Beyond CONSORT: reporting guidelines for other types of manuscript

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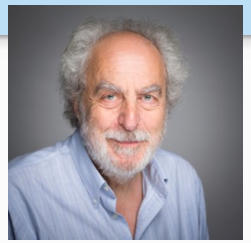
Medcomms networking workshop
Improving efficiency, transparency and integrity in medical publications: overview of the latest guidelines
Alderley Park, 3 December 2015

In the beginning there was...

CONSORT TRANSPARENT REPORTING of TRIALS

The EQUATOR Team



CENTRE for STATISTICS in MEDICINE

NDORMS
NUFFIELD DEPARTMENT OF ORTHOPAEDICS, RHEUMATOLOGY AND MUSCULOSKELETAL SCIENCES
Medical Sciences Division

UNIVERSITY OF OXFORD

Now nearly 300 reporting guidelines
But don't panic!

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions	Other
Observational studies	STROBE	Extensions	Other
Systematic reviews	PRISMA	Extensions	Other
Case reports	CARE		Other
Qualitative research	SRQR	COREQ	Other
Diagnostic / prognostic studies	STARD	TRIPOD	Other
Quality improvement studies	SQUIRE		Other
Economic evaluations	CHEERS		Other
Animal pre-clinical studies	ARRIVE		Other
Study protocols	SPIRIT	PRISMA-P	Other

See all 284 reporting guidelines

Pre-CONSORT

ARRIVE

Animal research

NC 3Rs National Centre for the Replacement Refinement & Reduction of Animals in Research

ARRIVE

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

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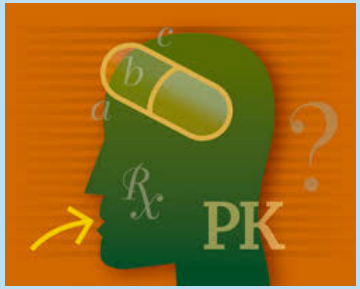
ClinPK

Pharmacokinetic & pharmacodynamic studies



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...

Hot off the press!

» Look Inside » Get Access

Original Research Article
Clinical Pharmacokinetics
July 2015, Volume 54, Issue 7, pp 783-795

First online: 31 January 2015

Reporting Guidelines for Clinical Pharmacokinetic Studies: The ClinPK Statement

	Checklist Item	
	Title/Abstract	Reported on Page Number
1	The title identifies the drug(s) and patient population(s) studied.	
2	The abstract minimally includes the name of the drug(s) studied, the route of administration studied, and the results of clinical pharmacokinetic	
3	Pharmacokinetic data excretion) that is kno is described	
4	An explanation of the	
5	Specific objectives or	
6	Eligibility criteria of	
7	Co-administration (or potentially interacting described.	
8	Drug preparation and dose, route, formulati frequency are described.	

Key Points

Incomplete study reporting can lead to misinterpretation and compromised generalizability of study findings.

Compliance with ClinPK reporting guidelines will promote transparent and complete reporting of clinical pharmacokinetic studies.

GNOSIS

Phase 1 and 2 (sometimes 3) trials

GNOSIS: Guidelines for neuro-oncology: Standards for investigational studies—reporting of phase 1 and phase 2 clinical 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

Table 1. Phase 1 checklist*

Section of Report	Item	Description
Title	1	☐ Phase 1 trial, intervention studied, newly diagnosed or recurrent tumor, tumor type, study population
		☐ State if PK studies are part of the research.
Abstract	2	☐ Structured abstract recommended, consisting of Introduction, Methods, Results, and Conclusions
Introduction	3	Scientific background and explanation of rationale
		☐ Drug background information: name, trademarked name, mechanism of action
		Rationale for trial/preclinical efficacy of study drug
		☐ In vitro studies
		☐ In vivo studies
		☐ Phase 1 studies in other tumor types
		☐ Any known PK information, especially regarding CNS penetration and the role of drug interactions
Methods		
• Eligibility criteria	4	☐ Age
		☐ Performance status
		☐ Estimated survival
		☐ Laboratory tests (required counts/levels/functions)
		☐ Informed consent and IRB approval
		☐ Newly diagnosed/recurrent tumor
		☐ If recurrent, state criteria for determining progression.
		☐ Measurable versus nonmeasurable evaluable disease
		☐ Surgical/radiographic criteria to confirm tumor if focal high-dose radiation was used previously
		☐ Tumor type/grade/stage: Use 2000 WHO scale
		☐ Histology review: Note if central review was required.
		☐ Prior treatment (resection/radiation/chemotherapy)
		☐ Number of prior treatments/relapses allowed
		☐ Recovery period after prior treatment
		☐ Comorbidity

Table 2. Phase 2 checklist*

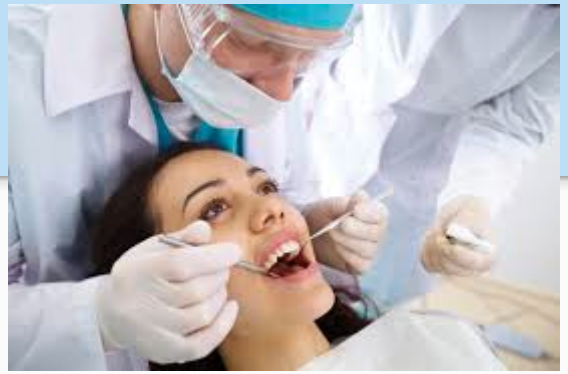
Section of Report	Item	Description
Title	1	☐ Phase 2 trial, intervention studied, newly diagnosed or recurrent tumor, tur
		☐ State if PK studies are part of the research.
Abstract	2	☐ Structured abstract recommended, consisting of Introduction, Methods, R
		☐ In the abstract Introduction, state the type of phase 2 study: e.g., open-lal single arm.
Introduction	3	Scientific background and explanation of rationale

CONSORT extensions

CONSORT extensions

Randomized trials

Designs	Interventions	Data
Cluster Trials	Herbal Medicinal Interventions	CONSORT-Pro
Non-Inferiority and Equivalence Trials	Non-Pharmacologic Treatment Intervention	Harms
Pragmatic Trials	Acupuncture Interventions	Abstracts
N-of-1 Trials		



Ten official CONSORT EXTENSIONS

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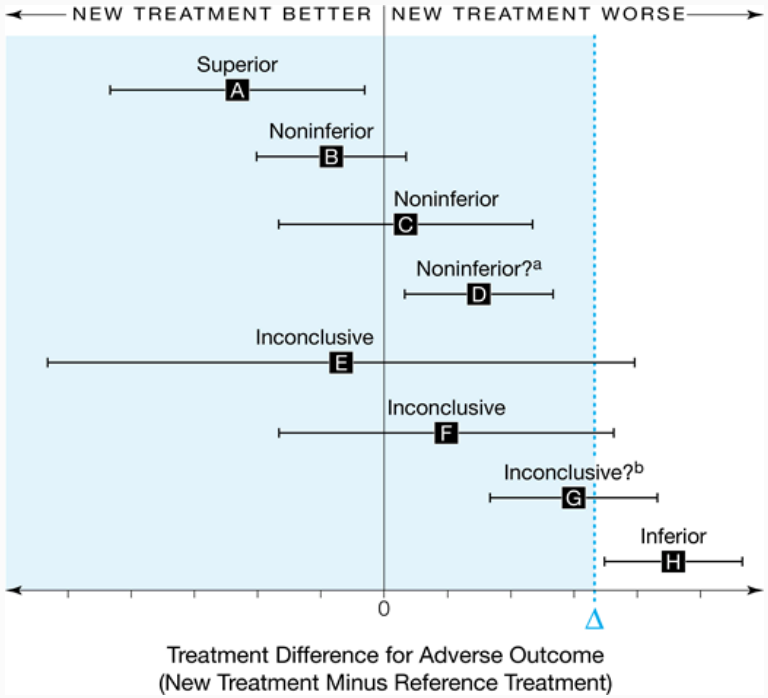
CONSORT

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

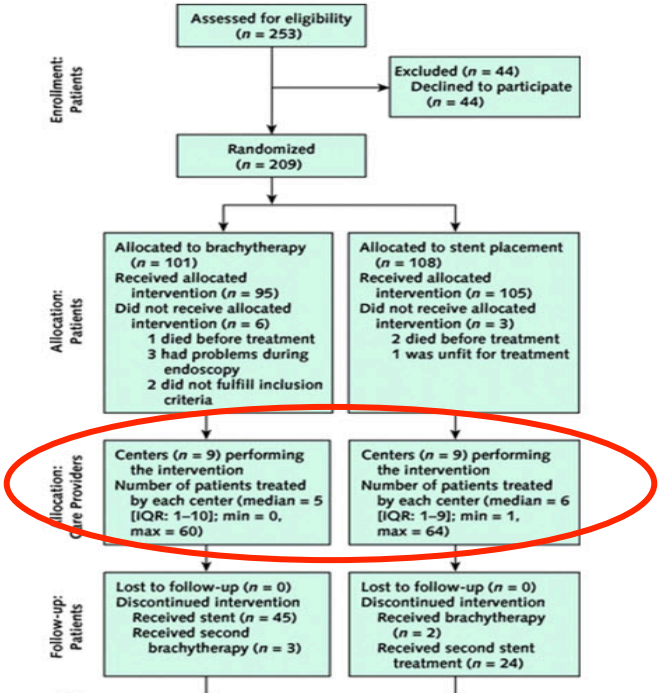


CONSORT NPI

Non-pharmacological interventions

Clinical research activities have taken a low profile in the medical devices industry.

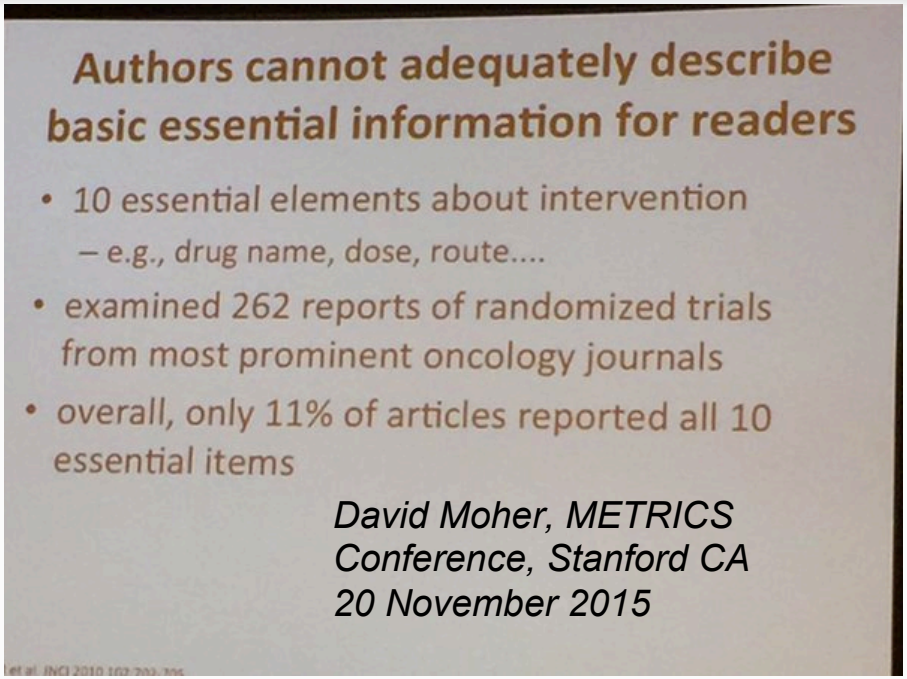
- The need for good quality clinical research within this industry will only increase.
- Guidelines address difficulties in blinding and complexity of non-pharm interventions
- Covers reporting details about how intervention was standardised
- Extra box in flow chart relating to care providers
- Need to report differences in intended implementation to what actually happened

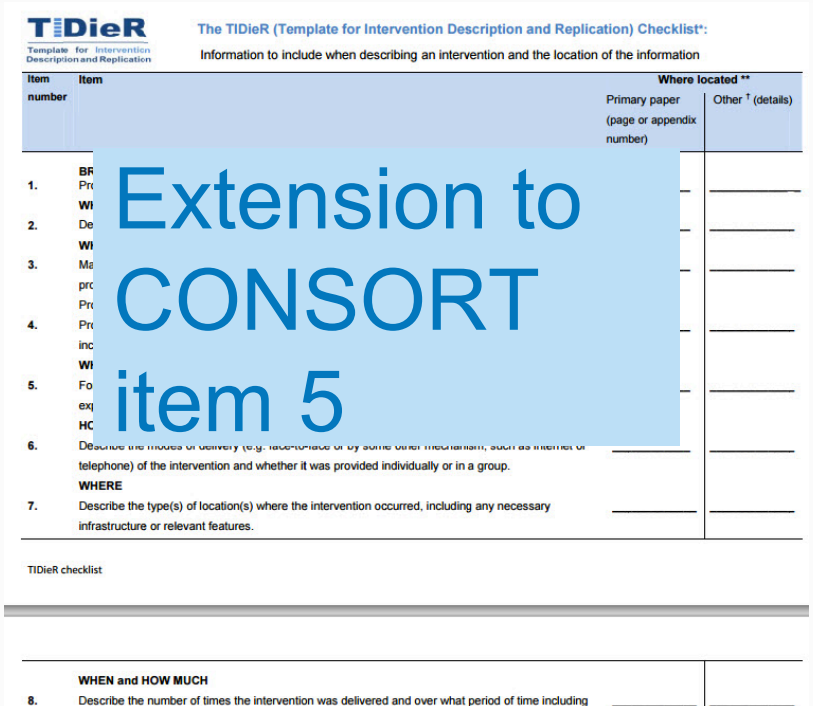


TIDieR

Interventions

TIDieR
Template for Intervention Description and Replication





Extension to CONSORT item 5

CONSORT

Harms data

Guideline extends ten CONSORT checklist items

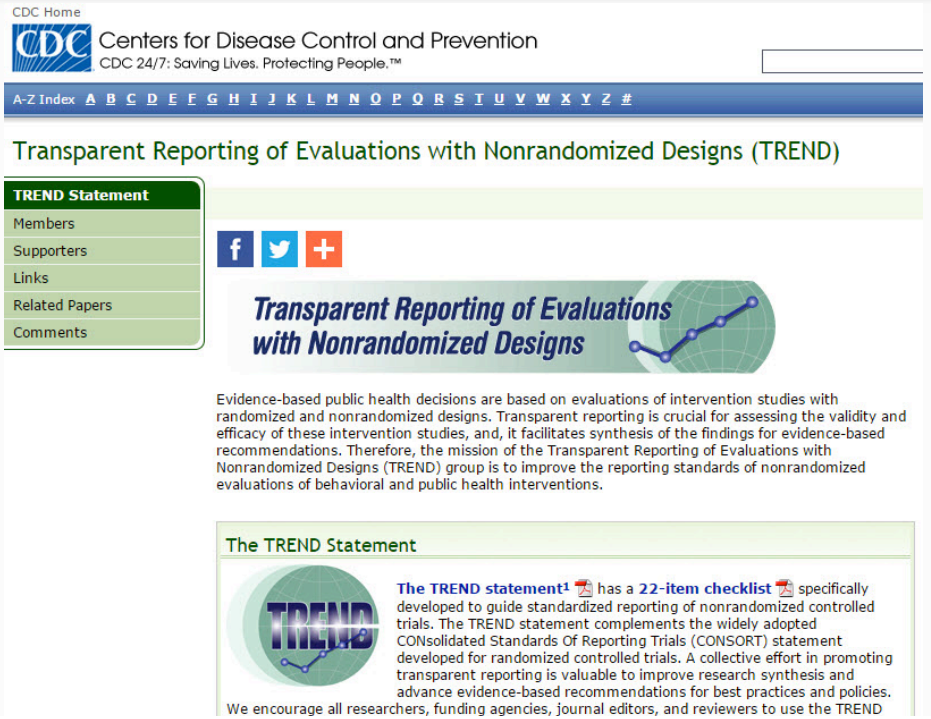
- Use term “harms”, not “safety”
- Explain use of non-standard measurement instruments
- Distinguish between expected and unexpected adverse events
- How was harms-related information collected? Observed or actively collected?
- Timing of surveillance, handling of recurrent events

TREND

Nonrandomised evaluations

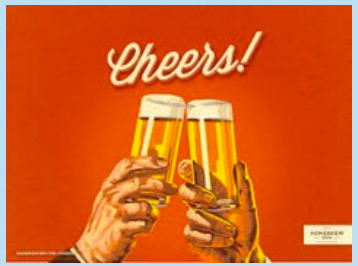
Came from the need to conduct systematic reviews and meta-analysis - initially in the field of HIV research

- 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 **C**onsolidated **H**ealth **E**conomic **E**valuation **R**eporting **S**tandards (CHEERS)
- CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

BMJ

INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH • ISPOR

ISPOR GOOD PRACTICES FOR OUTCOMES RESEARCH AND USE IN HEALTH CARE DECISIONS

Beyond CONSORT

STROBE

Observational studies

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

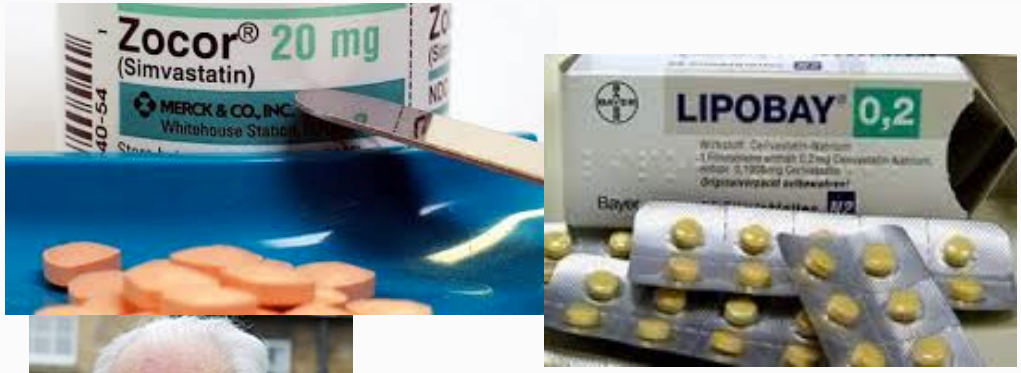
Covers three main observational study designs:

- 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)

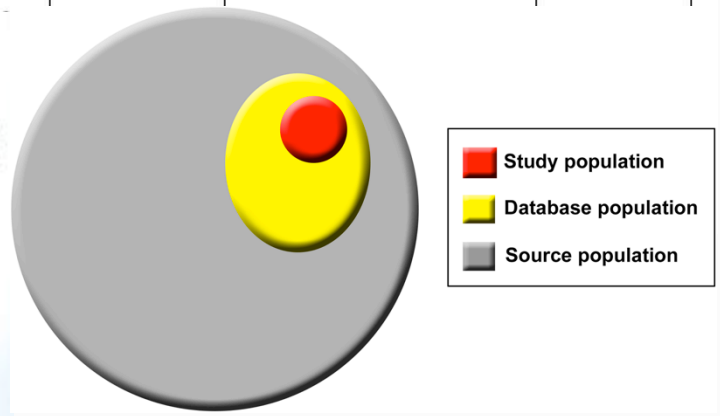
Observational studies using routinely collected health data

RECORD
REporting of studies Conducted using Observational Routinely-collected Data

- health administrative data
- electronic medical record data
- primary care surveillance data
- disease registries
- company registries

The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data.

	Item No.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
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		RECORD 1.1: The type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included.	



CARE

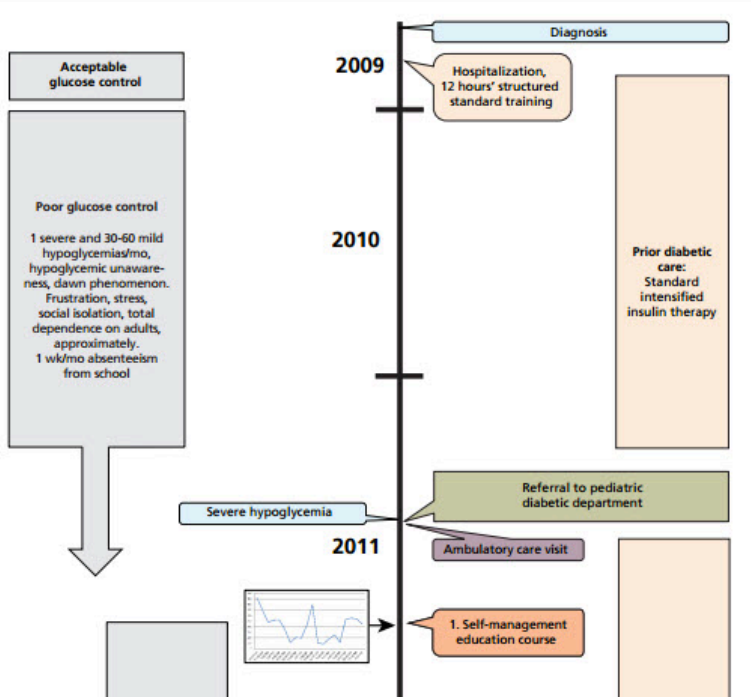
Generic case reports

case reports

a little structure goes a long way

CARE Checklist (2013) of information to include when writing a case report

Topic	Item	Checklist item description	Reported on Page
Title	1	The words "case report" should be in the title along with the area of focus	
Key Words	2	2 to 5 key words that identify areas covered in this case report	
Abstract	3a	Introduction—What is unique about this case? What does it add to the medical literature?	
	3b	The main symptoms of the patient and the important clinical findings	
	3c	The main diagnoses, therapeutics interventions, and outcomes	
	3d	Conclusion—What are the main "take-away" lessons from this case?	
Introduction	4	One or two paragraphs summarizing why this case is unique with references	
Patient Information	5a	De-identified demographic information and other patient specific information	
	5b	Main concerns and symptoms of the patient	
	5c	Medical, family, and psychosocial history including relevant genetic information (also see timeline)	
	5d	Relevant past interventions and their outcomes	
Clinical Findings	6	Describe the relevant physical examination (PE) and other significant clinical findings	
Timeline	7	Important information from the patient's history organized as a timeline	
Diagnostic Assessment	8a	Diagnostic methods (such as PE, laboratory testing, imaging, surveys)	
	8b	Diagnostic challenges (such as access, financial, or cultural)	
	8c	Diagnostic reasoning including other diagnoses considered	
	8d	Prognostic characteristics (such as staging in oncology) where applicable	
Therapeutic Intervention	9a	Types of intervention (such as pharmacologic, surgical, preventive, self-care)	
	9b	Administration of intervention (such as dosage, strength, duration)	
	9c	Changes in intervention (with rationale)	
Follow-up and Outcomes	10a	Clinician and patient-assessed outcomes (when appropriate)	
	10b	Important follow-up diagnostic and other test results	
	10c	Intervention adherence and tolerability (How was this assessed?)	
	10d	Adverse and unanticipated events	
Discussion	11a	Discussion of the strengths and limitations in your approach to this case	
	11b	Discussion of the relevant medical literature	
	11c	The rationale for conclusions (including assessment of possible causes)	
	11d	The primary "take-away" lessons of this case report	
Patient Perspective	12	When appropriate the patient should share their perspective on the treatments they received	
Informed Consent	13	Did the patient give informed consent? Please provide if requested	Yes ☐ No ☐



Adverse event case reports

International Society for Pharmacoepidemiology

PDS Pharmacoepidemiology & Drug Safety

Official Journal of the International Society for Pharmacoepidemiology

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2007; **16**: 581–587
Published online in Wiley InterScience (www.interscience.wiley.com) **DOI**: 10.1002/pds.1399

ISPE COMMENTARY

Guidelines for submitting adverse event reports for publication[†,‡]

William N. Kelly Pharm D, FISPE (Chair)[1]*, Felix M. Arellano MD, FISPE[2],
Joanne Barnes BPharm, PhD, MRPharmS, FLS[3],
Ulf Bergman MD, PhD, FISPE, FRCP (Edin) Professor[4],
I. Ralph Edwards MB, ChB, MRCS (Lond), FRCP (Lond), FRACP[5],
Alina M. Fernandez MD, MPH[6], Stephen B. Freedman MDCM, MSCI, FRCPC[7],
David I. Goldsmith MD, FISPE[8], Kui Huang PhD, MPH[9],
Judith K. Jones MD, PhD, FISPE[10], Rachel McLeay B Pharm, MPS[11],
Nicholas Moore MD, PhD, FRCP (Edin), FISPE[12], Rosie H. Stather MA[13],
Thierry Trenque MD, PhD[14], William G. Troutman Pharm D, FASHP[15],
Eugene van Puijenbroek MD, PhD[16],
Frank Williams MS, RPh[17] and Robert P. Wise MD, MPH, FISPE[18]

RATS, COREQ and SRQR

Qualitative studies

2003: RATS guidelines

- Can be accessed via SpringerOpen instructions to authors

2007: **CO**nsolidated Criteria for **RE**porting **Q**ualitative Studies

- Focus groups and interviews
- Patient/consumer opinions, priorities, barriers, expectations, needs

2014: **S**tandards for **R**eporting **Q**ualitative **R**esearch

Generic

Recent examples of reports

Way beyond CONSORT

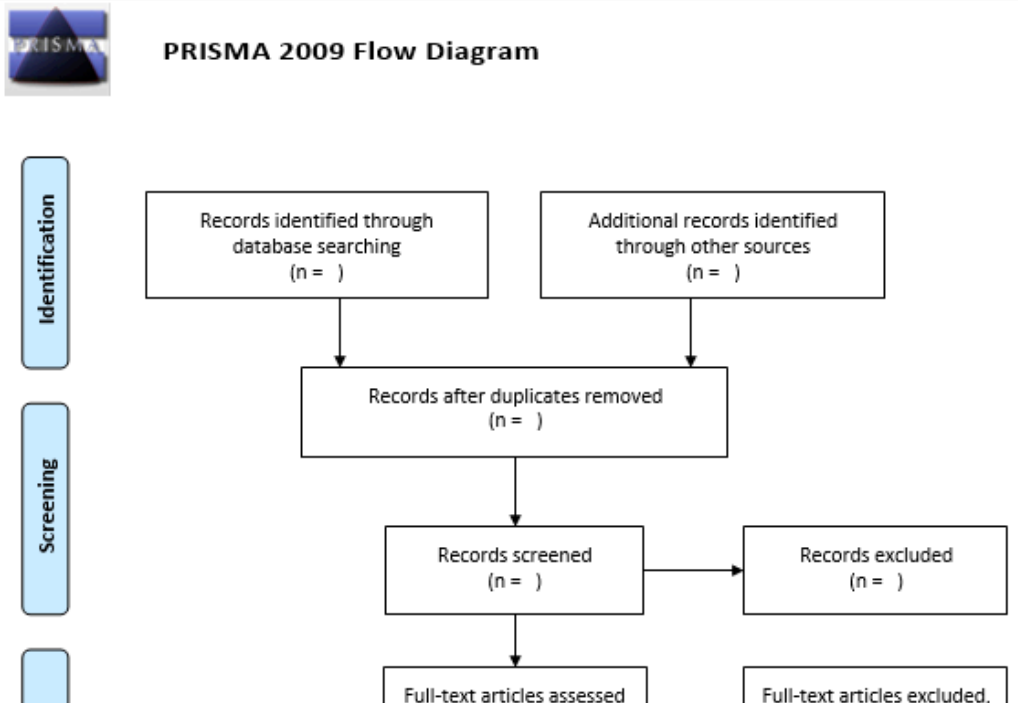
PRISMA

PRISMA
TRANSPARENT REPORTING OF SYSTEMATIC REVIEWS AND META-ANALYSES

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

BMC Medicine

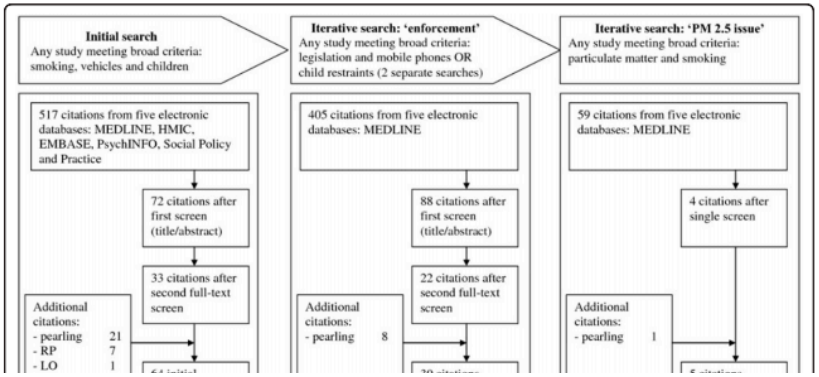
GUIDELINE Open Access

RAMESES publication standards: realist syntheses

Geoff Wong[1*], Trish Greenhalgh[1], Gill Westhorp[2], Jeanette Buckingham[3] and Ray Pawson[4]

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

TITLE		
1		In the title, identify the document as a realist synthesis or review
ABSTRACT		
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.
INTRODUCTION		
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.
METHODS		
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.
7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these.
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.



International Journal of Nursing Studies 47 (2010) 1167–1183

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/ijns

Review

District nurses' role in palliative care provision: A realist review

Catherine Walshe*, Karen A. Luker

The School of Nursing, Midwifery and Social Work, Jean McFarlane Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK

ARTICLE INFO

ABSTRACT

Objectives: The aim of this review is to construct a detailed account of the role of the district nurse (generalist registered nurse providing nursing care in primarily home settings) in providing palliative care, to determine if and how district nursing care provides effective care to such patients at home, and to examine the utility of a realist review for the above purpose.
Design: Realist review of literature.
Data sources: Papers in English reporting aspects of the district nurse role in the provision of palliative care are included. Electronic databases (Ovid Medline, Cinnahl, British Nursing Index, Embase, PsycINFO and EBM reviews) were searched, supplemented by citation tracking and grey literature searches.
Review methods: Assumptions about district nursing practice with palliative care patients are derived from a range of sources. Reviewed papers are interrogated to support, refute or develop these statements.
Results: Forty six papers employing a range of research methods are incorporated into the review. Studies focus on district nurses, patients, family carers and other professionals and include work from a range of countries. Studies highlight the value district nurses place on palliative care provision, the importance of developing a relationship with patients, and the emotional difficulties of providing such care. District nurses have key skills in providing physical care and in coordinating the work of others, but struggle more with psychological aspects of care. District nurses report feeling undervalued, and express some reluctance to work with other health and social care professionals to provide care.
Conclusions: There is little in this synthesis to shed light on the outcomes of care or to explicitly guide practice. District nurses clearly articulate what they consider to be important, but research in this area is limited and needs to undergo a renaissance to examine what is important: namely what district nurses do in practice; what patients and family carers views are on what they do and do not do; and how district nurses can improve care outcomes. The inclusiveness of realist review works well for this field of study.

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

Reporting guidelines under development

The following guidelines are currently being developed:

- PRISMA Harms: improving harms reporting in systematic reviews
- Guidelines for reporting the impact of patient and public involvement in research
- REporting Manualised INterventions for Dissemination and Evaluation (REMINDE) Statement
- CONSORT Extension for Social and Psychological Interventions: CONSORT-SPI
- STROBE checklist for conference abstracts
- CIRCLe SMT project (Consensus on Interventions Reporting Criteria List Spinal Manipulative Therapy)
- Guideline for reporting evidence based practice educational interventions and teaching (GREET) statement
- Guidelines for the Reporting of Neuro-Epidemiological Studies
- Developing Standards for Reporting Phase IV Implementation studies (StaRI)
- eMERGe – Meta-ethnography Reporting Guidelines
- STROBE-Nut: a STROBE extension for Nutrition Epidemiology
- Preferred Reporting Of CasE SerieS (PROCESS) checklist
- Reporting Items for Guidelines in Health Systems (Right)
- Development of a reporting guideline for pilot and feasibility studies
- Reporting Guidelines for IDEAL Prospective Development and Prospective Exploration Studies
- Developing reporting guidelines for single-case experimental designs: the SCRIBE project
- Checklist for assessing the reporting of the updating methodology in updated guidelines
- Checklist for the conduct and reporting of micro-costing studies in health care
- Consort extension to stepped wedge cluster randomised controlled trial
- CONSORT-equity: Improving the relevance of randomized controlled trials for equity-oriented decisions
- Development of a reporting guideline for reporting studies on time to diagnosis
- Consensus on Exercise Reporting Template (CERT)

EQUATOR Library of reporting guidelines

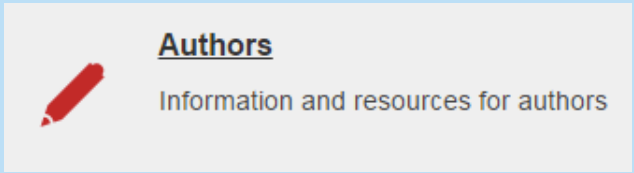
Search by

- 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

Based on work by: equator network

Made by: Penelope

Get in contact

Education and training

UK EQUATOR Centre Publication School

Publication School 2016

27 June-1 July

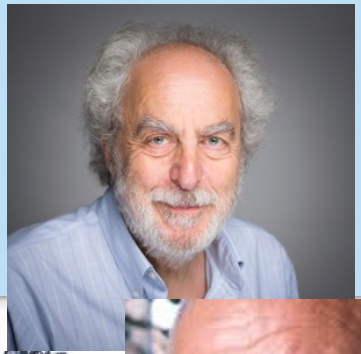
St Catherine's College, Oxford

Registration opening soon

Let me know if you want to go on the email list for priority booking

caroline.struthers@csm.ox.ac.uk

Take home messages from equator network



- 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


EQUATOR SUPPORTS:
Researchers and supervisors
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