Item 4a. Eligibility criteria for participants

Example—“Eligible participants were all adults aged 18 or over with HIV who met the eligibility criteria for antiretroviral therapy according to the Malawian national HIV treatment guidelines (WHO clinical stage III or IV or any WHO stage with a CD4 count and lactation or participation in another supplementary feeding programme.”

Explanation—

A comprehensive description of the eligibility criteria used to select the trial participants is needed to help readers interpret the study. In particular, a clear understanding of these criteria is one of several elements required to judge to whom the results of a trial apply that is, the trial’s generalisability (applicability) and relevance to clinical or public health practice (see item 21). A description of the method of recruitment, such as by referral or self selection (for example, through advertisements), is also important in this context. Because they are applied before randomisation, eligibility criteria do not affect the internal validity of a trial, but they are central to its external validity. Typical and widely accepted selection criteria relate to the nature and stage of the disease being studied, the exclusion of persons thought to be particularly vulnerable to harm from the study intervention, and to issues required to ensure that the study satisfies legal and ethical norms. Informed consent by study participants, for example, is typically required in intervention studies. The common distinction between inclusion and exclusion criteria is unnecessary; the same criterion can be phrased to include or exclude participants. Despite their importance, eligibility criteria are often not reported adequately. For example, eight published trials leading to clinical alerts by the National Institutes of Health specified an average of 31 eligibility criteria in their protocols, but only 63% of the criteria were mentioned in the journal articles, and only 19% were mentioned in the clinical alerts. Similar deficiencies were found for HIV clinical trials. Among 364 reports of RCTs in surgery, 25% did not specify any eligibility criteria