

In the wake of progress – ethical problems of renal failure treated by dialysis

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This article is based on the Osler Oration given at the Royal College of Physicians on 21 September 2005 by Christopher G Winearls DPhil(Oxon) FRCP, Clinical Director, Oxford Kidney Unit, Churchill Hospital, Oxford

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ABSTRACT – The ability of dialysis in the 1960s to prolong the lives of patients with terminal renal failure created a running and changing debate in bioethics. The first issue was the selection of suitable individuals to be treated in the limited facilities available. Progress in technology was ahead of any medical or ethical consensus. The costs of treatment soon exceeded the will or means of health funders to pay, creating a system of covert rationing and fiscal fudges with which physicians reluctantly colluded. Evidence, epidemiology and public opinion eventually prevailed and the UK now provides a satisfactory, if imperfect, programme of renal replacement therapy (RRT) for most patients with end-stage renal failure who can benefit. The ethical challenges in developed countries are now different and relate to end of life decisions. In poorer countries the issues are starker as treatment has to be rationed or provided only for those who can afford it.

KEY WORDS: beneficence, dialysis, distributive justice, erythropoietin, non-maleficence, patient autonomy, polycystic kidney disease, renal failure

Last year, 2005, was the 100th anniversary of William Osler taking up the Regius Chair of Medicine in Oxford. He had no special interest in diseases of the kidney but his famous textbook contains typically clear descriptions of uraemia, observing, ‘The prognosis is extremely grave.’¹ One wonders what he, a therapeutic sceptic, would have made of the problem of the ethics of treatment of end-stage renal

failure? He would at least be delighted that JJ Abel, whom he coaxed to work at Johns Hopkins, having built an extra-corporeal dialysis system, provided proof of the principle that blood could be ‘purified’ by this technique.²

The title of this oration was chosen to evoke the image of a lead vessel in a flotilla, moving fast, creating a turbulent wake rocking the boats behind it. The rapid progress in the treatment of renal failure – in particular the introduction of maintenance haemodialysis in the 1960s – created discomforting ethical issues for society and the medical profession. It is these that I will attempt to describe, largely from a British perspective. Because I am too young to have been on those vessels when they embarked (but I have been crewing on them for the last 30 years) I must rely on the log of Stewart Cameron for the first part of the journey.³ It is remarkable that the ethical issues have changed completely over the last 30 years. In the beginning, the issue was distributive justice or ethical rationing not, as it is now, about the decisions not to continue or embark on futile treatment.

Improvements in treatment, eg recombinant erythropoietin, and improved understanding of the nature and natural history of renal disease, eg adult polycystic kidney disease, have created and solved some ethical problems. I will explore these later in this essay.

The four ethical principles to which I will refer are:

- respect for patient *autonomy*
- *beneficence* – promotion of what is best for the patient
- *non-maleficence* – avoiding harm
- and *distributive justice*.

History: a study in medical ethics

The introduction of maintenance haemodialysis in the 1960s and the current provision of it are a remarkable, perhaps unique, case study in medical ethics. Nephrologists are especially fortunate in comparison to their colleagues in other disciplines in having the means to substitute for the failure of the organ, which is their special interest. Indeed, we can cut the Gordian knot of renal failure by transplantation, an act described by Sir Peter Morris as ‘A med-

Key Points

The advent of maintenance dialysis helped to start bioethics

The treatment of renal failure still provides ethical challenges

The dilemma is now about what *should* be done rather than what *can* be done

Ethical principles provide guidance but finance and politics determine decisions

ical miracle of the 20th century'. The ethics of that miracle is a subject in itself. This ability to replace and substitute for a failed organ, however, creates both power and responsibility.

Here are examples of the application, or not, of the four ethical principles mentioned above in managing end-stage renal failure – the first covers all four.

When haemodialysis first became technically possible the ethical question must have been around the principle of *non-maleficence*. Was it right to inflict an intrusive, uncomfortable treatment with limited prospect of success on human beings? Was surviving really preferable to dying? It would be interesting to know how a modern research ethics committee would respond to a proposal to subject very ill patients to regular cannulation of major blood vessels and up to 30 hours of treatment a week on equipment that would not be acceptable to the 'health and safety' department. In this country, haemodialysis pioneers in London, Birmingham, Newcastle and Edinburgh faced opposition from influential quarters – the *Lancet* had concluded that limited resources should not be 'squandered' on the enterprise⁴ and even the Medical Research Council had opined that the technology would have no place in British medicine – but the patients exercising their autonomy chose treatment. It is fortunate that the patients and their physicians persevered, proving their opponents wrong.

After hearing the advice of a working party chaired by Professor Hugh de Wardener (Professor of Medicine, Charing Cross Hospital Medical School), the Ministry of Health agreed in 1966 to set up a network of units in pilot sites. The immediate question was, of the many potential candidates, who should be offered the treatment? One has to admire the candour and pragmatism of the physicians who made the choices applying the ethical principle of *justice*. It was easier at first because there was hesitancy in the medical community about referring, low expectations or knowledge of dialysis among the public and a simple lack of staff and facilities. Finance was not the main issue – it was earmarked and came from the centre.

Shaldon described the criteria in his monograph in the *Postgraduate Medical Journal* in 1967 (see Table 1):

*Undoubtedly the best candidates are married, with young children and a stable home environment, free from economic worries with a sedentary occupation enabling them to work, with private transport, a telephone and an income to afford the expensive diet.*⁵

Table 1. Indications and exclusions for maintenance haemodialysis in the 1960s.⁵

Positive indications	Exclusions
Imminent death from uraemia	Coronary or cerebrovascular disease
Ill health preventing work	Another life threatening disease
Potential to return to productive social functioning	A multi-system disease eg SLE Children Adults >55 years

SLE = systemic lupus erthematosus.

Put pithily the patients needed, 'nous, house and a spouse'. Political correctness had not been invented.

Because renal units had a fixed number of stations the policy required that patients should be suitable for home haemodialysis and/or transplantation. Fortunately, public opinion supported dialysis being made available and there was a remarkable surge of community fund raising for kidney machines for local patients.

The unwritten rules were breached by 'special cases' for example transplants and home haemodialysis that failed, deterioration in health and aging of patients selected when in the age range and without the contraindications. How could a 60-year-old patient who had been on home haemodialysis, lost his spouse and job, and suffered another illness be denied hospital-based treatment?

Although nephrologists respected the views of leaders such as Sir Douglas Black who questioned whether expensive treatments should be made universally available, they made the legitimate point that it was not universal availability but reasonable availability that they sought.⁶ Once this conflict between beneficence and justice arose, funding became block ie it was no longer linked to activity and it had to compete with other services.

This was a miserable time for nephrologists. The General Medical Council declares as its first point in the description of the duties of a doctor, 'Make the care of your patient your first concern'.⁷ Nowhere does it advise on how to do this within financial constraints. There was no ethical guidance and the management view was 'Pilate-like' in essence:

You are the experts, use your professional judgement in deciding who should be treated from the capped budget, and please avoid the use of the word, rationing.

This led to an undoubted breach in the first principle of medical ethics – respecting patient *autonomy*. For patients not selected for treatment, direct contact with them was avoided by declining a consultation, by letter or telephone call, to the referring doctor. Patients were not told that their condition was treatable but that it would not be treated for financial reasons. There was the grotesque spectacle of patients travelling the country in search of a unit that would accept them. Various excuses for not treating patients were offered eg hepatitis B infection (because of the danger to staff and other patients), insulin dependent diabetes, social dysfunction, and age (though the upper limit seemed to rise to keep ahead of the nephrologists!).

The pressure was mitigated to some extent in the late 1970s by the advent of continuous ambulatory peritoneal dialysis (CAPD), of which the costs to the health system were less easy to control than haemodialysis.⁸ Indeed, one could set up a programme with a nurse, a box of PD catheters and an FP10 prescription pad, while GPs were invited to 'prescribe' dialysis fluids. This was a short-term fix as CAPD failed due to recurrent episodes of peritonitis, usually in the marginal candidates who had been accepted 'for PD only'. It did not take patients long to enquire whether they could at least try haemodialysis.

Happily the situation is now much improved, if not completely resolved – many units are full, there is a delay starting

patients on dialysis, and units cannot offer them choice of modality – but few patients are turned down for purely financial reasons. The quadrupling of the take-on rate for renal replacement therapy (RRT) in the last 20 years is in part a result of campaigning by the Renal Association culminating in the recommendations of a Working Party which were endorsed by the Royal College of Physicians of London.⁹ There was some shrouding but the statistics were persuasive. The original exclusions no longer hold and the extreme pessimism about age and multi-system disease proved unjustified. The numbers of patients on treatment increase each year (Fig 1) and the average age of new starters is >60 years – children and even infants are now treated successfully.

Non-maleficence – the case of acute renal failure

The introduction of dialysis for acute renal failure (ARF) was less controversial probably because the cost was less daunting. For many years peritoneal dialysis or haemodialysis had been offered to patients with ARF which was judged to be reversible and whose general state allowed the treatment to be applied. This conveniently excluded the majority of those on intensive care units with cardiogenic shock. Withholding treatment was simply justified on the grounds of impracticality.

In the early 1980s the ‘get-out clause’ was lost. Haemofiltration, initially extremely simple, made it possible to support patients with multisystem failure. It is now, however, more sophisticated and expensive. It successfully reverses the conse-

quence of acute renal failure and in patients with reversible disease it is life saving – in others it seems to do no more than delay death. The ethical dilemma is now between *beneficence* and *distributive justice*.

Intensivists and nephrologists repeatedly have to decide whether to institute haemofiltration just because it is technically possible. Until the outcome can be reliably predicted the default position is to intervene and hope for *beneficence* and ignore *distributive justice*.

Autonomy – the case of adult polycystic kidney disease

The counselling of families with inherited renal disease causing renal failure, in particular those with adult polycystic kidney disease (ADPKD), has changed completely over the last 30 years. Formerly, nephrologists managing the relatively young men and women with end-stage renal failure caused by ADPKD – witnessing the effects of dialysis dependency on marriages and livelihoods, the physical suffering and the premature deaths – took a strong line. Children of patients were invited or more usually summonsed to have intravenous urograms or ultrasounds so they could be told whether they too would have to prepare for the same fate. The justification was simple – ‘you need to know so you can plan your life, warn a potential spouse and be treated for complications’. They were urged to consider whether having a family themselves was appropriate. This policy was based on the belief that ADPKD was a disease of the fifth decade with a predictable time course, associated with significant suffering and premature death.

Such an approach would now be totally unacceptable. It overrode the autonomy of the individual and it could be argued that it added to, rather than reduced the suffering of families. Ironically, and to the chagrin of those of us who adopted this policy, it was based on a series of false and pessimistic assumptions:

- the median age of reaching end-stage renal failure in patients with ADPKD type 1 is 54 years, so at least half of patients will have completed their childrearing and three quarters of their careers before needing RRT.
- we now know that the phenotype is variable and inconsistent within families. Children do not imitate their affected parents.

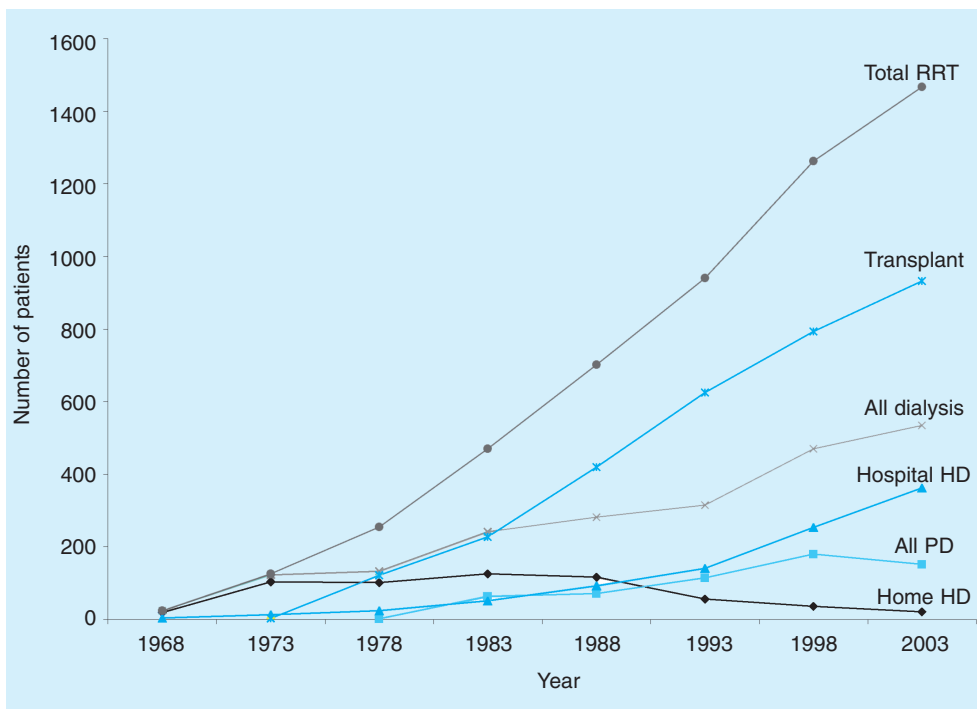


Fig 1. The growth in numbers of patients with end-stage renal failure treated by dialysis or transplantation and the changes in the prevalent modalities from 1968, after the Oxford Kidney Unit opened, until 2003. Note the decline in home haemodialysis, the rise in hospital-based haemodialysis and the major contribution of renal transplantation to the RRT programme. A steady state has not been reached. HD = haemodialysis; PD = peritoneal dialysis; RRT = renal replacement therapy.

- the prognosis of end-stage renal failure has improved dramatically. Renal transplantation is more widely available, safer, and more successful – 5-year graft and patient survival are 75% and 90% respectively. The mortality in dialysis patients without comorbidity has been reduced to <5% per annum. It is now not uncommon to have three generations of the same ADPKD family at various stages of their renal failure careers attending the same clinic.

Distributive justice – the case of erythropoietin

Because it was literally a matter of life and death, the argument for allocating funding to dialysis was simple and eventually won. The licensing in 1990 of recombinant human erythropoietin (Epo) for the treatment of the anaemia of chronic renal failure posed a more difficult issue of *distributive justice*. It was effective and safe but extremely expensive – at £6,000 per annum its prescription would increase the cost of treating a patient by up to 50%. The majority of dialysis patients were symptomatically anaemic (Hb <10g/dl) and 10% were blood transfusion dependent. It was, however, difficult to argue that Epo was an essential treatment. Nephrologists, sensitive to the criticism that their ‘treatments’ of 0.1% of the population already consumed 2% of the NHS budget, behaved with restraint. The Renal Association working with the Department of Health, drew up a set of indications which if applied would be affordable and allow treatment of patients in whom a benefit was most likely to accrue, eg those who were blood transfusion dependent. Restrictions on prescription and the pressure to reduce cost in the face of a price cartel had a curious benefit. It was shown that subcutaneous administration and ensuring patients were iron-replete reduced dose requirements by 50%. Within ten years of licensing, prescription became unrestricted despite a paucity of evidence of benefit other than the relief of symptoms and avoidance of transfusions. It would be very instructive to know what the National Institute for Health and Clinical Excellence (NICE) would have recommended had it been asked to provide an appraisal of Epo.¹⁰

Present challenges and conclusions

The present relative abundance of facilities has brought new ethical issues – we now face a conflict between respecting the autonomy of the individual and non-maleficence. This is characterised by the patients with end-stage renal failure in whom dialysis is very likely to provide a short unpleasant extension of lifespan. Neither the degree of prolongation nor the unpleasantness can be predicted with any certainty. If the patient opts for a trial of treatment, their autonomy overrides considerations of non-maleficence and distributive justice. One is bound to ask, ‘What price autonomy?’ It is high – not only financially but also for the morale of the staff obliged to carry out a treatment that appears futile.

The appropriate response to this problem has been to improve our communication with patients and suggest maximal conservative care as an option. The offer is to help the patient to live

and die well without dialysis, in contrast to offering death as the consequence of not starting it.

The issues surrounding withdrawing treatment are very relevant to dialysis as it is the immediate cause of death in 10–20% of patients on dialysis programmes. In practice this has not provided as much ethical difficulty as might have been predicted. If patients elect to stop dialysis they can do so. Some do it overtly, asking to be admitted for palliative care. Others do it covertly, not attending sessions or actually committing suicide. It is more difficult when the patient cannot express a wish. It is argued that the purpose of dialysis is to enable living not to prevent death and so to discontinue treatment is not *maleficent*. This is the one situation in which the law, ethics and common sense can collide.

A more difficult challenge in this era of near-adequate facilities comes from patients who exercise their rights but not their responsibilities. Should there for example be a right to miss dialysis repeatedly, aware of the consequences, and then expect an emergency ambulance and out-of-hours treatment to be provided when the inevitable crisis ensues? There are patients who wilfully discontinue their immunosuppressive drugs after transplantation, wasting the cadaver kidney or the donation of a relative. It is argued that this behaviour is part of the patient’s condition and response to it, but it creates great discomfort for those balancing the *autonomy* of the patient with respect for the principle of *distributive justice*.

These dilemmas are the problems of privileged nations. In many developing countries, which cruelly also have an even higher prevalence of renal failure, RRT is a luxury, the availability of which is determined by market forces.¹¹ There have been pleas from nephrologists who work in this libertarian system for an egalitarian solution – funded by the developed world. This is clearly impossible but the consequences of restricted access to treatment do impinge upon physicians in the UK. Patients with renal failure from overseas, not entitled to NHS care and unable to afford it in their own countries, present themselves to hospitals in the UK. Is this really an ethical dilemma for the individual nephrologist? I believe not; we are obliged ethically to do the best for the patient and not to do them harm – refusing them dialysis is not an ethical option. Not to provide treatment or to discontinue it is an administrative decision that flows from policy. Responsibility for this decision does not rest with the doctor.

Conclusion

The advances in nephrology did create ethical turbulence in their wake but the waters are now calmer.

Nephrologists can take some pride in having reached the present position. As Stewart Cameron remarked, ‘In sum, for a halfway technology, dialysis has been not half bad.’¹³

Society and the medical profession are now better prepared to face ethical challenges than they were.¹² One can only hope that those who decide what shall be and what shall not, are regularly reminded that we live, and doctors work, in a world that does not abide by the principles of medical ethics. It is neither just nor beneficent.

References

- 1 Osler W. *The principles and practice of medicine*, 4th ed. New York: London and Co, 1901.
- 2 Abel JJ, Rowtree LG, Turner BB. On the removal of diffusible substances from the circulating blood by dialysis. *Trans Assoc Am Physicians* 1913; 28:51–4.
- 3 Cameron JS. *The history of the treatment of renal failure by dialysis*. Oxford: Oxford University Press, 2002.
- 4 Editorial. Intermittent haemodialysis. *Lancet* 1962;1:1055–6.
- 5 Shaldon S. Haemodialysis in chronic renal failure. *Postgrad Med J* 1966;Suppl:671–695.
- 6 Black DAK. *The logic of medicine*. Edinburgh: Oliver and Boyd, 1968.
- 7 General Medical Council. *Good medical practice*. London: GMC, 1998.
- 8 Gokal R, McHugh M, Fryer R, Ward MK, Kerr DNS. Continuous ambulatory peritoneal dialysis: one year's experience in a UK dialysis unit. *BMJ* 1980;281:474–7.
- 9 Renal Association. *Provision of services for adult patients with renal disease in the United Kingdom*. London: Renal Association, 1991.
- 10 Rawlins MD. Pharmacopolitics and deliberative democracy. *Clin Med* 2005;5:471–5.
- 11 Schieppati A, Remuzzi G. Chronic renal diseases as a public health problem: epidemiology, social and economic implications. *Kidney Int* 2005;68:S7–S10.
- 12 Saunders J. Ethics in practice. *Clin Med* 2005;5:315–6.

Erratum

Burden R, Tomson C. Identification, management and referral of adults with chronic kidney disease: concise guidelines. *Clin Med* 2005;5:635–42

Please note that the guideline on management of haematuria printed on page 639 should be replaced by the following:

Haematuria

Management should include:

- Checking of serum **creatinine** concentration in all patients
- Checking for **proteinuria** in all patients
- Macroscopic **haematuria**, with or without **proteinuria**:
 - fast track urology referral: refer to nephrology if initial investigations negative
- Microscopic **haematuria** (dipstick or laboratory microscopy) without dipstick **proteinuria**:
 - Age > 50 years: refer to urology
 - Age < 50 years, or > 50 years after exclusion of urological cancer:
 - Refer to nephrology if GFR < 60 ml/min/1.73 m²; otherwise treat as CKD and ensure annual follow-up, to include urinalysis, blood pressure, and serum **creatinine** concentration
 - Microscopic **haematuria** with urine **protein:creatinine** ratio > 45 mg/mmol:
 - Refer to nephrology

There is no need for laboratory confirmation of dipstick positive haematuria.