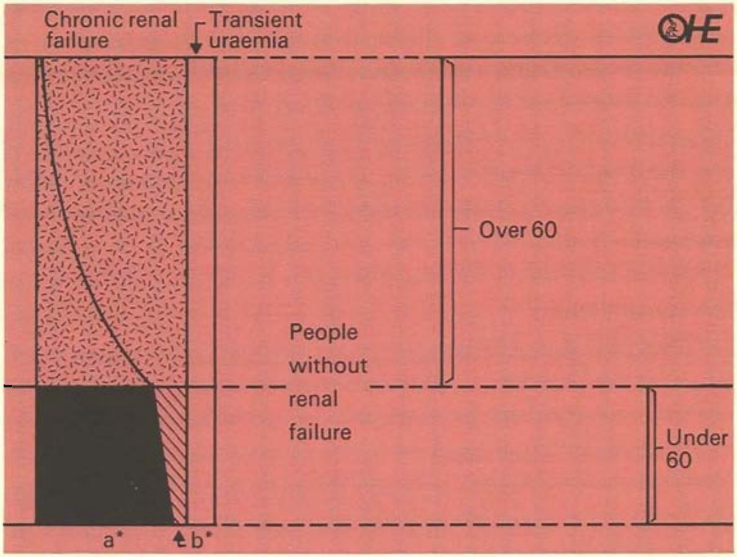
with diabetes, would still, in 1976, not be accepted for treatment in Britain. But this is more a function of shortage of facilities for new patients than any conviction that they would be unsuitable. In countries with a much higher intake of new patients there is nothing unusual in accepting such people. In the European countries from which the European Dialysis and Transplant Association receives regular data, 19 per cent of new patients in 1975 had some form of 'multi-system disease' apart from primary renal failure.

The same can be said of age. Sixty cannot be thought of as a natural barrier. The average age of acceptance of new patients has been steadily increasing in Europe as the yearly rate of intake has expanded. By 1975, 48 per cent of new patients in Europe were over 45. In America, average age at start of dialysis is even higher. Since 1972, Medicare has covered almost the entire population against renal failure. The result is that many elderly people can and do get accepted for long-term dialysis.

Figure 2 gives a schematic illustration of the populations of people with renal failure that would be accepted under different treatment policies.

Ignoring what may be called 'transient uraemia', (where kidney function is expected to return) it is the darkly shaded area that corresponds to the estimate of 35–40 potential new patients per year.

Figure 2 *Schematic Illustration of different populations that may be given access to dialysis and/or transplantation*



*a) chronic renal failure *without* any serious co-existing disease
*b) chronic renal failure *together with* a serious co-existing disease

If, however, all under 60-year-olds, regardless of any other co-existing disease, were accepted then facilities would have to be found for about 45–50 new patients per million total population per annum. This is represented by the dark shaded area plus the cross-hatched area.

Finally, in the most extreme case, if all over 60 year olds with terminal renal failure (whether with serious co-existing disease or not and regardless of age and frailty) were offered treatment as well then death rate figures (see Figure 1) suggest that, very roughly, provision could rise as high as 150 cases per million population per annum. This is represented by the addition of the lightly shaded area in Figure 2. Of course, many elderly people would only receive treatment for a very short time prior to death and would not, therefore, contribute significantly to the 'stock' of patients on treatment at any one time.

Survival and rehabilitation

Survival

In contrast with most conditions which are treated by the health services, hard data exist on the benefits achieved by dialysis and transplantation, in terms of survival and rehabilitation.

Such information is regularly collected by the European Dialysis and Transplant Association (EDTA). This is an organisation which was set up on the initiative of clinicians themselves, presumably recognising that money for such expensive treatment would be more likely to be forthcoming if requests were backed up by hard data. The EDTA coordinates information from over 1,000 known dialysis and/or transplantation units in Europe, including Eastern bloc countries, Turkey and Israel. By 1976 it had records on its computer files relating to almost 50,000 patients representing nearly all those ever treated by dialysis or transplantation in Europe. All the data quoted in this section come from this source.

Table 4 summarises the most important data on survival, taken from the entire EDTA register in 1976. There are various modes of treatment. Dialysis may take place in the patient's home or in a hospital ward and transplantation may be from a cadaver or from a living donor. In the common event of a graft failure, the transplantee may be returned to dialysis. A second and a third transplant may be attempted before the patient is returned permanently to dialysis. Cadaver grafts outnumber living donor grafts by about 6 to 1.

Table 4 shows, as might be expected, that patient survival rates decrease with increasing age of patients for all modes of treatment. For the particular age structure represented by this population, five-year survival rates were 72 per cent for patients selected for home dialysis, 69 per cent for first living donor grafts, 54 per cent for hospital dialysis and 53 per cent for first cadaver grafts. Rates for second and third grafts are not shown but are worse. So too are survival rates among patients with serious coexisting disease like lupus or diabetes.

Table 5 shows the distribution of causes of death among patients on the different modes of treatment. For both home and hospital dialysis vascular conditions are the major cause of death. Among transplantees, infection is the largest single cause, particularly in the earliest post-transplantation period. This reflects the use of immunosuppressive drugs which lower resistance to infections at the same time as they help to prevent rejection.

There is evidence that survival rates are improving for both dialysis and transplant patients. Figure 3 compares, in graphical form, survival rates for the whole EDTA register as at 1974 (ie

Table 4 *Percentage patient survival according to age groups on different modes of treatment. All cases on EDTA register 1976*

	Age	*Sample size*	*1 year*	*2 years*	*3 years*	*4 years*	*5 years*	*6 years*	*7 years*	*8 years*
Patient	15–34	14,626	88·5 ± 0·3	79·9 ± 0·4	74·2 ± 0·5	70·3 ± 0·6	66·3 ± 0·8	64·1 ± 0·9	61·8 ± 1·0	60·1 ± 1·2
Survival	35–44	10,886	87·1 ± 0·4	76·2 ± 0·5	68·0 ± 0·7	62·5 ± 0·8	56·9 ± 0·9	51·2 ± 1·1	47·9 ± 1·3	46·5 ± 1·4
Hospital	45–54	11,433	85,4 ± 0·4	73·4 ± 0·5	63·3 ± 0·7	55·2 ± 0·8	47·2 ± 1·0	41·2 ± 1·2	37·9 ± 1·4	33·9 ± 1·8
Haemodialysis	55–64	5,723	82·7 ± 0·6	67·4 ± 0·8	54·5 ± 1·0	44·4 ± 1·2	36·7 ± 1·4	27·1 ± 1·8	23·1 ± 2·1	†
	65	1,501	76·6 ± 1·3	57·6 ± 1·8	48·1 ± 2·1	34·5 ± 3·0	†			
	All*	45,336	86·2 ± 0·2	74·9 ± 0·3	66·3 ± 0·3	59·9 ± 0·4	54·0 ± 0·5	49·2 ± 0·6	46·4 ± 0·7	44·3 ± 0·8
Patient	15–34	2,647	95·5 ± 0·4	91·0 ± 0·7	87·5 ± 0·8	84·0 ± 1·1	80·5 ± 1·3	77·0 ± 1·7	74·2 ± 2·1	69·9 ± 3·1
Survival	35–44	2,054	93·0 ± 0·6	87·2 ± 0·9	80·7 ± 1·2	76·8 ± 1·4	73·0 ± 1·7	69·7 ± 2·1	65·0 ± 2·8	60·3 ± 3·7
Home	45–54	1,838	92·0 ± 0·7	85·1 ± 1·0	77·4 ± 1·3	69·8 ± 1·7	62·2 ± 2·2	56·4 ± 2·7	53·8 ± 3·1	†
Dialysis	55–64	589	88·6 ± 1·4	76·8 ± 2·1	67·6 ± 2·6	62·8 ± 3·0	57·5 ± 3·7	†		
	65	81	86·2 ± 4·3	73·3 ± 6·5	†					
	All*	7,339	93·5 ± 0·3	87·1 ± 0·5	81·3 ± 0·6	76·6 ± 0·7	72·0 ± 0·9	68·0 ± 1·2	64·8 ± 1·4	60·5 ± 2·0
Patient	15–34	1,084	87·4 ± 1·0	82·2 ± 1·2	77·6 ± 1·4	74·9 ± 1·5	71·9 ± 1·7	67·5 ± 1·9	65·2 ± 2·1	63·0 ± 2·3
Survival	35–44	294	81·3 ± 2·3	78·1 ± 2·5	70·3 ± 3·0	68·2 ± 3·2	65·3 ± 3·5	60·4 ± 4·0	55·1 ± 4·6	†
1st live donor	45–54	96	83·6 ± 3·9	77·0 ± 4·6	72·2 ± 5·1	66·4 ± 5·6	†			
graft	55–64	27	†							
	65	0								
	All*	1,621	85·9 ± 0·9	81·2 ± 1·0	75·5 ± 1·2	72·6 ± 1·3	69·3 ± 1·4	64·8 ± 1·6	62·0 ± 1·8	59·7 ± 2·0
Patient	15–34	4,312	80·3 ± 0·6	74·3 ± 0·7	70·3 ± 0·8	66·5 ± 0·9	62·3 ± 1·0	58·9 ± 1·1	56·8 ± 1·5	53·8 ± 1·5
Survival	35–44	2,730	74·4 ± 0·9	66·6 ± 1·0	60·7 ± 1·1	55·0 ± 1·2	50·6 ± 1·3	48·3 ± 1·4	43·9 ± 1·7	41·2 ± 2·1
1st cadaver	45–54	2,205	65·0 ± 1·0	57·0 ± 1·1	51·6 ± 1·2	46·5 ± 1·3	42·1 ± 1·4	38·4 ± 1·6	34·2 ± 2·1	†
graft	55–64	557	57·9 ± 2·2	47·9 ± 2·3	42·3 ± 2·4	37·1 ± 2·7	32·9 ± 3·1	†		
	65	21	†							
	All*	10,152	74·3 ± 0·4	67·1 ± 0·5	62·2 ± 0·5	57·6 ± 0·6	53·4 ± 0·7	50·3 ± 0·7	47·4 ± 0·9	44·9 ± 1·0

*Includes patients aged 0–15 years.

†Number of patients at risk from this interval onwards equals less than 30.

Table 5 *Percentage distribution of deaths among people on various modes of treatment in 1975, Europe*

	Hospital dialysis	*Home dialysis*	*Living donor transplantation*	*Cadaver transplantation*
Vascular diseases (including myocardial infarction and cerebrovascular accidents)	55·7	61·5	12·9	27·1
Infections (apart from viral hepatitis)	15·0	16·9	46·2	36·3
Uraemia caused by graft failure	NA	NA	7·7	6·7
Other causes	29·3	21·6	33·2	29·9
	100	100	100	100

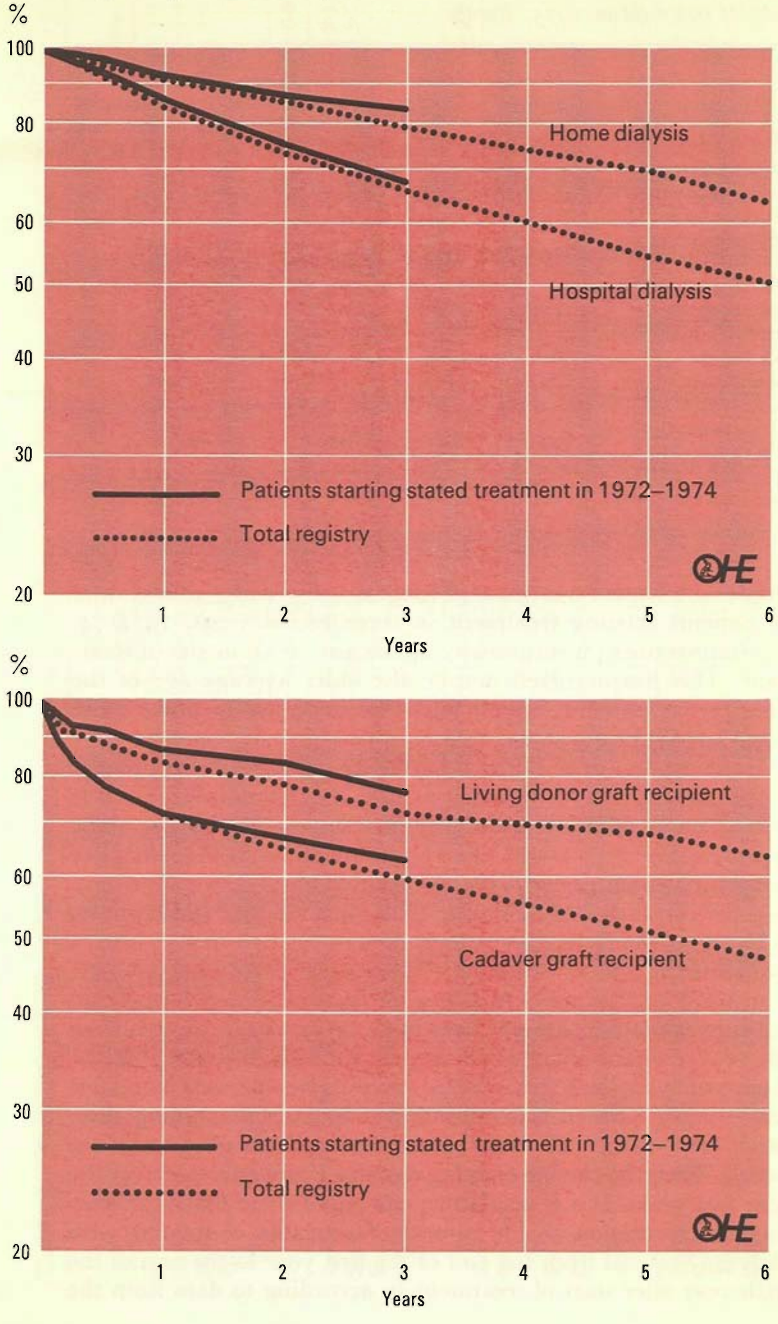
Source EDTA (1976)

people who started treatment as early as 1963) with survival rates for patients starting treatment in three recent years, 1972–74. The improvement is statistically significant for all modes of treatment. This has occurred despite the older average age of the more recent patients, which might be expected to make more recent survival rates worse.

Another point to be noted from Figure 3 is the different shapes of the survival curves for dialysis and transplantation. Each is plotted on a semi-log scale. In the case of dialysis the slope approximates to a straight line. This indicates that the chance of dying (in a given period) remains approximately constant over a long period on dialysis. That is, a patient's vulnerability appears to be about the same after a long time on dialysis as it is after a short time.

In contrast, the survival slopes for transplantation clearly do not approximate to straight lines over the first year, though from one year after transplantation they do so. This indicates that the chance of dying for a transplantee (over a given period) is greatest immediately after transplantation but in each succeeding time period the chance of dying decreases until about a year has passed. Then the chance of dying remains about constant over the next five years. If a transplantee can survive the first year then his/her expectation of life appears favourable compared with dialysis. Survival from the end of the first year to the end of the sixth year after start of treatment is, according to data from the

Figure 3 *Cumulative patient survival*



whole EDTA register at 1976, 75 per cent for first living donor transplantees, 73 per cent for those selected for home dialysis, 68 per cent for first cadaver transplantees and 57 per cent for those selected for hospital dialysis.

Of course, these survival rates may not be comparable because the populations receiving different modes of treatment may be highly selected in terms of age and fitness. This is certainly the case with home and hospital dialysis. The higher survival rate among people dialysing themselves at home undoubtedly reflects selection of fitter individuals for that mode of treatment. On the other hand, there is no doubt that the higher survival rate for living donor compared with cadaver transplantees does reflect a genuine advantage in receiving a kidney from a relative.

Finally, Figure 4 shows graft survival taken from 1974 data. As may be expected, graft survival is lower than patient survival. The 5-year survival rate for the first cadaver grafts, by far the largest group, was 32 per cent. Even among living donor grafts the five-year graft survival rate was only 52 per cent. For the very best matched living donor grafts it may reach about 80 per cent. About seven out of ten graft failures are attributed to rejection.

In contrast with patient survival, EDTA data does not show any improvement in graft survival. It has been suggested (EDTA 1975) that any improvements in tissue typing and immunosuppressive regimens (which might have been expected to improve graft survival) could have been offset by the acceptance of older and higher risk patients for transplantation.

The combined EDTA data hide wide variations from country to country which cannot be explained by differences in average age of transplantees. Holland has the best record. An analysis of the fate of cadaver transplantees by the EDTA (1976) found that percentage survival at three years was about one-third better in Holland than in Europe as a whole.

Even better survival was reported in a recent publication (McGeown *et al* 1977) which details the experience of 100 transplants (mostly from cadavers) carried out on ninety-one patients in Belfast over eight years. In this series five-year patient survival was, at 81 per cent, very significantly higher than in Europe as a whole.

These Northern Irish data are very different from other British and EDTA data in two major respects. First, there was a very low rate of graft failure classified as 'rejection', 5 per cent of all grafts over five years compared with almost 50 per cent that would be expected from EDTA data. (Non-immunological graft failure was of about the same order as expected). The other big difference is that, whereas 40 per cent of deaths are classified in

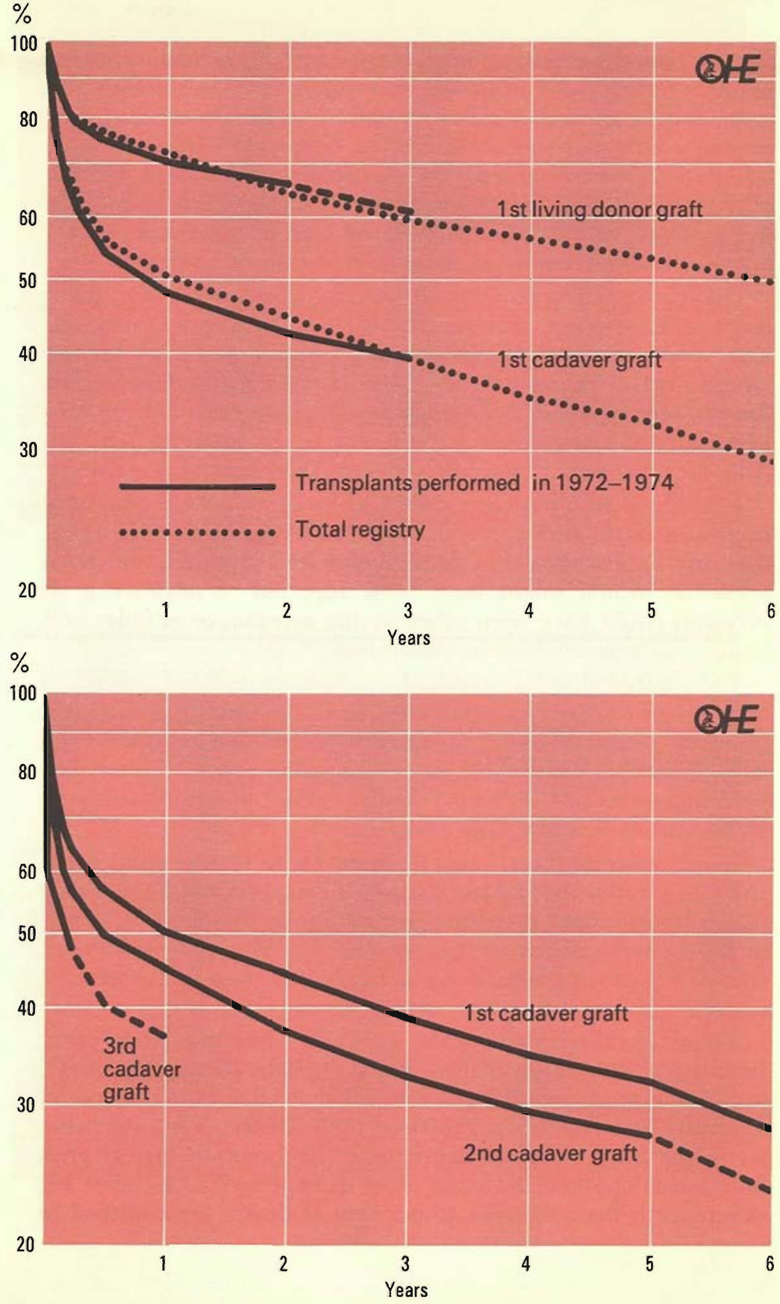


Figure 4 *Cumulative graft survival*

EDTA data as due to 'infection', there were no deaths classified as such in the Northern Irish series.

The authors attributed the lack of infective deaths partly to isolation techniques and partly to the sparing use of steroids. It is commonly supposed that a balance ought to be struck between the over-use of steroids, which is likely to predispose to infection, and under-use which might lead to rejection. But in the Northern Irish series, not only were there no deaths from infections but, at the same time, rejection was much less common than usual. What is more, the tissue-match grades achieved were not very good so the lower rejection rate cannot be explained in that way.

The very considerable differences between the Northern Irish series and the EDTA data could hardly be attributed to chance. If the same success could be achieved generally then the prospects for people with chronic renal failure would become much brighter. Since successful transplantation is relatively cheap, the average cost of treatment per case would also be significantly reduced.

Rehabilitation

In addition to data on survival, the EDTA records provide data on rehabilitation, shown in Table 6. This is even more unusual in the health services. Together, they provide a basis for the quantitative assessment of value for money spent on dialysis and transplantation.

Rehabilitation as measured by working status is considerably better for people undergoing home dialysis than for those being dialysed in hospital. Again, selection invalidates precise comparison. However, there is no doubt that, because of the relative inconvenience and inflexibility of hospital routine, a person is more likely to find and retain employment if trained for self-dialysis at home. Often, hospital dialysis (unlike home dialysis) is carried out during working hours. The table, therefore, does reflect a real advantage in home dialysis.

Rehabilitation, in terms of work status, is marginally better for those with cadaver transplants and significantly better for those with living donor transplants. That their employment rate is not even better may reflect the intensive anti-rejection treatment and monitoring that continues for many months after transplantation.

Despite the rather disappointing rate of graft survival for cadaver transplants, the usual option to dialysis, there is no doubt that transplantation is the preferred mode of treatment. It is, if successful, cheaper and, more important, it sets the patient free from the restrictions and pressures of undergoing dialysis three times a week for the rest of his/her life. It is a rare event for a

Table 6 *Working status of dialysis and transplant patients whose treatment had started more than three months previously. 20 European countries, 1974*

	Hospital dialysis			*Home dialysis*			*Cadaver transplant*			*Living donor transplant*		
	M %	F %	T %	M %	F %	T %	M %	F %	T %	M %	F %	T %
Working Full Time	33	26	30	67	58	65	69	62	66	76	75	76
Working Part Time	24	27	25	15	19	16	11	12	12	10	12	11
Not Working	43	47	45	18	23	19	20	26	22	14	13	13
	100	100	100	100	100	100	100	100	100	100	100	100

Source EDTA 1975. M=Male F=Female T=Total

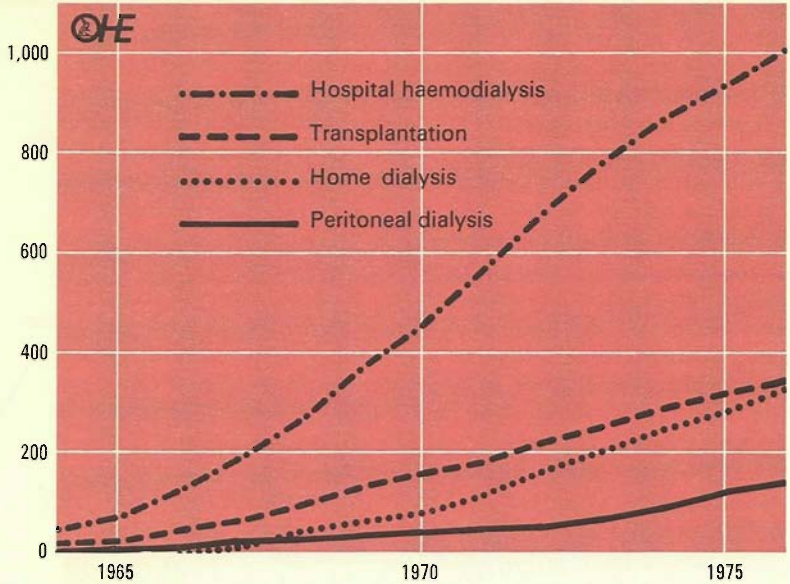
person who is offered dialysis to refuse it. Equally, however, there are few patients who will opt to remain on dialysis if a transplant is offered for the first time, despite the high risk of rejection and/or death from infection in the immediate post-transplant months.

The provision of services for dialysis and transplantation in Britain: comparisons with Europe

Figure 5 shows how the number of centres in Europe performing dialysis and transplantation has increased from a handful in the early sixties to over 1,000 by 1976. Initially it was Britain and Denmark, both with central financing systems, which were the pace-setters in the development of facilities for long-term dialysis. In Britain in the mid-sixties the DHSS became directly involved in promoting the establishment of dialysis units. The money for this, and for the evaluation of the technique, initially came from central funds. In fact, the network of treatment centres presently providing dialysis had been more or less established by the end of the sixties. However, other European countries, like France and Germany, which made a slower start in the mid-sixties, soon caught up and now have a much higher level of provision than Britain's.

The DHSS was also instrumental in setting up transplantation units. After a report from a DHSS working party the present network was developed alongside the dialysis units. Again, the

Figure 5 *Number of centres performing dialysis and transplantation in Europe, 1964–76*



Source EDTA.

programme was financed partly from central funds. In contrast with dialysis, Britain's kidney transplantation rate still compares favourably with similar European countries.

Finally, the DHSS provided the finance for setting up the National Organ Matching and Distribution Service and the National Tissue Typing Reference Laboratory. These two organisations are now known collectively as 'UK Transplant'.

There are now forty-seven dialysis and transplant units in England and Wales, giving between one and five units per region. After the mutual development stages the DHSS handed back the responsibility for financing, and any expansion of existing units, to the relevant regional authorities. Since the reorganisation in 1974 it has been general NHS policy not to intervene directly in regional and area resource allocation decisions except in a very restricted range of circumstances.

There are a number of ways in which the provision of services for chronic renal failure can be measured. For example, the 'stock' of people on treatment at a given time is perhaps the best measure of the magnitude of resources being devoted to treatment. In the period 1967 to 1977 the number of patients undergoing dialysis in England and Wales rose from 191 to 2,375 (Figure 6).

The source of these figures is the DHSS. They represent the longest statistical series available. It is evident, from Figure 6, that the rate of increase in provision, measured in this way, remained approximately constant over the whole period. It neither accelerated nor decelerated in the early seventies when the DHSS handed over responsibility for planning and financing the services to the regions. Nor was there any change in the rate of growth after the post-1973 restrictions on public spending.

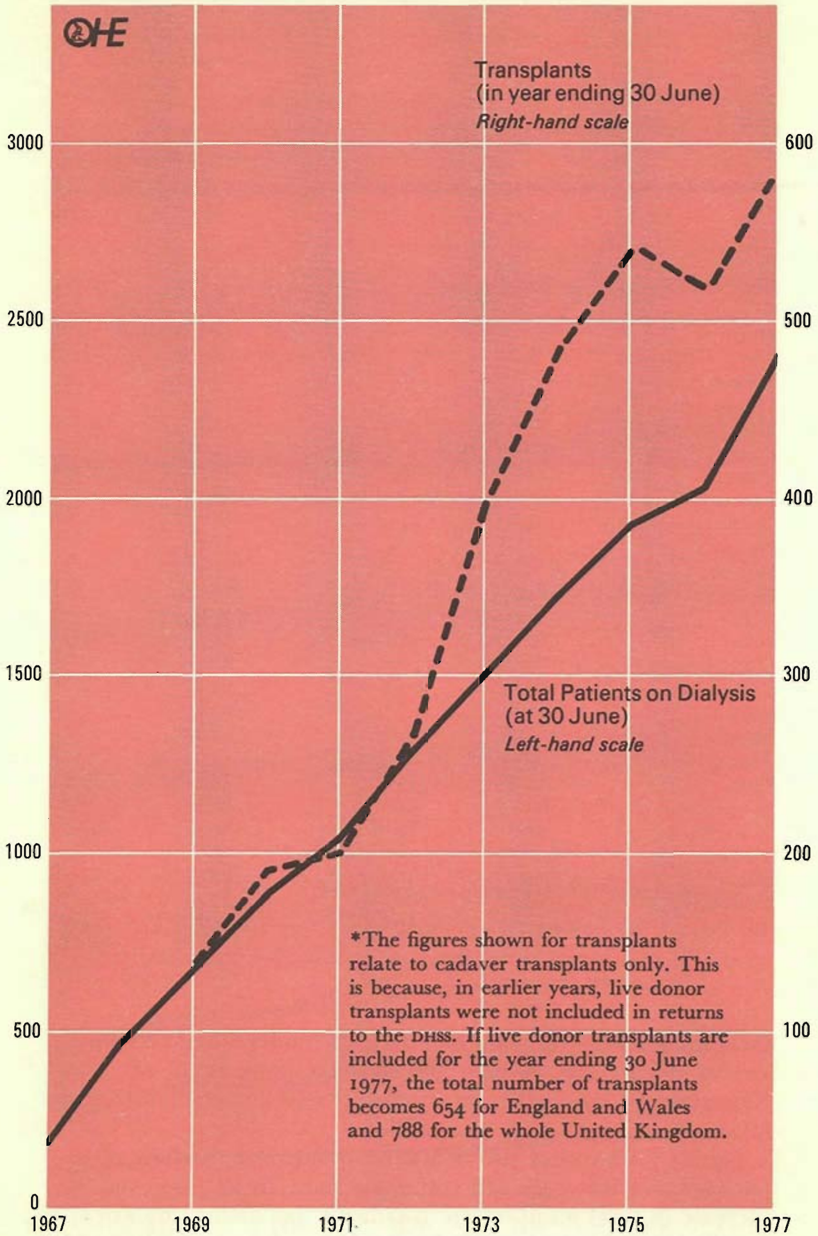
The EDTA publishes similar data for other European countries as well as Britain. In their case, the series which best measures the magnitude of resources provided is 'patients per million total population alive on dialysis or with a functioning transplant'. As might be expected, this also shows an approximately constant rate of increase in Britain over 1961 to 1976 (Figure 7). It can be seen, however, that Europe as a whole has been catching Britain up in her overall level of provision. In this context 'Europe' includes Eastern bloc countries, Turkey, Greece, Portugal and Spain as well as the richer countries of Western Europe. Table 7 shows the latest data by country. The Eastern bloc and the poorer Mediterranean countries all had fewer people on treatment per million population than Britain's 71.2 in 1976. On the other hand, all except Iceland, Ireland and Austria of the richer West European countries had more. Switzerland had the highest European rate in 1976, 150 people on treatment per million population. In the United States the rate is currently about 170 per million.

No attempt is made here to speculate on the reasons for the differences in provision though clearly two important factors are methods of financing and national wealth. With regard to the latter, Figure 8 shows a plot of renal patients per million population against GNP per capita. It is interesting to note that the level of British provision is not significantly different from that which might be predicted from level of GNP.

The discussion so far has concerned the stock of patients on treatment. Perhaps of more interest, especially to those unfortunate enough to experience renal failure in the future, is the number of new patients accepted for treatment each year. By this measure of provision Britain recently has compared even less well with similar European countries (Table 7). Average intake per unit population in the EDTA European countries overtook British intake in the early seventies.

By 1976, there were 19.1 new European patients per million population per year compared with 15.1 for Britain (though this may rise to up to 25 per million in 1978–79). The intake in West Germany and France exceeded 30 per million in 1976 and, highest of all, Israel's intake probably exceeded 40 per million in that year. These figures must be judged against the estimate that

Figure 6 *Number of patients treated for chronic renal failure 1967–77. England and Wales*



*The figures shown for transplants relate to cadaver transplants only. This is because, in earlier years, live donor transplants were not included in returns to the DHSS. If live donor transplants are included for the year ending 30 June 1977, the total number of transplants becomes 654 for England and Wales and 788 for the whole United Kingdom.

Source DHSS.

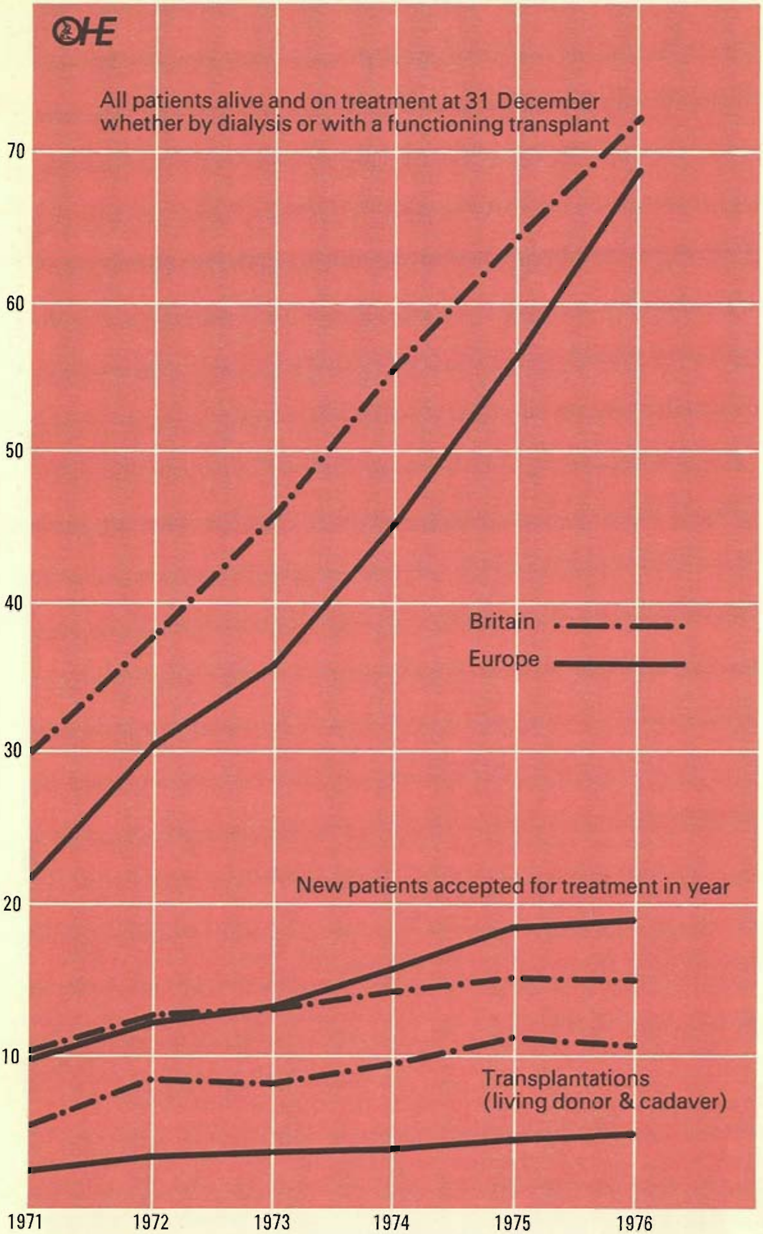
Table 7 *Treatment rates per million population. European countries providing information for EDTA*

	New patients per million population		*Patients being treated by dialysis or with a functioning transplant at 31 December, per million population*	
	1975	*1976*	*1975*	*1976*
Austria	25·3		55·1	65·8
Belgium	25·9		102·7	
Bulgaria	—		11·2	
Czechoslovakia	8·1		16·8	
Cyprus	—		34·3	
Denmark	28·7		132·4	
West Germany	29·6	30·8	87·7	105·0
Finland	27·4		71·0	
France	29·1	30·3	102·2	111·3
East Germany	10·5		28·4	
Greece	18·2		48·4	
Hungary	—		7·2	
Iceland	—		41·5	
Ireland	13·6		44·7	
Israel	38·6		117·0	
Italy	25·0	27·6	81·2	102·0
Luxembourg	—		90·6	
Netherlands	18·9	21·4	90·2	108·5
Norway	27·5		67·4	
Poland	1·6		3·3	
Portugal	—		4·4	
Spain	11·3	14·4	26·9	39·3
Sweden	28·7	28·7	85·4	99·3
Switzerland	34·2	30·9	136·1	150·0
Turkey	—		0·8	
UK	14·5	15·1	62·0	71·2
Yugoslavia	8·9		22·1	
'Europe'	17·4	19·1	56·7	68·8

there are about 35–40 potential patients (under 60 and having no serious co-existing disease) per million population per year. Relaxation of age and fitness criteria for selection could lead to an intake of as many as 150 per million.

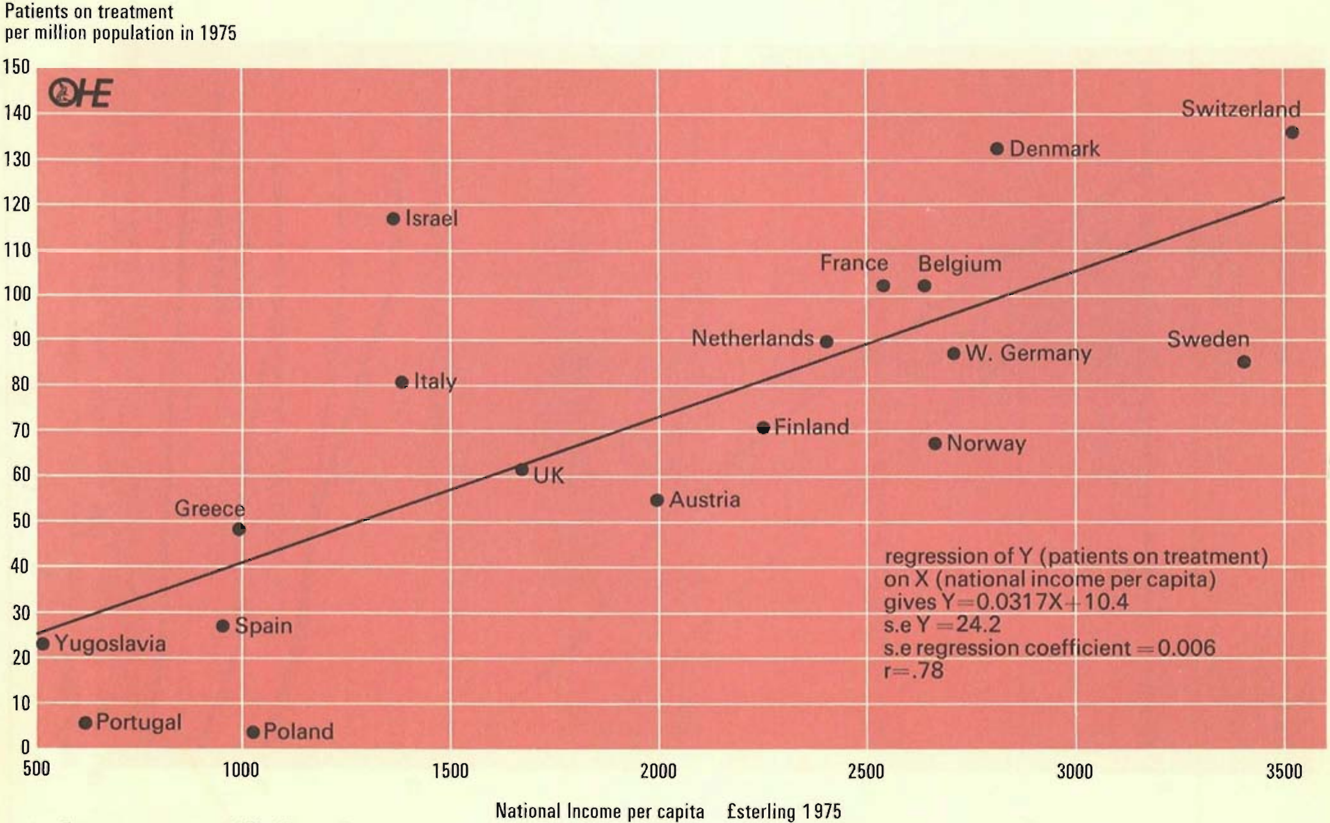
Figure 7 illustrates the relationship between the flow of new patients and the stock of existing patients. In any one year the increase in total numbers on 'treatment' (as defined by EDTA) is equal to new intake less deaths. As the stock increases it may be

Figure 7 *Patients treated for chronic renal failure, Great Britain and 'Europe' – rates per million population*



Source EDTA.

Figure 8 *Patients per million population on treatment for chronic renal failure in 1975 plotted against National Income per capita (£) in 1975, various European countries*



Sources EDTA and *The Economist.*

expected that deaths will increase and, unless intake continues to rise indefinitely, a plateau will be reached when the number of new patients per year equals the number of deaths. An important question is, what level will this plateau of provision be? It brings out the predicament of health authorities who may wish to provide treatment, but at the same time, wish to contain costs. If an authority decides to increase intake by, say, 10 per million population per year, it can hardly do so for just one year. But if it plans to continue the extra intake in succeeding years it will find its ultimate commitment is many times its first year's commitment. People on dialysis can expect to live for a considerable period. Each one may be a candidate for transplantation and, more important in terms of resources, each person who has had a transplant is a candidate for return to dialysis if the graft fails.

In calculating the plateau level the critical assumption that has to be made is the survival rate of patients accepted. In 1976, the death rate among all British patients (whether on dialysis or with a functioning transplant) was 11 per cent per annum. If this rate were maintained indefinitely then equilibrium would be approached (after about 30 years) when the stock of patients was nine times the annual intake. Of course, ageing of the population on treatment may be expected to raise the average death rate and reduce the equilibrium population. But, equally, death rates may decline because of other factors thus raising the equilibrium population.

No country has yet even reached half of its probable equilibrium level of provision. The EDTA publishes computer forecasts for European countries from which it receives information. One assumes that the annual intake of new paitents will increase at its present rate until it reaches 40 per million population per annum (ie on restrictive definitions of 'need'). This has already been achieved by Israel and, on past trends, will be reached by most West European countries by the 1980s, but not until the next century by Britain. In turn, the plateau, or equilibrium level, of provision will not be reached until many years after that.

In the EDTA forecasts the plateau for each country is estimated on the basis of the latest death rates among renal patients for that country. In fact, since a final intake of 40 per million per year is assumed for every country, the forecast plateau level is solely a function of present death rates.

In Britain, with an 11 per cent death rate in 1975, the plateau was forecast (EDTA 1976) at 340 patients per million population on dialysis or with a functioning transplant; that is, about five times the present level (to be reached well after the turn of the century). As an illustration of how important death rates are to the equilibrium level of provision, the EDTA estimates that if death rates were as high as Poland's were in 1975, the forecast plateau would only be 90 per million population. On the other hand, if annual death rates were as low as the 8 per cent experienced by Dutch patients in 1975, then the plateau level would be as much as 470 per million population.

Moreover, if death rates among renal patients were reduced so far as to approach the average for the rest of the population an even higher (and more costly) plateau level would be in prospect. If, for example, the average expectation of life of people accepted for dialysis or transplantation reached twenty years then an annual intake of 40 patients per million population would imply an eventual plateau of 800 patients on treatment per million. And, if substantial numbers of over 60-year-olds and those with serious co-existing diseases were accepted as well, then the plateau level would certainly exceed 1,000 patients per million population, some fifteen times greater than existing facilities.

It is unrealistic to attempt to forecast death rates or even attempt to foreshadow new technology that may be developed in the future, but the results that are obtained by application of the above assumptions illustrate the uncertainties with which health planning authorities are faced and the order of magnitude of resources that may potentially be consumed by the treatment of chronic renal failure.

The provision of dialysis and transplantation for children under 15 illustrates the problems faced by health service planners in a particularly sensitive area. Survival rates for children are better than those for adults, for all modes of treatment (EDTA 1976) and a substantial proportion of children accepted for treatment may be expected to survive to adult life. Their treatment, however, raises special problems, both technical and in terms of the child's physical, educational, social and psychological development. And, because of these special problems, the long-term treatment of children can impose very considerable strains on their families. It is probably for this reason that, in the past, few children who did not come from a stable middle-class home received treatment.

Perhaps eighty to a hundred children below 15 develop primary renal failure in the UK each year. According to EDTA data, thirty-one were accepted for treatment in 1976, that is, about a third of the total. (In this case UK provision is above the European average). This is, in fact, of a similar order to the proportion of potential adult patients treated. But because of the especially emotive issues raised by the refusal of treatment for children, and perhaps also because of the relatively limited numbers involved, the DHSS itself took steps in late 1977 to provide for an immediate increase of intake to 80–100 children a year. An offer was made to meet the capital costs of four extra dialysis machines for children in each of six centres. In addition, the DHSS offered to meet the first year's running costs for a similar number of home dialysis places. Four regional authorities accepted but one requested time for consideration and one, the South Western Region, refused at first. It may be that the South Western Regional Health Authority will eventually accept the offer but its initial refusal is understandable in terms of the foregoing discussion on the way in which the ultimate commitment for treatment of renal failure increases to many times the initial commitment. Undoubtedly, they would have preferred financial support to be offered for subsequent years' costs as well.

Despite Britain's poor level of intake of new patients in recent years relative to other European countries, there are two areas in which the mode of treatment offered to patients compares favourably.

Where it is possible, transplantation is the preferred mode of treatment to dialysis. Throughout the period for which figures are available Britain has maintained a relatively high transplantation rate (Figure 7). Table 8 shows that, according to EDTA data, 10·8 transplants per million population were carried out in the UK in 1976. 'UK Transplant', whose recent figures may be more comprehensive than those of the EDTA, reported 788 transplants in the year ending June 1977 in the UK, equivalent to 14 per million. This is still well below the record rate of 30.8 per million achieved by Denmark in 1973 but, nevertheless, it compares very favourably with the 1976 rate of 5.4 per million for 'Europe' as a whole. Only the Scandinavian countries and Switzerland have higher transplantation rates than Britain. Both West Germany and Italy are below the European average by this measure of performance, despite being near the top in the overall rate of intake of new patients (Table 7).

A functioning transplant is considerably cheaper, per year of life, than dialysis and this may have been an important influence on policy both during the direct involvement of the DHSS in setting up services and afterwards, when responsibility for new resource allocation was handed over to the regions. EDTA data shows that of the approximately 4,000 people 'on treatment' in the UK at the end of 1976, 38 per cent of them had a functioning transplant (the rest being on dialysis). A comparable figure for Europe as a whole was 19 per cent.

The other area where Britain's performance can be said to compare favourably with other European countries is the use of home dialysis in preference to hospital dialysis. When dialysis was first developed it was provided in hospital wards. Lack of space and lack of flexibility within hospital confines, together with the search for economy led to the development of extra-hospital

Table 8 Transplantation rates in European countries* 1976

Country	*Transplant rates per million population*		
	Cadaver transplants	*Living donor transplants*	*Total**
Finland	20·7	1·7	22·8
Denmark	19·9	—	21·1
Sweden	15·1	3·3	20·0
Norway	13·4	5·2	19·6
Switzerland	15·8	0·2	17·5
Netherlands	9·4	0·4	11·7
UK	8·9	1·2	10·8
Belgium	7·8	0·3	9·9
Iceland	—	4·6	9·1
Israel	7·5	0·9	8·9
Austria	6·8	0·5	8·1
France	5·7	1·8	6·8
Ireland	5·1	0·6	6·3
Cyprus	1·6	4·7	6·3
Europe	4·3	0·6	5·4

Source EDTA 1977.
*Includes grafts where the donor was not stated

facilities. In Britain this has taken the form of home dialysis.[8] Techniques have been developed to equip homes and to train people to dialyse themselves. Apart from the advantage of economy, home dialysis, by effectively isolating patients from each other and from hospital staff, has the advantage of limiting the transmission of viral hepatitis. In addition, for those patients able to take a positive attitude to treatment the self-reliance induced by home dialysis can be beneficial to both the patient and

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8 Another variation in the mode of treatment is the use of minimal care or 'satellite' hospital units which have been set up in some countries with the object of achieving a high turnover of dialysis sessions at lower cost per patient. This approach has been widely adopted in America and West Germany. The risk of cross-infection from hepatitis B has inhibited the development of this type of service in the UK until very recently. The DHSS has announced, however, that £1 million of special medical development money will be made available to set up and evaluate five or six minimal care dialysis units throughout the country.

his family. Finally, employment rates are very much better for home dialysis than for hospital dialysis patients.

About two-thirds of British dialysis patients are on home dialysis (by far the highest proportion in Europe) compared with about a fifth for all European dialysis patients. It is possible, of course, that the high proportion for Britain could be a result of the selection of only the fittest patients for treatment, that is those who would be particularly suitable for home dialysis. For this reason it may be preferable, in order to establish relative performances of British and other European countries, to compare rates of patients on home dialysis. In 1976, the UK had twenty-nine patients on home dialysis per million population (again highest rate in Europe) compared with 10 per million for the whole of Europe. West Germany had 26 per million, France 15 per million and Italy 8 per million.

A good illustration of how financing arrangements can affect not only the amount but the type and place of treatment is provided by the American experience. In 1972 the Senate voted (with little deliberation, it has been said – Rennie 1978) to extend Medicare coverage for chronic renal failure to almost the entire population. This was seen by some as the first step towards comprehensive national insurance against 'catastrophic' illness. However, the reimbursement arrangements discouraged transplantation as an alternative to dialysis and favoured dialysis in centres over dialysis at home. One of the results can be seen in Figure 9. A trend towards home dialysis was sharply reversed in line with the new financial incentives. Such has been the increase in the cost of the programme since then that new legislation is now before the Senate with a view to encouraging home rather than hospital dialysis and, at the same time, promoting transplantation.

Finally, Table 9 shows the very wide regional variations in 1975 in England and Wales in the provision of renal services. The West Midlands and the North Western regions took only 8 new patients per million population compared with 22 per million for both the Northern and the South Western regions. It seems unlikely that either differences in incidence or interregional transfer of patients could account for the variation – except in the Thames regions where considerable cross regional movement is known to take place.[9]

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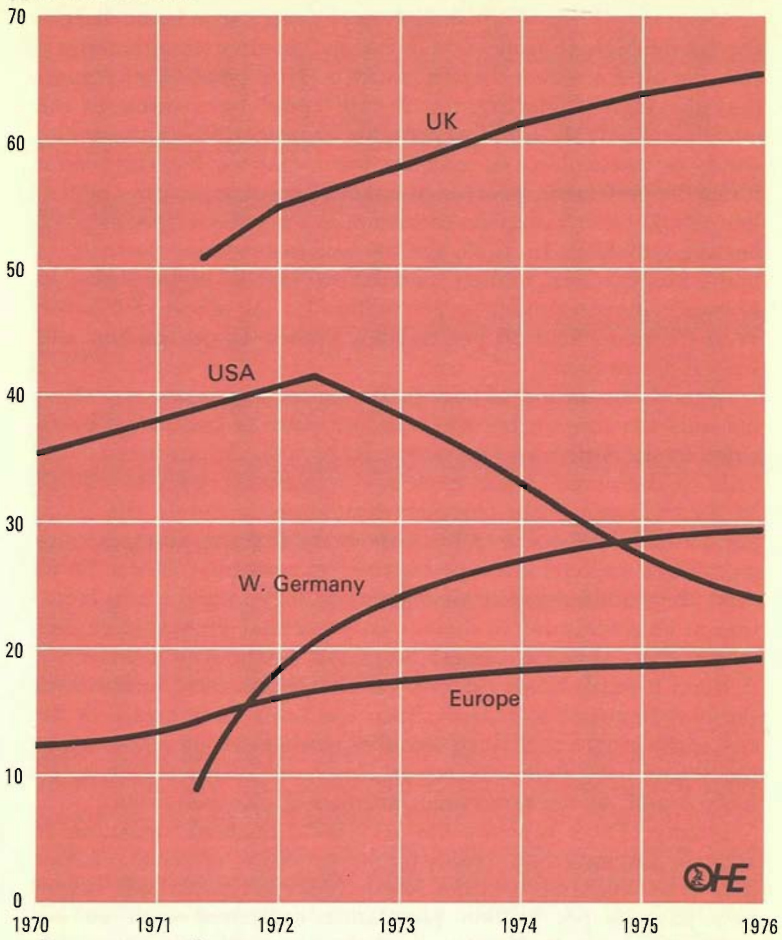
[9] A study of nephrological services for adults in Britain (*BMJ* 1976) confirms regional variation in services provided. The study did find that the numbers of new renal failure patients seen at least once were evenly spread throughout the regions – but the numbers actually followed up were not. This suggests, perhaps, that the bulk of potentially treatable people are considered but the number accepted depends on resources.

Figure 9 *Percentage of dialysis patients receiving dialysis at home, various countries*



Source EDTA 1976.

Barriers to availability of treatment

There are two major barriers to the extension of services for the treatment of chronic renal failure. The first is shortage of finance which relates particularly to dialysis. It is money that is lacking rather than kidney machines alone. As well as the equipment outlay it is necessary to cover such things as the cost of nursing and ancillary staff for hospital dialysis and training and services for home dialysis. The question of the degree to which extra money

Table 9 *Regional variation in services for chronic renal failure (England and Wales)*

Per million population

Region	*Transplants 1 July 1974– 30 June 1975*	*Patients on dialysis as at 30 June 1975*			*Patients starting dialysis (1 July 1974 – 30 June 1975)*
		Home	*Hospital*	*Total*	
Northern	19	20	26	46	22
Yorkshire	6	19	15	34	14
Trent	8	25	10	35	15
East Anglia	21	10	18	28	19
N W Thames	14	28	20	48	22
N E Thames	13	61	24	85	17
S E Thames	31	41	21	62	29
S W Thames*	—	6	5	11	4
Wessex	6	18	3	21	10
Oxford	4	56	6	63	10
South Western	5	28	15	43	22
West Midlands	12	15	7	22	8
Mersey	12	24	3	27	9
North Western	6	19	6	25	8
England	11	26	13	39	15
Wales	7	31	9	40	12

Source Pincherle 1977.

*Many patients living in this region are treated in adjacent ones and some transplants carried out in the region are done by a surgeon based in South East Thames and are credited to the latter region.

ought to be spent, and if so how much, is not easily resolved. It is discussed in the concluding sections of this paper.

The second major barrier to treatment is the shortage of kidneys for transplantation. Estimation of potential 'need' for kidneys runs into the same problems described earlier in relation to establishing the incidence of 'treatable' renal failure. That is, what age and fitness criteria for selection for transplantation are appropriate? And, even if these criteria can be described with reasonable confidence at present, are they likely to change, in the same way that criteria for acceptance for treatment generally have changed in the past ten or fifteen years?

The estimate of need quoted by Pincherle (1977) is 1,500 transplants per year in England and Wales, or, very roughly, 30 transplants per million population per year.[10] This is based on the assumption that 20 people per million population per year would be suitable for a first transplant (ie half of the estimated 40 per million otherwise fit 5–60 year olds going into renal failure each year). The remaining 10 transplants per million would be repeat transplants. 'Need' calculated on this basis, therefore, is about twice as high as the 1976/77 provision in the UK of 14 transplants per million population (according to 'UK Transplant' data).

Two factors could increase the potential demand for transplants; the first, already noted, is the relaxation of age and fitness criteria for first transplantation. The second, and very important factor, is the survival rate of transplantees. If patient survival were to increase, but graft survival were to remain the same, the potential demand for second, third and even subsequent transplants could be very considerably increased.[11]

There is no doubt that the number of transplants being performed at present is limited by a shortage of available cadaver kidneys. Potentially, however, there are more than sufficient possible cadaver donors to meet even the widest definition of need. Most kidneys for transplantation come from the victims of accidents and, to a lesser extent, cerebral haemorrhages. There are more than 20,000 accidental deaths in Britain every year and many of these could generate two usable kidneys. The problem is essentially one of 'harvesting' the organs.

Only a small proportion of kidneys is, in the event, harvested from suitable donors who die in district general hospitals or whose bodies arrive there sufficiently soon after death. Pincherle (1977) points out that if each district general hospital could provide six to eight kidneys a year then his estimate of need, 1,500 transplants a year, could be met. But although some hospitals provided more than twenty kidneys in 1974 others contributed none at all.

A random opinion survey in Britain has shown that most people are in favour of having their kidneys used for transplantation after death – in theory at least (Moores *et al* 1976). On the other hand a study at the Nuffield Transplant Unit at Edinburgh showed that when relatives are confronted with a real situation they will often refuse permission for removal of kidneys. In the Nuffield study, eighteen out of a possible fifty kidneys were lost for this reason (Jenkins 1976).

The 'harvesting' of kidneys also depends on the willingness of

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[10] The highest annual transplantation rate yet achieved in one country was 31 per million, in Denmark in 1973.

[11] In some units, while cadaver graft survival remains at about 50 per cent at two years and 30 per cent at five years after transplantation, *patient* survival exceeds 90 per cent at five years.

hospital staff, especially in accident and emergency departments, to co-operate with renal transplant units. A survey of doctors and nurses in a district general hospital has suggested two reasons why, on their side, they may be reluctant to take kidneys from their ex-patients (Crosby and Waters 1972). The first point was that all groups of doctors and nurses felt they had insufficient information about which patients might be suitable donors when dead. The second was that they were apprehensive about the practicalities of kidney removal, especially having to ask patients' relatives for permission.

As the law stands at the moment a doctor cannot assume that an organ donation would have been acceptable to the donor (or his family) simply because of the absence of any evidence of objection. It is, therefore, standard practice for doctors to seek permission from the potential donor's next of kin. For this reason, kidney donor cards, giving the explicit permission of the potential donor and next of kin, carried habitually by a large proportion of the population, might be expected to yield more kidneys for transplantation. Many millions of such kidney donor cards have been printed. However, the opinion survey quoted above (Moores *et al* 1976), found that only 4 per cent of people questioned actually carried donor cards.

An alternative approach may be a change in the law such that opting out becomes the rule. Then doctors would not necessarily have to consult relatives of the potential donor. Some other countries already have such legislation.

In the spring of 1978 the DHSS commenced efforts to increase the number of kidneys for transplantation. New ways are being sought to improve the availability of kidney donor cards and a discussion paper has been prepared setting out the arguments for and against amending the present law on the donation of kidneys. An attitude survey to test public opinion on 'contracting out' legislation is also planned.

It seems likely, however, that the improvement of the kidney donor situation will depend mainly on better motivation of doctors and nurses in individual district general hospitals to exploit more fully the present potential for kidney harvesting. If all British hospitals were able to provide as many cadaver kidneys as those hospitals with the best records then there would be no shortage. In California, liaison officers have been employed to encourage and inform the relevant doctors. This has been highly successful. Recognising the key role of doctors in initiating the process of organ removal, the DHSS is preparing a film which will attempt to provide the sort of information which, according to the Crosby and Waters survey, may encourage them to harvest potentially usable organs.

Costs and benefits

There is a large number of publications on the costs and benefits of dialysis and transplantation, in Britain and other countries. They have been summarised and discussed by Parkin (1978).

Estimation of the cost of treating renal failure is not straightforward. The health service accounts do not lend themselves to the easy extraction of data in this case. This section does not, therefore, attempt to give anything more than a rough order of magnitude estimate of the cost of dialysis and transplantation. EDTA data is used to give the number of people receiving different modes of treatment. Cost per unit treatment is then taken from an unpublished costing exercise undertaken by the DHSS (Glass 1977). This exercise chose a sample of thirty-six patients admitted for transplantation in 1974–75 and followed them through to the end of 1976 (or until their death), counting the costs generated by them at 1976–77 prices. For comparison, a sample of twenty patients destined for home dialysis were also followed up and their costs recorded in 1976–77 prices as well.

Table 10 estimates the total running costs in the UK by fitting each EDTA mode of treatment to the closest corresponding cost category in the DHSS costing exercise. This is, of course, by no means an ideal procedure, but it should provide an acceptable order of magnitude for the cost of dialysis and transplantation.

It can be calculated that the weighted average yearly cost among the 4,000 people on treatment in the UK was about £5,500 giving rise to national treatment costs of about £22 million. If capital costs of equipment (not included in Table 10) are added on then it may be said that the cost of transplantation and dialysis in the UK in 1976–77 was, very approximately, £25 million.

Table 10 also provides a basis for estimation of the ultimate cost of a programme designed to meet a particular definition of need. The main generator of costs is the number of people on treatment at a given time. At the end of 1976, this amounted, according to EDTA data, to 71 people per million population but, it has been noted above, if annual intake were increased to 40 per million per year and survival rates remained constant then the number of people on treatment would ultimately rise to a plateau of about 340 patients per million, that is about five times as many as at present. Then, if there were no change in the proportion of people on different modes of treatment, the cost of services would ultimately rise to about £120 million (in 1976–77 prices).

If UK survival rates improved to the present Dutch level then the forecast equilibrium level of provision rises to 470 per million, implying an ultimate annual cost of about £170 million.

Table 10 *Approximate running costs of dialysis and transplantation, UK 1976*

EDTA mode of treatment 1976	*DHSS costing exercise category*	*Cost per unit treatment £*	*Number treated in UK*	*Total Cost £ million*
Transplants which fail within 6 months (≏40% of all transplants)	Cost per transplant until death for those in sample who died after discharge from hospital without further transplantation (Average time from transplantation to death = 6 months)	£4,930*† per transplant	241	1·2
Transplants which do not fail within 6 months (≏60% of all transplants)	Cost per transplant until post transplant discharge for those alive and with first graft intact by the end of the study	£1,150* per transplant	362	0·4
Patients with functioning transplants at the end of the year	Cost per unit time after discharge from hospital for those alive and with first graft intact by the end of the study	£1,250 per annum	1,501	1·9
Patients on home haemodialysis	Cost per unit time after start of home dialysis	£5,770 per annum	1,611	9·3
Patients on hospital haemodialysis and on peritoneal dialysis	Cost per unit time, for patients destined for home dialysis, during the period in hospital prior to the start of home dialysis	£10,800 per annum	865	9·3
Total running costs				£22·1

Source Data taken from EDTA and Glass (1977) unpublished.

*The original DHSS costing exercise assumed that the cost of obtaining a kidney was £50. A more realistic figure may be about £400. (in £1976–77) and this figure has been included above.

†The high cost per transplant in this category reflects the high cost of intensive care during rejection episodes. If the rejection episode is prolonged the resources consumed may be very large indeed.

Finally, if it is assumed that substantial numbers of over 60 year olds and people with serious co-existing disease were accepted, and if it were also assumed that survival rates approached those of the general population without any kidney disease, then the equilibrium cost might rise to over £350 million per annum in 1976–77 terms. It should be noted, however, that none of these equilibrium levels would be reached until after the turn of the century, even if the maximum level of intake were reached within the next five years.

The benefits of treatment, for their part, are implicit in Table 10 itself, which gives costs per year of life on different modes of treatment, and in Tables 4 and 6 which give survival and rehabilitation rates for different treatment modes as well.

A more precise exercise could be carried out using EDTA data and a mathematical model such as that described by Farrow *et al* (1971). The basis of this model is the sequence of possible 'states' in which a patient who is accepted for treatment may find himself. Probabilities may be ascribed to the transition between each state and others over a period of time. Then, if various assumptions are made on intake and survival rates, the model could produce comprehensive projections over subsequent years on both total costs and total benefits. However, such an exercise would, in order to be useful, require better data on unit costs for each mode of treatment than are easily obtainable.

Should services be expanded? The value of human life

Should the NHS aim to provide dialysis and/or transplantation for all people who may be expected to benefit? Would it be worth the ultimate expenditure of somewhere between £120 million and £350 million (1976–77 prices)?[12]

Any attempt at an answer must (as noted in the Introduction) accept as a starting point that money spent on realising one objective involves a sacrifice of other objectives.

Then it is necessary to ask, what are the objectives of the NHS? Such a question would justify a book in itself but it may be postulated for clarity of discussion, that the NHS is in at least two quite distinct businesses.

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[12] The United States government has, in effect, accepted the principle of comprehensive provision in this area. Their current annual expenditure on dialysis is about $1,000 million among 37,000 patients (about 170 per million population). Projections show an increase in patients of about 50 per cent within the next six or seven years. New legislation before the Senate at the time of printing represents an attempt to limit escalating costs, but not to reverse the principle of comprehensive national insurance coverage instituted in 1972.

The one that seemed the more important in 1948, when the NHS was set up, was the diagnosis and cure or alleviation of diseases. This was a time when tuberculosis had recently become curable, cheaply and with near 100 per cent certainty, and similarly cheap control of fatal epidemic diseases like diphtheria had become possible. It is understandable that the original NHS planners had a very optimistic view of the extension of health services to all on the basis of 'need'. Very roughly, this 'cure' side of the NHS is covered by what are termed 'acute services' in present expenditure classifications.

The other major objective of the NHS can be described as 'caring' for people, for example old or mentally handicapped individuals, who will not 'get better' in the sense applicable to acute illness. Since the Ely Hospital scandal in the late 1960s the latter has been seen increasingly as an area which is deserving of highest priority.[13]

In an ideal planners' world there would be clear guidance on the relative values to be placed on the objectives of care and cure. And within the 'cure' sector, where dialysis and transplantation belongs, there would be equally clear guidance on the values to be placed on the various sub-objectives, avoidance of death, avoidance of pain and discomfort, rehabilitation. There would, in addition, be hard data on the effectiveness of given programmes in attaining their objectives. Together with data on costs, these pieces of information would provide the basis for a rational ordering of priorities. It would then be evident how many new patients with chronic failure should be accepted every year and medical resources could be redirected accordingly.

But this ideal planners' world does not exist and, probably, it will never be closely approached. Three essential conditions are missing. First, there is no consensus on how health service outputs should be valued. Second, and a more intractable problem, there is relatively little hard data on the effectiveness of given services in attaining objectives.[14] Dialysis and transplantation is an exception in this respect. Third, the assumption that medical resources can be easily redirected seems unjustified.

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[13] The 'caring' function of the NHS could itself be subdivided into discrete activities. For example, the objective underlying a 'social' admission into hospital (often to give patient's families a temporary respite from the rigours of home care) is quite different from trying to provide a severely handicapped person with a satisfactory overall way of life.

[14] The controlled trials that could provide information on effectiveness over a wide range of acute health services have for the most part, not been done. Controlled trials usually take a long time and many would be very expensive indeed. Furthermore, some of the potentially most interesting trials of treatment versus no treatment will never be done because they would, by now, be unethical.

The dearth of relevant planning information was reflected in the DHSS consultative document on priorities (DHSS 1976). When describing its 'programme budget' it stated that 'a complete breakdown of expenditure by objectives (eg treatment of specific medical conditions) would be extremely detailed and complex, and far too cumbersome for an across the board review; the necessary data are not in any case available'.

This comment was, of course, quite accurate. But it must be clearly recognised that it meant, in effect, that the DHSS could provide no coherent guidance on the allocation of resources in the most expensive sector of the NHS, the acute services.[15]

There is some irony in this situation as far as the proponents of more money for renal services are concerned. Renal specialists have, by their own efforts, been able to provide the sort of comprehensive information on 'outputs' that could form the basis for rational informed debate on priorities in the acute sector if only similar information were available in other treatment areas as well.

Thus renal specialists can point out that their output is a year of human life for between £1,000 and £11,000 (in 1976–77 prices) depending on mode of treatment (a weighted average for all treatments gives about £5,000 per year of life). They can also claim fairly good rehabilitation with between 30 per cent and 75 per cent of those life years spent in full-time employment (about 70 per cent for home dialysis). But the absence of similar data for most other areas competing for resources prohibits even the semi-quantitative comparisons that they maintain could draw more resources into renal services.

An alternative to the mammoth task of trying to place renal services in an overall order of NHS priorities would be to ask the more direct question, is a human life worth £5,000 per annum? The simplicity of this question could, on the one hand, be said to be deceptive. A great deal of academic effort has gone into providing a theoretically sound basis for valuing life, along with other health outputs, in money terms. On the other hand, a brief summary of such efforts (Appendix 1) leads to the conclusion that the valuation of human life is conceptually straightforward in the sense that it must be based on the same principles as the valuation of any good or service according to the ultimately subjective preferences of consumers. The difference is that, in a publicly funded health service, the role of consumers is performed jointly by politicians, planners and doctors, as well as by members of the public who receive health care.

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[15] 'General and acute hospital and maternity services' accounted for 41 per cent of all expenditure on health and Personal Social Services in England in 1975–76 (DHSS 1977).

There is no established consensus view on the value of human life and this may, in part, be attributed to its marginal relevance to practical resource allocation processes. It is perhaps a reflection of the absence of any serious debate that valuations of life implicit in certain policy decisions, inside and outside the NHS, have in the past differed from each other by many orders of magnitude.

This point has been illustrated very well by Card and Mooney (1977). They have drawn together a number of past policy decisions involving human life in which its implicit value can be estimated by dividing the cost of a given policy by the number of lives it may be expected to save. Their data are reproduced in Table 11. At one extreme the post-Ronan Point building regulations may be expected to save one life for £20,000,000. At the other extreme, failure to screen pregnant women for oestriol concentrations implicitly values the avoidance of a still-birth at £50 or less. In addition to Card and Mooney's data, an OHE estimate of the value of a person's life, implied by non-availability of treatment for chronic renal failure, is included in the table. For a fifty-year-old person this is about £30,000 at 1976–77 prices.[16]

These estimates can correctly be criticised as crude. For example, the estimate for renal failure takes no account of the cost of financial support during unemployment. But the magnitude of the differences between the various implied values is such as to suggest very little common ground among policy makers dealing with different issues where lives are at risk. It is interesting to note that the expected cost of saving one life by the post-Ronan Point building regulations is, at £20 million, of the same order as the cost of the entire dialysis and transplantation service in Britain.

One final point should be made here. Although the differences illustrated in Table 11 clearly point to inconsistency, it must be expected that there will be some variability in values attached to human life. Thus the comparatively poor quality of life of a dialysis patient must be a consideration. It may also be argued, by the proponents of more facilities for renal failure, that the refusal of treatment to a dying, otherwise fit individual is so abhorrent that a much higher value ought to be placed on saving an actual life than on a hypothetical life saved by some preventive measure. Undoubtedly, society does place extra value on the avoidance of deaths which, for some reason, impinge on the consciousness of the whole community. Support for this view can

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[16] The estimate is obtained by multiplying his/her expectation of life by the expected cost of treatment per year of life.

Table 11 *Values of life inferred from several public policy decisions*

Decision	*Implied value of life*	*Comment and source*
Screening of pregnant women to prevent stillbirths	£50 maximum	In 1968 it was estimated that if maternal oestriol concentrations were screened the cost per stillbirth averted would be £50. It has been claimed that, at that time, this procedure was not widely used which is why the figure is assumed to be a maximum value.
Not to introduce child-proof drug containers	£1,000 maximum	In 1971 the Government decided not to proceed with the child-proofing of drug containers. Allowing for the cost of drug-proofing and savings to NHS from reduced admissions, Gould calculated that a child's life was implicitly valued at under £1,000.
Legislation on tractor cabs	£100,000 minimum	In 1969 the fitting of cabs to farm tractors, to reduce the mortality risk for drivers, was made compulsory. The cost per annum was estimated at £4m (£40 for each of 100,000 tractors). About 40 lives would be saved yearly; the implied value of life was thus £100,000.
Changes in building regulations as a result of partial collapse of Ronan Point high-rise flats	£20,000,000 minimum or perhaps actual	After a high-rise block of flats partially collapsed, killing some residents, the report of the inquiry recommended changes in the building standards of such blocks. It has been estimated from the change in risk and the costs involved that the implied value of life was £20m.
Not to provide treatment for chronic renal failure for a person of 50	£30,000 (OHE estimate 1976–77 prices)	Particularly in regions where facilities are in short supply, a person over the age of 45 or 50 may stand little chance of being accepted for treatment by dialysis or transplantation.

Source Card and Mooney (1977), except for the renal failure estimate.

be claimed from observation of the practice of cost/benefit analysis in public sectors other than the NHS.[17]

The determinants of policy

Since NHS planners rarely have hard comparative data on outputs, nor any agreed way of valuing them, it may be asked how are resource allocation decisions taken at present and what is the justification for more rapid expansion of renal services? The question can be considered in three ways, at the regional and area levels where money is divided between services, at the level of national policy and at the level of public pressure.

At the regional and area levels it is a familiar idea that yearly budgetary allocations are the end result of largely informal competition between interest groups. Success in obtaining funds depends on persuasive power as well as on the merits of the case being presented. Although there is now, through DHSS planning cycles, a means of formalising such decision-making processes, from the district to the national level, there is little doubt that the nature of post-reorganisation processes are essentially the same as those of the pre-reorganisation NHS. There is little doubt, either, that members of the medical profession still play the central role in competition for resources. The outcome of such competition is that only marginal changes can usually take place in one year's budget compared with the last. Resistance to rapid change is enhanced by the relatively fixed division of the medical profession into its various specialities, each of which guards its claim on expenditure generators like hospital beds and admission rights.

Many renal specialists, who may have to turn dying people away, are passionate advocates of a more rapid expansion of facilities. On the other hand, many senior doctors in other specialities consider transplantation and dialysis as a medical 'frill', maintaining that the numbers of patients involved are tiny compared with those that may be treated with comparable expenditure elsewhere. Unless, therefore, something occurs to alter radically the balance of the two opposing views, like a major

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[17] For example, the level of aircraft safety measures is set such as to ensure a much lower risk of accidental death than in other forms of transport. It is recognised that 500 deaths in one accident are more important than 500 deaths in separate accidents and 'carnage value' is the term used to describe the extra cost of safety measures that is considered worthwhile.

Mining disasters provide an illustration of the situation where the idea of inaction would be so abhorrent to the public that the expenditure of massive resources is considered worthwhile regardless of the chances of success. The value of life implicit in such rescue operations must be very high indeed (though not as much as the Ronan Point value of £20 million).

advance in the control of immune reactions, there is no reason to suppose that any policy changes will emerge out of pressure from the medical profession at these levels.

At the level of national policy-making it is important to recognise that the NHS is only just coming out of a period of adjustment following the administrative reorganisation of 1974. The policy-making relationships between the DHSS and the regions and areas may still be subject to further modification as experience of planning cycles increases.

One point, however, that did seem to have become established quite quickly was that the regions and areas are expected to take responsibility for setting their own priorities, subject to advice from the DHSS, and make their allocations of resources accordingly. This philosophy of minimal intervention can be justified by reference to those occasions, pre-reorganisation, when the DHSS attempted to take a number of initiatives simultaneously. It then found that it was being criticised for asking health authorities to take specific action in a number of priority areas at once, without being able to provide more money or tell the authorities how savings could be made in other services to finance the supposed priorities.

Since reorganisation, however, the DHSS has been criticised by renal specialists, among others, who maintain that the policy of minimal intervention can be used as an ideal mechanism by which responsibility for shortages can be passed from the DHSS to the regions and the areas, and vice versa.

The post-reorganisation DHSS has developed quite strict criteria for intervening directly in resource allocation. It earmarks a certain amount of 'special medical development' (SMD) money which may be given to regions and areas to pay for the initial stages of specific programmes. But this is seen very much as 'pump priming'. The two normal criteria for SMD are, a) that the object of expenditure must be just emerging from an experimental stage and, b) that the period of direct financial support must be short-term, although in many cases regions' allocations would be adjusted to take into account the revenue consequences of the scheme.

In the case of the central initiative on paediatric dialysis in late 1977 these criteria were met and extra machines were made available for children. However, there were special circumstances (the money used had previously been earmarked for breast cancer screening trials) which did not permit funding of recurring revenue. It was the absence of any committment to cover the latter costs, during a period of general restraint, that led to criticism of the initiative and failure of some regional authorities to support it enthusiastically. Furthermore, a strict application of SMD criteria would appear to preclude future financial support from the DHSS for even the initial costs of the extra facilities which would be required in each subsequent year to maintain a continuing intake of 80–100 children.[18]

However, events in April 1978 suggest that the policy of minimal intervention may be in a process of reformulation with respect to facilities for renal failure. After the budget in that month it was announced that £3.5 million would be made available to cover the costs of 400 extra dialysis machines in the following year. This initiative was clearly outside the SMD criteria since the machines would be for adult dialysis, which certainly cannot be described as experimental. In addition, provision was made for the recurring revenue costs of the extra machines for at least the first two years. In so far as money has been designated specifically for dialysis machines this represents a shift in general policy with regard to central involvement in regional resource allocation decisions although there are some precedents for such 'earmarking', as in the perhaps unfortunate case of secure units for the mentally ill.[19] It also represents a significant change in stated priorities on the part of the DHSS since neither of the two post reorganisation documents on health service priorities (HMSO 1976, HMSO 1977) mentioned adult dialysis as a priority area.[20]

The 400 extra machines will have the effect of raising the annual intake from about fifteen new patients per million population (in 1976/77) to between twenty and twenty-five per million. It would, however, be premature to interpret this as the first step towards a committment to comprehensive provision for renal failure. It remains to be seen, for example, whether a satisfactory arrangement will be worked out for longer term funding of the regions' recurring revenue costs. It also remains to be seen whether, next year and in subsequent years, yet more extra money will become available for new machines just to maintain (let alone further increase) the rate of intake of new patients with chronic renal failure. It is unfortunate that even if a figure of

[18] Chantler *et al* (1974) estimate that, at equilibrium, somewhere between 600 and 900 children aged 5–15 would be on treatment.

[19] The position of DHSS prior to April 1978 was that, whilst the level of provision of dialysis facilities for adults was a matter of national concern, decisions on local development of these services must remain a matter for health authorities to decide in the light of competing local priorities and the resources available to them. As for the shortage of donor kidneys for transplantation, this too was, and is, a national problem but one which does not involve local resource consideration, and therefore one on which the Department has always accepted a major role on a national basis, in initiating measures which could improve the supply of kidneys.

[20] The second consultative document, *The Way Forward* (HMSO 1977), said 'there should be more paediatric dialysis'. This was followed later in 1977 by the DHSS initiative on facilities for children.

forty new patients per annum were reached and held that would only be sufficient provision for otherwise fit people under sixty years old. The question of whether to extend provision to elderly people would still remain.

One of the consequences of the past policy of minimal central involvement in resource allocation has been the perpetuation of large regional variations in facilities (Table 9). Although the central assumption of the Resource Allocation Working Party (that there should, in general, be 'equal opportunity of access to care for people at equal risk') is widely agreed, there seems to have been no suggestion hitherto that the criteria of equal access should be applied to specific, demonstrably effective services like dialysis and transplantation. It is still uncertain whether or not, subsequent to the present reformulation of DHSS policy, the equalisation of regional provision for renal failure will emerge as a priority.

A major determinant of resource allocation is the pressure of public opinion. Its effect on policy, especially where issues are highly emotive, can be very significant indeed.[21] In the area of dialysis and transplantation, the British Kidney Patient Association has been very active and was to a considerable degree instrumental in forming the climate of opinion which led to the DHSS initiatives in early 1978. There are a number of intriguing and novel ways in which it may in the future bring further pressure to bear on the relevant authorities.

One possibility that has been discussed is a legal action against the Secretary of State claiming negligence for failure to provide facilities for dialysis in a particular case. If such a case were ever brought to law the result would turn on the meaning of the word 'reasonable'. The National Health Service Act of 1977 says that the Secretary of State is under a duty to provide services 'to such an extent as he considers necessary to meet all reasonable requirements.'[22]

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[21] For example, it was the public outcry following the Ely Hospital and other revelations that had led to the apparent consensus of opinion throughout the NHS that the 'care' sector is deserving of priority. A very different example is the case of Anthony Nolan, the bone-marrow transplant child. A great deal of money has been raised by public appeal even though no rational case at all could be made for such expenditure on the basis of cost and expected benefit.

[22] Another possible way in which patients' organisations may put pressure on the NHS is suggested by the report of the Health Service Commissioner for 1976–77 (HMSO 1977). This refers to a case in which a seriously ill patient was refused access to a NHS hospital and was placed instead in a private nursing home. The health service commissioner considered that the health authority should have reimbursed the patient for her nursing home fees. The findings of the Health Service Commissioner do not, of course, have the force of law, but it is interesting to speculate whether an analogous recommendation would have been made in the case of a patient who requested reimbursement after dialysis at a private clinic.

To the extent that pressure groups are successful in mobilising public opinion the DHSS may find itself having to reconsider its policy of minimal intervention in regional and area resource allocation. In Britain, press and television are predominantly national (rather than local) and there can be little doubt that pressure groups see national action (from the DHSS) as one means of attaining their goals.

Conclusions

Failure to provide effective treatment for all those likely to benefit must put considerable strain on the NHS as an institution dedicated to egalitarian principles. In the area of dialysis and transplantation, as in others, this is felt particularly acutely among the clinicians who are responsible not only for treating patients but also for choosing who shall receive treatment. It has already been noted that chronic renal failure is, as yet, the only area of NHS activity where shortages of resources prevent clinicians from extending routine life-saving treatment to otherwise fit individuals who present with a terminal condition. For this reason, renal specialists have a particularly onerous task in selecting their patients.

It is likely that selection procedures differ widely among dialysis and transplantation units, depending on how rich or how poor a region is in facilities. One major criterion that appears to be generally agreed is that otherwise healthy people under 45 should have access to treatment. There are already sufficient resources to cope with this. It seems a reasonable criterion in that expectation of life (on treatment) decreases with age. But it still leaves the problem of how to decide in the marginal case, whether, for example, a fit 55 year old should have preference over an over-weight smoker in his or her late forties.

The methods of selection that have grown up reflect attempts to share or minimise the burden of responsibility. For example, the whole treatment team, both medical and non-medical, will often be involved in the decision-making process. Also, units may try to avoid as far as possible the necessity for choice between two or three marginal claimants by adopting a 'first come, first served' policy among them. Finally, the clinician may be aided to some extent in the task of denying a person access to treatment by a screening process which involves general practitioners in limiting potential patients' expectations of treatment. But even so, it seems inevitable that clinicians will sometimes have to equivocate about a potential patient's prognosis in order to hide the unpalatable fact that his/her life is not considered to be worth as much as another's.

The situation is far from satisfactory for both clinicians and consumers of medical care. On the part of clinicians, there is little doubt that many of them would prefer, if possible, to avoid such responsibilities. Their willingness to continue to act as arbiters of life and death probably reflects a realisation that there is no easy alternative means of selection that would, a) avoid inflexibility, b) be acceptable to potential patients, c) be politically acceptable, and, d) be rational in relation to the overall distribution of medical resources.

On the part of consumers of medical care, what seems extraordinary is that individuals will still apparently accept the decision of the clinician (or the clinical team) without question. It is only rarely that unfavourable decisions are challenged and then it is, understandably, the family rather than the sick person who will take the issue up. But in the future it must be anticipated that patients, or their representatives, will increasingly call into question clinical judgements. And, by challenging selection criteria they could seriously undermine public trust in the reasonableness and authority of clinical judgement that still underlies the orderly provision of medical care. Such a development, while in the direction of open decision-making, could only exacerbate the problems of the NHS in meeting public expectations with limited resources.

Of course, renal failure only affects a tiny proportion of the population. Selection of people for life-saving treatment does not, at present, take place in any other part of the health services. But this may not be a unique situation for very much longer.

Progress in the medical treatment of cancers may soon make this another area where life-saving treatments exist, but at too high a price to be available for all. An even more alarming prospect (in the context of NHS resource allocation) and one which is not entirely fanciful, is the development of an implantable artificial heart. How would the practitioner in the relevant speciality select patients from the massive number of people, especially middle-aged men, who could benefit, without his competence to do so being challenged by patients or their representatives? Since a considerable proportion of the most articulate and most powerful section of society would be affected, the potential for pressure group activity would be that much greater. The issues and conflicts raised could go far beyond the efficient functioning of the NHS.

In the hypothetical circumstances described above there are a number of ways in which the pressure on clinicians could be relieved. One is that the NHS could concentrate its resources on life-saving and other demonstrably effective treatments so as to minimise the number of difficult decisions that have to be taken with respect to people able and likely to complain. This would involve limitations on the provision of services for which there are little or no hard data on effectiveness and, in turn, limitation of clinical freedom.

Another possibility is that a great deal more money could be drawn into the health services to meet the extra cost of new treatments. If extra finance could not be found by the NHS from taxation revenue it is possible that it could be drawn from medical insurance. Some people may argue in favour of insurance schemes to cover those conditions for which life-saving treatment was too expensive to be freely available under the NHS. But in such circumstances the NHS would have become a radically different undertaking to the one which, in 1948, set out to provide treatment for all on the basis of need rather than ability to pay.

Advances in preventive medicine and pharmacology may, of course, obviate the problems described above. This provides an argument for increasing research towards this end; but research success cannot be guaranteed. There might even, therefore, be an argument for a moratorium on the development and refinement of highly expensive non-pharmaceutical treatments. Yet since Britain is not isolated from the rest of the world such a policy could hardly be carried out by the NHS alone.

More significantly, the examples of renal dialysis and transplantation show that such life-saving treatments often emerge as a result of individual enthusiasts realising the therapeutic potential of unrelated technological advances. No planned moratorium on research could prevent such individuals from making life-saving break-throughs in the future. However difficult it may appear, the NHS must plan to cope with the problems exemplified by the treatment of renal failure.

Appendix
The valuation of health service outputs

It might be expected that health economics could provide some guidance on the value of human life and health. But no simple formulae have been forthcoming. Indeed, it is only recently that a consensus seems to have been developed regarding the conceptual framework within which cost/benefit analysis might potentially be applied to health services. A good summary of cost/benefit methods is provided by Jonnson (1976).

The first attempts at cost/benefit analysis in the 1950s reflected an obsessive concern with establishing some sort of objective value for life. A spurious objectivity was obtained by valuing human life in terms of expected future production (as measured by earnings) of a person whose life was saved by intervention. The method was also used to value sickness in terms of earnings loss.

The limitations of the method become obvious when one considers the implication that the lives and health of pensioners are worthless because they earn nothing. 'Production' calculations took no account at all of the value of life and health to the individual himself and his family. These considerations were relegated to the status of 'intangibles', unquantifiable and, therefore, to be ignored. It was eventually recognised that these intangibles were, in fact, central to the valuation of human life and health. Indeed the present view (Williams 1974) is that 'production' estimates should be placed on the cost side of the cost/benefit accounts, as negative costs.

Having given up spurious objectivity, what criteria can be used to value life and health? One suggestion has been that an analysis of past health service rationing decisions can be used to make explicit the value of iife and health implicit in such decisions. But the tautology implied by going on to use this as a basis for future rationing decisions is obvious.

Another method, which has been called the 'insurance method' is to give a questionnaire to a panel of knowledgeable people asking how much they would be willing to spend on insurance to cover themselves for a set of discrete health services including, for example, treatment for renal failure. This is essentially an attempt to mimic the expression of consumer preferences in the market. The condition that knowledgeable people be used is an attempt to overcome the problem that consumers cannot be expected to have sufficient knowledge of health service 'products' to express rational preferences. But a second problem arises from the use of questionnaires. It seems dubious whether money values of anticipated health benefits derived in this way would truly reflect behaviour in the real world. And, since there will never be even an approximation to a perfect market, there can be no means of validation.

A final method of putting values on life and health can be described under the heading 'health indices'. Williams (1974) and Culyer *et al* (1971) have described a framework which could potentially be used for measuring the costs and benefits of alternative NHS programmes. Their approach involves giving points values to defined states of health. This is in some ways analogous to using a points system in the allocation of council houses. The relative values implicit in giving points to different states of health are simply assumed in the first instance. But as with Council house allocations it must be expected that there would be continuing re-evaluation of any 'health points' system.

Thus, in the absence of any simple and convincing health service formula, the valuation of NHS outputs must inevitably be a matter of continuing debate, sometimes objective but usually subjective, between politicians, planners, doctors, other health workers and members of the public. In effect these groups perform the same functions as do individual consumers in the textbook model of demand and supply.

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