

and their emotional needs are analogous to women with pseudocyesis — there is one reported case of both pseudocyesis and baby stealing.<sup>10</sup> Yet though women with pseudocyesis might receive psychotherapy or treatment for concurrent depression,<sup>11</sup> non-psychotic women who abduct infants are as likely to be given a punitive sentence.

Even when women receive treatment this does not mean that their behaviour has been understood or that their treatment has been rationally based. The relation between treatment and outcome, and even what the treatment should be, is unknown. Furthermore, women who commit unusual offences may be recommended for psychiatric care without much exploration of their motives and therapeutic needs, a practice that has been called “playing the labels” to provide a “ticket to the psychiatrist.”<sup>12</sup>

A humane recommendation by the courts is not the same as understanding an offence. If better awareness of the causes of baby stealing and the most suitable legal outcomes are to be achieved a precise study of outcome, the impact of hospital treatment, and the prediction of repetition and persistent vulnerability is necessary, extending previous work beyond the point of the court’s initial recommendation.

There is also a more delicate, perhaps controversial, use for such information—to help detect the offender<sup>13</sup> and to reassure the parents of the stolen child, who are the real victims of the offence. They can take comfort from the

knowledge that most abducted babies are found quickly as there is often no attempt to conceal them. And, although there are dramatic exceptions,<sup>14</sup> the babies are almost always well cared for by the women who are desperate and disturbed enough to steal them.<sup>4</sup>

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## Randomisation

### *Essential for reducing bias*

In the past year the *BMJ* has rejected several otherwise satisfactory studies for publication because of faulty randomisation. How can researchers avoid this fate for their papers?

Randomisation is one of many statistical ideas that have permeated medical research but are imperfectly understood. Its use is most familiar in controlled trials, where patients are given one of two or more treatments chosen at random. The purpose is to eliminate possible biases that may lead to systematic differences between the treatment groups—in particular to eliminate any influence on the allocation of treatment by the investigator (either subconscious or deliberate).

Random does not mean the same as haphazard: random allocation in a clinical trial means that all patients have the same chance of receiving any particular treatment (and in most cases each treatment is equally likely). Patients should be entered into a trial before their allocation to a particular treatment is known. A common misconception exists that allocation based on, for example, odd or even dates of birth or hospital numbers is random. These systematic allocation methods, however, clearly violate the requirement that all patients have the same chance of receiving each treatment. Alternate allocation does not in principle suffer from such problems, but there is a risk of abuse because the investigator’s knowledge of the next treatment may lead to some patients being excluded from the trial<sup>1</sup>—making this method inadvisable. Trials using these inferior methods of allocation are not acceptable to the *BMJ*.

Even with proper randomisation a risk of bias exists when the investigators are aware of the treatment awaiting the next patient to be entered into the trial. Better to use a method of allocation that aims to remove the problems of bias—such as by telephone to a randomisation centre, by the pharmacy, or

by a secure system of sequentially numbered opaque sealed envelopes. These are the considerations that underlie the requirement to provide information about the method of randomisation in the statistical checklist used by the *BMJ*’s statistical referees.<sup>2</sup>

Exclusion of some of the randomised patients from the analysis of a controlled trial, for whatever reason, will destroy the unbiased comparison of treatments. This is the reason for the recommendation to analyse all randomised patients in the groups they were allocated to, even if some did not receive the intended treatment (an “intention to treat” analysis). For controlled trials, it is desirable for the groups receiving each treatment to be as similar as possible. Simple randomisation does not guarantee this for any particular trial, especially if the sample is small.<sup>3</sup> Imbalance may be greatly reduced by using stratified randomisation.<sup>1</sup>

In some circumstances randomisation is not possible, either for ethical reasons or because few patients are willing to be randomised. An unrandomised study of concurrent groups treated differently on the basis of clinical judgment or patient preference, or both, will need careful analysis to take account of differing characteristics of the patients and may still be of doubtful value. Failure to use randomisation when it could be used may fatally compromise the credibility of research, as happened in a study of periconceptional vitamin supplementation.<sup>4</sup>

Randomisation is also valuable in other types of research. In surveys it may not be practicable to contact the whole target population. A representative subset can be chosen by random sampling, whereby each person is equally likely to be selected. A low response rate will negate the advantage of random selection because of the strong possibility that those who respond are a biased subset. Thus it is more sensible to

put resources into trying to get complete information from a random sample than to get poor data from the whole population of interest.<sup>5</sup> Random sampling is feasible only when there is a list of all members of the relevant population. A sample survey can be made more representative of the population by stratified sampling—for example, to preserve the age-sex distribution.

Likewise, in case-control and cohort studies it may not be feasible to investigate all of the people of interest—again, random samples should be taken. Randomisation also has a place in laboratory experiments—for example, when locating samples on a 6×6 plate in an automatic analyser. Comparative experiments on animals should also use random selection of animals rather than using those most easily caught.<sup>6</sup>

In all types of study the use of randomisation means that no systematic bias is introduced and the samples selected should be representative of the populations of interest. Once the principles are understood, random selection or allocation is straightforward, using tables of random numbers or a random number generator on a computer.<sup>1</sup> The use of randomisation

does not obviate the need for care in other aspects of the design and analysis of research. For example, though randomised controlled trials are widely agreed to yield the most reliable scientific information, careless or inappropriate analysis may lead to misleading conclusions. The standard of statistics in published reports of clinical trials can be greatly improved.<sup>7,8</sup>

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## Juniors' new deal on hours

### *A 72 hour week by the end of a 5½ year plan*

The pace has quickened on the long, slow march towards more humane working conditions for junior doctors. Last week their employers should have begun taking action to ensure that "as soon as practicable" no doctor in training should have to work longer than 83 hours a week. That maximum should fall to 72 hours by the end of 1994 for doctors in hard pressed posts and for all doctors by the end of 1996 (p 1483).<sup>1</sup> These reductions should go some way towards improving a situation that has shamed all those who have condoned it.

For many the pace of change is still too slow: the juniors originally wanted an immediate reduction to an 83 hour week with the 72 hour maximum achieved by next year. What has been offered instead, according to the Secretary of State for Health, is an achievable timetable. Its great virtue is that all sides—the government, colleges, consultants, and juniors—have signed up to it and can be held to it. Backed by the ministerial group on junior doctors' hours, regional task forces will be keeping health authorities and trusts to the timetable, providing advice as well as cracking the whip. The ministerial group, which was responsible for the agreement, will continue to monitor progress.

No one should underestimate the problems that lie ahead. On the basis of a recent BMA survey,<sup>2</sup> an estimated one in four juniors are now working longer than 83 hours a week; these on call commitments are supposed to fall "as soon as practicable." Nearly half of all doctors work in hard pressed posts; their working week is not meant to exceed 72 hours by the end of 1994. The mechanisms suggested for achieving these reductions—introducing shifts, replacing firms with teams, and allocating work done inappropriately by doctors to clerical, technical, and nursing staff—will all cause upheaval. Consultants' support will evaporate if the work is simply shifted on to them. Juniors will quickly lose their enthusiasm for the changes if their salaries decrease in proportion to their

hours. The pay review body will need convincing that although the hours of work may fall the intensity of the work will increase.

The royal colleges must throw their weight around a little more on behalf of the juniors. They could follow the lead given by the University of London and withdraw educational approval from posts that require doctors to perform duties that are the responsibilities of others.<sup>3</sup> They could serve notice now that training posts remaining more onerous than one in three in 12 months' time will automatically forfeit their approval. And they might reconsider endorsing the statement that "for educational purposes there is normally no requirement for doctors in general professional training to be on duty for more than 72 hours per week." What "abnormal" demands of training could ever justify doctors being on duty this long? A glance across the English Channel shows that most European countries manage to train their specialists without requiring them to work longer than 60 hours a week.

This begs the question of what should be the destination of the juniors' long march. The juniors have said a 60 hour week—resources and training needs permitting. From the recent summit of 90 hours that must have seemed unattainable enough to adopt as a goal. Now it seems possible—even if the rest of the population will probably be working 35 hours a week by the time they have achieved it. Sooner or later doctors will have to address this disparity. Are their needs for a life beyond work really so different from everyone else's?

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