2022

ISMPP EUROPE

25–26 January

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Advancing Our Profession:

Driving Leadership and Best Practices in Medical Communications

2022
ISMPP
EUROPE
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Advancing Our Profession: Driving Leadership and Best Practices in Medical Communications

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Consensus-based methods in biomedical research and clinical practice: **The ACCORD study protocol for establishing a reporting guideline**

Tuesday 25th January 2022, 15.15-15.35

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Learning objectives

1

Recognize the value of well-conducted and reported consensus publications

2

Understand that methods of differing rigor exist for reaching consensus

3

Understand the process for developing reporting guidelines

4

Raise awareness that guidance is being established for reporting consensus publications

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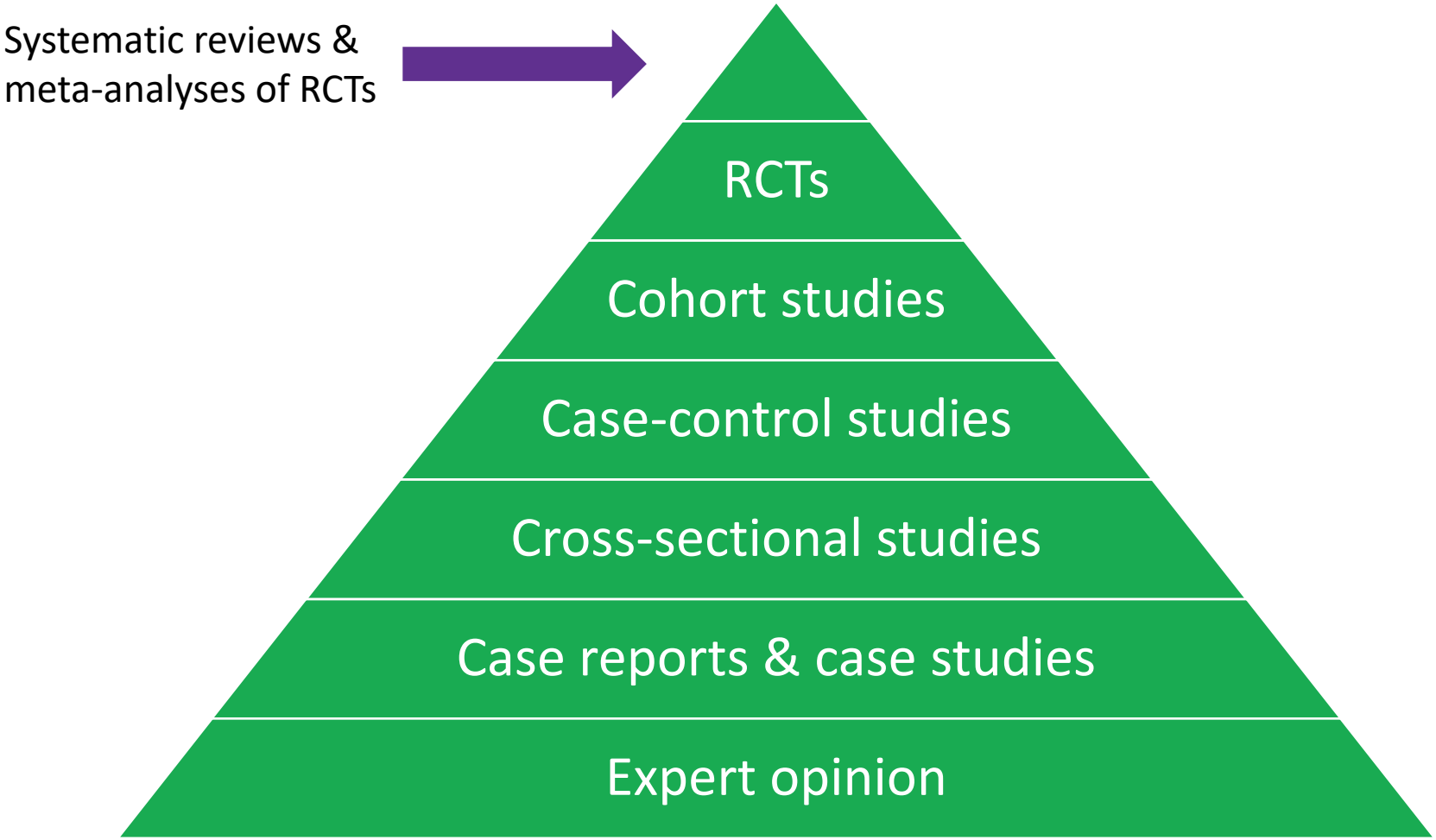
The hierarchy of evidence pyramid



RCTs: randomized controlled trials

Consensus methods can harness expert knowledge to support decision making in areas of uncertainty

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Examples where consensus methodology is used

Forecasting[1]

AN EXPERIMENTAL APPLICATION OF THE DELPHI METHOD TO THE USE OF EXPERTS *†

NORMAN DALKEY AND OLAF HELMER

The RAND Corporation, Santa Monica, California

This paper gives an account of an experiment in the use of the so-called DELPHI method, which was devised in order to obtain the most reliable opinion consensus of a group of experts by subjecting them to a series of questionnaires in depth interspersed with controlled opinion feedback.

1. Introduction

"Project DELPHI" is the name for a study of the use of expert opinion that has been intermittently conducted at The RAND Corporation. The technique employed is called the DELPHI method. Its object is to obtain the most reliable consensus of opinion of a group of experts. It attempts to achieve this by a series of intensive questionnaires interspersed with controlled opinion feedback.

The present paper gives an account of an experiment conducted about ten years ago. The content of the paper has, for security reasons, only now been released for open publication.

The experiment was designed to apply expert opinion to the selection, from the viewpoint of a Soviet strategic planner, of an optimal U. S. industrial target system and to the estimation of the number of A-bombs required to reduce the munitions output by a prescribed amount.

Clinical guidelines[2]

NICE National Institute for Health and Care Excellence

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Read about our approach to COVID-19

Home > News

NICE publishes first rapid COVID-19 guidelines

New guidelines cover the management of patients in critical care, the management of patients who are having kidney dialysis and the management of patients who are receiving systemic anticancer treatments.

21 March 2020

NICE has published its first 3 rapid guidelines on the care of people with suspected and confirmed COVID-19, and in patients without COVID-19.

These guidelines have been developed to maximise patient safety whilst making the best use of NHS resources and protecting staff from infection. The guideline has been developed using the interim process and methods for developing rapid guidelines on COVID-19 and recommendations are based on evidence and expert opinion.

COVID-19 rapid guideline: critical care

The guideline on critical care says that all patients on admission to hospital, irrespective of COVID-19 status, should continue to be assessed for frailty using a recognised frailty score (for example, the Clinical Frailty Scale [CFS]).

It also says the risks and benefits and likely outcomes should be discussed with patients, carers or advocates and families using decision support tools (where available) so that they can make informed decisions about their treatment wherever possible.

For patients with confirmed COVID-19, the guideline says decisions about admission to critical care should be made on the basis of medical benefit, taking into account the likelihood that the person will recover to an outcome that is acceptable to them and within a period of time consistent with the diagnosis.

Reporting guidelines[3,4]

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
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 pre-specified 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	
Randomisation:			
° Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; 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	

PRISMA-2020-Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	

1. Dalkey and Helmer. Management Science Vol. 9, No. 3 (Apr 1963), pp. 458-467
2. https://www.nice.org.uk/news/article/nice-publishes-first-rapid-covid-19-guidelines
3. http://www.consort-statement.org/ 4. http://www.prisma-statement.org/ [accessed January 2022]

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Methods used to develop consensus-based publications

Method	Structured interaction	Face-to-face	Anonymous decisions	Formal feedback	Pros	Cons
Informal meeting	No	Yes	No	No	Speed, simplicity	All voices may not be equal
…and everything in between						
Delphi technique	Yes	No	Yes	Yes	Rigour, transparency	Complex; definition of consensus varies

Other methods include: Nominal Group Technique (NGT); RAND (NGT version); Staticised Group Method

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As with all studies, conduct and reporting are key

"In some cases, the modifications to Delphi are meaningful and contribute to a better understanding of the technique, while in others they are random and arbitrary" [1]

"We believe there is a need to improve the reporting on Delphi studies, along the lines of a CONSORT-like guideline, as is used for randomized controlled trials." [3]

"One final solution would be to phase out the use of the term 'Delphi research' …authors would be obliged to transparently describe the methods that they used without hiding behind the apparent strength of the title 'Delphi research' " [2]

"…undisclosed analytic flexibility makes it unacceptably easy to data mine for and selectively report consensus." [4]

1. Technological Forecasting and Social Change 53, 1996, pp 185-211 (taken from Information & Management 2013, 207)
2. Fam Pract. 2009 Oct;26(5):420-4; 3. J Clin Epidemiology 2014, 67, 401-409; 4. J Clin Epidemiology 2018, 99, 96-105

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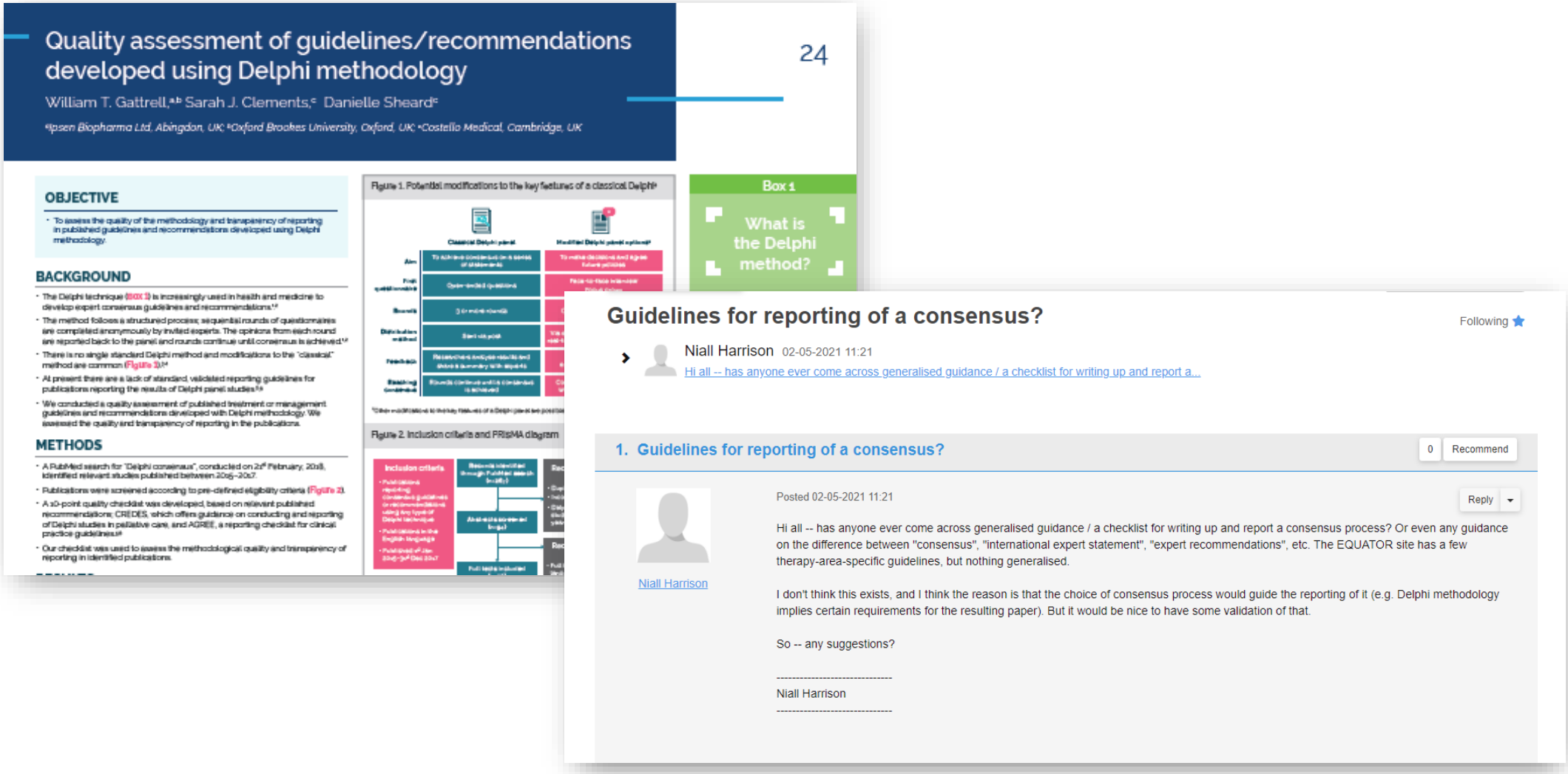
Key role of ISMPP in the genesis of the ACCORD guidelines



Quality assessment of guidelines/recommendations developed using Delphi methodology

24

William T. Gattrell,[a,b] Sarah J. Clements,[c] Danielle Sheard[c]

[a]Ipsen Biopharma Ltd, Abingdon, UK; [b]Oxford Brookes University, Oxford, UK; [c]Costello Medical, Cambridge, UK

OBJECTIVE

- To assess the quality of the methodology and transparency of reporting in published guidelines and recommendations developed using Delphi methodology.

BACKGROUND

- The Delphi technique (Box 1) is increasingly used in health and medicine to develop expert consensus guidelines and recommendations.[1,2]
- The method follows a structured process; sequential rounds of questionnaires are completed anonymously by invited experts. The opinions from each round are reported back to the panel and rounds continue until consensus is achieved.[1,2]
- There is no single standard Delphi method and modifications to the "classical" method are common (Figure 1).[3,4]
- At present there are a lack of standard, validated reporting guidelines for publications reporting the results of Delphi panel studies.[5,6]
- We conducted a quality assessment of published treatment or management guidelines and recommendations developed with Delphi methodology. We assessed the quality and transparency of reporting in the publications.

METHODS

- A PubMed search for "Delphi consensus", conducted on 2nd February, 2018, identified relevant studies published between 2005–2017.
- Publications were screened according to pre-defined eligibility criteria (Figure 2).
- A 30-point quality checklist was developed, based on relevant published recommendations; CREDES, which offers guidance on conducting and reporting of Delphi studies in palliative care, and AGREE, a reporting checklist for clinical practice guidelines.[5,6]
- Our checklist was used to assess the methodological quality and transparency of reporting in identified publications.

Figure 1. Potential modifications to the key features of a classical Delphi[3]

Figure 2. Inclusion criteria and PRISMA diagram

Box 1

What is the Delphi method?

Guidelines for reporting of a consensus?

Following

Niall Harrison 02-05-2021 11:21

Hi all -- has anyone ever come across generalised guidance / a checklist for writing up and report a...

1. Guidelines for reporting of a consensus?

0 Recommend

Niall Harrison

Posted 02-05-2021 11:21

Reply

Hi all -- has anyone ever come across generalised guidance / a checklist for writing up and report a consensus process? Or even any guidance on the difference between "consensus", "international expert statement", "expert recommendations", etc. The EQUATOR site has a few therapy-area-specific guidelines, but nothing generalised.

I don't think this exists, and I think the reason is that the choice of consensus process would guide the reporting of it (e.g. Delphi methodology implies certain requirements for the resulting paper). But it would be nice to have some validation of that.

So -- any suggestions?

Niall Harrison

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Role of EQUATOR in supporting reporting guidelines

EQUATOR is an international network that seeks to improve the reliability and value of published health research literature by promoting transparent and accurate reporting and wider use of robust reporting guidelines

1. Moher, D., K.F. Schulz, I. Simera, and D.G. Altman, Guidance for developers of health research reporting guidelines. PLoS Med. 2010;7(2):e1000217

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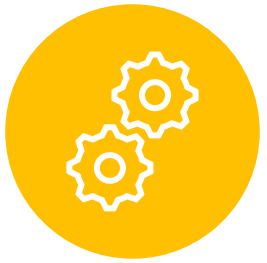
EQUATOR toolkit for developing reporting guidelines

1
Identify the need for a reporting guideline

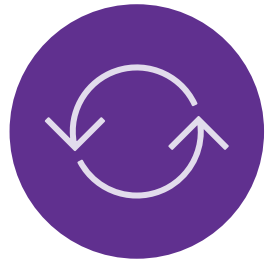
2
Literature review, registration, and funding



3
Develop the guideline

4
Write up and publish the guideline

5
Disseminate the guideline



6
Update the guideline

How to develop a reporting guideline. Avialable at: https://www.equator-network.org/toolkits/developing-a-reporting-guideline/ [Accessed January 2022]

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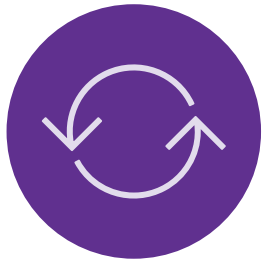
The process for developing the ACCORD guideline

We are here

May-July 2022

Ongoing



TBC!

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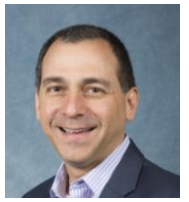
The Steering Committee has a wide range of experience

- Clinician practitioners
- Methodologists
- Publication professionals
- Patient representative
- Publishing industry
- Pharmaceutical industry

Will Gattrell
Ipsen

Niall Harrison
Ogilvy Health



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Zbys Fedorowicz, *University of Sao Paolo*

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A clear need was identified

A search of the EQUATOR network website[1] for "consensus" identified:

- The CREDES statement (2017), providing recommendations for the reporting of Delphi consensus in palliative care specifically[2]
- A protocol for development of a preferred items checklist for reporting e-Delphi studies (REDS) was registered in 2016[3] but has not been published*

- PubMed search on 1 July 2021 for "reporting guidelines" AND "Delphi" found no published guidelines
- The need for reporting guidelines has been identified in systematic reviews[4] and by publication professionals[5]

*REDS organisers subsequently invited to ACCORD Delphi panel

1. https://www.equator-network.org/. 2. https://www.equator-network.org/reporting-guidelines/credes/ 3. Guerreiro MP et al. Available at: https://www.equator-network.org/wp-content/uploads/2009/02/Protocol-E-Delphi-studies-reporting-guideline.pdf Humphrey-Murto et al. Med Teach 2017;39:14-19. 4. J Clin Epidemiology 2014 Apr;67(4):401-9. doi: 10.1016/j.jclinepi.2013.12.002. 5 Gattrell 2019. ISMPP EU, poster 24. All URLs accessed January 2022.

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The objective of ACCORD

To **systematically develop** a reporting guideline to help the **biomedical research and clinical practice community** describe the **methods used to reach consensus** in a complete, transparent, and consistent manner

August-September 2021

Writing up, registering and submitting the protocol

ACCORD – ACcurate COnsensus Reporting Document (registered 7 October 2021)

Guidelines for clinical decision making may be formulated based on expert consensus only in situations where there is no robust evidence available, when divergent guidance exists, or when there is a need for collective judgement to increase reliability and validity. Consensus methods provide the opportunity to harness the knowledge of experts to support clinical decision making in areas of uncertainty. However, the lack of appropriate description of the consensus methods used in publications (including the definition or threshold for agreement, the analytical methods, the expert recruitment process, funding sources and others) suggests that a reporting guideline is needed.

This project aims to systematically develop a reporting guideline to help the scientific community describe the methods used to reach consensus in a complete and transparent manner. A literature revie
except for the CRESS Statement, which is focused on palliative care only.
published soon. A Delphi process will guide the development of a checklist a
explanation and elaboration document, will be published with open access d
darwinhc.

Registered with EQUATOR[1]

1 **Consensus-based methods in biomedical research and clinical practice: The**
2 **ACCORD study protocol for establishing a reporting guideline**
3
4 William T. Gattrell,[1] Amrit Pali Hungin,[2] Bernd W. M. Arents,[3] Christopher C. Winchester,[4] David
5 Tovey,[5] Ellen L. Hughes,[6] Esther J van Zuuren,[7] Keith Goldman,[8] Patricia Logullo,[9] Rob
6 Matheis,[10] Niall Harrison,[11]
7 Affiliations: 1. Ipsen, UK. 2. University of Newcastle, UK. 3. Dutch Association for People with
VMCE). 4. Oxford PharmaGenesis, UK. 5. Journal of Clinical Epidemiology,
imited. 7. Leiden University Medical Centre, Leiden, The Netherlands. 8.
9. Centre for Statistics in Medicine (CSM), University of Oxford, and
k UK Centre, Oxford, UK. 10. ISMPP, USA. 11. Ogilvy Health, UK.
hor: Will Gattrell

Submitted to Research Integrity and Peer Review

OSF REGISTRIES — Add New | My Registrations | Help | Donate | Join | Login

Consensus-based methods in biomedical research and clinical practice: The ACCORD study for establishing a reporting guideline

Public registration | Updates

Overview
Files
Wiki
Components 0
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Analytics
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Study Information

Hypotheses

Inconsistencies in how consensus processes are reported makes it difficult for the rigor and quality of the outcomes to be assessed. It is hypothesized that a systematically developed reporting guideline will help the biomedical research and clinical practice community describe the methods used to reach consensus in a complete, transparent, and consistent manner.

Design Plan

Study type
Other

Blinding
No blinding is involved in this study.

Is there any additional blinding in this study?
Extractors will be blinded to each other's evaluations for the

Contributors
Rebecca Hornby

Description
The ACCORD (ACcurate COnsensus Reporting Document) reporting guideline will provide a set of minimum items that should be reported about methods used to achieve consensus, including approaches ranging from simple unstructured opinion gatherings to highly structured processes.

Registration type
OSF Preregistration

Date registered
December 15, 2021

Date created
December 15, 2021

Registered with OSF[2]

1. https://www.equator-network.org/library/reporting-guidelines-under-development/reporting-guidelines-under-development-for-other-study-designs/#ACCORD 2. https://osf.io/973zu [Accessed January 2021]

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Creating online channels

The final checklist and related publications will be archived at https://accordstatement.wordpress.com/

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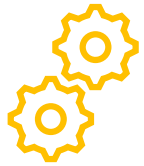
Ongoing

Literature research ongoing



- Systematic review process is informed by and will be reported according to PRISMA guidelines
- Search strategy developed covering **multiple databases**: Web of Science (core collection), MEDLINE (Web of Science), PubMed, MEDLINE (OVID), Embase (OVID), Cochrane Library, Emcare (OVID), Academic Search Premier, and PsycInfo
- Identifying research assessing the **quality of reporting of consensus recommendations** in biomedicine
- Ineligible studies will include individual reporting guidelines or treatment guidelines
- Screening of search results and analysis of the findings is **underway**
  - Preliminary results are that 2736 references were identified; review and adjudication of references for relevance is ongoing

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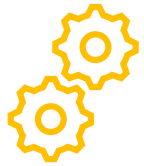
Ongoing

Join us!



- What we need:
  - Qualified individuals to join a Delphi panel to validate the draft ACCORD reporting guideline in March/April
  - Time commitment ~8 hours over ~2 months
- Qualified individuals include:
  - Those who **support, design, and report** consensus research (methodologists, clinicians, publication professionals, pharmaceutical industry representatives)
  - Those **who publish, use, or are affected by** consensus research (journal editors, clinicians, patients)
- To nominate yourself or another individual, please contact ACCORD@ogilvy.com

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Thank you for your attention!