REGOLAMENTO del CENTRO STUDI AIPO

1. ISTITUZIONE

Il Centro Studi (CS) AIPO è istituito con delibera del Consiglio Direttivo AIPO, in attuazione di quanto previsto dai programmi associativi. La sua organizzazione è definita dal presente regolamento.

2. FINALITA'

Il CS è la struttura tecnica dell'Associazione alla quale compete la progettazione e l'implementazione di studi clinici, dei registri di patologia, delle ricerche epidemiologiche e di altri strumenti per il miglioramento continuo della qualità, nonché la revisione metodologica e scientifica delle indagini e delle ricerche promosse dall'Associazione.

3. ORGANO DI GESTIONE

Il CS è coordinato dal Direttore Scientifico con funzioni di supervisione gestionale e di programmazione, che si avvale come organo tecnico della Direzione Generale di AIPO.
Fanno parte dell'Organo di Gestione del CS con funzione di programmazione anche:

- i Responsabili delle Aree Scientifiche;
- il Responsabile della Scuola di Formazione;
- il Responsabile dell'Editoria;
- il Responsabile della BIMP.

L'organo di gestione del CS si riunisce con cadenza semestrale ed è convocato dal Direttore Scientifico.
Il Direttore Scientifico del CS è nominato dal Consiglio Direttivo AIPO su proposta del Comitato Esecutivo e dura in carica due anni, eventualmente rinnovabili per altri due in considerazione della durata pluriennale dei progetti di ricerca.
Il Presidente Nazionale, il Presidente Eletto ed il Past Presidente di AIPO, partecipano di diritto agli incontri dell'organo di gestione.
Il Direttore del CS dovrà presentare semestralmente al Consiglio Direttivo AIPO i progetti e le attività del CS in fase di sviluppo e/o di realizzazione.

Il Direttore Scientifico del CS può coinvolgere esperti e studiosi (Internisti, Colleghi di altre specialità mediche, Infermieri, ecc.) e/o consulenti con particolari competenze (statistica medica, informatica, comunicazione, ecc.) utili al raggiungimento degli obiettivi di progetto.
Il Direttore Scientifico del CS, per specifiche attività, può nominare un Responsabile di Progetto con funzioni di Collaboratore del CS.
Il Direttore Scientifico coordina la programmazione del CS avvalendosi della collaborazione dei Responsabili di Area Scientifica AIPO e quest'ultimi dei Responsabili dei Gruppi di Studio.

4. METODOLOGIA DI LAVORO

La metodologia di lavoro per la progettazione degli studi clinici del CS fa riferimento alle Linee Guida e agli standard internazionali, alla Good Clinical Practice, nonché a tutti i riferimenti cogenti in vigore ed alla normativa AIFA per gli studi clinici e alle Linee Guida AIFA per la conduzione degli studi osservazionali.
Per quanto riguarda la produzione dei report adotta gli standard:

- CONSORT - *Consolidated Standards of Reporting Trials*, per la redazione di report in merito agli studi clinici di tipo interventistici (allegato 1);
- STROBE - *The Strengthening the Reporting of Observational Studies in Epidemiology*, per la reportistica degli studi osservazionali e dei registri (allegato 2).

5. MODALITA' DI PRESENTAZIONE DEI PROGETTI

Ogni singolo Ricercatore deve proporre programmi e progetti di ricerca al CS AIPO attraverso i Responsabili dei Gruppi di Studio e questi attraverso i Responsabili di Area Scientifica.
I programmi e i progetti di ricerca devono essere trasmessi al CS entro 30 gg.
I progetti, per essere valutati dall'organo di gestione, devono possedere i requisiti di validità e fattibilità e devono essere presentati su apposito modello (allegato 3) ed inviati all'indirizzo: aipocentrostudi@aiporicerche.it.
I progetti vengono approvati dal Direttore Scientifico del CS sentito il parere dell'organo di gestione e ratificati dal Presidente.
I progetti che prevedono la collaborazione ed il sostegno economico di soggetti esterni (aziende, consulenti, ecc.) e che necessitano la definizione di contratti vengono demandati per gli aspetti formali alla Struttura Tecnica.

6. *STRUTTURA TECNICA*

Il Centro Studi è dotato di una Struttura Tecnica che viene fornita da AIPO Ricerche Srl.
AIPO Ricerche Srl è un'organizzazione certificata da AIFA (CRO ID 192) per il coordinamento ed il management delle sperimentazioni cliniche di medicinali e dei progetti di ricerca clinica (allegato 4).

Annals of Internal Medicine | Academia and Clinic

CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomized Trials

Kenneth F. Schulz, PhD, MBA; Douglas G. Altman, DSc; and David Moher, PhD for the CONSORT Group*

The CONSORT (Consolidated Standards of Reporting Trials) statement is used worldwide to improve the reporting of randomized, controlled trials. Schulz and colleagues describe the latest version, CONSORT 2010, which updates the reporting guideline based on new methodological evidence and accumulating experience.

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For author affiliations, see end of text.

* For the CONSORT Group contributors to CONSORT 2010, see the Appendix, available at www.annals.org.

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Editor's Note: In order to encourage dissemination of the CONSORT 2010 Statement, this article is freely accessible on www.annals.org and will also be published in BMJ, The Lancet, Obstetrics & Gynecology, PLoS Medicine, Open Medicine, Journal of Clinical Epidemiology, BMC Medicine, *and* Trials. *The authors jointly hold the copyright of this article. For details on further use, see the CONSORT Web site (www.consort-statement.org).*

Randomized, controlled trials, when appropriately designed, conducted, and reported, represent the gold standard in evaluating health care interventions. However, randomized trials can yield biased results if they lack methodological rigor (1). To assess a trial accurately, readers of a published report need complete, clear, and transparent information on its methodology and findings. Unfortunately, attempted assessments frequently fail because authors of many trial reports neglect to provide lucid and complete descriptions of that critical information (2–4).

That lack of adequate reporting fueled the development of the original CONSORT (Consolidated Standards of Reporting Trials) statement in 1996 (5) and its revision 5 years later (6–8). While those statements improved the reporting quality for some randomized, controlled trials (9, 10), many trial reports still remain inadequate (2). Furthermore, new methodological evidence and additional experience has accumulated since the last revision in 2001. Consequently, we organized a CONSORT Group meeting to update the 2001 statement (6–8). We introduce here the result of that process, CONSORT 2010.

Intent of CONSORT 2010

The CONSORT 2010 Statement is this paper, including the 25-item checklist in the **Table** and the flow diagram (**Figure**). It provides guidance for reporting all randomized, controlled trials but focuses on the most common design type—individually randomized, 2-group, parallel trials. Other trial designs, such as cluster randomized trials and noninferiority trials, require varying amounts of additional information. CONSORT extensions for these designs (11, 12), and other CONSORT products, can be found through the CONSORT Web site (www.consort-statement.org). Along with the CONSORT statement, we have updated the explanation and elaboration article (13), which explains the inclusion of each checklist item, provides methodological background, and gives published examples of transparent reporting.

Diligent adherence by authors to the checklist items facilitates clarity, completeness, and transparency of reporting. Explicit descriptions, not ambiguity or omission, best serve the interests of all readers. Note that the CONSORT 2010 Statement does not include recommendations for designing, conducting, and analyzing trials. It solely addresses the reporting of what was done and what was found.

Nevertheless, CONSORT does indirectly affect design and conduct. Transparent reporting reveals deficiencies in research if they exist. Thus, investigators who conduct inadequate trials, but who must transparently report, should not be able to pass through the publication process without revelation of their trials' inadequacies. That emerging reality should provide impetus to improved trial design and conduct in the future, a secondary indirect goal of our work. Moreover, CONSORT can help researchers in designing their trial.

Background to CONSORT

Efforts to improve the reporting of randomized, controlled trials accelerated in the mid-1990s, spurred partly by methodological research. Researchers had shown for many years that authors reported such trials poorly, and empirical evidence began to accumulate that some poorly conducted or poorly reported aspects of trials were associated with bias (14). Two initiatives aimed at developing reporting guidelines culminated in one of us (D.M.) and Drummond Rennie organizing the first CONSORT statement in 1996 (5). Further methodological research on similar topics reinforced earlier findings (15) and fed into the

See also:

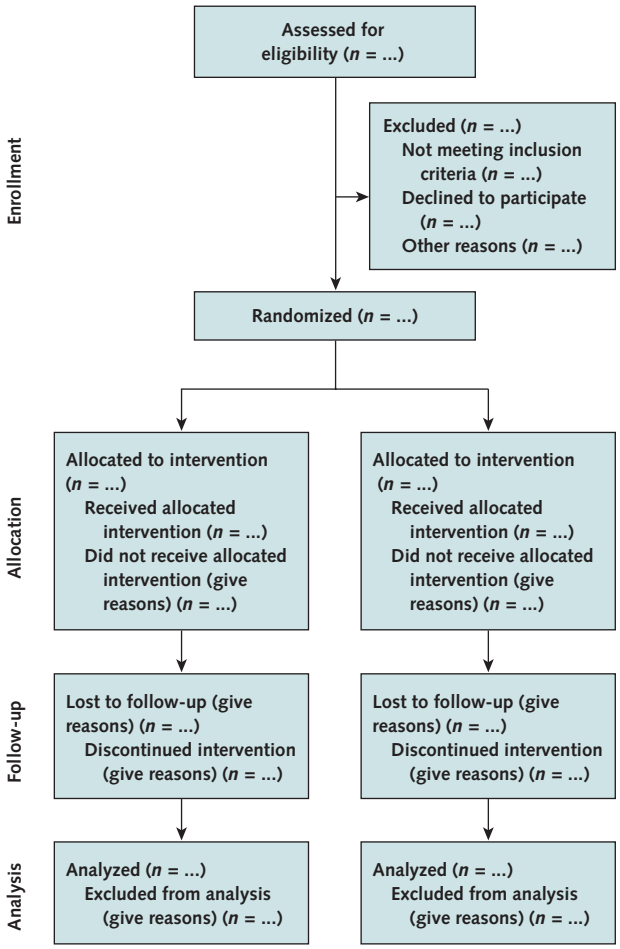
Web-Only
Appendix
Conversion of graphics into slides

Table. **CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial***

Section/Topic	Item Number	Checklist Item	Reported on Page Number
Title and abstract	1a	Identification as a randomized trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts [21, 31])	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial), including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomization			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	
	13b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms [28])	
Discussion			
Limitations	20	Trial limitations; addressing sources of potential bias; imprecision; and, if relevant, multiplicity of analyses	
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

* We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration (13) for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials (11), noninferiority and equivalence trials (12), nonpharmacologic treatments (32), herbal interventions (33), and pragmatic trials (34). Additional extensions are forthcoming: For those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

Figure. **Flow diagram of the progress through the phases of a parallel randomized trial of 2 groups (that is, enrollment, intervention allocation, follow-up, and data analysis).**



revision of 2001 (6–8). Subsequently, the expanding body of methodological research informed the refinement of CONSORT 2010. More than 700 studies comprise the CONSORT database (located on the CONSORT Web site), which provides the empirical evidence to underpin the CONSORT initiative.

Indeed, CONSORT Group members continually monitor the literature. Information gleaned from these efforts provides an evidence base on which to update the CONSORT statement. We add, drop, or modify items based on that evidence and the recommendations of the CONSORT Group, an international and eclectic group of clinical trialists, statisticians, epidemiologists, and biomedical editors. The CONSORT Executive (K.F.S., D.G.A., D.M.) strives for a balance of established and emerging researchers. The membership of the group is dynamic. As our work expands in response to emerging projects and needed expertise, we invite new members to contribute. As such, CONSORT continually assimilates new ideas and perspectives. That process informs the continually evolving CONSORT statement.

Over time, CONSORT has garnered much support. More than 400 journals, published around the world and in many languages, have explicitly supported the CONSORT statement. Many other health care journals support it without our knowledge. Moreover, thousands more have implicitly supported it with the endorsement of the CONSORT statement by the International Committee of Medical Journal Editors (www.icmje.org). Other prominent editorial groups, the Council of Science Editors and the World Association of Medical Editors, officially support CONSORT. That support seems warranted: When used by authors and journals, CONSORT seems to improve reporting (9).

Development of CONSORT 2010

Thirty-one members of the CONSORT 2010 Group met in Montebello, Quebec, Canada, in January 2007 to update the 2001 CONSORT statement. In addition to the accumulating evidence relating to existing checklist items, several new issues had come to prominence since 2001. Some participants were given primary responsibility for aggregating and synthesizing the relevant evidence on a particular checklist item of interest. Based on that evidence, the group deliberated the value of each item. As in prior CONSORT versions, we kept only those items deemed absolutely fundamental to reporting a randomized, controlled trial. Moreover, an item may be fundamental to a trial but not included, such as approval by an institutional ethical review board, because funding bodies strictly enforce ethical review and medical journals usually address reporting ethical review in their instructions for authors. Other items may seem desirable, such as reporting on whether on-site monitoring was done, but a lack of empirical evidence or any consensus on their value cautions against inclusion at this point. The CONSORT 2010 Statement thus addresses the minimum criteria, although that should not deter authors from including other information if they consider it important.

After the meeting, the CONSORT Executive convened teleconferences and meetings to revise the checklist. After 7 major iterations, a revised checklist was distributed to the larger group for feedback. With that feedback, the executive met twice in person to consider all the comments and to produce a penultimate version. That served as the basis for writing the first draft of this paper, which was then distributed to the group for feedback. After consideration of their comments, the executive finalized the statement.

The CONSORT Executive then drafted an updated explanation and elaboration manuscript, with assistance from other members of the larger group. The substance of the 2007 CONSORT meeting provided the material for

Box 1. **Noteworthy general changes in the CONSORT 2010 Statement.**

We simplified and clarified the wording, such as in items 1, 8, 10, 13, 15, 16, 18, 19, and 21.

We improved consistency of style across the items by removing the imperative verbs that were in the 2001 version.

We enhanced specificity of appraisal by breaking some items into subitems. Many journals expect authors to complete a CONSORT checklist indicating where in the manuscript the items have been addressed. Experience with the checklist noted pragmatic difficulties when an item comprised multiple elements. For example, item 4 addresses eligibility of participants and the settings and locations of data collection. With the 2001 version, an author could provide a page number for that item on the checklist but might have reported only eligibility in the paper, for example, and not reported the settings and locations. CONSORT 2010 relieves obfuscations and forces authors to provide page numbers in the checklist for both eligibility and settings.

the update. The updated explanation and elaboration manuscript was distributed to the entire group for additions, deletions, and changes. That final iterative process converged to the CONSORT 2010 Explanation and Elaboration (13).

Changes in CONSORT 2010

The revision process resulted in evolutionary, not revolutionary, changes to the checklist (**Table**), and the flow diagram was not modified except for 1 word (**Figure**). Moreover, because other reporting guidelines augmenting the checklist refer to item numbers, we kept the existing items under their previous item numbers except for some renumbering of items 2 to 5. We added additional items either as a subitem under an existing item, an entirely new item number at the end of the checklist, or (with item 3) an interjected item into a renumbered segment. We have summarized the noteworthy general changes in **Box 1** and specific changes in **Box 2**. The CONSORT Web site contains a side-by-side comparison of the 2001 and 2010 versions.

Implications and Limitations

We developed CONSORT 2010 to assist authors in writing reports of randomized, controlled trials, editors and peer reviewers in reviewing manuscripts for publication, and readers in critically appraising published articles. The CONSORT 2010 Explanation and Elaboration provides elucidation and context to the checklist items. We strongly recommend using the explanation and elaboration in conjunction with the checklist to foster complete, clear, and transparent reporting and aid appraisal of published trial reports.

CONSORT 2010 focuses predominantly on the 2-group, parallel randomized, controlled trial, which accounts for over half of trials in the literature (2). Most of the items from the CONSORT 2010 Statement, however, pertain to all types of randomized trials. Nevertheless, some types of trials or trial situations dictate the need for additional information in the trial report. When in doubt, authors, editors, and readers should consult the CONSORT Web site for any CONSORT extensions, expansions (amplifications), implementations, or other guidance that may be relevant.

The evidence-based approach we have used for CONSORT also served as a model for development of other reporting guidelines, such as for reporting systematic reviews and meta-analyses of studies evaluating interventions (16), diagnostic studies (17), and observational studies (18). The explicit goal of all these initiatives is to improve reporting. The Enhancing the Quality and Transparency of Health Research (EQUATOR) Network will facilitate development of reporting guidelines and help disseminate the guidelines: www.equator-network.org provides information on all reporting guidelines in health research.

With CONSORT 2010, we again intentionally declined to produce a rigid structure for the reporting of randomized trials. Indeed, Standards of Reporting Trials (SORT) (19) tried a rigid format, and it failed in a pilot run with an editor and authors (20). Consequently, the format of articles should abide by journal style; editorial directions; the traditions of the research field addressed; and, where possible, author preferences. We do not wish to standardize the structure of reporting. Authors should simply address checklist items somewhere in the article, with ample detail and lucidity. That stated, we think that manuscripts benefit from frequent subheadings within the major sections, especially the methods and results sections.

CONSORT urges completeness, clarity, and transparency of reporting, which simply reflects the actual trial design and conduct. However, as a potential drawback, a reporting guideline might encourage some authors to report fictitiously the information suggested by the guidance rather than what was actually done. Authors, peer reviewers, and editors should vigilantly guard against that potential drawback and refer, for example, to trial protocols, to information on trial registers, and to regulatory agency Web sites. Moreover, the CONSORT 2010 Statement does not include recommendations for designing and conducting randomized trials. The items should elicit clear pronouncements of how and what the authors did, but do not contain any judgments on how and what the authors should have done. Thus, CONSORT 2010 is not intended as an instrument to evaluate the quality of a trial. Nor is it appropriate to use the checklist to construct a "quality score."

Box 2. **Noteworthy specific changes in the CONSORT 2010 Statement.**

Item 1b (title and abstract)—We added a subitem on providing a structured summary of trial design, methods, results, and conclusions and referenced the CONSORT for abstracts article (21).

Item 2b (introduction)—We added a new subitem (formerly item 5 in CONSORT 2001) on "Specific objectives or hypotheses."

Item 3a (trial design)—We added a new item including this subitem to clarify the basic trial design (such as parallel group, crossover, cluster) and the allocation ratio.

Item 3b (trial design)—We added a new subitem that addresses any important changes to methods after trial commencement, with a discussion of reasons.

Item 4 (participants)—Formerly item 3 in CONSORT 2001.

Item 5 (interventions)—Formerly item 4 in CONSORT 2001. We encouraged greater specificity by stating that descriptions of interventions should include "sufficient details to allow replication" (3).

Item 6 (outcomes)—We added a subitem on identifying any changes to the primary and secondary outcome (end point) measures after the trial started. This followed from empirical evidence that authors frequently provide analyses of outcomes in their published papers that were not the prespecified primary and secondary outcomes in their protocols, while ignoring their prespecified outcomes (that is, selective outcome reporting) (4, 22). We eliminated text on any methods used to enhance the quality of measurements.

Item 9 (allocation concealment mechanism)—We reworded this to include mechanism in both the report topic and the descriptor to reinforce that authors should report the actual steps taken to ensure allocation concealment rather than simply report imprecise, perhaps banal, assurances of concealment.

Item 11 (blinding)—We added the specification of how blinding was done and, if relevant, a description of the similarity of interventions and procedures. We also eliminated text on "how the success of blinding (masking) was assessed" because of a lack of empirical evidence supporting the practice, as well as theoretical concerns about the validity of any such assessment (23, 24).

Item 12a (statistical methods)—We added that statistical methods should also be provided for analysis of secondary outcomes.

Subitem 14b (recruitment)—Based on empirical research, we added a subitem on "Why the trial ended or was stopped" (25).

Item 15 (baseline data)—We specified "A table" to clarify that baseline and clinical characteristics of each group are most clearly expressed in a table.

Item 16 (numbers analyzed)—We replaced mention of "intention to treat" analysis, a widely misused term, by a more explicit request for information about retaining participants in their original assigned groups (26).

Subitem 17b (outcomes and estimation)—For appropriate clinical interpretability, prevailing experience suggested the addition of "For binary outcomes, presentation of both relative and absolute effect sizes is recommended" (27).

Item 19 (harms)—We included a reference to the CONSORT paper on harms (28).

Item 20 (limitations)—We changed the topic from "Interpretation" and supplanted the prior text with a sentence focusing on the reporting of sources of potential bias and imprecision.

Item 22 (interpretation)—We changed the topic from "Overall evidence." Indeed, we understand that authors should be allowed leeway for interpretation under this nebulous heading. However, the CONSORT Group expressed concerns that conclusions in papers frequently misrepresented the actual analytical results and that harms were ignored or marginalized. Therefore, we changed the checklist item to include the concepts of results matching interpretations and of benefits being balanced with harms.

Item 23 (registration)—We added a new item on trial registration. Empirical evidence supports the need for trial registration, and recent requirements by journal editors have fostered compliance (29).

Item 24 (protocol)—We added a new item on availability of the trial protocol. Empirical evidence suggests that authors often ignore, in the conduct and reporting of their trial, what they stated in the protocol (4, 22). Hence, availability of the protocol can instigate adherence to the protocol before publication and facilitate assessment of adherence after publication.

Item 25 (funding)—We added a new item on funding. Empirical evidence points toward funding source sometimes being associated with estimated treatment effects (30).

Nevertheless, we suggest that researchers begin trials with their end publication in mind. Poor reporting allows authors, intentionally or inadvertently, to escape scrutiny of any weak aspects of their trials. However, with wide adoption of CONSORT by journals and editorial groups, most authors should have to report transparently all important aspects of their trial. The ensuing scrutiny rewards well-conducted trials and penalizes poorly conducted trials. Thus, investigators should understand the CONSORT 2010 reporting guidelines before starting a trial as a further incentive to design and conduct their trials according to rigorous standards.

CONSORT 2010 supplants the prior version published in 2001. Any support for the earlier version accumulated from journals or editorial groups will automatically extend to this newer version, unless specifically requested otherwise. Journals that do not currently support CONSORT may do so by registering on the CONSORT Web site. If a journal supports or endorses CONSORT 2010, it should cite one of the original versions of CONSORT 2010, the CONSORT 2010 Explanation and Elaboration, and the CONSORT Web site in their "instructions to authors." We suggest that authors who wish to cite CONSORT should cite this or another of the original journal versions of CONSORT 2010 Statement and, if appropriate, the CONSORT 2010 Explanation and Elaboration (13). All CONSORT material can be accessed through the original publishing journals or the CONSORT Web site. Groups or individuals who desire to translate the CONSORT 2010 Statement into other languages should first consult the CONSORT policy statement on the Web site.

We emphasize that CONSORT 2010 represents an evolving guideline. It requires perpetual reappraisal and, if necessary, modifications. In the future, we will further revise the CONSORT material considering comments, criticisms, experiences, and accumulating new evidence. We invite readers to submit recommendations via the CONSORT Web site.

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Potential Conflicts of Interest: Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M10-0379.

Corresponding Author: Kenneth F. Schulz, PhD, MBA, Family Health International, PO Box 13950, Research Triangle Park, NC 27709.

Current author addresses and author contributions are available at www.annals.org.

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Current Author Addresses: Dr. Schulz: Family Health International, PO Box 13950, Research Triangle Park, NC 27709.
Dr. Altman: Centre for Statistics in Medicine, University of Oxford, Wolfson College Annexe, Linton Road, Oxford OX2 6UD, United Kingdom.
Dr. Moher: Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Department of Epidemiology and Community Medicine, University of Ottawa, 501 Smyth Road, 6th Floor, Critical Care Wing, Room W6112, Ottawa, Ontario K1H 8L6, Canada.

Author Contributions: Conception and design: K.F. Schulz, D.G. Altman, D. Moher.
Analysis and interpretation of the data: K.F. Schulz, D. Moher.
Drafting of the article: K.F. Schulz, D.G. Altman, D. Moher.
Critical revision of the article for important intellectual content: K.F. Schulz, D.G. Altman, D. Moher.
Final approval of the article: K.F. Schulz, D.G. Altman, D. Moher.
Statistical expertise: D.G. Altman, K.F. Schulz.
Obtaining of funding: D. Moher.
Administrative, technical, or logistic support: D. Moher.
Collection and assembly of data: K.F. Schulz, D. Moher.

Appendix: The CONSORT Group Contributors to CONSORT 2010

Douglas G. Altman, Centre for Statistics in Medicine, University of Oxford; Virginia Barbour, *PLoS Medicine*; Jesse A. Berlin, Johnson & Johnson Pharmaceutical Research and Development; Isabelle Boutron, University Paris 7 Denis Diderot, Assistance Publique des Hôpitaux de Paris, INSERM; P.J. Devereaux, McMaster University; Kay Dickersin, Johns Hopkins Bloomberg School of Public Health; Diana Elbourne, London School of Hygiene & Tropical Medicine; Susan Ellenberg, University of Pennsylvania School of Medicine; Val Gebski, University of Sydney; Steven Goodman, *Clinical Trials: Journal of the Society for Clinical Trials*; Peter C. Gøtzsche, Nordic Cochrane Centre; Trish Groves, *BMJ*; Steven Grunberg, American Society of Clinical Oncology; Brian Haynes, McMaster University; Sally Hopewell, Centre for Statistics in Medicine, University of Oxford; Astrid James, *Lancet*; Peter Juhn, Johnson & Johnson; Philippa Middleton, University of Adelaide; Don Minckler, University of California, Irvine; David Moher, Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute; Victor M. Montori, Knowledge and Encounter Research Unit, Mayo Clinic College of Medicine; Cynthia Mulrow, *Annals of Internal Medicine*; Stuart Pocock, London School of Hygiene & Tropical Medicine; Drummond Rennie, *JAMA*; David L. Schriger, *Annals of Emergency Medicine*; Kenneth F. Schulz, Family Health International; Iveta Simera, EQUATOR Network; and Elizabeth Wager, Sideview.

Contributors to CONSORT 2010 who did not attend the Montebello meeting: Mike Clarke, UK Cochrane Centre, and Gordon Guyatt, McMaster University.

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ORIGINAL ARTICLES

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies

Erik von Elm[a,g], Douglas G. Altman[c], Matthias Egger[a,b,*], Stuart J. Pocock[d], Peter C. Gøtzsche[e], Jan P. Vandenbroucke[f]
for the STROBE Initiative

[a]*Institute of Social and Preventive Medicine (ISPM), University of Bern, 3012 Bern, Switzerland*
[b]*Department of Social Medicine, University of Bristol, Bristol, United Kingdom*
[c]*Centre for Statistics in Medicine, University of Oxford, Oxford, United Kingdom*
[d]*London School of Hygiene and Tropical Medicine, University of London, London, United Kingdom*
[e]*Nordic Cochrane Centre, Copenhagen, Denmark*
[f]*Department of Clinical Epidemiology, Leiden University Hospital, Leiden, The Netherlands*
[g]*Department of Medical Biometry and Medical Informatics, University Medical Centre, Freiburg, Germany*

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Abstract

Much of biomedical research is observational. The reporting of such research is often inadequate, which hampers the assessment of its strengths and weaknesses and of a study's generalizability. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Initiative developed recommendations on what should be included in an accurate and complete report of an observational study. We defined the scope of the recommendations to cover three main study designs: cohort, case–control, and cross-sectional studies. We convened a 2-day workshop in September 2004, with methodologists, researchers, and journal editors to draft a checklist of items. This list was subsequently revised during several meetings of the coordinating group and in e-mail discussions with the larger group of STROBE contributors, taking into account empirical evidence and methodological considerations. The workshop and the subsequent iterative process of consultation and revision resulted in a checklist of 22 items (the STROBE Statement) that relate to the title, abstract, introduction, methods, results, and discussion sections of articles. Eighteen items are common to all three study designs and four are specific for cohort, case–control, or cross-sectional studies. A detailed Explanation and Elaboration document is published separately and is freely available on the web sites of *PLoS Medicine*, *Annals of Internal Medicine*, and *Epidemiology*. We hope that the STROBE Statement will contribute to improving the quality of reporting of observational studies.

1. Introduction

Many questions in medical research are investigated in observational studies [1]. Much of the research into the cause of diseases relies on cohort, case–control, or cross-sectional studies. Observational studies also have a role in research into the benefits and harms of medical interventions [2]. Randomized trials cannot answer all important questions about a given intervention. For example, observational studies are more suitable to detect rare or late adverse effects of treatments and are more likely to provide an indication of what is achieved in daily medical practice [3].

Research should be reported transparently so that readers can follow what was planned, what was done, what was found, and what conclusions were drawn. The credibility of research depends on a critical assessment by others of the strengths and weaknesses in study design, conduct, and analysis. Transparent reporting is also needed to judge whether and how results can be included in systematic reviews [4,5]. However, in published observational research important information is often missing or unclear. An analysis of epidemiological studies published in general medical and specialist journals found that the rationale behind the choice of potential confounding variables was often

* Corresponding author.
E-mail address: strobe@ispm.unibe.ch (M. Egger).

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not reported [6]. Only few reports of case–control studies in psychiatry explained the methods used to identify cases and controls [7]. In a survey of longitudinal studies in stroke research, 17 of 49 articles (35%) did not specify the eligibility criteria [8]. Others have argued that without sufficient clarity of reporting, the benefits of research might be achieved more slowly [9], and that there is a need for guidance in reporting observational studies [10,11].

Recommendations on the reporting of research can improve reporting quality. The Consolidated Standards of Reporting Trials (CONSORT) Statement was developed in 1996 and revised 5 years later [12]. Many medical journals supported this initiative [13], which has helped to improve the quality of reports of randomized trials [14,15]. Similar initiatives have followed for other research areas—e.g., for the reporting of meta-analyses of randomized trials [16] or diagnostic studies [17]. We established a network of methodologists, researchers, and journal editors to develop recommendations for the reporting of observational research: the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

1.1. Aims and use of the STROBE Statement

The STROBE Statement is a checklist of items that should be addressed in articles reporting on the three main study designs of analytical epidemiology: cohort, case–control, and cross-sectional studies. The intention is solely to provide guidance on how to report observational research well: these recommendations are not prescriptions for designing or conducting studies. Also, while clarity of reporting is a prerequisite to evaluation, the checklist is not an instrument to evaluate the quality of observational research.

Here, we present the STROBE Statement and explain how it was developed. In a detailed companion paper, the Explanation and Elaboration article [18–20], we justify the inclusion of the different checklist items and give methodological background and published examples of what we consider transparent reporting. We strongly recommend using the STROBE checklist in conjunction with the explanatory article, which is available freely on the web sites of *PLoS Medicine* (http://www.plosmedicine.org/), *Annals of Internal Medicine* (http://www.annals.org/), and *Epidemiology* (http://www.epidem.com/).

1.2. Development of the STROBE Statement

We established the STROBE Initiative in 2004, obtained funding for a workshop and set up a web site (http://www.strobe-statement.org/). We searched textbooks, bibliographic databases, reference lists, and personal files for relevant material, including previous recommendations, empirical studies of reporting and articles describing relevant methodological research. Because observational research makes use of many different study designs, we felt that the scope of STROBE had to be clearly defined early on. We decided to focus on the three study designs that are used most widely in analytical observational research: cohort, case–control, and cross-sectional studies.

We organized a 2-day workshop in Bristol, UK, in September 2004. Twenty-three individuals attended this meeting, including editorial staff from *Annals of Internal Medicine*, *BMJ*, *Bulletin of the World Health Organization*, *International Journal of Epidemiology*, *JAMA*, *Preventive Medicine*, and *The Lancet*, as well as epidemiologists, methodologists, statisticians, and practitioners from Europe and North America. Written contributions were sought from 10 other individuals who declared an interest in contributing to STROBE, but could not attend. Three working groups identified items deemed to be important to include in checklists for each type of study. A provisional list of items prepared in advance (available from our web site) was used to facilitate discussions. The three draft checklists were then discussed by all participants and, where possible, items were revised to make them applicable to all three study designs. In a final plenary session, the group decided on the strategy for finalizing and disseminating the STROBE Statement.

After the workshop, we drafted a combined checklist including all three designs and made it available on our web site. We invited participants and additional scientists and editors to comment on this draft checklist. We subsequently published three revisions on the web site and two summaries of comments received and changes made. During this process the coordinating group (i.e., the authors of the present paper) met on eight occasions for 1 or 2 days and held several telephone conferences to revise the checklist and to prepare the present paper and the Explanation and Elaboration paper [18–20]. The coordinating group invited three additional coauthors with methodological and editorial expertise to help write the Explanation and Elaboration paper, and sought feedback from more than 30 people, who are listed at the end of this paper. We allowed several weeks for comments on subsequent drafts of the paper and reminded collaborators about deadlines by e-mail.

1.3. STROBE components

The STROBE Statement is a checklist of 22 items that we consider essential for good reporting of observational studies (Table 1). 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 three designs, whereas four (items 6, 12, 14, and 15) are design specific, with different versions for all or part of the item. For some items (indicated by asterisks), information should be given separately for cases and controls in case–control studies, or exposed and unexposed groups in cohort and cross-sectional studies. Although presented here as a single checklist, separate checklists are available for each of the three study designs on the STROBE web site.

Table 1
The STROBE statement—checklist of items that should be addressed in reports of observational studies

	Item number	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) 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	(a) *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 (b) *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*	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	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) *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 (e) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow up, and analyzed (b) Give reasons for nonparticipation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders (b) Indicate the number of participants with missing data for each variable of interest (c) *Cohort study*—Summarize follow-up time (e.g., average and total amount)
Outcome data	15*	*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	(a) 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 (b) Report category boundaries when continuous variables were categorized (c) 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

(*Continued*)

Table 1
Continued

	Item number	Recommendation
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

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

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the websites of *PLoS Medicine* at http://www.plosmedicine.org, *Annals of Internal Medicine* at http:/www.annals.org, and *Epidemiology* at http://www.epidem.com). Separate versions of the checklist for cohort, case-control, and cross-sectional studies are available on the STROBE website at http://www.strobe-statement.org.

1.4. Implications and limitations

The STROBE Statement was developed to assist authors when writing up analytical observational studies, to support editors and reviewers when considering such articles for publication, and to help readers when critically appraising published articles. We developed the checklist through an open process, taking into account the experience gained with previous initiatives, in particular CONSORT. We reviewed the relevant empirical evidence as well as methodological work and subjected consecutive drafts to an extensive iterative process of consultation. The checklist presented here is thus based on input from a large number of individuals with diverse backgrounds and perspectives. The comprehensive explanatory article [18–20], which is intended for use alongside the checklist, also benefited greatly from this consultation process.

Observational studies serve a wide range of purposes, on a continuum from the discovery of new findings to the confirmation or refutation of previous findings [18–20]. Some studies are essentially exploratory and raise interesting hypotheses. Others pursue clearly defined hypotheses in available data. In yet another type of studies, the collection of new data is planned carefully on the basis of an existing hypothesis. We believe the present checklist can be useful for all these studies, since the readers always need to know what was planned (and what was not), what was done, what was found, and what the results mean. We acknowledge that STROBE is currently limited to three main observational study designs. We would welcome extensions that adapt the checklist to other designs—e.g., case-crossover studies or ecological studies—and also to specific topic areas. Four extensions are now available for the CONSORT statement [21–24]. A first extension to STROBE is underway for gene–disease association studies: the STROBE Extension to Genetic Association studies (STREGA) initiative [25]. We ask those who aim to develop extensions of the STROBE Statement to contact the coordinating group first to avoid duplication of effort.

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. For instance, we discuss the reporting of results under a number of separate items, while recognizing that authors might address several items within a single section of text or in a table. Also, item 22, on the source of funding and the role of funders, could be addressed in an appendix or in the methods section of the article. We do not aim at standardizing reporting. Authors of randomized clinical trials were asked by an editor of a specialist medical journal to ‘‘CONSORT’’ their manuscripts on submission [26]. We believe that manuscripts should not be ‘‘STROBEd,’’ in the sense of regulating style or terminology. We encourage authors to use narrative elements, including the description of illustrative cases, to complement the essential information about their study, and to make their articles an interesting read [27].

We emphasize that the STROBE Statement was not developed as a tool for assessing the quality of published observational research. Such instruments have been developed by other groups and were the subject of a recent systematic review [28]. In the Explanation and Elaboration paper, we used several examples of good reporting from studies whose results were not confirmed in further research—the important feature was the good reporting, not whether the research was of good quality. However, if STROBE is adopted by authors and journals, issues such as confounding, bias, and generalizability could become more transparent, which might help temper the overenthusiastic reporting of new findings in the scientific community and popular media [29], and improve the methodology of studies in the long term. Better reporting may also help to have more informed decisions about when new studies are needed, and what they should address.

We did not undertake a comprehensive systematic review for each of the checklist items and subitems, or do our own research to fill gaps in the evidence base. Further, although no one was excluded from the process, the

composition of the group of contributors was influenced by existing networks and was not representative in terms of geography (it was dominated by contributors from Europe and North America) and probably was not representative in terms of research interests and disciplines. We stress that STROBE and other recommendations on the reporting of research should be seen as evolving documents that require continual assessment, refinement, and, if necessary, change. We welcome suggestions for the further dissemination of STROBE—e.g., by republication of the present article in specialist journals and in journals published in other languages. Groups or individuals who intend to translate the checklist to other languages should consult the coordinating group beforehand. We will revise the checklist in the future, taking into account comments, criticism, new evidence, and experience from its use. We invite readers to submit their comments via the STROBE web site (http://www.strobe-statement.org/).

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TITOLO DELLO STUDIO

ANALISI STRUTTURATA DEL PROGETTO (RAZIONALE)

Descrizione ed analisi del problema

Soluzioni proposte sulla base delle evidenze

Metodologia

- **Popolazione (caratteristiche e numerosità)**
- **Metodo di raccolta dati**
- **Altre informazioni**

Fattibilità/criticità delle soluzioni proposte

OBIETTIVI DEL PROGETTO

Obiettivo generale

-

Obiettivi secondari

-
-

End-point primario

-

End-points secondari

-
-

TEMPISTICA DEL PROGETTO (FLOW-CHART)

Data di inizio del Progetto:
Data Fine:
Data (eventuale) report ad interim:

Data report finale:

Dettagliare la timeline di progetto nella Flow-chart evidenziando le celle relative al numero di mesi per attività:

Attività/Mesi	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
Protocollo def.																												
CRF																												
Aut. AIFA/C. Etici																												
Realizzazione DB																												
Inv. Meeting																												
Arruolamento																												
Monitoraggio																												
Follow-up																												
Analisi ad interim																												
Fine studio																												
Analisi finali																												

CENTRI OPERATIVI COINVOLTI

Centro Responsabile

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Centri Collaboratori

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BIBLIOGRAFIA

Attività fornite da AIPO RICERCHE Srl in qualità di Struttura Tecnica del CENTRO STUDI AIPO

(CRO certificata ai sensi del D.M. 31/03/2008, ed inserita nell'elenco dell'OsSC AIFA con numero identificativo 192)

1) Progettazione e coordinamento Studi Clinici:

- ✓ Studio, redazione e revisione dei protocolli scientifici
- ✓ Progettazione di CRF-Case Report Form per la raccolta dei dati (web e cartacee)
- ✓ Relazione con Autorità Competenti (ASL, Comitati Etici)
- ✓ Realizzazione dei materiali di studio
- ✓ Attività comunicazionali, informative ed educazionali
- ✓ Monitoraggio inserimento dati
- ✓ Gestione del database
- ✓ Analisi statistica
- ✓ Coordinamento della revisione dei dati
- ✓ Redazione di report per le pubblicazioni scientifiche

2) Analisi delle opportunità nell'ambito della ricerca sanitaria nazionale ed internazionale:

- ✓ Individuazione delle risorse messe a disposizione dalle Istituzioni Sanitarie nazionali ed internazionali in merito a progetti di ricerca in ambito pneumologico