Summary of discussions 2 (as of Sept 2005)

This document covers changes in the STROBE checklist between version 2 and version 3. It aims to keep track of changes in the checklist and to share the discussions that have led to these changes with a wider group of people interested in the STROBE initiative. Any comments are welcome and will be considered for future revisions. Please refer to the most recent version of the checklist available on the STROBE website.

Note:

Version 3 was an intermediate version; changes from v2 to v3 are not presented separately.

generic item = item is identical for all three study designs,

specific item = item wording / content differs between study designs

Table of structural changes:

Version 2 Item #	Version 3 Item #
#6 Participants	#6 was split in sub-items #6a), #6b), and #6c)
#7 Variables of interest	#7 is now a generic item.
#8 Measurement	#8b) was changed to a generic item. A footnote was added.
#11 Statistical methods	#11a) was split in 3 sub-items: #11a) and #11b{1}) are now generic items; #11b{2} comprises content that is different for each study design. #11b) was renumbered #11c).
#12 Quantitative exposures	Item title was changed to "Quantitative variables". #12b) was moved to #17e)
#14 Participants	#14a) is now a generic item. For case-control studies split into #14a) and #14e). For cohort studies, last sentence of #14a) was moved and combined with #15c). #14b) was split in #14b) and #14c). #14d) was added. A footnote was added.
#15 Descriptive data	#15 is now a generic item. For cohort studies, item was split into #15a) and #15c) (now specific item). A footnote was added.
#16 Outcome data	A footnote was added.
#17 Main results	#17b), #17d) were added. #17e) was moved from #12. #17b) was renumbered #17c).
#20 Limitations	#20b) was added.

Changes in content or wording of items:

TITLE AND ABSTRACT

Item 1: Title and abstract

#1b) It was argued that asking for "all key issues" may result in a conflict with the often limited space accorded to abstracts. We changed the wording to "key items" and leave open which items to be included in the abstract and with how much detail. We omitted the word "highly".

INTRODUCTION

Item 2: Background / Rationale

"for the study" was reworded in order to clarify the meaning.

Item 3: Objectives

The word "hypothesis" was considered closely linked to statistical considerations (e.g. the formulation of a null hypothesis). We changed to "pre-specified hypotheses". These are regarded as a type of specific objective. This will be discussed in the explanatory paper.

METHODS

Item 4: Study design

We discussed how much information about the original study is appropriate. Although a detailed description may not be necessary (in particular if the original study is no longer related to the subject of the present report), a brief note about the original purpose of the collection of data presently being used is important. However, it was argued that such information has a potential to mislead since it labels a study as secondary. The explanatory paper will precise that the intention is not to dismiss secondary analyses of existing data. Item wording was not changed.

Item 5: Setting

A commentator argued that periods of data collection do not include the time relationships of studied conditions and events if the latter are in the past. Item wording was not changed, but this may be accounted for in the explanatory paper.

Item 6: Participants

It was argued that eligibility is a concept with a broader meaning since it includes both in- and exclusion. However, using "eligibility" alone may be difficult to understand, in particular for non-native English speakers. We therefore decided to re-introduce "inclusion and exclusion criteria". For cohort studies, we reconsidered the separate reporting of participant information for exposed and unexposed. We decided to drop this sentence, since it may be misleading (i.e. suggesting that pre-defined study groups need to be distinguished in cohort studies).

We added methods of follow-up to be reported for cohort studies. We also discussed the reporting of time relationships, but did not decide to add a separate item for time relationships. In discussions, it was noted that the time frame of accrual in case-control studies is not covered in the present checklist version.

Item 7: Variables of interest

Following several comments, this item was reworded and is now generic.

Item 8: Measurement

The item is now generic for all study designs. We added a footnote to explicitly state that there are different meanings for case-control studies as compared to cohort or cross-sectional studies. Same footnote also applies to several other items.

In #8a) we added "measurement" since the meaning differs from assessments. In #8b) "procedures" was replaced by "assessment methods".

Item 9: Bias

We discussed the re-introduction of more detail on different types of bias. However, there was a consensus that this could be better placed in the explanatory paper.

Item 10: Sample size

No changes.

Item 11: Statistical methods

For case-control studies, content on matching was reworded. For cross-sectional studies, we discussed "design effect" and decided to keep the term since it is widely used in the related literature.

Item 12: Quantitative variables

#12a) was reworded and simplified.

#12b): we followed recommendations and moved this to the Results section (#17).

Item 13: Funding

Minor change to improve syntax (add "for").

RESULTS

Item 14: Participants

The item text is now generic except for #14e) on participants in case-control studies. A footnote was added (see #8). Longer paragraphs were split in sub-items. #14b) was shortened.

Item 15: Descriptive data

A footnote was added (see #8). The item text is now generic for #15a) and #15b). Removed "baseline" for cohort studies.

Item 16: Outcome data

A footnote was added (see #8) and the wording was simplified.

Item 17: Main results

Following the suggestion of one commentator, sub-item #17b) was introduced to address the issue of comparisons using categories derived from quantitative variables. #17c) was shortened. We also followed the argument of another commentator who stressed the importance of sufficient information to assess the generalizability of results and added sub-item #17d).

Item 18: Other analyses

No changes.

DISCUSSION

Item 19: Key findings

"findings" replaced by "results".

Item 20: Limitations

Following one commentator, #20a) was complemented to cover magnitude and direction of bias. #20b) was added following the suggestion of another commentator.

Item 21: Generalizability

No changes.

Item 22: Interpretation

No changes.