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. (21) 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 (22) 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 (23) provide another example of the dangers of allocation schemes that do not involve allocation concealment. In a hypothetical example involving an antiobesity drug, called *Slimmenow*, these authors wrote:

> If the referring health care provider is aware of the next allocation, he … may (even unknowingly) influence enrollment or selection of participating subjects. For example, if the referring health care provider knows the next subject will be allocated to *Slimmenow*, he … may be inclined to try to help a certain patient he/she thinks may benefit more. Or perhaps knowing the next subject is to be allocated to placebo, he/she refers someone who really does not need to lose much weight.

Pildal et al. (24) characterized the failure to conceal allocation as, "[w]ithout concealment the person in charge of enrolment might channel patients with a better prognosis into his … preferred treatment."

Schulz (25) described a number of intentional attempts to subvert allocation, thereby resulting in unblinding of clinical trials. These include attempts to obtain the master randomization list, and using X-rays to screen sealed envelopes containing the patient's allocation to drug or placebo. In another publication, Schulz et al. (26),

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