Item 8a. Method used to generate the random allocation sequence

Examples—“Independent pharmacists dispensed either active or placebo inhalers according to a computer generated randomisation list.”

“For allocation of the participants, a computer-generated list of random numbers was used.”

Explanation—Participants should be assigned to comparison groups in the trial on the basis of a chance (random) process characterised by unpredictability (see box 1). Authors should provide sufficient information that the reader can assess the methods used to generate the random allocation sequence and the likelihood of bias in group assignment. It is important that information on the process of randomisation is included in the body of the main article and not as a separate supplementary file; where it can be missed by the reader. The term “random” has a precise technical meaning. With random allocation, each participant has a known probability of receiving each intervention before one is assigned, but the assigned intervention is determined by a chance process and cannot be predicted. However, “random” is often used inappropriately in the literature to describe trials in which non-random, deterministic allocation methods were used, such as alternation, hospital numbers, or date of birth. When investigators use such non-random methods, they should describe them precisely and should not use the term “random” or any variation of it. Even the term “quasi-random” is unacceptable for describing such trials. Trials based on non-random methods generally yield biased results. Bias presumably arises from the inability to conceal these allocation systems adequately (see item 9). Many methods of sequence generation are adequate. However, readers cannot judge adequacy from such terms as “random allocation,” “randomisation,” or “random” with‑ out further elaboration. Authors should specify the method of sequence generation, such as a random-number table or a computerised random number generator. The sequence may be generated by the process of minimisation, a non-random but generally acceptable method (see box 2). In some trials, participants are intentionally allocated in unequal numbers to each intervention: for example, to gain more experience with a new procedure or to limit costs of the trial. In such cases, authors should report the randomisation ratio (for example, 2:1 or two treatment participants per each control participant) (see item 3a). In a representative sample of PubMed indexed trials in 2000, only 21% reported an adequate approach to random sequence generation16; this increased to 34% for a similar cohort of PubMed indexed trials in 2006. In more than 90% of these cases, researchers used a random number generator on a computer or a random number table.