



## STROBE Statement

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Rational health care practices require knowledge about the etiology and pathogenesis, diagnosis, prognosis and treatment of diseases. However, use of hierarchies to grade evidence from various research designs may sometimes lead to erroneous conclusions if applied uncritically. Thus different kind of hierarchies may be used to infer evidence about different research questions (1).

A large amount of clinical or public health knowledge emanates from observational research ranging from knowledge about the transmission of infectious diseases and local outbreaks to the global spread of acquired immunodeficiency virus. All human genetic knowledge is observational-from initial observations of clustering of diseases in families up to molecular linkage analysis. The effects of environmental scourges including smoking, lead exposure in paint or gasoline, or occupationally-induced exposures such as asbestos, have been analyzed in observational research. Further, almost all knowledge on adverse effects of medical interventions derives from observational research as all description of diseases, their definition and their subdivisions. To say the least, most diagnostic and all prognostic research is essentially observational. Time will tell whether "STROBE" which is an acronym for STrengthening Reporting of OBServational Studies in Epidemiology will be able to do to publication of observational research as "CONSORT" (Consolidated Statement of Reporting Trial) has been to clinical trials.

The STROBE initiative (2004) was undertaken by a group of epidemiologists, methodologists, statisticians and editors of journals to facilitate reporting of epidemiological research. As stated earlier, STROBE sprang from the success of CONSORT, a set of guidelines found successful for reporting randomized clinical trials (RCTs).

It is ironic though, not many in medical fraternity seem to be aware of true potential of STROBE. STROBE does have the potential to facilitate understanding of complex phenomena of multi-factorial diseases only if the reporting follows scientific rigor. To reiterate, some research questions are amenable to exploration by observational epidemiology alone.

STROBE is actually a checklist of 22 items concerning three classical approaches in observational epidemiology viz. cross sectional, case control and cohort studies. These items relate to the article's title and abstract (item 1), the introduction (items 2 and 3), methods (items 4-12), results (items 13-17), and discussion sections (items 18-21) and other information (item 22 on funding). Eighteen items are common to all 3 designs, while 4 (items 6, 12, 14, and 15) are design-specific. The STROBE Statement should not be interpreted as an attempt to prescribe the reporting of observational research in a rigid format. The checklist items should be addressed in sufficient detail and with clarity somewhere in an article, but the order and format for presenting information depends on author preferences, journal style, and the traditions of the research field.

Upon realization that STROBE statement does not specifically address genetic linkage studies, infectious disease modeling, case reports and case series (2,3) a flurry of statements appeared focusing on areas left untouched by the STROBE. Therefore we have STREGA (STrengthening the Reporting of Genetic Association studies), GRIPS (Strengthening the reporting of genetic risk prediction studies), STROBE-ME (STrengthening and Reporting of OBServational studies in Epidemiology-Molecular Epidemiology) so forth and so on. It is pertinent to mention that many of the key elements in STROBE apply to these designs as well and

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authors who report such studies may nevertheless find these recommendations useful.

The evolution of STROBE has been breezy but not without hiccoughs e.g., initial drafts referred to S in STROBE as Standard rather than STreng- thening in its current form. Some changes have found favor with experts whereas for others no consensus has been possible. Standard to strengthening has been regarded as meaningful since it takes away the intent to judge. Similarly, an understanding that it is difficult and perhaps unnecessary to have common reporting format for a field as complex and heterogeneous as observational epidemiology is another area consensually agreed upon. Issues like statement of hypothesis is under scrutiny and is currently evading agreement on specificity, underlying rationale and testing. Nonetheless, these and other contentious issues including naturalistic research must be seen as drivers for further improvements in inferring evidence.

Evidence based medicine not only includes generation of evidence employing robust research design but also how the evidence is adjudged and reported before being published. Notwithstanding the relative volume of observational epidemiological research vis-à-vis experimental, much of the evidence generated by it is often is seen much inferior and therefore assigned lesser weight (4). Whatever the reasons may be, the research is better served if the reporting undergoes an overhaul considering that such control over other processes in the generation of evidence are not readily amenable to standardization because of inherent difficulties in conducting observational research.

The statement was published simultaneously in BMJ, Bulletin of the World Health Organization, The Lancet and Preventive Medicine. Longer versions as E & E document (Explanation & Elaboration) were published in Annals of Internal Medicine (5) and PLoS Medicine in year 2007. As stated earlier, it is a 22 item checklist relating to title, abstract, introduction, methods, results and discussion sections of an article addressing three main types of observational studies- cross sectional, case control and cohort. 18 of the items are common to all three research designs with 4 being specific to each one of them.

The collaborators did recognize that the recommendations were likely to be interpreted variously and therefore the statement might be used for purposes not intended. In this context, the authors readiness to share dilemma and trade-offs on some of the elements should be seen as an earnest desire to produce a statement that serves the primary purpose of reporting results in the most effective manner possible. The most important of all was how the statement should not be viewed as a recipe for conducting epidemiological research and least for judging the quality of a study. These fears were not unfounded as evidenced by a recent report by da Costa BR *et al* (6) investigating the use of STROBE for purposes intended and un intended. The authors concluded that STROBE was frequently used inappropriately (appropriateness decided on the basis of original purpose of STROBE) as an instrument to assess methodological quality particularly in areas like meta-analysis and systematic reviews.

In view of the above, it is clear that STROBE is likely to see many more changes before it could be adopted as a yardstick for reporting observational research. The editors however felt that it is opportune time to remind all the readers of this journal to be aware of the potential of the STROBE statement in reporting their research work.

#### References

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