support for single parent families, programmes giving away smoke detectors, and legislation on the installation and maintenance of smoke alarms in rental accommodation, with responsibility placed on landlords. Jacobi used clinical intuition to link private troubles with public issues. Today we have modern epidemiology. But without the political will to use epidemiological evidence to influence public policy the potential of this advance will never be realised.

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Randomised controlled trials in general practice

Gold standard or fool's gold?

Randomised controlled trials are a widely accepted means of applying experimental methods to a clinical setting and have been advocated as the gold standard for comparing and evaluating different treatments.[1 2] General practice has been promoted as an appropriate arena for evaluating interventions ranging from drug treatment to developments in services[3 4]: nine out of 10 health service consultations take place here; it is the point of first contact for most medical conditions; and existing population registers and computer systems allow potential access to large amounts of clinical data. An increasing number of randomised controlled trials are being performed in this setting to contribute to the culture of evidence based medicine.[5] But despite the theoretical attractions, applying experimental methods in clinical practice presents problems that, if not properly addressed or acknowledged, may invalidate the findings.[6] The particular problems of recruitment and randomisation merit consideration with respect to primary care.

Recruitment to randomised controlled trials is justified in situations of genuine clinical uncertainty. Sample sizes must be large enough to establish the presence or absence of a worthwhile benefit in terms of either effectiveness or cost, or both. This may mean the need for larger numbers of patients than are available to single general practices, requiring practices to club together if they are to perform meaningful research. General practitioners, however, have no contractual obligation to participate in research, and they may be unwilling to take part in studies that produce no immediate benefit for their patients while possibly disrupting the delivery of health care. Practitioners who do participate are often atypical, so that extrapolating their results to the general population may be misleading. Maintaining the motivation and involvement of participating practices can be difficult in long term studies.[7]

General practitioners may be unwilling to participate if they believe that experimental studies will disrupt the normal interaction between them and their patients.[8] They may experience a conflict of interest between their role in promoting patients' autonomy and their wish to recruit participants to benefit future patients or to gain academic merit. The need to obtain informed consent will not necessarily erase their anxiety about such conflicts, since the long term nature of the relationship between practitioner and patient may engender loyalties that unfairly coerce patients to give their consent.[9] From the patients' point of view, fears about confidentiality, the risks of the intervention, or the apparent disadvantage of being allocated to a control group may further inhibit recruitment. Failure to recruit consecutive patients introduces the potential for selection bias, something that is not often reported in published studies[4] but that can make extrapolating the results to the general population inappropriate.

General practitioners may feel uncomfortable in randomising patients themselves,[10] but if they delegate the task to a researcher this can further compromise the doctor-patient relationship. The alternative of randomising interventions by practice (cluster randomisation) introduces analytical problems, which ultimately require larger sample sizes.[11] Furthermore, some interventions such as counselling need a high degree of involvement on the part of the patients and will succeed only if they are in line with the patients' expectations. True randomisation may lead to patients being allocated to treatments that they would not normally accept—an unreasonable test of an intervention.[12] Although the problems may be mitigated by partial randomisation, this reduces the study population and jeopardises generalisability of the findings.

Randomised controlled trials are not impossible to perform in general practice. Published reports of failed trials in this setting are rare but those which do exist highlight the difficulties discussed.[7 13] Those most likely to succeed, however, are ones that minimise disruption to the normal working environment and compensate general practitioners for the additional time commitment. Consecutive eligible patients should be recruited or at least recorded, and no patient should be knowingly disadvantaged by participating. When interpreting the results of published randomised controlled trials, researchers and clinicians need to be alert to the possibility of biased recruitment or incomplete randomisation.

There is no doubt that experimental methods provide a rigorous, sound basis for evaluating treatments, but their introduction may either disrupt the culture of primary care to such an extent that the findings do not reflect real practice, or the methodological problems encountered may reduce the scientific reliability of the results. General practice is not a laboratory, and our patients are not experimental animals. Case-control studies, retrospective and prospective cohort studies, and descriptive studies are all acceptable methods; we should accept alternative methods when a randomised study will be too difficult or the results too biased to be of value. It

would be wrong to stick blindly to a gold standard which is likely to produce the wrong findings—methodologically pure but clinically meaningless.

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Reforming England's blood transfusion service

Why the changes and why the delay?

The blood transfusion service in England is changing. In precipitating change the British government has unleashed an ill informed and acrimonious debate in the media and elsewhere. Although the change itself may be necessary, the process has been poorly handled, and delays in the implementation of decisions now risk damaging an essential service.

With the dissolution of the 14 regional health authorities in England and their replacement in April this year with eight regional offices of the NHS Executive, the regional blood transfusion centres could not have been left unchanged. The government's strategy was to establish a new special health authority, the National Blood Authority, to take their place. The National Blood Authority, set up in 1993 undertook a national review of the provision, costs, and structure of services.

Such a review was long overdue. There was, and still is, wide variation in the quality of products and clinical services offered by the 14 centres. In 1987 Professor John Cash highlighted this variation,[1] but the anomalous situation has drawn little public comment. This is generally attributed to the fact that consultants in transfusion medicine are isolated from the rest of clinical medicine and are often perceived as "failed haematologists." But the blood transfusion service faces other problems: how to adapt to new management practices in the NHS, how to cope with the costs of increased automation and instrumentation in laboratories, and how to share donated blood as a national resource so as to prevent local shortages.

In its review the National Blood Authority has proposed setting up three zonal management teams—northern, midlands and south west, and London and south east—to replace the 14 independent regional directorates and their support staff [2]; each zone will have a budget of about £45m, similar to that of a district general hospital. The plan is to reduce the number of processing and testing sites to standardise good manufacturing practice and allow the introduction of the most advanced technology for testing the safety of blood components. The availability within each zone of a larger pool of scientists and clinicians, and the consolidation of specialised reference services, should facilitate specialisation in what is a rapidly developing field. Donor sessions will be centrally coordinated in each zone. In time, through the information technology strategy recently agreed by the Treasury, the authority plans to set up a single computer system, which will link all the centres and provide computers at donor sessions.

The authority's strategy seems timely and reasonable. Why then is the morale within the blood transfusion service now so low? Why, too, is there a public outcry that could damage the vital recruitment of donors and have an impact on all our clinical services? Perhaps one reason is that some doctors and managers in the blood transfusion service have not appreciated the need for change, and the government has failed to communicate its plans and the reasons behind them. The proposals for reorganisation were poorly presented, and subsequent publicity fiascos have not helped. Announcements of the partial closure of centres on academic sites that had great potential for development and collaboration, the attempt at "gagging" staff, and proposals to use sponsorship to raise funds for the service[3] have dented the confidence of users, donors, and recipients.

In expressing their concerns consultants and managers have contributed to the discontent and concern among their staff relating both to their own jobs and, more altruistically, to the provision of services. Some of the concerns expressed by those in the service could, however, have been allayed. Consultants at some teaching hospitals have suggested, for example, that removing the processing and testing of blood from their sites will adversely affect their clinical services. The experience of teaching hospitals and specialist centres in London shows that this need not be the case. Moreover, it is unfortunate that so far only two of the eight regional blood transfusion centres that are based in teaching hospitals have had the vision to take advantage of their location for developing collaborative services and scientific links.

The blood transfusion service needs informed and open debate. Issues for discussion include the question of additional microbiological screening with the attendant costs and risks; whether Britain should export surplus derivatives of fractionated plasma; the role of leucodepletion of red cells and platelets; and, from a hospital perspective, the problem of inappropriate use of blood components, especially in surgery.

We need a modern transfusion service with skill and an unimpeachable record of safety in collecting, testing, processing, and storing blood components. We need to develop tissue banking for bone and placental blood and selection and expansion of stem cells for cellular therapy and immunotherapy. The blood transfusion service should also contribute to the collective effort of gene therapy. To achieve all of this the service needs a well directed programme of research and development. For now it needs strong leadership, nationally and in each of the three zones. A prime