Beyond CONSORT: reporting guidelines for other types of manuscript

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Medcomms networking workshop
Improving efficiency, transparency and integrity in medical publications: overview of the latest guidelines
Alderley Park, 3 December 2015
In the beginning there was...
The EQUATOR Team

CENTRE for STATISTICS in MEDICINE

www.equator-network.org

NDORMS
Nuffield Department of Orthopaedics, Rheumatology and musculoskeletal Sciences
Medical Sciences Division
UNIVERSITY OF OXFORD
Now nearly 300 reporting guidelines
But don’t panic!
Pre-COMSORT
A Cautionary Tale Tail

July 2015: Systematic review of animal studies on new vaccine for TB raises questions about the evidence justifying trials in children

Eight small studies (192 animals), low quality, poorly reported

The review gave no evidence to support the effectiveness of the vaccine

Largest animal trial with the longest follow-up published a year after recruitment to the trial in children had started

Five of the six monkeys in the vaccine group died compared with two of the six monkeys in the control group.

Trial report did not include the name of the vaccine in the title or the abstract
Only one review of pharmacokinetic studies has ever been done

- Antibiotics in patients with sepsis receiving continuous renal replacement therapy
- None of the trials identified reported all the criteria deemed essential for readers to adequately interpret the results.
- Basic pharmacokinetic parameters were reported in only 80% of studies

*Would be helpful therefore to publish the guideline in an open access journal...*
GNOSIS

*Phase 1 and 2 (sometimes 3) trials*

The GNOSIS checklists can be adapted for other clinical fields

Incomplete, unclear, or inaccurate design, interpretation, and reporting of the results from these vital early phase trials can hamper timely drug development and lead to erroneous conclusions as to efficacy

*Mariani and Marubini, 2000*
CONSORT extensions
CONSORT extensions

Randomized trials

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<th>Designs</th>
<th>Interventions</th>
<th>Data</th>
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<td>N-of-1 Trials</td>
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Ten official CONSORT EXTENSIONS
CONSORT
Noninferiority & equivalence studies

Dramatic increase in frequency of this study design since 2000

- Enough detail about the participants, the reference treatment, and outcomes to know if they are similar to the trials which initially established the efficacy of the reference treatment
- Checklist extends CONSORT guidance for abstracts, objectives, outcomes, and interpretation and more
- Examples of good reporting practice
Clinical research activities have taken a low profile in the medical devices industry.

The need for good quality clinical research within this industry will only increase.

Guidelines address difficulties in blinding and complexity of non-pharm interventions

Covers reporting details about how intervention was standardised

Extra box in flow chart relating to care providers

Need to report differences in intended implementation to what actually happened
Authors cannot adequately describe basic essential information for readers

- 10 essential elements about intervention – e.g., drug name, dose, route....
- examined 262 reports of randomized trials from most prominent oncology journals
- overall, only 11% of articles reported all 10 essential items

David Moher, METRICS Conference, Stanford CA
20 November 2015
CONSORT

Harms data

Guideline extends ten CONSORT checklist items

Use term “harms”, not “safety”

Explain use of non-standard measurement instruments

Distinguish between expected and unexpected adverse events

How was harms-related information collected? Observed or actively collected?

Timing of surveillance, handling of recurrent events
TREND
Nonrandomised evaluations

Came from the need to conduct systematic reviews and meta-analysis - initially in the field of HIV research

- Usually applied to interventions being evaluated in settings where randomisation is either not ethical or practical
- Emphasises the need to report the theoretical framework used to interpret the evaluation data
- Allows assessment of the likelihood that an intervention “caused” an outcome in the absence of a control group created by randomization.
CHEERS
Economic evaluations

- 1995: BMJ set up a working party to improve the quality of economic articles
- 1996: BMJ published a guideline for authors and peer reviewers - BMJ EE
- 2013: The International Society for Pharmacoeconomics and Outcomes Research Good Practices Task Force published the Consolidated Health Economic Evaluation Reporting Standards (CHEERS)
- CHEERS Statement checklist format is based on the format of the CONSORT statement checklist
Beyond CONSORT
Covers three main observational study designs:
- Cohort
- Case-control
- Cross-sectional

Most important items to report fully and transparently is confounding factors and sources of bias (population characteristics, sample selection etc.) which are better-controlled in RCTs

Use a participant flow diagram

NB: Documents, checklists and extensions all on EQUATOR site as STROBE website no longer being updated

Most famous “post-marketing” case-control study discovered the likely link between smoking and lung cancer in 1950, and proved it by 1956 with a cohort study of 40,000 British Doctors
RECORD (extension to STROBE)

Observational studies using routinely collected health data

- health administrative data
- electronic medical record data
- primary care surveillance data
- disease registries
- company registries
Guidelines for submitting adverse event reports for publication

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RATS, COREQ and SRQR

Qualitative studies

2003: RATS guidelines
  - Can be accessed via SpringerOpen instructions to authors

2007: CONSolidated Criteria for REPORTing Qualitative Studies
  - Focus groups and interviews
  - Patient/consumer opinions, priorities, barriers, expectations, needs

2014: Standards for Reporting Qualitative Research
  - Generic
  - Recent examples of reports
Way beyond CONSORT
PRISMA Systematic reviews and meta-analyses

Covers reporting systematic reviews of all health care evaluation study designs

- Includes guidance on reporting
  - Search strategy
  - Protocol (PRISMA-P)
  - Flow diagram
- Endorsed by
  - 200 journals
  - Cochrane
  - Council of Science Editors
RAMESES
Qualitative (realist) reviews

Wong et al. BMC Medicine 2013, 11:21
http://www.biomedcentral.com/1741-7015/11/21

GUIDELINE
Open Access

RAMESES publication standards: realist syntheses
Geoff Wong1, Trish Greenhalgh1, Gill Westhorp2, Jeanette Buckingham3 and Ray Pawson4

Table 1 List of terms to be included when reporting a realist synthesis

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>RAMESES</td>
<td>The acronym used to identify the document as a realist synthesis in reviews.</td>
</tr>
<tr>
<td>Qualitative</td>
<td>The type of synthesis described as being a qualitative (realist) synthesis.</td>
</tr>
<tr>
<td>reviews</td>
<td>The type of study being reviewed, specifically qualitative (realist) reviews.</td>
</tr>
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ARTICLE INFO

Objective: The aim of this review is to conduct a detailed account of the role of the district nurse (generalist registered nurse providing care in primary care settings) in residential care homes for elderly people. The review will aim to identify the factors that influence the effective care of each patient, and to examine the utility of a realist review for the evidence gap.

Design: Systematic review of published literature.

Data sources: Electronic searches of databases (Cochrane Library, Medline, CINAHL, EMBASE, PsycINFO, Web of Science) and hand searches of relevant publications were conducted.

Search strategy: The search strategy included the following terms: "district nurse," "residential care," "elderly," and "healthcare." These terms were combined using Boolean operators (AND, OR) to identify articles relevant to the review. Only articles published in English were included.

Data extraction: Data extracted included study design, population, intervention, outcomes, and conclusions. The data were then synthesized using a realist framework.

Conclusions: District nurses play a significant role in residential care homes for elderly people. They are responsible for assessing the health needs of patients, implementing care plans, and coordinating care with other healthcare professionals. The effectiveness of district nurse care is influenced by multiple factors, including the patient's health status, the quality of the care environment, and the resources available to the district nurse. Further research is needed to identify effective strategies to improve the quality of care provided by district nurses in residential care homes.

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In the pipeline...

- StaRI: Standards for Reporting Phase IV implementation studies with a comparator group
- CONSORT extension for stepped wedge cluster randomised trials
- PRISMA Harms - reporting harms in systematic reviews
Search by

- Study type: eg. experimental, observational, qualitative, economic evaluation...
- Clinical area: eg. cardiovascular, oncology, haematology, pharmaceutical medicine...
- Section of report: eg. statistical methods, biospecimen/bioresource information, ethical issues

Or use free text search
Resources for writers of industry sponsored research

http://www.equator-network.org/

Plus general guidance and training opportunities for writers

- Writing up your research
- Data sharing, reporting data
- Additional guidance for industry sponsored research
- Ethical guidelines and considerations
- Publishers’ resources for authors
- Reviewing research articles
- Communicating research to the media
- Training opportunities
New tools for writers

Study design wizard

www.peneloperesearch.com/equatorwizard

WHICH GUIDELINES ARE RELEVANT TO MY WORK?

We've been working with the EQUATOR Network to make a tool that helps authors find useful resources from their library. Please take a look and tell us what you think. Journals can embed the tool into their pages, for free - email us for more info.

Everyone can forget things - have you?

Scientists frequently forget to report details about their study that are important to readers. This can delay publication and stop your work being used, cited or replicated.

To help you, experts have made checklists that set out the most important things other people need to know about your work.

There are different checklists for different types of study design. This tool will help you find the right checklist for your work, or you can search the EQUATOR library directly.

Help me find a useful checklist
I already know which checklist I need

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Education and training

UK EQUATOR Centre Publication School

Publication School 2016
27 June-1 July
St Catherine’s College, Oxford
Registration opening soon

Let me know if you want to go on the email list for priority booking
caroline.struthers@cs.m.ox.ac.uk

Class of 2015
Take home messages from

○ Help keep this smile on Doug’s face
○ Report, publish and/or share
  - everything that was done
  - everything that was found
○ Cite reporting guidelines in your reference list
○ Reporting guidelines keep systematic reviewers at bay - good for your clients!
○ What you write will contribute to the big picture and improve healthcare for all
Thank you! Any questions?

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