STROBE Long list of items extracted from previous recommedations (for discussion in Bristol, Sept 2004)			
PAPER SECTION ***Topic***	**Description**	**Reference #** **Key:** 1=Bracken; 2=CONSORT; 3=Wolfe; 4=Carson; 5=Lichtenstein; 6=Margetts; 7=MOOSE; 8=IRLG Guidelines **(Full ref. listed at bottom of table)**	**Comments**
TITLE & ABSTRACT			
	(To be defined)	-	
INTRODUCTION / BACKGROUND			
Study rationale	State research question and importance.	3	
	Is the literature review current and complete?	1	
	Pertinent scientific background (literature reviews, supporting rationale)	8	
METHODS			
Objectives / hypothesis	Specific objectives and hypotheses.	2	
	Has the specific hypothesis being addressed by the study been made explicit?	1	
	Hypothesis statement	7	
	A statement of the research question	5	
	Problem definition	7	
	Statement whether hypotheses are being generated or tested	8	
Study design	Has the research design been clearly identified?	1	
	Is it a design which can challenge the study hypothesis?	1	
	Prospective, retrospective or mixed.	3	
	Type of study designs used	7	
	Study design / underlying assumptions / limitations of design in relation to stated objectives	8	
Outcomes	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	2	
	Description of study outcome(s)	7	
	Describe principal und subsidiary outcome measures	3	
	Has the way in which outcome was assessed been clearly described?	6	
Exposure	Information on exposure (duration, intensity)	5	
	Type of exposure or intervention used	7	
Study population	Is the reference population clearly defined?	6	
	Identification of the source of cases and controls	5	
	Is it clear how the sample relates to the reference population and what inclusion criteria have been used?	6	
	True population-based, catchment population or consecutive series.	3	
	Describe calendar time, geographic, referral and access factors.	3	
	Study population	7	
	Specified population from which study and comparison subjects were drawn, and method of selection	8	
Participants	Eligibility criteria for participants and the settings and locations where the data were collected.	2	
	Describe minimal criteria and when criteria were satisfied?	3	
	Were the criteria for inclusion and exclusion specified?	4	
	Exclusion criteria for cases and controls	5	
	Is there a clear exposition of how the study groups were initially identified or selected?	1	
	Method of case and control identification and selection	3	
	Rationale and criteria for the inclusion and exclusion of subjects	8	
	Was the selection process for patient enrolment specified?	4	
	A description of the sampling technique	5	
	Is there a clear exposition of how the study groups were approached for entry into the study?	1	
	Was it possible to determine whether the study institution was a referral center?	4	
	Information on whether the cases are incident or prevalent	5	
	Describe timing of recruitment in relation to disease onset: cases followed from disease onset, cases followed from first presentation, or prevalent cases	3	
	Diagnostic procedure used to identify cases	5	
	Is there a clear exposition of how the study groups were diagnosed or assessed?	1	
	Is there a clear exposition of how the study groups were confirmed in their diagnosis (of exposure or disease)?	1	
	Were the patients uniformly identified at presentation (i.e., at the same stage in the disease process)?	4	

	Was any comparative information obtained for the patients who were not enrolled in the study?	4	
	Has diagnosis been confirmed? (...) Have unconfirmed cases been excluded?	6	
	A statement of the non-response rate	5	
	What is the response rate in those asked to participate?	6	
Study groups	If study groups were 'matched', have the rationale and detailed criteria for matching, and success (i.e. number of cases not matched) been provided?	1	
	Information on the matching procedure, if used	5	
	If multiple control groups have been used, has the assembly of each group and its rationale been made explicit?	1	
	If control groups represent a population sample, have sampling fractions and full details of other sampling criteria been provided?	1	
	If hospital controls rather than healthy controls have been used, has the rationale been stated and reassurance given that this forms an unbiased control group?	1	
	If historical rather than concurrent controls have been used, has it been explained why this does not introduce bias into the study?	1	
	The appropriateness and possible limitations of the comparison groups	8	
	The methods used to classify study and comparison subjects according to the degree of exposure and the presence or absence of specific diseases	8	
Sample size	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	2	
	Have sample size calculations performed before the study in order to determine the required number of subjects been presented?	1	
	Indicate the power to detect clinically meaningful change.	3	
	Has the statistical power of the study been assessed a priori?	6	
Data collection	Were special data collection forms or existing records used, were interviewers trained in collecting data, were they aware of the study hypothesis and the status of the individuals being interviewed? What steps were taken to avoid 'interviewer bias'?	1	
	Indicate means of follow-up data collection (clinical interview, questionnaire, mail or telephone)	3	
	Was a structured data collection instrument used, was the interview conducted in a standard way, and were all interviews conducted in the same environment (home or delivery ward, for example)?	1	
	Has the timing of the interview with respect to the respondents' knowledge of their diagnosis, or exposure, been described?	1	
	Information on the method of data collection (interviewer, self administered questionnaire, record review)	5	
	Specify data collected at baseline	3	
	Distinguish between items ascertained from routine medical records and those collected prospectively using a standard proforma	3	
	Provide data on reliability and validity of instruments and study assessments	3	
	validity (accuracy) and reliability (reproducibility) of the methods used to determine exposure and disease status	8	
	Have the precise questions used in the interview in order to ascertain exposures of special interest been reported? Have measures of 'duration' and 'recency' been described?	1	
	Have the methods for grading the exposure to an agent, or the intensity of a treatment manoeuvre or the stage of illness been described adequately?	1	
	Rationale and criteria for disease and exposure classification	8	
	If an interviewer or record review were used, information on whether or not these observers were blinded to the status of cases and controls	5	
	Report number of observers, nature of training, observer variability and blindness	3	
	A statement of whether or not the controls undergo the same diagnostic procedures as the cases	5	
Confounding / effect modification	Has the measurement of important confounding or effect modifying variables been described so the reader can judge how they have been controlled?	1	
	Information on the presence of possible confounding variables	5	
	Assessment of confounding (e.g., comparability of cases and controls in studies where appropriate)	7	
Follow-up	Indicate means of follow-up data collection (clinical examination, clinic interview, questionnaire, mail or telephone)	3	
	Has reassurance been provided that the follow-up of all study groups to ascertain study outcomes has been unbiased?	1	
	Have all subjects been accounted for at follow-up?	1	
	Were all the patients who were initially entered into the study accounted for in the results?	4	
	Specify frequency of follow-up, decision rules about timing of assessments	3	
Bias	Information on the investigation of possible sources of bias	5	

	If different classifications are applied to the various groups under study, the effect of the different procedures and an assessment of potential bias	8	
	The extent to which the choice of subjects depends upon existing or specially developed record systems	8	
	If different procedures are used to classify exposure or health status of study versus comparison subjects, the potential effects of these different procedures on the validity of or inferences from study results.	8	
	Direction and possible magnitude of any bias introduced into the study results by differing response or follow-up rates, indication of whether determined by a sub-sample or solely by judgment.	8	
	Methods applied to ensure completeness and validity of collected data, e.g., procedures for avoiding bias and for addressing the independent ascertainment and classification of study variables	8	
Statistical methods	Describe rationale for statistical methodology	3	
	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	2	
	Where appropriate, perform sensitivity analyses to account for loss to follow-up.	3	
	Specify strategies used to limit missing data, and to analyze missing data und loss to follow-up.	3	
	If a statistical model is generated, indicate performance in a validation sample.	3	
	Describe key model assumptions.	3	
	When appropriate, a statement of the underlying assumptions of the procedures and statistical methods used	8	
	Information on the methods used for dealing with confounding variables	5	
	Methods used to account for confounding factors, e.g. adjustment or matching.	8	
	Utilize appropriate time dependent variable based analyses and survey methods.	3	
	A description of the analytic methods	5	
	Description of statistical methods (...) in sufficient detail to be replicated	7	
	Reference to the literature and / or specific formulae for statistical tests	8	
	Reference if established programming procedures or statistical packages are applied	8	
	If new or modified methods are used in a study, a description of the method(s), including limitations and advantages	8	
	Description of the procedures and statistical methods used to detect and measure the direction and magnitude of possible bias, e.g., selection bias.	8	
	Description of the methods to account for missing data, such as from non-response or attrition	8	
Ethics	Was the study conducted in an ethical manner?	1	
	Steps taken to ensure confidentiality and privacy of both the study and comparison subjects	8	
RESULTS			
Baseline data	Baseline demographic and clinical characteristics of each group.	2	
	Describe demographic und baseline characteristics of participants	3	
Participant flow	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants (...) , completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from stud	2	
	For each stage of the study, from first identification to assessment of eligibility, interview, and entry into analysis, has the number of subjects included or excluded been tabulated?	1	
	Was the vital status of all patients reported?	4	
	Number of participants (denominator) in each group included in each analysis (...). State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	2	
	Full description of missing patients at each stage of follow-up	3	
	Describe missing data and missing subjects	3	
	Completeness and length of follow-up for each group or subgroup of subjects	8	
	Dates defining the periods of recruitment and follow-up.	2	
	How complete is the follow-up of subjects?	6	
	For how long have subjects been followed up?	6	
	Response rates, including the reasons for and implications of differential response.	8	
	Procedures used for following study and comparison subjects in reports of cohort studies	8	
Statistical reporting	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval).	2	

	Has the basic contingency table for the study been reported (or can it be reconstructed)? Have correct measures of association been reported?	1	
	Do measures of association (e.g. relative risks, odds ratios) have their confidence intervals reported? Are mean values accompanied by a measure of variance (standard deviation or standard error)?	1	
	Presentation of confidence limits	5	
	Indication of statistical uncertainty of findings	7	
	Were any statistical tests used?	4	
	When reporting hypothesis tests, the measure of effect, statistical significance, power, and other criteria, such as the reason for choosing either one- or two-tailed tests.	8	
	With estimation, the point estimates and their standard errors and/or confidence intervals	8	
	Have unadjusted results been presented?	6	
	Where data are grouped, do these form natural cut-off points, or do they suggest that they have been created to 'force' an association?	1	
	If the study groups were 'matched', has the appropriate analysis been done?	1	
	Has an analysis of potential confounding or effect modification of the principal relations been presented? Have potentially important synergistic effects been explored in the analysis?	1	
	Have important multivariable analyses been reported in tabular form (e.g. showing the data stratified across important variables), or as summaries of regression analyses (linear logistic or log linear models)?	1	
	Was adjustment for extraneous prognostic factors carried out?	4	
	Were mortality rates (for different follow-up time periods in the study) and/or Cox proportional hazards models used in the analysis?	4	
	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	2	
	An evaluation of the presence and effect of potential confounding factors, e.g. age, sex, ethnic group, life style	8	
	Description of any special or unusual handling of data, such as combining of subgroups of study or comparison subjects when multiple resources of data are used, e.g., data from multiple investigators or multiple populations.	8	
Adverse events	All important adverse events or side effects in each (...) group. *(relevant to observational studies?)*	2	
DISCUSSION			
Interpretation	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	2	
	Is the conclusion based on the analysis? Are the conclusions overly liberal (e.g. stated as being 'strongly suggestive', or 'highly significant') when the data more properly suggest a chance finding? Alternatively, have important observations been ignored	1	
	A statement of the conclusions reached from the data	5	
	Have statistical associations been distinguished from causal relations? Have competing explanations for the study outcome been discussed?	1	
	Are there additional statistical analyses which the investigators could do to test competing explanations?	1	
	Is 'clinical significance' discussed in a manner which separates it from 'statistical significance'?	1	
	Has the power of the completed study to detect differences been reviewed?	1	
	Has discussion of a priori hypotheses been separated from discussion of ex post facto hypotheses?	1	
	Identify and discuss possible sources of bias and misinterpretation	3	
	Discussion of assumptions underlying the methods, the rationale for their use, and the direction and magnitude of any important anticipated bias.	8	
	Consideration of alternative explanations for observed results	7	
Generalizability	Have the study results been placed in context of existing findings? Have the reasons for differences with previous work been discussed? Have fairly precise directions been given for future hypothesis testing?	1	
	Generalizability (external validity) of the (...) findings.	2	
	Generalization of the conclusions (i.e., appropriate for the data presented and within the domain of the literature review)	7	
Overall evidence	Guidelines for future research	7	
	General interpretation of the results in the context of current evidence.	2	
	If policy implications have been drawn from the data, have they been justified?	1	
Funding	Disclosure of funding source	7	

Data storage	Data and supporting documentation should be retained in sufficient detail so that they can be made available for independent peer review. Such documentation could include data collection instruments, computer programs, and descriptions of facilities or procedures. (...) it is imperative that the basic data from which a final paper was written be retained for reasonable periods of time.	8	

References:

1. Bracken MB. Reporting observational studies. *Br.J.Obstet.Gynaecol.* 1989/04// 1989;96(4):383-388.

2. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet.* Apr 14 2001;357(9263):1191-1194.

3. Wolfe F, Lassere M, van der HD, et al. Preliminary core set of domains and reporting requirements for longitudinal observational studies in rheumatology. *J.Rheumatol.* 1999/02// 1999;26(2):484-489.

4. Carson CA, Fine MJ, Smith MA, Weissfeld LA, Huber JT, Kapoor WN. Quality of published reports of the prognosis of community-acquired pneumonia. *J.Gen.Intern.Med.* 1994/01// 1994;9(1):13-19.

5. Lichtenstein MJ, Mulrow CD, Elwood PC. Guidelines for reading case-control studies. *J.Chronic.Dis.* 1987/// 1987;40(9):893-903.

6. Margetts BM, Thompson RL, Key T, et al. Development of a scoring system to judge the scientific quality of information from case-control and cohort studies of nutrition and disease. *Nutr.Cancer.* 1995/// 1995;24(3):231-239.

7. Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. *Jama.* Apr 19 2000;283(15):2008-2012.

8. Anonymous. Guidelines for documentation of epidemiologic studies. Epidemiology Work Group of the Interagency Regulatory Liaison Group. *Am.J.Epidemiol.* 1981/11// 1981;114(5):609-613.