Summary of discussions

This document refers to checklist version 1 and is an attempt to share the thread of discussions during and after the Bristol workshop with a wider group of people interested in the STROBE initiative.

Please comment on checklist version 2 (revised version). Comments on any of the points mentioned are welcome and will be taken into account in version 3.

Table of changes in the order of items:

Version 1 Item #	**Version 2 Item #**
# 3 Aims + # 4 Objectives	merged to # 3 Objectives
# 5 Study design	# 4
# 6 Participants: 2nd part on dates, setting, locations of recruitment	becomes new item # 5 Setting
# 12 Participants	# 14
# 13 Descriptive data	# 15
# 14 Numbers of outcomes	# 16 Outcome data
# 15 Quantitative exposures	# 12
# 16 Confounding	# 17 Main results
# 17 Other analyses	# 18
# 18 Limitations	1st part on main findings becomes new item # 19; 2nd part becomes new item # 20
# 19 Generalizability	# 21
# 20 Interpretation / Overall evidence	# 22 Interpretation
# 21 Funding	# 13 Funding

TITLE AND ABSTRACT

Item 1: Title and abstract

An editor stressed the need for a structured summary of the article in the abstract. Following this recommendation, we extended the item to recommend the use of structured abstracts (addition of item 1b).

INTRODUCTION

Item 2: Background / Rationale

There were no specific comments.

Item 3: Aims

Several people found the distinction between Aims and Objectives (in two items) difficult and suggested combining them. In general, it was felt that the end of Introduction is the best place for this item. Therefore, we created a new item "Objectives" in the Introduction section.

The explanatory paper will clarify the meaning of objectives and hypotheses, including the distinction between conceptual hypotheses and null hypotheses in the context of statistical testing.

METHODS

Item 4: Objectives

We moved this item to the Introduction section (see comments on item 3).

Item 5: Study design

We rephrased the item to ask for key elements of the design in more detail.

One editorial team commented: "We do request protocols for observational studies on occasion, and sometimes we receive one, so if there was a protocol we would find it useful to be mentioned here." We did not include this point explicitly but we will mention in the explanatory paper that the submission of the study protocol (along with the article reporting the results) may be helpful.

A commentator stressed the importance of a statement on the purpose of the original study if the present paper reports on one of several analyses from an ongoing study. It was also suggested that "for studies based on well-established cohorts it may suffice to provide a suitable reference to previous publications" for details on the methods. We agree with these comments: authors should make any relationship of the present paper with previous publications as transparent as possible. The problem of multiple publication in reporting observational studies will be considered in the explanatory document.

Item 6: Participants

For case-control studies, we rephrased the item to make it clear that some information is needed separately for cases and controls. We also added that the rationale for the choice of controls, the matching criteria, and the number of controls per case should be given.

For cohort and cross-sectional studies, we added eligibility and exclusion criteria.

For cohort studies, a commentator suggested that the diagnostic criteria for disease endpoints should be mentioned here. We believe that the items on "Variables of interest" and "Measurement" cover this important point.

We decided to separate the item on dates, setting, and locations of data collection. This become the new item 5, entitled "Setting" in version 2. Opinions diverged whether information on dates of data collection are better placed in Methods or Results. For the time being, we kept it under Methods.

Item 7: Variables of interest

It was suggested that we should not ask for "**all**" variables of interest. In particular, it may not be possible to list "all" potential confounders. For the time being, we decided to keep the wording unchanged. However, we will explain in the explanatory paper that listing all variables may be difficult in some circumstances.

It was suggested to distinguish between primary and secondary outcomes. Since this concept is less pertinent to observational studies we decided not to include it for the time being.

One commentator asked for reporting of the rationale for choosing categories or cut-offs of variables. The item on quantitative exposures covers this; the corresponding paragraph of the explanatory paper will discuss the choices of categories in detail.

Item 8: Measurement

Several commentators stressed the importance to show the comparability of procedures across study groups. This is now addressed, with wording that is specific to each design.

Item 9: Bias

The term "information bias" was not unequivocally understood. We decided to delete it to avoid ambiguity.

We also followed one commentator's suggestion to rephrase to "potential sources of bias".

A commentator suggested to move the item on bias to the results section. However, we decided to keep it under Methods since the focus is on the reporting of any planned procedures to prevent bias.

Item 10: Sample size

Several people pointed out that *post hoc* power calculations are not appropriate and that only the achieved study size matters, once the study has been done. It was also proposed to drop the item completely. After completion of a study, it is more informative and important to report the effect estimates together with a measure of the degree of precision the study achieved, for example confidence intervals. However, we deemed valuable that authors describe the rationale they used *a priori* to determine sample size as part of the study methods. This rationale can be practical (e.g. a clearly defined cohort population or limited resources) or statistical (needed study power to detect a meaningful difference) or both, depending on the nature of the study. The explanatory paper will give examples.

One commentator suggested an account of interim analyses or stopping rules, if applicable, and referred to the problem of repeated analyses when recruitment is ongoing. For the time being, we did not include this point because we felt it was not a very common situation.

Item 11: Statistical methods

As for the item on "Variables of interest" (item 7) it was suggested not to ask for "all" statistical methods used. Again, we decided to leave it in for the time being.

The item was split into two sub-items in version 2 to make the text more readable.

RESULTS

Item 12: Participants

For case-control studies, it was suggested that the information on participants should be given separately for cases and controls and we rephrased the item accordingly. Furthermore, people pointed out that the distribution of the number of controls per case in matched studies should be reported, and this has been included. For example, the number of cases with no matching control / with one control / two controls etc should be given. The explanatory paper will explain this in more detail.

Dates of recruitment are now covered by the new item on "Settings" in the section under Methods. Opinions diverged whether information on when the study was actually conducted is best placed in Methods or Results.

The number of potentially eligible individuals is not necessarily known in a cross-sectional or cohort study, as pointed out by one commentator. We therefore added "if known" to the corresponding text passage for all three study designs.

Finally, the (strong) recommendation of a flow diagram elicited comments. The use of such diagrams may be hampered by space limitations of journals. If not essential, we believe that their use is often helpful for the reporting of numbers of participants on the different stages of an observational study. We removed the word 'strongly' and now simply say that flow diagrams "are recommended." Examples of flow charts will be presented in the explanatory document.

Item 13: Descriptive data

As suggested by one commentator we added that information about the completeness of data should be reported for each variable of interest.

Item 14: Numbers of outcomes

The title has been changed to “outcome data”.

An editorial team suggested “more clarity and guidance (…), perhaps spelling out that measures of absolute risk, effect sizes, measures of precision, should be listed.”

A difficulty with this item was to find universally applicable and unambiguous terms like “summary measures” or “outcome events” without being too specific. Clearly, more explanation and examples are needed and checklist users will be referred to the explanatory paper for this.

Item 15: Quantitative exposures

Following several comments, the item was shortened, revised and split in a generic and a study-specific part. Also, it was moved to the Methods section.

One commentator stated: “The two major problems I see are the use of mindless categories, like quintiles, which may sometimes utterly obscure patterns, and the failure to examine whether the same results obtain using some type of continuous analysis.” We agree. STROBE will hopefully improve reporting in this context.

Item 16: Confounding

The item title was changed to “Main results”. It was deemed important to have a statement not only on confounders that were adjusted for but also on those that were considered potentially relevant but not included in the multivariable model.

Following the recommendation of one editor, we added text to stress the importance of absolute risk differences (as compared to relative measures).

Item 17: Other analyses

One suggestion was to add “…and whether they were chosen a priori”. In the interest of simplicity, we did not add this, but will mention this important point in the explanatory paper.

DISCUSSION

Item 18: Limitations

Several comments were on the order of items within the Discussion section. See also general comments on the website.

Before the item on limitations, we inserted a new item on the reporting of “Key findings” and their relevance with regard to the study hypotheses.

A commentator argued that multiplicity may only be problematic if a study focuses on more than one issue; we rephrased the item to account for this.

Item 19: Generalizability

There were no specific comments.

Item 20: Interpretation / Overall evidence

One commentator stated: “I see over-interpretation as THE major problem of epidemiological studies. That should be discouraged – no interpretation is better than over-interpretation, and a study can have merit even without interpretation. Furthermore in most cases it is wildly unrealistic to expect a full contextual review; that would require another article.”

Another commentator recommends “a more careful argument in terms of biological or clinical plausibility.”

We do not want to define the extent of interpretation that is adequate for a discussion of epidemiological results. We inserted the phrase “a cautious overall interpretation” and added the context of study limitations and alternative interpretations. The explanatory paper will need to discuss the issue of interpretation of study findings in more detail.

Item 21: Funding

The question whether or not disclosure of funding sources is essential remained contentious. Since sponsors are potentially involved in the design or analysis of a study, we followed the suggestion of one editorial team and included this at the end of the Methods section. We also changed the wording to clarify that only information on the funding source of the present study and, if applicable, the original study on which the present report is based is asked for.

Reporting of other aspects (e.g. competing interests or ethical approval) may be important as well. We did not add this here but felt this should be left to the editorial policy of the journal.