European Science Foundation

Standing Committee for the European Medical Research Councils (EMRC)

Scientific Report

Exploratory workshop

Developing Standards of Reporting of Observational Studies in Epidemiology (STROBE)

Department of Social Medicine, University of Bristol

Bristol, United Kingdom

1-3 September, 2004

1. Executive summary

The critical appraisal of medical research is hampered by the inadequate reporting of studies. Reporting guidelines that are adopted by leading medical journals can improve the quality of reporting, as demonstrated by the CONSORT statement for randomised controlled trials. However, no such standards exist in epidemiology.

We convened a workshop with 23 epidemiologists, medical statisticians, methodologists, and journal editors from European countries and the USA in order to initiate the process of developing Standards of Reporting of Observational Studies in Epidemiology (STROBE). The goal of this initiative is to draft a consensus statement for wider dissemination.

The Bristol workshop comprised plenary sessions and parallel work group sessions with the objective to establish a draft checklist of items deemed important for the reporting of observational studies. The focus of this first workshop was on three epidemiological study designs: case-control, cross-sectional, and cohort studies. Later extensions to other study designs, e.g. nested case-control studies, and topic areas, e.g. genetic and molecular epidemiology, are possible and intended. Similarities and differences in the reporting of studies of these different designs were discussed. For each item, participants asked whether its content and wording could be harmonized for all three study designs. Relevant differences in the reporting of either cohort, case-control, or cross-sectional studies were explored. The checklist will follow the structure of a research journal article and will comprise about 25 items. It will be made available on the website www.strobe-statement.org and interested persons will then be invited to comments and criticism. At the workshop, comments, examples etc. were collected for each item to be used in the preparation of a longer explanatory article that will be published together with the checklist.

Several general medical and epidemiology journals were represented at the Bristol workshop and manifested their interest in supporting STROBE. A recent editorial in a general medical journal of wider dissemination further stimulated the interest in this initiative (BMJ 2004;329: 868-9). This ongoing initiative will strengthen the standing of epidemiology, facilitate critical appraisal of reports of observational studies and promote the adequate use of epidemiological evidence.

2. Scientific content of the event

Workshop rationale:

Incomplete and inadequate reporting of research in the medical literature is a widely recognised problem which hampers the critical appraisal and appropriate interpretation of research findings and complicates the practice of evidence-based health care and prevention. An appropriate assessment of study quality is of crucial importance for valid systematic reviews and meta-analyses of experimental as well as observational studies: if the “raw material” is flawed, then the conclusions of reviews will be compromised.

Reporting guidelines that are adopted by leading medical journals can improve the quality of reporting, as demonstrated by the CONSORT statement for randomised controlled trials. In the framework of the European Science Foundation’s (ESF) Exploratory Workshop scheme, we convened a workshop of an interdisciplinary group of epidemiologists, methodologists, medical statisticians and journal editors from several European countries and the USA to launch an initiative to develop reporting guidelines for observational studies including case-control, cohort, and cross-sectional studies.

This first workshop initiated the process of developing reporting standards with the goal to draft a consensus statement (STROBE) for wider dissemination. Improved reporting of epidemiological studies will facilitate critical appraisal and promote the adequate use of research evidence to inform public health policy.

Workshop preparation:

In 2003, the planning committee established a preliminary agenda for a first workshop and started to secure its funding. Also, a comprehensive search in bibliographic databases, reference lists, and personal files for relevant publications including existing reporting guidelines and empirical studies was done.

A major point of initial discussions was the exact scope of the initiative. Since epidemiological research comprises several study designs and multiple topic areas, a

restriction to three major areas, i.e. cohort, case-control, and cross-sectional studies, was considered appropriate for the first workshop. Later extensions of the initiative to other study designs, in particular nested case-control studies, and topic areas, in particular, genetic and molecular epidemiology, are possible and intended.

The planning committee then identified epidemiologists, methodologists, statisticians, researchers involved in observational studies, and editors from major international journals in epidemiology and general medicine and invited about 40 individuals. Twenty-three attended the workshop in the Department of Social Medicine of the University of Bristol / UK in September 2004. A website dedicated to STROBE (www.strobe-statement.org) was implemented and access provided to the collected literature.

Workshop format and process:

The workshop included smaller work groups and plenary sessions. A series of presentations in plenary sessions on the 1st and 2nd day helped to set the scene and to prepare for the following discussions in small groups. For work groups the participants split up first by study design (cohort, case-control, or cross-sectional studies) and second by article section (methods or results). Participants were asked previously to indicate in which of the three groups on study design or two groups of article sections they wished to participate. Each work group was facilitated by a member of the planning committee.

From a longer list of items extracted from the collected literature, a draft list of items for a checklist of reporting standards was prepared for each of the three study designs. The work groups then identified items that they deemed important to be included in a checklist and discussed the content and wording of each item. One participant of each group documented agreed changes to the proposed draft checklist on screen and noted principal points of discussion. Most of the sessions were tape-recorded.

In plenary sessions, results of the three work groups were presented, the three independently elaborated draft checklists were compared and discussed by all participants. For each item, participants asked whether the item content and wording

could be harmonized for all three study designs. Relevant differences in the reporting of either cohort, case-control, or cross-sectional studies were explored.

On the 2nd and 3rd day, participants split into two groups and worked on harmonization of items in either the Introduction and Methods sections or the Results and Discussion sections.

A final plenary session was devoted to the presentation of workshop results and a discussion on further steps and strategies to enhance the acceptance and impact of the initiative. The experience with CONSORT shows that a detailed explanatory document is useful to describe to future users, item by item, the theoretical underpinnings and relevant empirical data and to give concrete examples of good reporting (Altman DG et al. Ann.Intern.Med 2001;134: 663-94). The group agreed that a similar document should be written for STROBE. After posting of a first draft of the STROBE statement on the website, interested epidemiologists, methodologists, statisticians, journal editors, and other people will be invited to comment on the draft statement, suggest examples etc.

3. Assessment of the results, contribution to the future direction of the field, outcome

Summary of achievements:

- A network of interested epidemiologists, methodologists, medical statisticians and journal editors from several European countries and the USA was established.
- A draft checklist was elaborated. The question of flow diagrams could not be tackled due to time constraints.
- For each item, comments, examples etc. were collected to be used in the preparation of a longer explanatory article.
- Appropriate dissemination of the workshop outcome was discussed with editors. Leading journals will support the initiative and will draw the attention of their readers to the STROBE statement.

Agreed action points:

- Circulate draft checklist to all workshop participants and to interested persons who could not attend (*November 2004*).
- Continued collection of relevant literature, in particular empirical studies on the reporting of observational studies (*continues*).
- Collect literature including examples for flow diagrams / charts for reporting of the “flow” of participants in case-control, cross-sectional, and cohort studies (*continues*).
- Prepare comments, notes, examples gathered at the workshop to draft an explanatory paper together with the STROBE statement (*continues*).
- Follow-up meeting of steering group to revise checklist based on collected comments and criticism (*before end of 2004*).
- Posting of mature draft on the web (*January 2005*)

4. Final programme

Wednesday, September 1, 2004 (4 pm – 5:30 pm):

Plenary session:

Introduction *Matthias Egger*

Self-Introduction of participants

Developing standards of reporting – the CONSORT experience *Doug Altman*

Developing Standards of Reporting for Observational Studies in Epidemiology (STROBE) *Matthias Egger*

STROBE - Overview of literature *Erik von Elm*

Short presentation of supporting institutions:
European Science Foundation, MRC Research & Development programme, MRC Health Services Research Collaboration, Swiss National Science Foundation *Erik von Elm*

Thursday, September 2, 2004(9 am – 6 pm):

Plenary session:

Bias in observational epidemiology: Data dredging, bias and confounding *George Davey Smith*

The Quality, Content and Style of Published Observational Epidemiology: A Survey of Recent Practice *Stuart Pocock*

Preliminary proposal for checklists *Matthias Egger*

Work in small groups:

Group 1: Checklist items specific for case-control studies *(facilitator: M. Egger)*

Group 2: Checklist items specific for cohort studies *(facilitator: D. Altman)*

Group 3: Checklist items specific for cross-sectional studies *(facilitator: S. Pocock)*

Plenary session:

Reports from working groups; plenum discussion of drafts

Work in small groups:

Harmonisation of checklist items

Group 1: sections Introduction and Methods *(facilitator: Matthias Egger)*

Group 2: sections Results and Discussion *(facilitator: Doug Altman)*

Friday, September 3, 2004(9am –12am):

Continued work in two small groups:

Harmonisation of checklist items

Group 1: sections Introduction and Methods *(facilitator: Matthias Egger)*

Group 2: sections Results and Discussion *(facilitator: Doug Altman)*

Plenary session:

Presentation of draft checklist items; plenum discussion;

Discussion on further steps to be taken and strategies

5. Final list of participants

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6. Statistical information on participants

Represented countries (by affiliation):

United Kingdom	9
Switzerland	6
USA	3
Germany	2
France	1
Denmark	1
Netherlands	1

Represented countries (by nationality of participants):

United Kingdom	8
Switzerland	3
USA	3
Germany	3
France	1
Denmark	1
Netherlands	1
Brazil	1
Italy	1
Turkey	1

Male / Female participants: 16 / 7

Biomedical journals represented:

Annals of Internal Medicine
British Medical Journal
Bulletin of the World Health Organization
International Journal of Epidemiology
Journal of the American Medical Association
Sozial- und Präventivmedizin
The Lancet