Irrationality, the market, and quality of care

Consider the irrationality of a person who pays extra so as not to share a hotel room with a colleague while on a business trip. He does this because he values privacy but he also scoffs at taking out long term care insurance to guarantee a private room in a nursing home. Why is he willing to risk sharing a room for the rest of his life with a person he does not like? This common irrationality is often masked by rationalisations such as "I would rather die than have to live in a nursing home." Yet we know that when the time comes most prefer the limited pleasures of life in a nursing home to suicide

their feet. There are even more fundamental reasons why depending on the rationality of the market will never work well for quality of care (box). Sensible policy for providing nursing home care requires a larger welfare state, a larger regulatory state, and encouragement of public, non-profit providers. Australia's recent experience shows that to head in the opposite direction is medically, economically, and politically irrational.

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Statistics Notes

Concealing treatment allocation in randomised trials

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We have previously explained why random allocation of treatments is a required design feature of controlled trials[1] and explained how to generate a random allocation sequence.[2] Here we consider the importance of concealing the treatment allocation until the patient is entered into the trial.

Regardless of how the allocation sequence has been generated—such as by simple or stratified randomisation[2]—there will be a prespecified sequence of treatment allocations. In principle, therefore, it is possible to know what treatment the next patient will get at the time when a decision is taken to consider the patient for entry into the trial.

The strength of the randomised trial is based on aspects of design which eliminate various types of bias. Randomisation of patients to treatment groups eliminates bias by making the characteristics of the patients in two (or more) groups the same on average, and stratification with blocking may help to reduce chance imbalance in a particular trial.[2] All this good work can be undone if a poor procedure is adopted to implement the allocation sequence. In any trial one or more people must determine whether each patient is eligible for the trial, decide whether to invite the patient to participate, explain the aims of the trial and the details of the treatments, and, if the patient agrees to participate, determine what treatment he or she will receive.

Suppose it is clear which treatment a patient will receive if he or she enters the trial (perhaps because there is a typed list showing the allocation sequence). Each of the above steps may then be compromised because of conscious or subconscious bias. Even when the sequence is not easily available, there is strong anecdotal evidence of frequent attempts to discover the sequence through a combination of a misplaced belief that this will be beneficial to patients and lack of understanding of the rationale of randomisation.[3]

How can the allocation sequence be concealed? Firstly, the person who generates the allocation sequence should not be the person who determines eligibility and entry of patients. Secondly, if possible the mechanism for treatment allocation should use people not involved in the trial. A common procedure, especially in larger trials, is to use a central telephone randomisation system. Here patient details are supplied, eligibility confirmed, and the patient entered into the trial before the treatment allocation is divulged (and it may still be blinded[4]). Another excellent allocation concealment mechanism, common in drug trials, is to get the allocation done by a pharmacy. The interventions are sealed in serially numbered containers (usually bottles) of equal appearance and weight according to the allocation sequence.

If external help is not available the only other system that provides a plausible defence against allocation bias is to enclose assignments in serially numbered, opaque, sealed envelopes. Apart from neglecting to mention opacity, this is the method used in the famous 1948 streptomycin trial (see box). This

Description of treatment allocation in the MRC streptomycin trial[5]

"Determination of whether a patient would be treated by streptomycin and bed-rest (S case) or by bed-rest alone (C case) was made by reference to a statistical series based on random sampling numbers drawn up for each sex at each centre by Professor Bradford Hill; the details of the series were unknown to any of the investigators or to the co-ordinator and were contained in a set of sealed envelopes, each bearing on the outside only the name of the hospital and a number. After acceptance of a patient by the panel, and before admission to the streptomycin centre, the appropriate numbered envelope was opened at the central office; the card inside told if the patient was to be an S or a C case, and this information was then given to the medical officer of the centre."

method is not immune to corruption,[3] particularly if poorly executed. However, with care, it can be a good mechanism for concealing allocation. We recommend that investigators ensure that the envelopes are opened sequentially, and only after the participant's name and other details are written on the appropriate envelope.[3] If possible, that information should also be transferred to the assigned allocation by using pressure sensitive paper or carbon paper inside the envelope. If an investigator cannot use numbered containers, envelopes represent the best available allocation concealment mechanism without involving outside parties, and may sometimes be the only feasible option. We suspect, however, that in years to come we will see greater use of external "third party" randomisation.

The desirability of concealing the allocation was recognised in the streptomycin trial[5] (see box). Yet the importance of this key element of a randomised trial has not been widely recognised. Empirical evidence of the bias associated with failure to conceal the allocation[6 7] and explicit requirement to discuss this issue in the CONSORT statement[8] seem to be leading to wider recognition that allocation concealment is an essential aspect of a randomised trial.

Allocation concealment is completely different from (double) blinding.[4] It is possible to conceal the randomisation in every randomised trial. Also, allocation concealment seeks to eliminate selection bias (who gets into the trial and the treatment they are assigned). By contrast, blinding relates to what happens after randomisation, is not possible in all trials, and seeks to reduce ascertainment bias (assessment of outcome).

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The public health benefits of mobile phones

The bread and butter of public health on call is identifying contacts in the case of suspected meningococcal disease. On the whole this is straightforward but can occasionally cause difficulties. Most areas that I have worked in include several universities, and during October it is common to experience the problem of contact tracing in the student population.

There are two main problems. The first is how to define household contacts when the index patient lives in a hall of residence containing several hundred students. Finding the appropriate university protocol and not being too concerned about the different approaches adopted by neighbouring universities can reduce the number of sleepless nights. The second problem is harder. "Close kissing contacts" among 18 year olds who have been set free from parental control for the first time is a minefield. My experience suggests that it is best to assume there will be lots and that names and contact details will not necessarily have been obtained. By the end of a weekend on call, you will feel like a cross between a detective and an "agony aunt."

One year I volunteered to cover Christmas weekend in the belief that at least the students would be gone by then. I could not have been more mistaken. To add a further difficulty, the index patient presented to hospital on the night of the last day of term, and all contacts had already set off to the far reaches of the country. I could not believe my luck when the friend accompanying the patient produced both their mobile phones and confidently reassured me that between the two of them they would have the mobile numbers of all 15 "household" contacts. She was right, and in just over two hours all of them had been contacted.

There has been much coverage in the medical and popular press about the potential health hazards of mobile phones, and if these fears are realised the 100% ownership among this small sample of students is worrying. However, in terms of contact tracing for suspected meningococcal disease, mobile phones have potential health benefits not just for their owners but also for the mental health of public health doctors. Of course, this may not solve the "close kissing contact" problem.

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We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.