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Langan, S. M.; Schmitt, J.; Coenraads, P. J.; Svensson, A.; von Elm, E.; Williams, H. C.; EDEN

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STROBE and reporting observational studies in dermatology

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The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) initiative (<http://www.strobe-statement.org/>) is a recent major development about which all who undertake and report observational research in dermatology should be aware.¹ The STROBE criteria aim to assess and improve the quality of reporting of epidemiological studies, but are not necessarily a measurement of the quality of the research. Clarity of reporting is a necessary criterion of judging study quality. For example, if a small poorly designed study is clearly reported as such, then at least readers will be able to see its shortcomings, as opposed to being left to guess what exactly was done in the study. One of the challenges authors of scientific articles face is to ensure that readers will understand what was planned, what was done, what the key findings were and what the results mean, so that the research can be interpreted appropriately.

In an international initiative, experts comprising methodologists, researchers and journal editors have, through an involved iterative process, developed clear guidance for authors on how to improve the quality of reporting of observational research. Specific checklists of essential items which should be reported for case-control, cohort and cross-sectional studies have been developed.² Table 1 shows a combined STROBE checklist for reporting of these three types of studies. A recent extension of STROBE has been the development of STrengthening the REporting of Genetic Association studies (STREGA) to improve reporting of genetic epidemiological studies.³

We recently studied the reporting of 183 observational studies that were published in five major dermatology journals between January 2005 and December 2007.⁴ Our focus was on the three study designs covered by a STROBE checklist. Assessment tools, modified from the STROBE checklists for cohort, case-control and cross-sectional studies, were piloted by members of the European Dermato-Epidemiology Network (EDEN) to clarify scoring and interpretation of the checklist items (http://eden.dermis.net/eden/content/e02eden/e01aims/e01programm/index_ger.html). Study articles were randomly allocated to pairs of reviewers and the assessment tools were used to determine the quality of reporting.

Areas where the reporting of observational dermatology studies was quite good (in more than 80% of articles) included reporting of key results in relation to study objectives detailing the scientific background and rationale for carrying out the study, summarizing the research in the abstract, and describing study objectives, design and outcomes.

Significant areas of concern identified in the study included sample size calculations, description and management of missing data, details of losses to follow-up, statistical methods and the role of funders in the research.

Our survey of epidemiology studies from the dermatology literature underscores the need to improve the reporting of observational studies overall. Specifically, there is a need to focus on improving the reporting of the methods sections of such papers. These sections are critically important as they allow readers to determine whether bias and confounding may have impacted the study conclusions. Poor reporting limits the readers' ability to assess the strengths and limitations of the data and to interpret and use the research findings appropriately. The latter includes secondary data analysis such as meta-analysis. It is also worth remembering the duty of researchers to give a faithful presentation of the results of their research in the public forum. The Helsinki Declaration emphasizes that authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. 'Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports' (Declaration of Helsinki: Basic Principles for all Medical Research).

Reporting guidelines have helped improve the quality of reporting of studies in the dermatology literature. For example, after the introduction of the Consolidated Standards for Reporting Trials (CONSORT) guidelines improvements in reporting of randomized controlled trials (RCTs) in dermatology were found.^{5,6} Adetugbo and Williams⁷ reported significant deficiencies in the reporting of RCTs in the dermatology literature between 1976 and 1997 and recommended the adoption of the CONSORT guidelines by dermatology journals. Alvarez et al.⁸ in 2009 reported an improvement in the reporting of dermatology RCTs in two selected journals between those published in 1997 and in 2006 after introduction of the CONSORT guidelines by those journals.

We believe the STROBE criteria are an excellent resource to guide authors, editors, peer reviewers and readers/users of the dermatology scientific literature. As from 1 January 2011, the BJD will request all authors submitting articles based on an observational study design to comply with the STROBE guidelines.

The BJD is proud of its tradition of publishing interesting and important epidemiological articles in the field of dermatology. Adoption of the STROBE guidelines can only serve to strengthen the quality of reporting and interpretability of such articles.

Table 1 STROBE statement: checklist of items that should be included in reports of observational studies

	Item no.	Recommendation
Title and abstract	1	1 Indicate the study's design with a commonly used term in the title or the abstract
		2 Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	1 Cohort study – Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study – Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study – Give the eligibility criteria, and the sources and methods of selection of participants
		2 Cohort study – For matched studies, give matching criteria and number of exposed and unexposed Case-control study – For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8 ^a	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	1 Describe all statistical methods, including those used to control for confounding 2 Describe any methods used to examine subgroups and interactions 3 Explain how missing data were addressed 4 Cohort study – If applicable, explain how loss to follow-up was addressed Case-control study – If applicable, explain how matching of cases and controls was addressed Cross-sectional study – If applicable, describe analytical methods taking account of sampling strategy
		5 Describe any sensitivity analyses
Results		
Participants	13 ^a	1 Report numbers of individuals at each stage of study – e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed 2 Give reasons for nonparticipation at each stage 3 Consider use of a flow diagram
Descriptive data	14 ^a	1 Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders 2 Indicate number of participants with missing data for each variable of interest 3 Cohort study – Summarize follow-up time (e.g. average and total amount)
Outcome data	15 ^a	Cohort study – Report numbers of outcome events or summary measures over time Case-control study – Report numbers in each exposure category, or summary measures of exposure Cross-sectional study – Report numbers of outcome events or summary measures
Main results	16	1 Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included 2 Report category boundaries when continuous variables were categorized 3 If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done – e.g. analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarize key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalizability	21	Discuss the generalizability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

^aGive information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Department of Dermatology,
University of Pennsylvania,
Philadelphia, PA 19103, U.S.A.

*Department of Dermatology,
TU Dresden,
01307 Dresden, Germany

†Department of Dermatology,
University Hospital
Groningen, 9700 RB Groningen,
the Netherlands

‡Department of Dermatology,
Malmö University Hospital,
SE-205 02 Malmö, Sweden

§Department of Health Science & Policy,
University of Lucerne, Lucerne, Switzerland

¶Department of Dermatology,
Queen's Medical Centre,
Nottingham NG7 2UH, U.K.
E-mail: sineadlangan@hotmail.com

S.M. LANGAN

J. SCHMITT*

P.J. COENRAADS†

A. SVENSSON‡

E. VON ELM§

H.C. WILLIAMS¶

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DERMATO-EPIDEMIOLOGY
NETWORK (EDEN)

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Conflicts of interest

None declared.