Item 19. All important harms or unintended effects in each group For specific guidance see CONSORT for harms.

Example—“The proportion of patients experiencing any adverse event was similar between the rBPI21 [recombinant bactericidal/permeability-increasing protein] and placebo groups: (88.4%) of 190 and 180 (88.7%) of 203, respectively, and it was lower in patients treated with rBPI21 than in those treated with placebo for 11 of 12 body systems … the proportion of patients experiencing a severe adverse event, as judged by the investigators, was numerically lower in the rBPI21 group than the placebo group: 53 (27.9%) of 190 versus 74 (36.5%) of 203 patients, respectively. There were only three serious adverse events reported as drug-related and they all occurred in the placebo group.”

Explanation—Readers need information about the harms as well as the benefits of interventions to make rational and balanced decisions. The existence and nature of adverse effects can have a major impact on whether a particular intervention will be deemed acceptable and useful. Not all reported adverse events observed during a trial are necessarily a con‑ sequence of the intervention; some may be a consequence of the condition being treated. Randomised trials offer the best approach for providing safety data as well as efficacy data, although they cannot detect rare harms. Many reports of RCTs provide inadequate information on adverse events. A survey of 192 drug trials published from 1967 to 1999 showed that only 39% had adequate reporting of clinical adverse events and 29% had adequate reporting of laboratory defined toxicity. More recently, a comparison between the adverse event data submitted to the trials database of the National Cancer Institute, which sponsored the trials, and the information reported in journal articles found that low grade adverse events were underreported in journal articles. High grade events (Common Toxicity Criteria grades 3 to 5) were reported inconsistently in the articles, and the information regarding attribution to investigational drugs was incomplete. Moreover, a review of trials published in six general medical journals in 2006 to 2007 found that, although 89% of 133 reports mentioned adverse events, no information on severe adverse events and withdrawal of patients due to an adverse event was given on 27% and 48% of articles, respectively. An extension of the CONSORT statement has been developed to provide detailed recommendations on the reporting of harms in randomised trials. Recommendations and examples of appropriate reporting are freely available from the CONSORT website (www.consort-statement.org). They complement the CONSORT 2010 Statement and should be consulted, particularly if the study of harms was a key objective. Briefly, if data on adverse events were collected, events should be listed and defined, with reference to standardised criteria where appropriate. The methods used for data collection and attribution of events should be described. For each study arm the absolute risk of each adverse event, using appropriate metrics for recurrent events, and the number of participants withdrawn due to harms should be presented. Finally, authors should pro‑ vide a balanced discussion of benefits and harms.