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AUDIT, OUTCOMES AND PLANNING: WHERE IS NEPHROLOGY?*

C. P. Swainson, Department of Renal Medicine, Royal Infirmary of Edinburgh

These are unusual topics at a scientific meeting. Much of the thinking and the published work around audit and outcomes is viewed as 'non-scientific' in that it is based on observation, uncontrolled studies and opinion, and is not testable. However, they are important practical skills for a modern doctor, and their inclusion in this symposium marks a coming of age. My theme is that we should make greater efforts to turn what knowledge we have into clinical reality for our patients and to use what we know to maintain the medical standards to which we are committed.

Nephrology is approaching middle-age. We have passed the bloom of youth in a thirty year period of rapid growth and development in both the scientific basis of our discipline and in our clinical services. The former will continue to grow, as it reflects our intellectual energy and enthusiasm, but growth in the latter may not be sustained in the closing years of this century. We are competing with other services for a diminishing share of resources. We have done our share of shroud waving, like everyone else, and we are now met with a more critical response from purchasers and from fellow doctors.

> Cast a cold eye on life, on death
> Horseman pass by!

Poets like W. B. Yeats provide quotable inspiration and so do figures from the past. In the first thousand years of our profession it is likely that medicine killed more than it saved as our forebears obeyed slavishly the teachings of Galen. He held that all diseases were caused by an imbalance of the body's four humours, blood, phlegm, black bile and yellow bile.

Disease was remedied by allowing the offending humour out, through blood letting, purging and vomiting. It was left to 20th century medicine to add the techniques of plasma exchange, lactulose and induced sputum, but the Scottish Poisons Information Bureau recommends now that ipecacuanha should be used no longer to induce vomiting. Any contrary views were drowned out. Dissection classes in 15th century Italian medical schools were laughable as the teachers read aloud from the works of Galen to drown out any questions from the students. Reliance on past knowledge is a valuable characteristic of any profession, whether it is medicine, law or accountancy, but it is equally important that the knowledge is updated and refined when new information comes to light. Such is the speed of medical progress now that the new *Oxford Textbook of Nephrology* contains already out of date material.

AUDIT

The 16th century Renaissance, which began in Italy and spread through France

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to Scotland, challenged Galen's precepts. A Belgian, Vesalius (1514–64) was an early dissenter and convinced students at the University of Padua that Galen was wrong and that his knowledge of anatomy had been based on dissection of pigs and dogs, not humans. A German Swiss, Aureolas Theophrastos Bombastus von Hohenheim (1493–1541), otherwise known as Paracelsus, also did much to debunk Galen and build our knowledge of anatomy and disease on direct observations from dissection of the human body and from the appearance of wounds and subsequent healing on the battlefield. Vesalius and Paracelsus are the earliest examples of medicine based on evidence and not on dogma. Just as it took many years for new ideas to achieve recognition in the 16th and 17th centuries, so we too have similar delays.

Clinical research is the foundation of modern medical practice and advances our knowledge by testing hypotheses often to destruction. By this method, good ideas survive but this knowledge base is not applicable often to individual patients. The focus of research is narrow and much does not cover the variety of expression of human disease, for example across age groups or common complications. Yet all doctors have a strong desire to develop their knowledge and skills to improve their care of patients. Other tools are required to bring our current knowledge to bear on our patients.

Audit is seen often as late 20th century fashion. It is of course much older than that and has been used by business and commerce for over 200 years. It is important that an independent professional body now provides this service. It is unfortunate that this principle has been applied only partially to medicine in that doctors are the guardians who generate and interpret the available data. There are no independent auditors for medical practice. Perhaps this is one reason that audit has not assumed the central position that it should. How many in this audience take part in regular clinical audit with repeated cycles of improved standard setting and feedback? The achievements of audit in medicine are as yet modest and the enormous investment expended on audit during the current NHS reforms represent poor value for money. A simple concept has been lost, hijacked by the NHS bureaucracy. It is time for a re-think of this facet of medical practice and I would like to see nephrology take a new lead.

In a small speciality like ours, there is a place for clinical audit within each unit and an equally important place for it across Scotland. We have made a start with the Scottish Renal Registry and developed a model worth following. We are collecting data now which compares one unit with another and hopefully in the next year, we will drop our bashfulness and display the data more openly. The use of erythropoietin for the relief of anaemia in chronic renal failure provides a good example of the limitations of our current audits. The data demonstrates wide variations between units in the use of erythropoietin. Why? At least two reasons are apparent: first, we have no agreed standards for its use, and second, there is no evidence that we have changed practice by displaying this data. In Tayside, the data was used effectively to provide adequate treatment in that region.[1] We need to collaborate more over isues such as this.

The current NHS reforms, with purchasing authorities and NHS Trusts, has removed from the government direct responsibility for local health services. It is a classic 'divide and rule' tactic in which the real problems of the NHS can be hidden among the distractions of competition between providers, and the elegant contract dances between providers and purchasers, consuming so much energy for

so little gain.

The Renal Association has produced a splendid document that sets out standards for the delivery of haemodialysis in the UK.[2] We do not need to invent new standards; these ones are more than adequate and many of this audience had the opportunity to influence them. Our audit activity should be about how each of us matches up to these standards; where we do not this should be used as a tool to persuade purchasers to help us meet these standards. Audit can be used in a national context to ensure that the management executive are aware of their responsibilties.

OUTCOMES

Outcomes in nephrology are at an embryonic stage. The database, held by the clearing house on outcomes in Leeds, registers that only Aberdeen and Dundee have any projects examining outcomes. It will be hard to develop outcomes in nephrology that are useful for patients.[3] For the moment we are stuck with mortality and morbidity but these can prove useful as I hope that the current projects will demonstrate. As a proxy for outcomes, we can use process measures and these have been useful in the past. The new patient rates for starting dialysis in Europe in 1994 range from 1·5/million of the population in Lebanon to 118/million in Greece. The UK rate was just over 60/million; France, West Germany and Scotland had rates around 80/million. So we are doing well in comparison to other European countries and significantly better than England and Wales. This is a matter for public congratulation and acknowledgement which should be shared with management executives. It indicates that purchasers overall are buying dialysis services at approximately the right rate. However, comparisons between the different regions in Scotland show marked variation from Ayrshire & Arran and Lothian at 57/million to Greater Glasgow at 100/million.

This is a matter for concern because it would appear that patients in different parts of Scotland have a nearly twofold chance of not getting on to a dialysis programme, depending on whether they live in the east or the west of our country. This discrepancy in health service provision needs to be more widely discussed.

A number of published papers show the effects of anti-platelet treatment on fistula patency and these have been analysed.[4] There are nine published randomised trials of anti-platelet therapy versus controls that have monitored vascular occlusion systematically. These are all small trials but with a total of 418 patients. Allocation to anti-platelet therapy in these nine trials was associated with a proportional reduction of 70 per cent (SD 14 per cent) in vascular occlusion which was highly significant ($2P < 0{\cdot}00001$). The reductions in occlusion rate were of similar magnitude in both fistulas and shunts. Thrombotic occlusion can occur rapidly. The mean duration of these trials was only two months, yet 38·7 per cent of the controls suffered an occlusion as against only 16·5 per cent of the anti-platelet allocated patients with a greater risk of occlusion in arteriovenous shunts. How many in this audience monitor their fistula occlusion rates? And how many regularly prescribe aspirin? The data are published,[4] widely available and yet not used. Why is this? Doctors seem reluctant to use data from trials unless they are either very large or they have been involved personally. There is an unwillingness to use trial data from others and there is suspicion of a meta-analysis by someone else. The very few letters published by the *BMJ* from nephrologists in response to that article[4] were not critical of the methodology or its results, but raised a number of minor points which were dealt with by the authors satisfactorily. There will always be good reason not to use aspirin in every patient, as some will have a history of duodenal ulcer or other sensible contraindication. There is no good reason for not monitoring fistula patency rates, as the failure rate is so high, and for not providing aspirin to those who are able to tolerate it.

These two examples show that the use of simple outcome and audit data can and should be used to maintain clinical standards and to influence purchasing. We should agree to share the data, to make it more public and to use it effectively; if we do not, then we are failing our patients.

PLANNING

Good planning depends on good data, and if the data are not there, it must be generated; otherwise no plan can be sensibly developed and the options that arise cannot be evaluated properly. Planning in nephrology is no different. Examples have been given where the existing data could be used to justify improved services; the differences in new patients/million taken onto dialysis programmes in different Health Board areas is a matter for concern, and should prompt an inquiry into the planning process at Health Boards. The data should enable clinical directors to justify an increase in resources in their business plan; how can purchasers make sensible decisions if they are not given data? Planning in acute hospitals is dominated by considerations of the use of clinical services, commonly beds, and by finance. The appraisal of options for most schemes is heavily dependent on comparing capital and running costs, and most planning documents contain little more than a passing reference to clinical care.

Epidemiology is a useful tool in medical planning. It has been used often by cardiologists and by those promoting breast screening, to increase resources for these services. It is being used currently by neurologists and geriatricians to develop stroke units and there is no doubt that health planners listen to well researched medical data. We need to develop the speciality of renal epidemiology. The large numbers that are necessary for this work can be achieved only if we collaborate.

A single UK centre of renal epidemiology would be a valuable addition to the research endeavour. We have an impressive track record in the collection of data sets for the European Dialysis and Transplant Association (EDTA), UK transplant and the Scottish Renal Registry. This is a good base on which to build and to improve data collection on primary renal diseases, and their complications and treatment. It is a necessary pre-requisite to understanding the challenges that these present for our speciality and for ensuring that our patients get from the Health Service the resources required.

COCHRANE COLLABORATION

Improving the standards of medical care requires an improved knowledge base. Medical knowledge is expanding at such a rapid rate that it is impossible for any of us to keep up with the existing literature. Many of us scan at least six journals in general medicine and nephrology each month and attempt to retain what appears to be useful. This is both inefficient and incomplete. It does not allow time to reflect and to synthesise adequately the knowledge we acquire, nor does it allow us to acquire comprehensive data on which to base a judgement. More

sophisticated tools are needed and one such is the growing Cochrane Collaboration around the world.

You only have to read a recent review of treatment of membranous nephropathy in adults[5] to realise how a single reviewer writing an invited article over the space of a few months is biased and selective of the studies included. The more systematic approach is to engage in a collaborative group. This is not a strait-jacket to restrict clinical freedom but a helpful way of making the best knowledge available for the benefit of our patients.

There are few randomised trials in nephrology. These have been gathered together by Denis Fouque and colleagues.[6] There is growing recognition that we need a Renal Review group to pull together the systematic reviews of randomised control led trials and other data that can be used to inform our clinical judgement. Meetings in Lyon, at the EDTA in Madrid and at the American Society of Nephrology (ASN) in San Diego have demonstrated that there is a small but willing band prepared to consider the daunting task of writing systematic reviews in renal disease. This is a movement which will grow and hopefully many of you will feel motivated to take part. Many hands make light work, especially in the arduous task of hand searching journals for randomised clinical trials. I urge you to follow the development of the Review Group and, if you would like to participate, to contact Denis Fouque in Lyon or me in Edinburgh.

As an example of the usefulness of this approach, there is a recent ASN abstract.[7] Here is an analysis of the randomised, controlled trials of low protein diets in renal disease, all relatively small, and including the USA modification of diet in renal disease trial which was inconclusive. A meta-analysis of all of these trials demonstrates that a low protein diet is useful in slowing the progress of renal failure, particularly for patients with glomerulonephritis. This is important. It is data that does not just affect our clinical practice but also justifies the use of scarce resources, for example dietitians.

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LESSONS FROM A SYMPOSIUM ON RENAL MEDICINE HELD IN THE COLLEGE ON 20 SEPTEMBER 1995*

W. D. Plant, Department of Renal Medicine, Royal Infirmary of Edinburgh

This Symposium addressed several major issues in renal medicine, focusing upon the current state of clinical practice and upon experimental work in the pathogenesis of disease. A theme running through all presentations was the ongoing difficulty in generating evidence-based recommendations because of the dearth of large well executed clinical trials, the heterogeneity of renal disease and the difficulties in extrapolating from experimental models to human clinical disease. There has been impressive progress in certain areas; the key messages that struck this reviewer are detailed below.

ACUTE RENAL FAILURE (ARF)

This is still associated with high mortality (c. 50 per cent of cases) despite advances in general supportive care and in the technologies of renal replacement therapy. Over the past 30 years there has been a shift in the pattern of diseases associated with ARF and requiring dialysis. Obstetric causes are now extremely uncommon, whereas ARF associated with complex severe medical diseases has increased dramatically. The case-mix now features a much more elderly population, many of whom have associated significant reno-vascular, cardiac or liver disease. The increase in complex cardiac, vascular and hepato-biliary surgical procedures has also produced more difficult cases of ARF.

As ARF is now frequently seen in the context of multi-organ failure, much of the renal replacement therapy (RRT) now takes place in the intensive therapy unit (ITU) rather than on renal wards. Standard haemodialysis is not always appropriate in the setting of significant haemodynamic instability and modalities of continuous renal replacement therapy (CRRT) are increasingly used. These include continuous veno-venous haemofiltration (CVVH), continuous arterio-venous haemodialfiltration (CAVHD) and slow continuous haemodialysis. These techniques utilise more biocompatible membranes and pharmaceutically purer replacement fluids, and consequently are less likely to cause haemodynamic instability. The care of such patients is now a multi-disciplinary endeavour, which requires a different approach to previous mono-speciality practice.

In the Royal Infirmary of Edinburgh about 200–250 cases of severe ARF are seen each year, with about 50 per cent of these requiring RRT. The mean total cost of an in-patient event for renal patients not requiring ITU is about £5,500; a patient treated with CVVH (mean stay 7·4 days) has a cost of £7,500; one surviving to have CVVH and haemodialysis in the ITU (mean stay 19·3 days) costs more than £20,000.

The understanding of the pathogenesis of ARF in different contexts has advanced dramatically particularly in the setting of acute sepsis, where acute derangements in cardiovascular function and the role of inflammatory mediators

*A list of speakers and the titles of their papers presented at this symposium is recorded in *Proceedings* Vol. 25 p. 717.