Item 22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

Example—“Studies published before 1990 suggested that prophylactic immunotherapy also reduced nosocomial infections in very-low-birth-weight infants. However, these studies enrolled small numbers of patients; employed varied designs, preparations, and doses; and included diverse study populations. In this large multicenter, randomised controlled trial, the repeated prophylactic administration of intravenous immune globulin failed to reduce the incidence of nosocomial infections significantly in premature infants weighing 501 to 1500 g at birth.” Explanation—Readers will want to know how the present trial’s results relate to those of other RCTs. This can best be achieved by including a formal systematic review in the results or discussion section of the report. Such synthesis may be impractical for trial authors, but it is often possible to quote a systematic review of similar trials. A systematic review may help readers assess whether the results of the RCT are similar to those of other trials in the same topic area and whether participants are similar across studies. Reports of RCTs have often not dealt adequately with these points. Bayesian methods can be used to statistically combine the trial data with previous evidence. We recommend that, at a minimum, the discussion should be as systematic as possible and be based on a comprehensive search, rather than being limited to studies that support the results of the current trial.