#### Item 11: DATA ITEMS.

List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.

**Examples.** “Information was extracted from each included trial on: (1) characteristics of trial participants (including age, stage and severity of disease, and method of diagnosis), and the trial's inclusion and exclusion criteria; (2) type of intervention (including type, dose, duration and frequency of the NSAID [non-steroidal anti-inflammatory drug]; versus placebo or versus the type, dose, duration and frequency of another NSAID; or versus another pain management drug; or versus no treatment); (3) type of outcome measure (including the level of pain reduction, improvement in quality of life score (using a validated scale), effect on daily activities, absence from work or school, length of follow up, unintended effects of treatment, number of women requiring more invasive treatment).”

#### Explanation.

It is important for readers to know what information review authors sought, even if some of this information was not available . If the review is limited to reporting only those variables that were obtained, rather than those that were deemed important but could not be obtained, bias might be introduced and the reader might be misled. It is therefore helpful if authors can refer readers to the protocol (see Item 5), and archive their extraction forms (see Item 10), including definitions of variables. The published systematic review should include a description of the processes used with, if relevant, specification of how readers can get access to additional materials.

We encourage authors to report whether some variables were added after the review started. Such variables might include those found in the studies that the reviewers identified (e.g., important outcome measures that the reviewers initially overlooked). Authors should describe the reasons for adding any variables to those already pre-specified in the protocol so that readers can understand the review process.

We advise authors to report any assumptions they made about missing or unclear information and to explain those processes. For example, in studies of women aged 50 or older it is reasonable to assume that none were pregnant, even if this is not reported. Likewise, review authors might make assumptions about the route of administration of drugs assessed. However, special care should be taken in making assumptions about qualitative information. For example, the upper age limit for “children” can vary from 15 years to 21 years, “intense” physiotherapy might mean very different things to different researchers at different times and for different patients, and the volume of blood associated with “heavy” blood loss might vary widely depending on the setting.