Domestic contexts often represent health hazards and make the task of living itself a hazardous pursuit. Where there is a link between the hazard and some disease state the law provides for cooperation between doctors and others to remedy the problem. But the proposal is more akin to the accident category of threat, and thus does not provide a case for doctor intervention.

Hazardous voluntary pursuits such as boxing are even less problematic. Enthusiasts choose such pastimes and do not welcome interference from doctors. By virtue of their specialist knowledge, doctors might form a powerful pressure group to curb such activities. But few believe it their business to control the sport any more than it is the business of doctors to report or apprehend motor cyclists who fail to wear crash helmets. Insofar as place of abode is largely a matter of choice, similar considerations attach to doctors' interventions in accidents due to remediable faults.

Environmental hazards

Environmental pollutants are possible causes of disease in the population. Those responsible for such pollution are subject to legal controls. Doctors are specially qualified to identify and measure such threats and are obliged to seek remedial action. Similar considerations apply to health hazards connected with sanitation and drainage that might be associated with particular dwelling places. There is a statutory obligation on the public health physician to identify these irrespective of the relations between the landlord and tenant.

Other kinds of environmental hazards are not the doctor's responsibility. All cities have accident black spots where people are more likely to suffer injuries than in normal situations. Road safety measures are an important form of health protection, but it does not fall to doctors to identify the need for, nor implement, the provision of such measures. The threats involved in the proposal are more akin to the latter suggesting that doctors are not the proper people to address them.

Dangerous people

Aggressive, reckless, or negligent behaviours of others threaten citizens' health. In cases where a clinical condition explains the threat, doctors have an indisputable role to play in health protection. In other cases different bodies have this responsibility. The negligent builder, the reckless driver, and the violent criminal constitute identifiable dangers to everyone. But is not the business of doctors to police their activities to protect the public, for clinical expertise is not required to establish either the explanation or the remedy of the dangers.

Although in the case of child injuries caused by criminal assault it is not the business of the doctor to engage in police work, nevertheless the concealment of grave suspicions is unethical. But the cases with which the proposal is concerned do not concern injuries of this sort. Careless landlords are more akin to those categories of dangerous people identified as not being the responsibility of the doctor. Comparison with other public health cases offers little support to the proposal, and suggests that it would be unethical for the information in question to be divulged without consent.

Competing interests: None declared.

Understanding controlled trials

Randomisation methods: concealment

David J Torgerson, Chris Roberts

Randomisation is the best method removing selection bias between two groups of patients.[1] However, the process of randomisation can be compromised such that the allocation results in biased groups of patients. A trial which has had its randomisation compromised may apparently show a treatment effect that is entirely due to biased allocation. The results of such a study are more damaging than an explicitly unrandomised study, as bias in the latter is acknowledged and the statistical analysis and subsequent interpretation takes this into account. Changes in clinical management based on a compromised trial may, at best, waste valuable health care resources on a useless treatment; at worst, they may also damage patients' health. The randomisation process must therefore not be compromised.

In the past attempts were not generally made to conceal randomisation schedules from investigators who recruited patients. However, unconcealed randomisation can lead to clinicians scheduling patients such that patients with particular characteristics would receive a certain allocation, thereby biasing the allocation.[2] Because of this, administration of randomisation sequences was changed, and forms of concealment were introduced.

Perhaps the most common is the sealed envelope system. In this participating clinicians are given randomly generated treatment allocations within sealed opaque envelopes. Once a patient has consented to enter a trial an envelope is opened and the patient is then offered the allocated treatment regimen. However, this process is open to deliberate tampering as the investigator can open several envelopes before a clinic and then allocate patients to the desired treatment. Indeed, sometimes treatment allocation can be seen if the envelope is held against very bright light.[3] Even if randomisation envelopes and allocation are sequentially numbered to detect any attempt to allocate a patient out of sequence, the process can still be compromised. For instance if the clinician knows the next allocation—for example, by opening an envelope in advance—he or she may postpone trial recruitment until a patient with certain characteristics presents, thus preferentially recruiting patients with certain characteristics into a given treatment arm. While the problem is most serious when interventions are unblinded, even when a drug trial is double blind treatment allocation has been compromised by investigators identifying drugs through poor labelling, or accessing unsecured codes which describe

National Primary Care Research and Development Centre, Centre for Health Economics, University of York, York YO1 5DD

David J Torgerson, *senior research fellow*

National Primary Care Research and Development Centre, University of Manchester, Manchester M13 9PL

Chris Roberts, *senior research fellow*

Correspondence to: Dr Torgerson.

BMJ 1999;319:375–6

the codes of the active and inert drugs.[3] Furthermore, treatment allocation can be guessed if blocking is used. For instance if patients are randomised in a series of blocks of four—that is, for every four patients randomised two will receive one treatment and two will receive the other—an investigator who remembers the treatments the previous three patients received will be able to predict the treatment for the fourth.

While much of the evidence on subverting randomisation is anecdotal, a recent review found that randomisation has been compromised in several controlled trials.[2] This review showed that trials which did not adequately conceal randomisation from the investigators demonstrated, on average, a 41% increase in effect for the active treatment compared with an adequately concealed trial.[2] Indeed, in a current multicentre randomised trial of a surgical procedure in the United Kingdom the median age of patients for the experimental treatment was found to be significantly lower for three groups of clinicians when an envelope system was used. This age imbalance disappeared when better concealment measures were introduced.[4]

Owing to the problems of using envelopes it is methodologically more sound to undertake "distance" randomisation (although in some instances sealed envelopes may be the only practical means of randomisation). Distance randomisation usually involves the investigator, on recruiting a patient, telephoning a central randomisation service which notes basic patient details and then issues a treatment allocation. Indeed, distance randomisation can now be performed over the internet. Such a system is being used, alongside telephone randomisation, in the Medical Research Council's growth restricted intervention trial (GRIT). Distance randomisation is much less likely to be compromised than an envelope system.

Thus, to avoid bias it is important that randomisation is well concealed. Recent evidence has questioned the rigor of using local randomisation. Randomisation should be distant and separate from clinicians conducting the trial.

1 Pocock SJ. *Clinical trials: a practical approach*. Chichester: John Wiley, 1983.
2 Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias: dimensions of methodological quality associated with estimates of effects in controlled trials. *JAMA* 1995;273:408-12.
3 Schulz KF. Subverting randomisation in controlled trials. *JAMA* 1995;274:1456-8.
4 Kennedy A, Grant A. Subversion of allocation in a randomised controlled trial. *Control Clin Trials* 1997;18(suppl 3):77-8S.

Methods in health service research

Evaluation of health interventions at area and organisation level

Obioha C Ukoumunne, Martin C Gulliford, Susan Chinn, Jonathan A C Sterne, Peter G J Burney, Allan Donner

This is the second of four articles

Department of Public Health Sciences, Guy's, King's, and St Thomas's School of Medicine, King's College, London SE1 3QD
Obioha C Ukoumunne, *research associate*
Martin C Gulliford, *senior lecturer*
Susan Chinn, *reader*
Jonathan A C Sterne, *senior lecturer*
Peter G J Burney, *professor*

continued over

BMJ 1999;319:376–9

Healthcare interventions are often implemented at the level of the organisation or geographical area rather than at the level of the individual patient or healthy subject. For example, screening programmes are delivered to residents of a particular area; health promotion interventions might be delivered to towns or schools; general practitioners deliver services to general practice populations; hospital specialists deliver health care to clinic populations. Interventions at area or organisation level are delivered to clusters of individuals.

The evaluation of interventions based in an area or organisation may require the allocation of clusters of individuals to different intervention groups (see box 1).[1 2] Cluster based evaluations present special problems both in design and analysis.[3] Often only a small number of organisational units of large size are available for study, and the investigator needs to consider the most effective way of designing a study with this constraint. Outcomes may be evaluated either at cluster level or at individual level (table).[4] Often cluster level interventions are aimed at modifying the outcomes of the individuals within clusters, and it will then be important to recognise that outcomes for individuals within the same organisation may tend to be more similar than for individuals in different organisational clusters (see box 2). This dependence between individuals in the same cluster has important implications for the design and analysis of organisation based studies.[2] This paper addresses these issues.

Summary points

- Health interventions are often implemented at the levels of health service organisational unit or of geographical or administrative area
- The unit of intervention is then a cluster of individual patients or healthy subjects
- Evaluation of cluster level interventions may be difficult because only a few units of large size may be available for study, evaluation may be at either individual or cluster level, and individuals' responses may be correlated within clusters
- At the design stage, it is important to randomise clusters whenever possble, adapt sample size calculations to allow for clustering of responses, and choose between cohort and repeated cross sectional designs
- Methods chosen for analysis of individual data should take into account the correlation of individual responses within clusters

Nature of the evidence

We retrieved relevant literature using computer searches of the Medline, BIDS (Bath Information and