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 rationalizations 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 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.

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 and explained how to generate a random allocation sequence. 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—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. All this good, of course, is 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 unconscious 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.

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?). 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).
The desirability of concealing the allocation was recognised in the streptomycin trial (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 and explicit requirement to discuss this issue in the CONSORT statement 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: 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).

**Description of treatment allocation in the MRC streptomycin trial**

“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.”