Assessing allocation concealment and blinding in randomised controlled trials: why bother?

The EBN users’ guide in the previous issue of *Evidence-Based Nursing* outlined the primary and secondary questions for evaluating studies of healthcare interventions. One of the primary questions for assessing the validity of a study’s findings is whether the assignment of patients to treatments was randomised and whether randomisation was concealed. One of the secondary questions is whether patients, clinicians, outcome assessors, and data analysts were unaware of (blinded to or masked from) patient allocation. Beginning with the October 1999 issue of *Evidence-Based Nursing*, allocation concealment and blinding have been given more attention. The “design” section of abstracts of randomised trials now includes a statement of whether randomisation was concealed from those responsible for entering patients into trials, and who was blinded to treatment allocation during the trials. These additional specifications provide readers with more information to judge the internal validity of trials. In this editorial, the background and rationale for these decisions are addressed.

### Allocation concealment

Random allocation to intervention groups remains the only method of ensuring that the groups being compared are on an equivalent footing at study outset, thus eliminating selection and confounding biases. This has allowed randomised controlled trials (RCTs) to play a key part in advancing healthcare practice.

The success of randomisation depends on 2 interrelated processes. The first entails generating a sequence by which the participants in a trial are allocated to intervention groups. To ensure unpredictability of that allocation sequence, investigators should generate it by a random process (e g, computer generated numbers, random number tables, or coin flipping). The second process, allocation concealment, shields those involved in a trial from knowing upcoming assignments in advance. Without this protection, investigators have been known to change who gets the next assignment, making the comparison groups less equivalent.

Suppose, for example, that an investigator creates an adequate allocation sequence using a random number table. However, the investigator then affixes the list of that sequence to a bulletin board, with no allocation concealment. Those responsible for admitting patients could ascertain the upcoming assignment, allowing for the classification as concealed or not concealed. Allocation concealment should not be confused with blinding. Allocation concealment concentrates on preventing selection and confounding biases, safeguards the assignment sequence before and until allocation, and can always be successfully implemented. By comparison, blinding concea-
Blinding
Blinding or masking involves keeping patients, clinicians, outcome assessors, and/or data analysts unaware of patient allocation to avoid bias. For example, if unblinded, patients may have a heightened sensitivity to the good (or bad) effects of the treatment, clinicians may unwittingly alter the way they provide care or look for good or adverse outcomes, outcome assessors may distort outcome measurement, and data analysts may alter their approach to analysing the data. Ideally, although not usually possible in studies evaluating nursing interventions, all 4 groups are blinded. In the study by Richter et al described above, 2 of these groups were blinded, the outcome assessors and the data analysts. The authors explained that blinding of patients was not possible because the patients could easily identify the (side) effects of β₂-agonists. There was no mention of clinician blinding.

Double blinding (variably but usually defined as blinding patients, clinicians, and outcome assessors) also appears to reduce bias. Trials that were not double blinded yielded larger estimates of treatment effect than trials in which authors reported double blinding (odds ratios exaggerated, on average, by 17%). Another recent analysis similarly indicated the importance of double blinding. However, although double blinding seems to prevent bias, its effect appears weaker than that of allocation concealment. Indeed, Moher et al found that double blinding had little influence on estimates of effect. In the “design” section of abstracts of RCTs in Evidence-Based Nursing, the study is now identified as blinded, with specification of who was blinded; unblinded, if all parties were aware of patients’ group assignments; or blinded (unclear) if the authors did not report or provide an indication of who was aware or unaware of patients’ group assignments.

Reporting of methods
Investigators must not only minimise bias but must also communicate those efforts to the reader. Readers should not have to assume or guess which methods were used. Yet assessments of the reporting quality of published trials have consistently found major flaws. Only 9% of trials in specialist journals and 15% in general journals reported both an adequate method of generating random sequences and an adequate method of allocation concealment. Of trials reported as double blind, only 45% described similarity of the treatment and control regimens, and only 26% provided information on the protection of the allocation schedule. Most reports simply provide no information on methods. When reports of studies abstracted for Evidence-Based Nursing do not include information about allocation concealment or blinding, the authors are asked to provide this information.

With so little relevant information, many readers resort to inappropriate markers of trial quality. Two noteworthy examples highlight this concern. Firstly, many designate a trial as high quality if it is “double blind,” as if double blinding is the essential requirement of an RCT. Although double blinding, on average, reflects good methods, it is not the sole criterion of quality. Adequate allocation concealment actually appears to be the more important indicator. Moreover, many trials cannot be double blinded. Those trials must be judged on other merits and not on an inapplicable standard based on double blinding. To further complicate matters, a study recently found that the term “double blind” was interpreted differently both by readers and by experts. Surveys of physicians and review of recent textbooks including definitions for blinding revealed numerous unique interpretations for the term; for example, some thought it meant that the patients and clinicians were blinded, whereas others thought that the patients and outcome assessors were blinded. This has led to the recommendation that the terms single, double, and triple blinded be abandoned and replaced with descriptions specifically stating which of the groups were unaware of allocation.

Secondly, some assume that a good quality trial contains arms of equal size, whereas a poor quality trial contains unequal sizes. This standard has marginal value only when the investigators used a restricted randomisation generation scheme that aimed for equality. Otherwise, exactly equal numbers in treatment groups in a simple randomised trial may mean that some process other than randomisation was used (eg, allocation of every second patient to the intervention group).

Although RCT reporting remains weak, it is improving. Methodologists, editors, and clinicians addressed the prevailing flaws in reporting by publishing the Consolidated Standards of Reporting Trials (CONSORT) statement. Currently, 48 journals have adopted the standards, including such high profile healthcare journals as JAMA, BMJ, Pediatrics, and Archives of Internal Medicine. These journals were 4 of the highest contributors of articles to Evidence-Based Nursing in 1998 and 1999. Sadly, no nursing journals have yet adopted the standards. Even with these improvements, readers of RCTs should be wary of the information provided in many current trial reports.

Summary
As users of RCT results, we must understand the potential for humans to interject bias. By describing assessments of allocation concealment and blinding, abstracts included in Evidence-Based Nursing will help readers to discern those trials that have made superior efforts to minimise bias. Judging the quality of allocation concealment and blinding reflects current empirical research and reflects the commitment of the editors of this journal to apply the principles of evidence-based practice to reporting of study findings.

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