

the same thing as blinding. In contrast, to allocation concealment, blinding seeks to prevent the introduction of bias after allocation.

As explained by Poolman et al. (5), “[a]llocation in a trial is concealed when investigators cannot beforehand determine the allocated treatment of the next patient enrolled into their study. Allocation concealment is necessary to prevent selection bias, whereas blinding is important to prevent detection bias, i.e. a biased assessment of outcome.”

Schultz et al. (6) distinguish between allocation concealment and blinding by way of an example. This example is a clinical study that involves surgery. In a hypothetical clinical trial that compares *a new type of knee surgery technique* for sports injuries (arm A) with *an established knee surgery technique* for sports injuries (arm B), a goal will be to use randomization techniques that ensure that arm A does not consist mainly of people with arthritis. Allocation concealment prevents study personnel from secretly putting all of the arthritic people in arm B. But in this particular hypothetical, blinding is impossible (at least as it applies to blinding of the physician), because the physician will know which of the two types of surgery she is required to perform. In comments about allocation concealment, Rios et al. (7) found that lack of allocation concealment can permit selective assignment of the clinical study design, thereby destroying the purpose of randomization. Thus, in this hypothetical, we do have allocation concealment, but we do not have blinding.

Vickers (8) provides a concrete example of how an investigator can inadvertently subvert a clinical trial:

*Say that, on a given day, the surgeon has seen the randomization list and knows that the next patient will be randomly assigned to the surgery group. In walks a patient who meets the eligibility criteria for the trial but who the surgeon feels, on balance, is probably not going to do that well. Accordingly, the surgeon advises against surgery and does not raise the study with the patient; the next patient, however, is a great candidate for surgery, and although he is rather wary of research, the surgeon pressures him to consent. In other words, the surgeon is able to subvert randomization and select which patients get which treatment, the very problem randomization was designed to avoid.*

Viera and Bangdiwala (9) provide another example of the dangers of allocation schemes that do not involve allocation concealment. In a hypothetical example involving an anti-obesity drug, called *Slimmenow*, these authors wrote:

<sup>5</sup> Poolman RW, Struijs PA, Krips R, et al. Reporting of outcomes in orthopaedic randomized trials: does blinding of outcome assessors matter? *J Bone Joint Surg Am.* 2007;89:550–558.

<sup>6</sup> Schulz KF, Chalmers I, Altman DG. The landscape and lexicon of blinding in randomized trials. *Ann Intern Med.* 2002;136:254–259.

<sup>7</sup> Rios LP, Oduyungbo A, Moitri MO, Rahman MO, Thabane L. Quality of reporting of randomized controlled trials in general endocrinology literature. *J Clin Endocrinol Metab.* 2008;93:3810–3816.

<sup>8</sup> Vickers AJ. How to randomize. *J Soc Integr Oncol.* 2006;4:194–198.

<sup>9</sup> Viera AJ, Bangdiwala SI. Eliminating bias in randomized controlled trials: importance of allocation concealment and masking. *Fam Med.* 2007;39:132–137.