Crystal clear reporting: importance of using PRISMA for systematic reviews

Cochrane Webinar - 21\textsuperscript{st} April 2010

Outline of talk

- Reporting research: setting the context
- Developing reporting guidelines
- The PRISMA statement
- Do reporting guidelines work
- The EQUATOR Network
Research articles: context

- Reports of any type of research need clarity and transparency to:
  - Enable readers to comment on its reliability and validity
  - Help readers make informed decisions about what they have just read
- “Good reporting is not an optional extra: it is an essential component of good research . . . we all share this obligation and responsibility.”
  - Altman

Role and function of journals in disseminating knowledge

- COPE (Committee of Publication Ethics) code of conduct
  - “Editors should take all reasonable steps to ensure the quality of the material they publish…”
  - “failures in the system of reporting clinical trials findings can result in harm to patients”
Journal resources to help ensure their product is of the highest possible quality

- Instructions to Authors
- Peer review
  - Jefferson et al. CDSR, 2008 (Issue 2)
- Editorial processes
  - Dickersin et al BMC Medical Research Methodology 2007, 7:44

Have these suite of tools helped?

- What do we know about the quality of reporting of health research?
  - Substantial body of evidence that the quality of research reports, including systematic reviews, is not optimal
- The exception are Cochrane reviews
Have these suite of tools helped?

- 80 consecutive studies
  - Subsequently published in Evidence based Medicine (October 2005 for 12 months)
- 55 RCTs; 25 SRs
- Intervention information missing from 41/80
- Retrieved through additional methods

Fig 2 | Percentage of studies with sufficient description of treatment initially (based only on the published paper) and after supplementary information was obtained

New ‘Guidelines for Guidance’ section

- Articles that raise awareness of emerging and novel methodological approaches
- Consensus standards for reporting or carrying out particular types of research
- How to guides to commonly encountered statistical or methodological issues
BMJ initiative

- New “Research methods and reporting” section of journal
  - 25th October 2008
New tool: reporting guideline

- What is a reporting guideline?
- We define a reporting guideline as:
  - *checklist*, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology.
  - A consensus process is a crucial characteristic of developing a reporting guideline.

Attributes of a good reporting guideline

- Evidence based, whenever possible
- various stakeholders, particularly editors, involved from the beginning
- Face-to-face meeting
- Extensive post-meeting iteration
- Responsive to criticism
- Evaluation
- ‘Living’ document
- Updated regularly
How reporting guidelines are developed

- Catalogue of 90 reporting guidelines
  - Simera et al EJCI 2010
- Systematic review of 81 reporting guidelines
  - Moher et al. working on getting it published
- Assessed their development against an 18-item checklist
  - For most of the items, due to poor reporting, we were unable to evaluate the methods used to develop the reporting guidelines
  - Unfortunately the majority of reporting guidelines included in this review did not report on any (intention to) evaluation of their guideline

Brief history of checklists

The 1935 crash of Boeing's sleek, four-engine bomber set back airpower for years.

When the Fortress W

By: Philip S. Thames

The B-17B was a beautiful plane. It was the story of how it was built and how it was flown, with a great deal of attention to detail. As a result, it was a great success. Unfortunately, the majority of reporting guidelines included in this review did not report on any (intention to) evaluation of their guideline.
A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population


ABSTRACT

BACKGROUND

Surgery has become an integral part of global health care, with an estimated 284 million operations performed yearly. Surgical complications are common and often preventable. We hypothesized that a program to implement a 19-item surgical safety checklist designed to improve team communication and consistency of care would reduce complications and deaths associated with surgery.

METHOD

Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, From the Hospital for Sick Children (A.B.H., T.C.R., W.B.B., A.A.G.S., Matteo- Ghetti General Hospital (A.B.H.), and Brigham and Women’s Hospital (S.H.L., A.A.C.) — all in Eastern University of California-Davis, Sacramento (T.C.R.), Prince Hamza Hospital, Ministry of Health, Amman, Jordan (A.H.S.B.), University of Washington, Seattle (C.P.D.), College of Medicine, University of the

Hayes et al. NEJM 2009;360:491-499

Table 1. Elements of the Surgical Safety Checklist.*

<table>
<thead>
<tr>
<th>Time Out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before skin incision, the entire team (nurses, surgeons, anesthesiologists, and any other health care providers in the operating room) should:</td>
</tr>
<tr>
<td>- Confirm that all team members have been introduced by name and role;</td>
</tr>
<tr>
<td>- Confirm that the patient’s identity, surgical site, and procedure are correct;</td>
</tr>
<tr>
<td>- Review the anticipated critical events;</td>
</tr>
<tr>
<td>- Confirm that prophylactic antibiotics have been administered at least 60 minutes before incision is made or that antibiotics are not indicated;</td>
</tr>
<tr>
<td>- Confirm that all essential imaging results for the correct patient are displayed in the operating room;</td>
</tr>
</tbody>
</table>

Sign out

Before the patient leaves the operating room:

- Nurse receives correct item from the doctor;
- Name of the procedure is recorded;
- That the needle, sponge, and instrument counts are complete (or not applicable);
- Whether there are any issues with equipment to be addressed;
- The surgeon, nurse, and anesthesiologist review aloud the key concerns for the recovery and care of the patient.

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery. For the complete checklist, see the Supplementary Appendix.
Why use checklists?

• They work!
• They are a way for authors to remember to report on the (often complex) design, conduct, and results of their research
• They can facilitate appraisal of a research report under peer review
• It puts authors, peer reviewers, and editors on a level playing field as to the importance of a minimum set of items that should be included when reporting and assessing research reports
• They are evidence-based, whenever possible
• They can be updated to incorporate new evidence
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

- A 3-day meeting was held in Ottawa, Canada, in June 2005
  - 29 participants: systematic reviewers, methodologists, editors and a consumer
- Meeting preparation activities were presented
- Statement consists of
  - 27-item checklist

- Open Medicine 2009; 3:123-130
- Annals of Internal Medicine 2009;151:264-269
- BMJ 2009 ;339:332-336
- Journal of Clinical Epidemiology 2009; PMID: 19631508
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

- Includes long explanatory document
  - Example of good reporting
  - Explanation and rationale for reporting this information (item)
  - Relevant data about how this information is reported presently
- Flow diagram

- Annals of Internal Medicine 2009;151:w65-w94
- Journal of Clinical Epidemiology 2009; PMID: 19631507
PRISMA – Item 8, search

• “Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated”
Databases searched for systematic review

- ABI/Inform (ProQuest)
- ProQuest Digital Dissertations & Theses
- CINAHL (1982 to present) (hosted by EBSCOhost)
- Clinical Evidence (BMJ Publishing Group)
- Evidence-Based Medicine Reviews (hosted by Ovid; incorporates ACP Journal Club, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Cochrane Methodology Register, Database of Abstracts of Reviews of Effectiveness, Health Technology Assessments, NHS Economic Evaluation Database)
- EconLit (1969 to present) (hosted by EBSCOhost)
- EMBASE (1980 to present) (hosted by Ovid)
- International Pharmaceutical Abstracts (IPA) (hosted by Ovid)
- MEDLINE (1966 to present with daily update) (hosted by Ovid)
- PAIS International and PAIS Archive (hosted by CSA)
- Web of Science (hosted by ISI)

Search strategy and terms

- “Our search strategy was to combine searches of terms clustered around the concepts of prescription drugs, intervention types and study methodologies (not applicable for some databases), as detailed below. Each of these term clusters was “translated” into the syntax and vocabulary of each database we searched. Wherever possible, we used subject headings, exploded to include all relevant subheadings. We also employed key word synonyms for the concepts of drugs and our interventions of interest. In databases where it was possible and useful, search filters for methodologies were applied or key words for impact, assessment, and outcomes were added.”
Rationale for reporting search

- Perusing the search strategy allows interested readers to assess the comprehensiveness and completeness of the search, and to replicate it
  - Essential for updating (i.e., keeping systematic reviews up-to-date)
Reporting guidance

- Journal restrictions vary and that having the search strategy in the text of the report is not always feasible
  - Expensive real estate
- Encourage all journals, however, to find ways, such as a “Web extra,” appendix, or electronic link to an archive, to make search strategies accessible to readers
- Authors to archive their searches so that:
  - others may access and review them (e.g., replicate them or understand why their review of a similar topic did not identify the same reports)
  - future updates of their review are facilitated

PRISMA – Item 12,
Risk of bias in individual studies

- Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis
Rationale for reporting risk of bias

- The likelihood that the treatment effect reported in a systematic review approximates the truth depends on the validity of the included studies, as certain methodological characteristics may be associated with effect sizes
  - For example, trials without reported adequate allocation concealment exaggerate treatment effects on average compared to those with adequate concealment.
- Therefore, it is important for authors to describe any methods that they used to gauge the risk of bias in the included studies and how that information was used.
- Additionally, authors should provide a rationale if no assessment of risk of bias was undertaken.

Reporting risk of bias

- Authors should report how they assessed risk of bias
- Whether assessment was in a blind manner
- If assessments were completed by more than one person, and if so, whether they were completed independently.
- Report any calibration exercises among review team members that were done.
- Report how their assessments of risk of bias are used subsequently in the data synthesis
PRISMA – Item 15, Risk of bias across studies

- Specify any assessment of risk of bias that may affect the cumulative evidence
  - publication bias
  - selective reporting within studies

Rationale for reporting assessment of bias across studies

- Reviewers should explore the possibility that the available data are biased.
- They may examine results from the available studies for clues that suggest there may be:
  - missing studies (publication bias)
  - missing data from the included studies (selective reporting bias)
PRISMA – Item 17, study selection

- Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.
Rationale for reporting study selection

- The X-Files factor!
- Authors should report, ideally with a flow diagram, the total number of records identified from electronic bibliographic sources (including specialized database or registry searches), hand searches of various sources, reference lists, citation indices, and experts.
- It is useful if authors delineate for readers the number of selected articles that were identified from the different sources so that they can see, for example, whether most articles were identified through electronic bibliographic sources or from references or experts.

PRISMA – Item 27, funding

- Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review.
Rationale for reporting funding

- Given the potential role of systematic reviews in decision making, we believe authors should be transparent about the funding and the role of funders, if any.
- Lexchin and colleagues observed that outcomes of reports of randomized trials and meta-analyses of clinical trials funded by the pharmaceutical industry are more likely to favor the sponsor’s product compared to studies with other sources of funding.
  - Similar results have been reported elsewhere.
- Analogous data suggest that similar biases may affect the conclusions of systematic reviews.

Guidance for reporting funding

- Sometimes the funders will provide services, such as those of a librarian to complete the searches for relevant literature or access to commercial databases not available to the reviewers.
  - Any level of funding or services provided to the systematic review team should be reported.
- Authors should also report whether the funder had any role in the conduct or report of the review.
The Effectiveness Of A Home Care Program For Supporting Caregivers Of Persons With Dementia In Developing Countries: A randomised controlled trial from Goa, India

<table>
<thead>
<tr>
<th>Heading</th>
<th>Subheading</th>
<th>Descriptor</th>
<th>Was it reported?</th>
<th>Yes or No</th>
<th>If “Yes”, what section?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td></td>
<td>1. Identify the study as a randomised trial</td>
<td>Yes</td>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Abstract</td>
<td></td>
<td>2. Use a structured format</td>
<td>Yes</td>
<td>Abstract</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td></td>
<td>3. State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses.</td>
<td>Yes</td>
<td>Introduction</td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>Protocol</td>
<td>4. Planned study population, together with inclusion/ exclusion criteria</td>
<td>Yes</td>
<td>Method</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>5. Planned interventions and their timing</td>
<td>Yes</td>
<td>Method, Intervention</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>6. Primary and secondary outcome measure(s) and the minimum important difference(s); ...and how the target sample size was projected.</td>
<td>Yes</td>
<td>Outcome Results</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>7. Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis</td>
<td>Yes</td>
<td>Analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>8. Prospectively defined stopping rules (if warranted).</td>
<td>None</td>
<td>Analysis</td>
<td></td>
</tr>
<tr>
<td>Assignment</td>
<td>Describe</td>
<td>9. Unit of randomisation (eg individual, cluster, geographic).</td>
<td>Yes</td>
<td>Method, Randomisation</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>10. Method used to generate the allocation schedule.</td>
<td>Yes</td>
<td>Method</td>
<td></td>
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<td></td>
<td></td>
<td>11. Method of allocation concealment and timing of assignment.</td>
<td>Yes</td>
<td>Method</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>12. Method to separate the generator from the executor of assignment</td>
<td>Yes</td>
<td>Method</td>
<td></td>
</tr>
<tr>
<td>Masking</td>
<td>(Blinding)</td>
<td>13. Describe mechanism (eg, capsules, tablet(s)); similarity of treatment characteristics (eg appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful masking (blinding) among participants, person doing intervention, outcome assessors, and data analysts.</td>
<td>Yes (No placebo involved in this study. Evaluators were masked to intervention status)</td>
<td>Outcome / Analysis</td>
<td></td>
</tr>
</tbody>
</table>

www.prisma-statement.org
Do reporting guidelines improve the quality of reporting of health research reports?

- CONSORT systematic review
- STARD
- STRICTA
- QUOROM
- Need a systematic review of reporting guideline evaluations
Why wasn’t there a stronger effect?

- Fidelity of intervention
- Endorsement
- Adherence
EQUATOR: Enhancing the QUALity and Transparency Of health Research

- EQUATOR grew out of the work of CONSORT and other guidelines groups
- Guidelines are available but not widely supported by medical journals or adhered to by researchers
  - Their potential impact is blunted
  - They need to be actively promoted
- EQUATOR Network
  - Editors of general and specialty journals, researchers, guideline developers, medical writers
    “Better reporting, better reviewing, better editing”

EQUATOR program

- Developed guidance on how to develop reporting guidelines
- Completed catalogue, and systematic review of existing reporting guidelines
- Developing tool to gauge the quality of how reporting guidelines are developed
- Training for authors, peer reviewers and editors
Welcome to the EQUATOR Network website – the resource centre for good research reporting

Too often, good research evidence is undermined by poor quality reporting.

The EQUATOR Network is a new initiative that seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.

Latest news

CONSORT extended for non-pharmacologic treatments.

Register now – 26 June
The EQUATOR Network launch meeting, London, UK

Highlights

Achieving Transparency in Reporting Health Research
- Register now for the conference on Thursday 26th June 2008 at the The Royal Society of Medicine.

Resource centre
- Find up-to-date information about the reporting of health research.

Training courses
- View educational materials and training modules for editors, peer reviewers and researchers.

Library for health research reporting

The EQUATOR Network library currently contains:

- An introduction to reporting guidelines
- Comprehensive lists of the available reporting guidelines, listed by study type
  - Experimental studies
  - Observational studies
  - Diagnostic accuracy studies
  - Systematic reviews
  - Qualitative research
  - Economic evaluations
  - Quality improvement studies
  - Other reporting guidelines
  - Sections of research reports
  - Specific conditions or procedures
- Reporting guidelines under development
- Guidance on scientific writing
- Guidance developed by editorial groups
- Medical writers – additional resources
- Research ethics, publication ethics and good practice guidelines
- Development and maintenance of reporting guidelines
- Editors
  - Introducing RCTs
- Examples of guidelines for peer reviewers

Developers

Resources for developers of reporting guidelines

Authors

Information for authors of research reports

Editors

Resources for journal editors and peer reviewers

Reporting guidelines

Go straight to the reporting guidelines
<table>
<thead>
<tr>
<th>Reporting guidance provided for:</th>
<th>Name of guideline website (where available)</th>
<th>References including PMID</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMJ 2009; 339:b2515, PMID: 19622551</td>
<td></td>
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<td>J Clin Epidemiol 2009; 62(10):1006-12, PMID: 19631508</td>
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<td>Open Med 2009; 3(3):123-130</td>
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<tr>
<td>BMJ 2009; 339:b2700, PMID: 19622552</td>
<td></td>
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<tr>
<td>PRISMA Statement replaces the QUOROM guideline (PMID: 10584762)</td>
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</tbody>
</table>

Slide 51

dm1 recommended updating this as of 21st July when PRISMA will appear - it's been a long and, at times painful, birth!
Resources for authors

The following resources will help you to produce high quality research publications:

- Planning and conducting your research
- Writing up your research
- Medical writers – additional resources
- Ethical guidelines and considerations
- Other resources
- What can I do to support the EQUATOR Network's effort

Planning and conducting your research

It is important to be aware of reporting requirements and think about reporting when you are planning and conducting your research study:

- UK National Health System Research Flowchart (tool providing resources and points for consideration for all stages of the research process, from formulating a research question to the reporting and dissemination of new findings)
- UK MRC Route Map (Medical Research Council guidance through the legal and good practice requirements when designing, conducting and disseminating experimental medicine studies)

Writing up your research

A good scientific article combines clear writing style with a high standard of reporting of the research content:

- Guidance on scientific writing
- Reporting guidelines (comprehensive lists of the available guidelines appropriate to each study type)
- Examples of good research reporting (specific examples showing why and how to correctly describe important aspects of your trial or other types of research studies)

Resources for editors and peer reviewers

The following resources will help you to produce high quality research publications:

- Developing a journal's policies on research reporting
- Guidance for peer reviewers
- Other resources
- What can I do to support the EQUATOR Network's effort

Developing a journal's policies on research reporting

The following resources will be useful for developing or updating a journal's policies and instructions for research reporting:

- Guidelines developed by influential editorial groups (WAME, ICMJE, etc.)
- Research ethics, publication ethics and good practice guidelines
- Reporting guidelines
- Editors' introductions to reporting guidelines and new reporting policies into a journal
- Instructions to Authors (collected by the University of Toledo, note that not all listed instructions provide good guidance on research reporting)

Guidance for peer reviewers

Reporting guidelines are useful tools for strengthening the peer review process. Here are a few examples of how to implement this in your journal:

- Examples of guidelines for peer reviewers
What can you do to help improve the quality of reporting health research?

• Ensure your workplace:
  • implements a policy whereby
    • research from your institution must use reporting guidelines
  • Insist upon researchers populating a reporting guideline checklist for each journal submission
  • Ask your institution leadership to set aside resources to develop courses on reporting research and peer review
Thank you!