

Using the ACCORD guideline to report consensus research

What medical writers need to know

Disclosure

William T. Gattrell is an employee of Bristol Myers Squibb

Patricia Logullo is a member of the UK EQUATOR Centre, based in the University of Oxford; EQUATOR promotes the use of reporting guidelines, many of which are developed using consensus methods, and she is personally involved in the development of other reporting guidelines

Niall Harrison is an employee of OPEN Health Communications

Tim Warren is an employee of Triducive Partners Limited

At the outset of the work, Niall Harrison was an employee of Ogilvy Health UK and William Gattrell was an employee of Ipsen

Introduction

Niall Harrison

Today's objectives

Understand the value of reporting guidelines for medical writers

Be aware of the variety of consensus methods available

Learn how ACCORD can support the reporting of studies using consensus methods

Agenda

Timing	Topic	
10 minutes	Introduction	Niall Harrison
10 minutes	How reporting guidelines help medical writers	William Gattrell
10 minutes	An overview of consensus methods	Tim Warren
15 minutes	The development and structure of the ACCORD checklist	Niall Harrison
20 minutes	Examples of good consensus reporting	Patricia Logullo
20 minutes	Panel and Q&A	All
5 minutes	Summary and close	William Gattrell

ACCORD steering committee



Will Gattrell
Bristol Myers Squibb



Niall Harrison
OPEN Health



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*University of Oxford and
EQUATOR*



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Christopher C. Winchester
Oxford PharmaGenesis



David Tovey
*Journal of Clinical
Epidemiology*



Keith Goldman
AbbVie



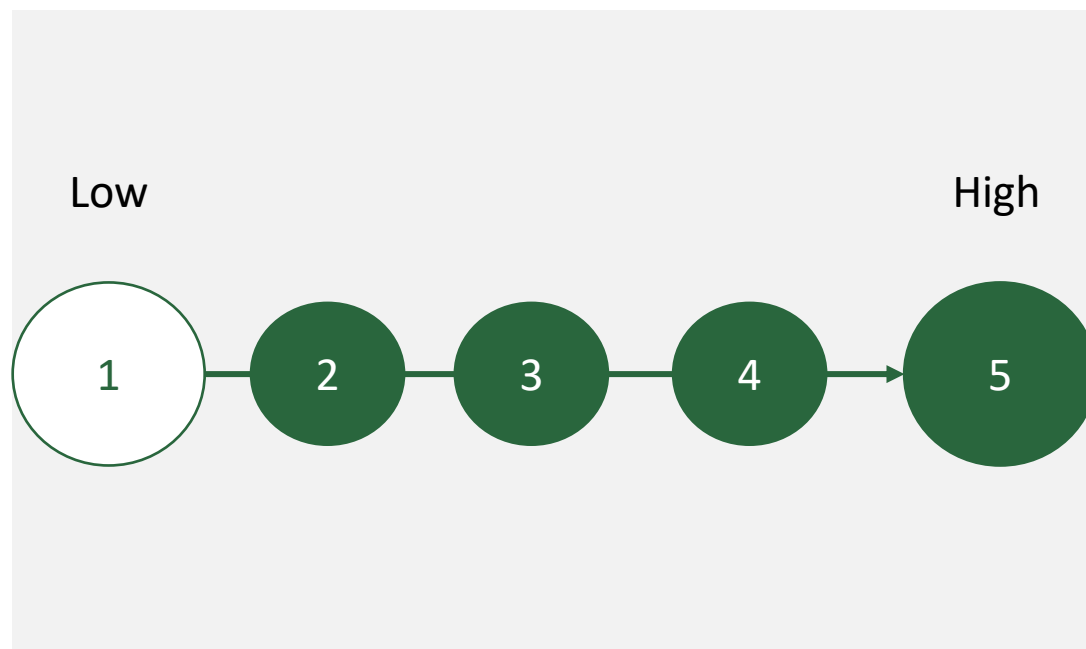
Amrit Pali Hungin
University of Newcastle



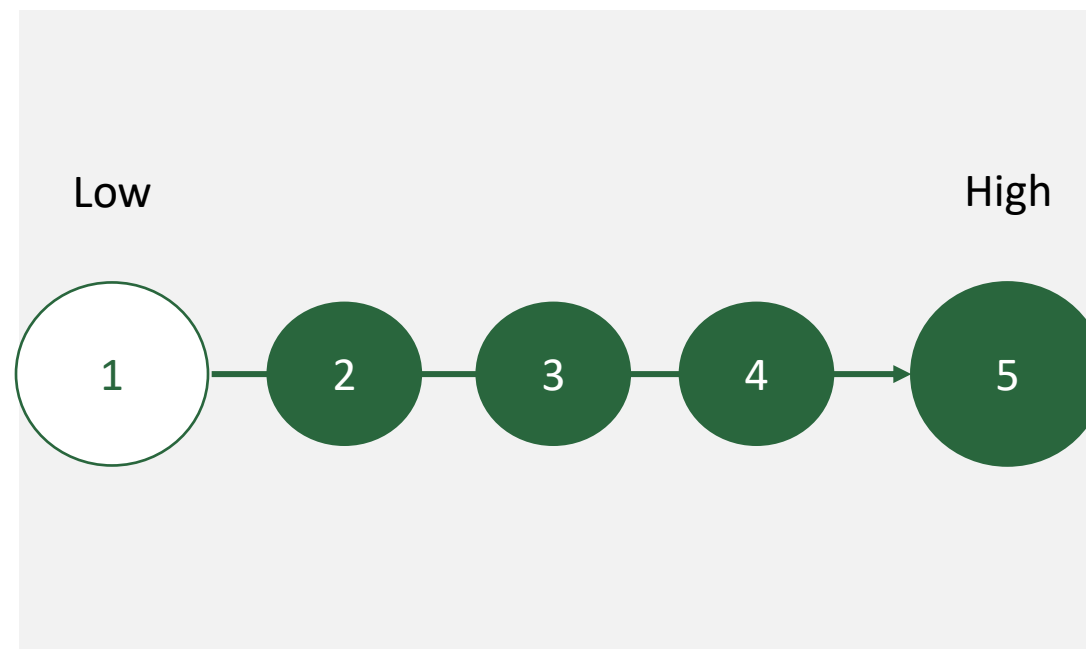
Ellen L. Hughes
Camino Communications

Poll

1. How confident are you in using reporting guidelines?



2. How experienced are you with studies using consensus methods?



How reporting guidelines help medical writers

William Gattrell

Early example of a controlled trial

“On the 20th of May 1747, I selected twelve patients in the scurvy, on board the Salisbury at sea. Their cases were as similar as I could have them. They all in general had putrid gums, the spots and lassitude, with weakness of the knees...

Two were ordered each a quart of cyder a day. Two others took twenty-five drops of elixir vitriol three times a day ... Two others took two spoonfuls of vinegar three times a day ... Two of the worst patients were put on a course of sea-water ... Two others had each two oranges and one lemon given them every day...

The consequence was, that the most sudden and visible good effects were perceived from the use of oranges and lemons”

Poor reporting in scientific publications

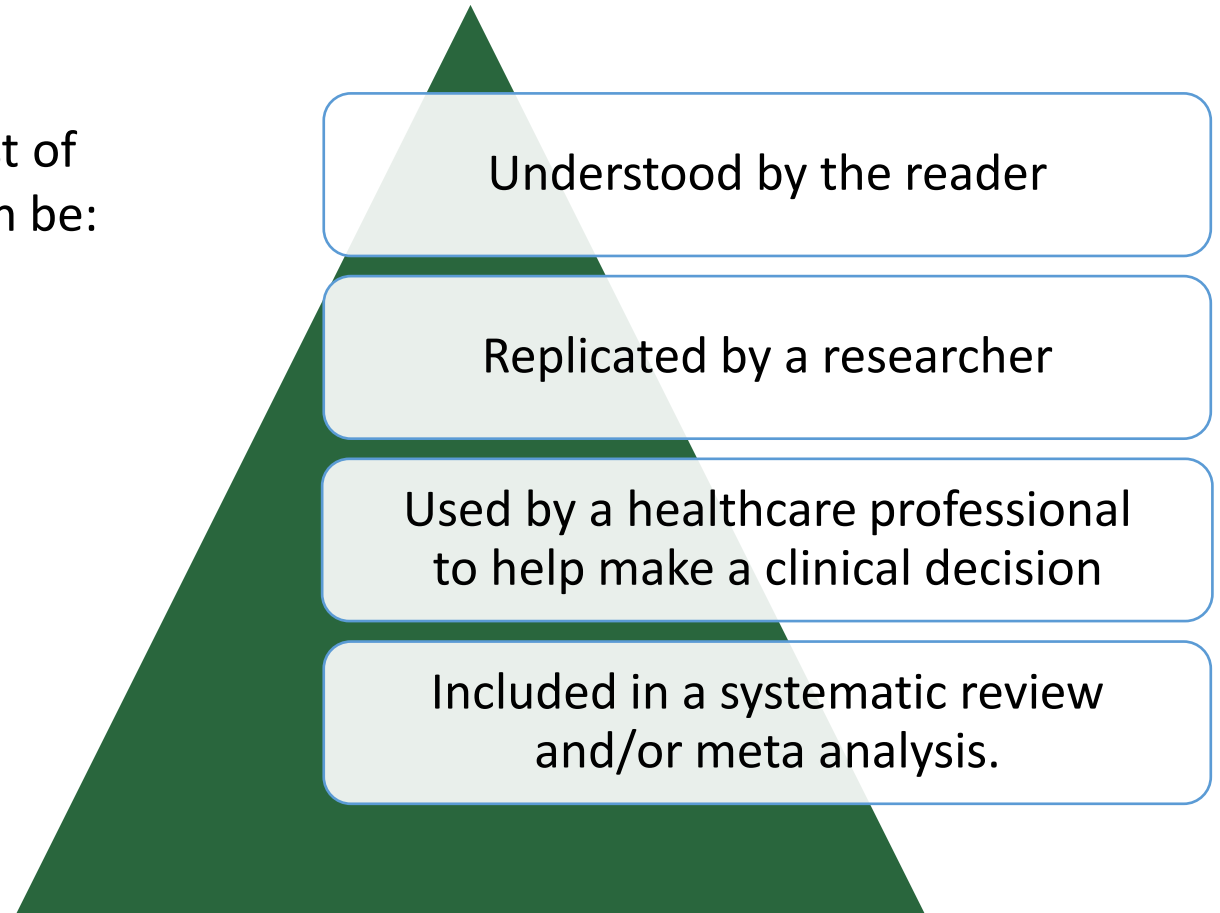
“... incompleteness of evidence is not merely a failure to satisfy a few highly critical readers. It not infrequently makes the data that are presented of little or no value.”¹

“In one in three published clinical trials on covid-19 drugs, the quality of reporting of adverse events was low or very low.”²

“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

What is a reporting guideline?

A reporting guideline provides the minimum list of information needed to ensure a manuscript can be:



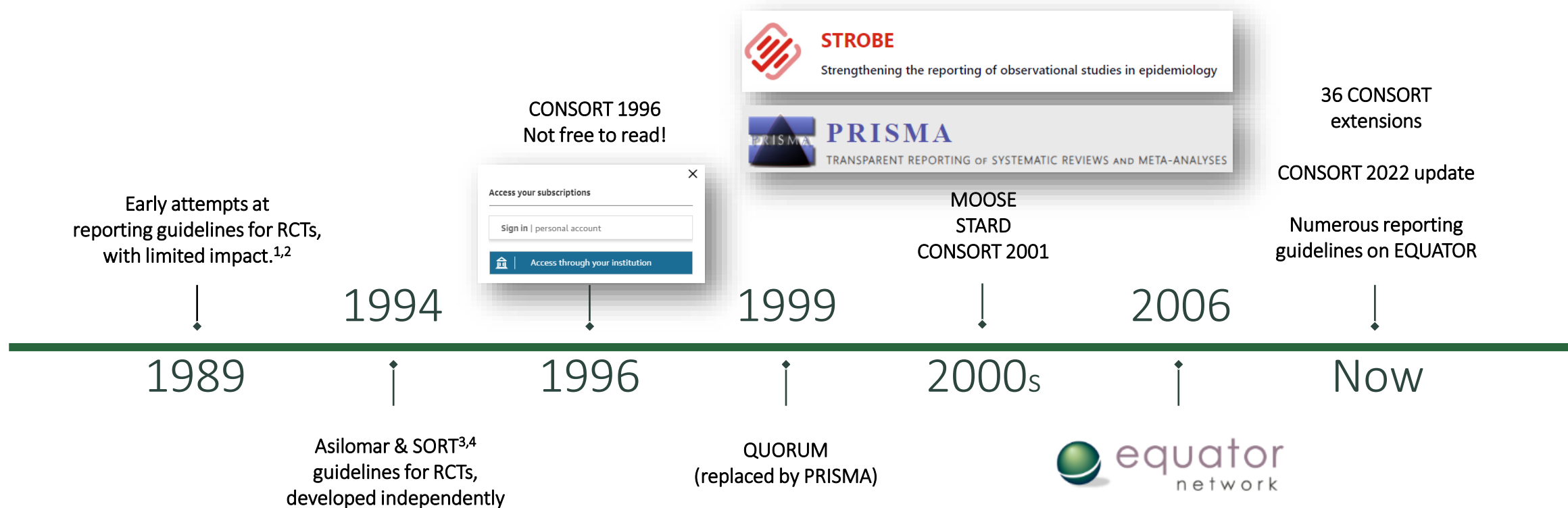
A note of caution

A reporting guideline is not a tool to measure the quality of reporting¹

Reporting guidelines do not provide guidance on study design

A *well-reported* study may not be a *well-designed* study

Evolution of reporting guidelines



Major reporting guidelines often provide additional resources

Section/Topic	Item No	Checklist item	Reported on page No
CONSORT 2010 checklist of information to include when reporting a randomised trial*			
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 interventions	_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	_____

Methods

Item 3a. Description of trial design (such as parallel, factorial) including allocation ratio

Example—“This was a multicenter, stratified (6 to 11 years and 12 to 17 years of age, with imbalanced randomisation [2:1]), double-blind, placebo-controlled, parallel-group study conducted in the United States (41 sites).”

Explanation—The word “design” is often used to refer to all aspects of how a trial is set up, but it also has a narrower interpretation. Many specific aspects of the broader trial design, including details of randomisation and blinding, are addressed elsewhere in the CONSORT checklist. Here we seek information on the type of trial, such as parallel group or factorial, and the conceptual framework, such as superiority or non-inferiority, and other related issues not addressed elsewhere in the checklist.

Explanation & Elaboration Document

BMJ. 2010;340:c869
J Clin Epidemiol. 2010;63(8): e1-e37

Ann Int Med. 2010;152(11):726-32; BMC Medicine. 2010;8:18.
BMJ. 2010;340:c332; J Clin Epidemiol. 2010;63(8): 834-40.
Lancet. 2010;375(9721):1136 [supplementary webappendix](#)
Obstet Gynecol. 2010;115(5):1063-70. 783; Trials. 2010;11:32.
Open Med. 2010;4(1):60-68; PLoS Med. 2010;7(3): e1000251

Summary

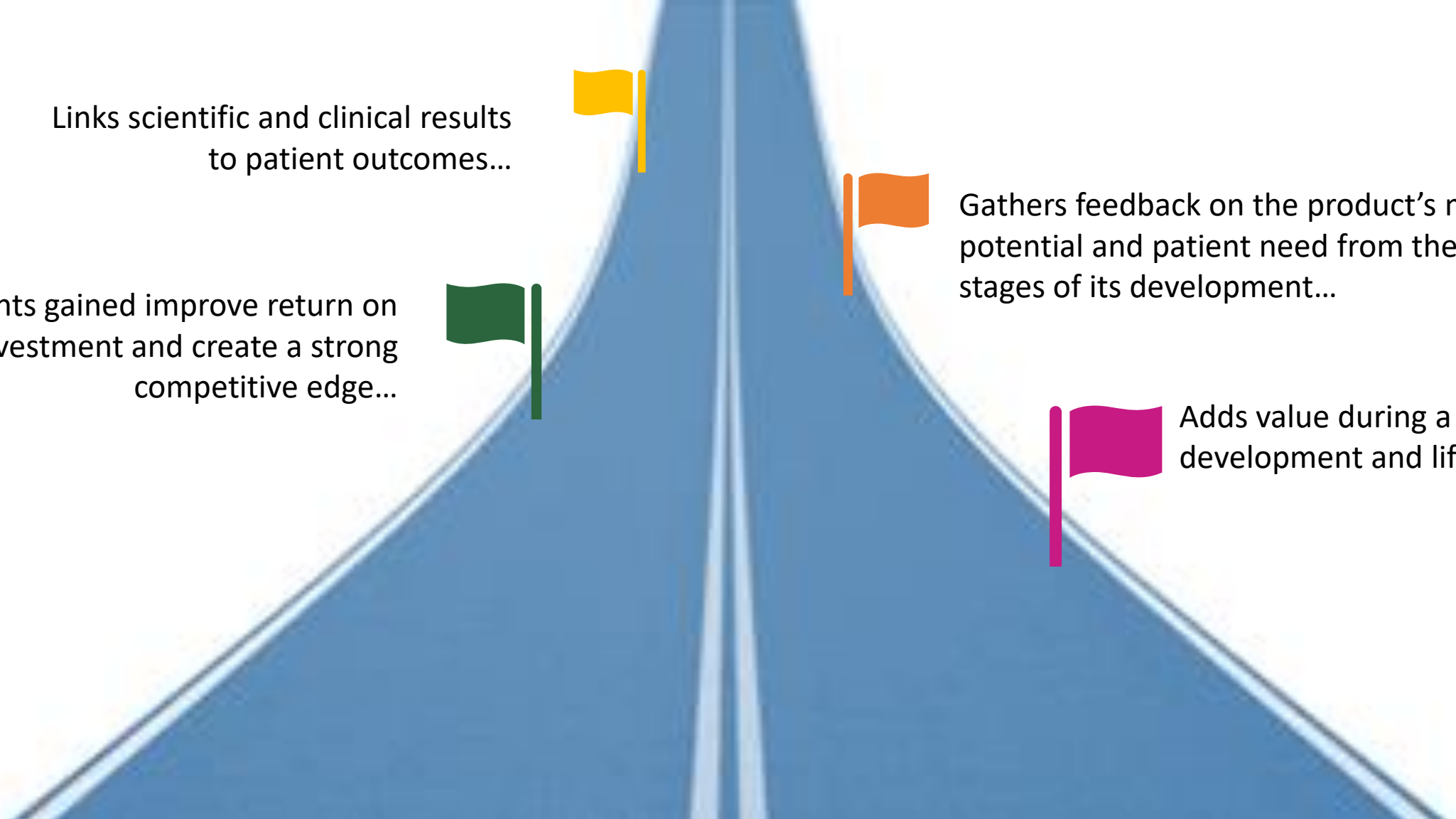
- Reporting guidelines are available for most study types
- Using them will improve the quality of reporting in your manuscript
- Often, supporting materials are available:
 - Explanation & Elaboration document
 - Downloadable templates
 - Translations
- See EQUATOR Network: <https://www.equator-network.org/>

An overview of consensus methods

Tim Warren

Better decisions, actioned... ...the benefit of Consensus

What does a Medical Team do?



Links scientific and clinical results
to patient outcomes...

Insights gained improve return on
investment and create a strong
competitive edge...

Gathers feedback on the product's market
potential and patient need from the earliest
stages of its development...

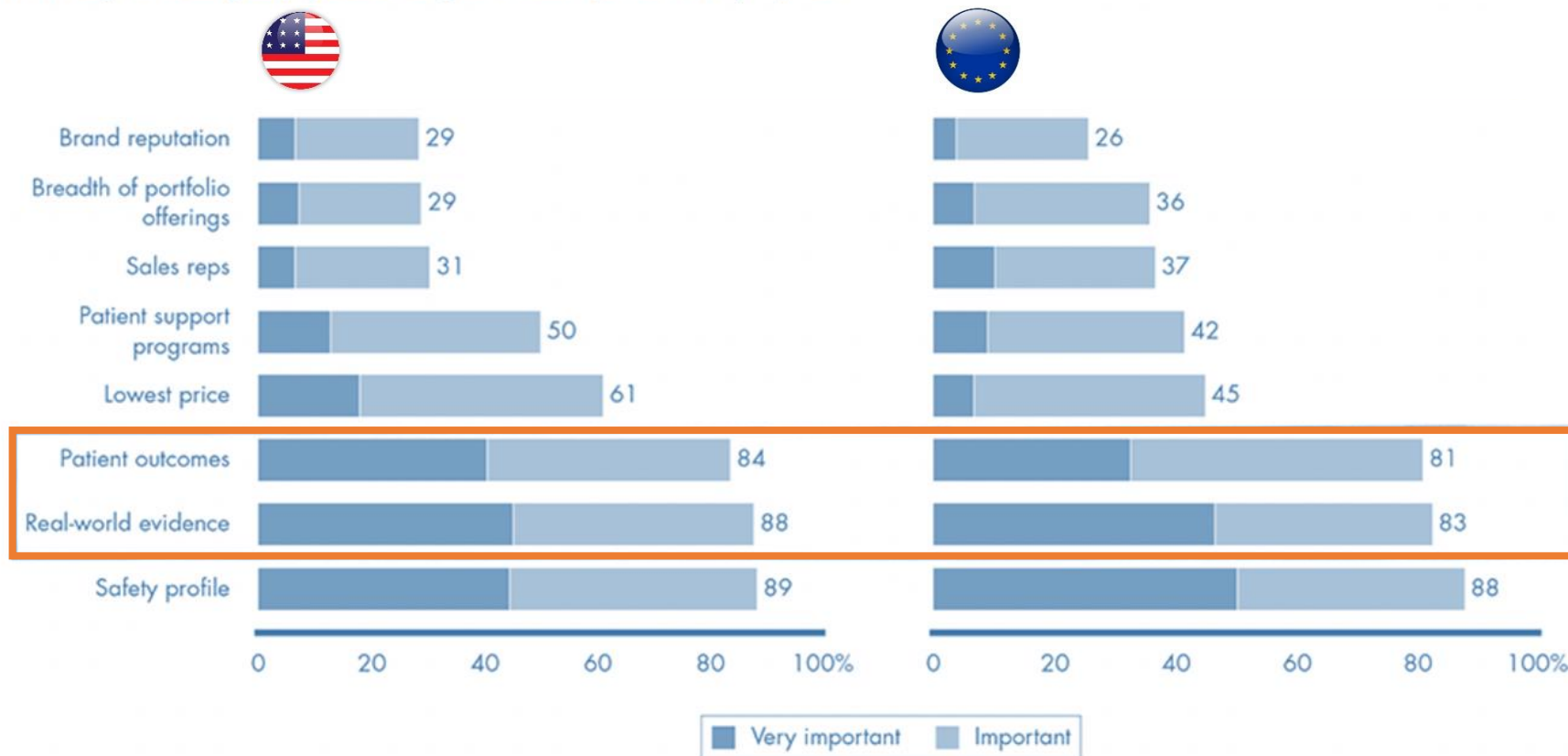
Adds value during a product's
development and lifecycle...

But is there ... should there be more?



US and EU Physicians Rate Patient Outcomes and Real-World evidence as the Key Prescribing Criteria

Percentage of nonsurgical physicians rating criteria as important or very important



...on a par with the product's safety profile!

Source: Bain Europe Front Line of Healthcare Survey, 2016

Health economic models

Well conducted case control or cohort studies

Retrospective studies

High quality meta-analysis

Real-world data, audits and registries

HTA guidance

Opinion

Guidelines

Time in motion studies

Patient stories

Health policy

Systematic reviews of randomised controlled trials (RCTs)

High quality systematic reviews

QoL studies

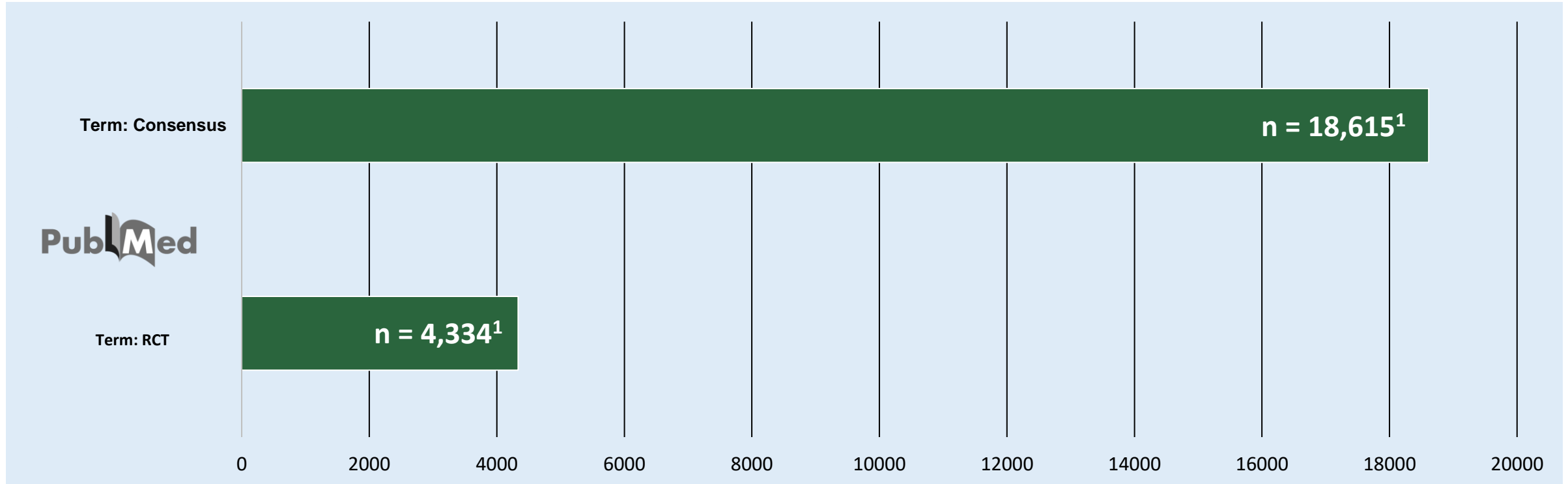
Non-analytical studies, e.g. case reports, case series



A genuine leader is not a searcher for consensus, but a moulder of consensus.

Martin Luther King, Jr.

Consensus dominates published literature



A simple *PubMed* search (using MeSH terms) demonstrated the number of published RCT studies versus consensus studies in 2021¹.

Consensus decisions are beneficial & implementable

*Adapted from: Kotter's
8 Step Process for Leading Change



Consensus decision-making is a process that builds trust and creates ownership and commitment.

An effective consensus process (consensus-building) is inclusive and engages all participants.

Consensus decisions can lead to better quality outcomes that empower the group or community to move forward to create **their future together**.

Create urgency

Form consensus

Create a vision

Communicate the vision

Create easy wins

Build on the change

Anchor the change

ACCORD



Accurate Consensus Reporting Document

**“Evidence based on expert opinion
remains a necessary component in the
armamentarium used to determine the
answer to a clinical question”**

How to achieve consensus

Meetings

NGT

Delphi

Rigor

How to achieve consensus

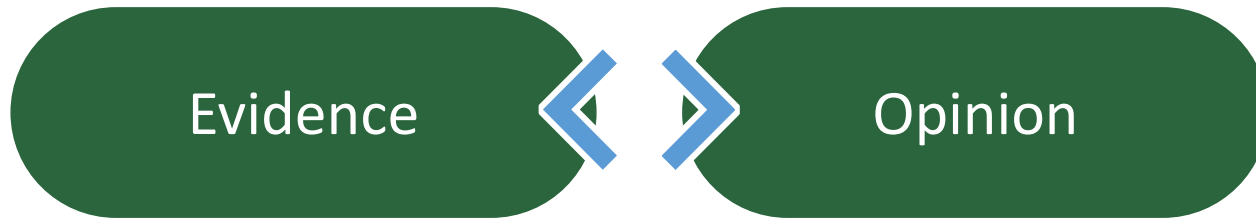
Individual

Peer

Community

Meetings	Ad Board	NGT	Delphi
Easy to organise	Require organisation and compliance	Require organisation and compliance (similar to ad board)	Require independent facilitator
Need to be well run to avoid going off-piste	More specificity	Create a higher-quality decision than a vote decision or a decision by a single individual	Do not involve a Chairperson and mitigate dominance
Cynicism about why (and who) made decisions	Potential skepticism about bias and outputs achieved	Enables a group to take advantage of all members' ideas	Inclusive and engages all participants
	Confidential in nature limiting impact of decisions reached	Structured, specific and inclusive	Allows for testing, learning and iteration
	Round tables may be published	Confidence in outputs because clarity as to HOW/WHY they were included	Consensus decisions can lead to better quality outcomes
			Empowers the group or community to move forward to create their future together
Limited external impact	Often confidential	Can be published	Can be published

The Nominal Group Technique (NGT)



The Nominal Group Technique was initially conceived by Andrew H. Van de Ven and Andrew L. Delbecq in their 1975 book *Group techniques for program planning: A guide to nominal group and Delphi processes*.

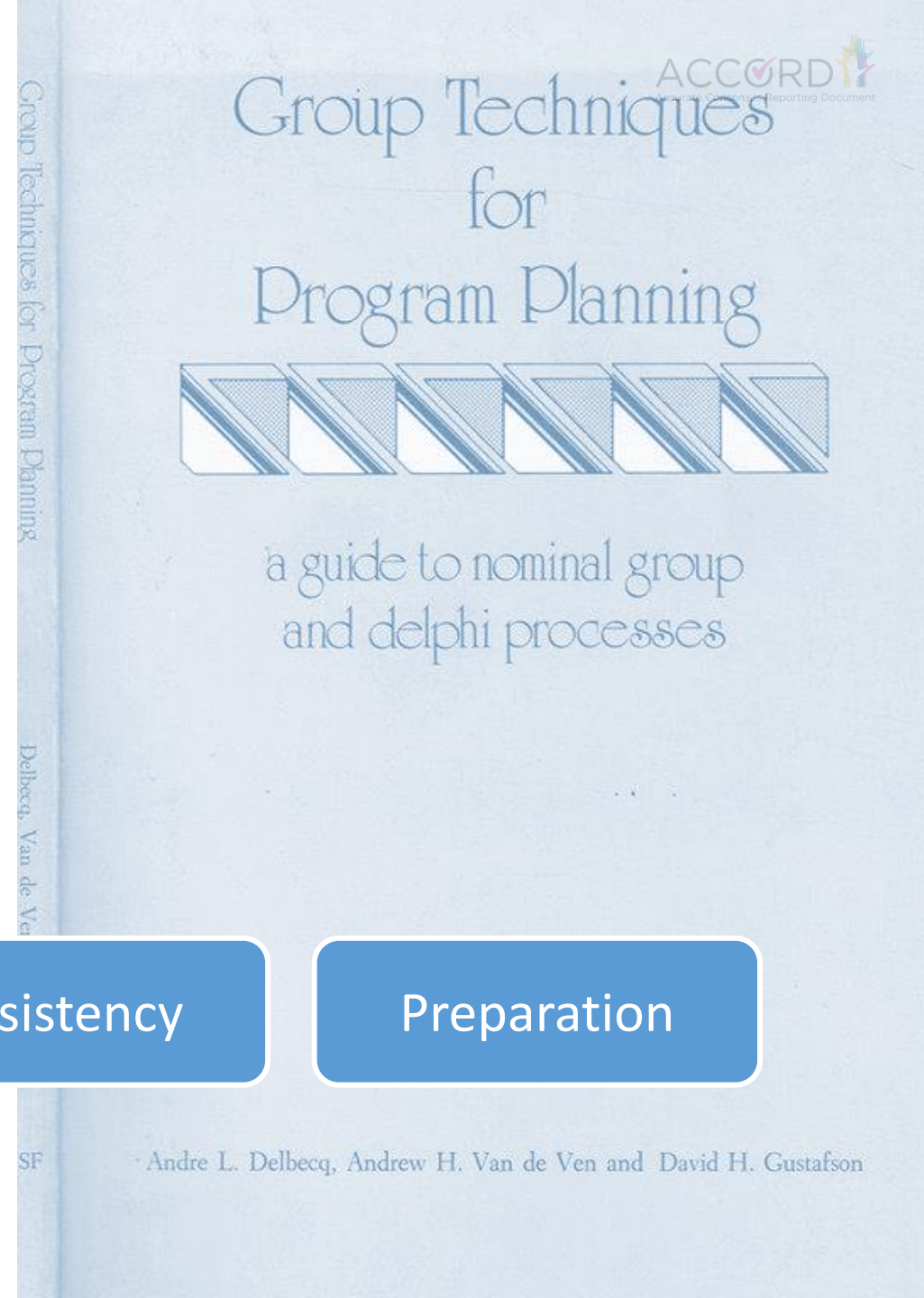
The Nominal Group Technique (NGT) is a brainstorming framework that encourages equal contribution from stakeholders and facilitates group consensus on key issues, problems, and their solutions.

Recognition

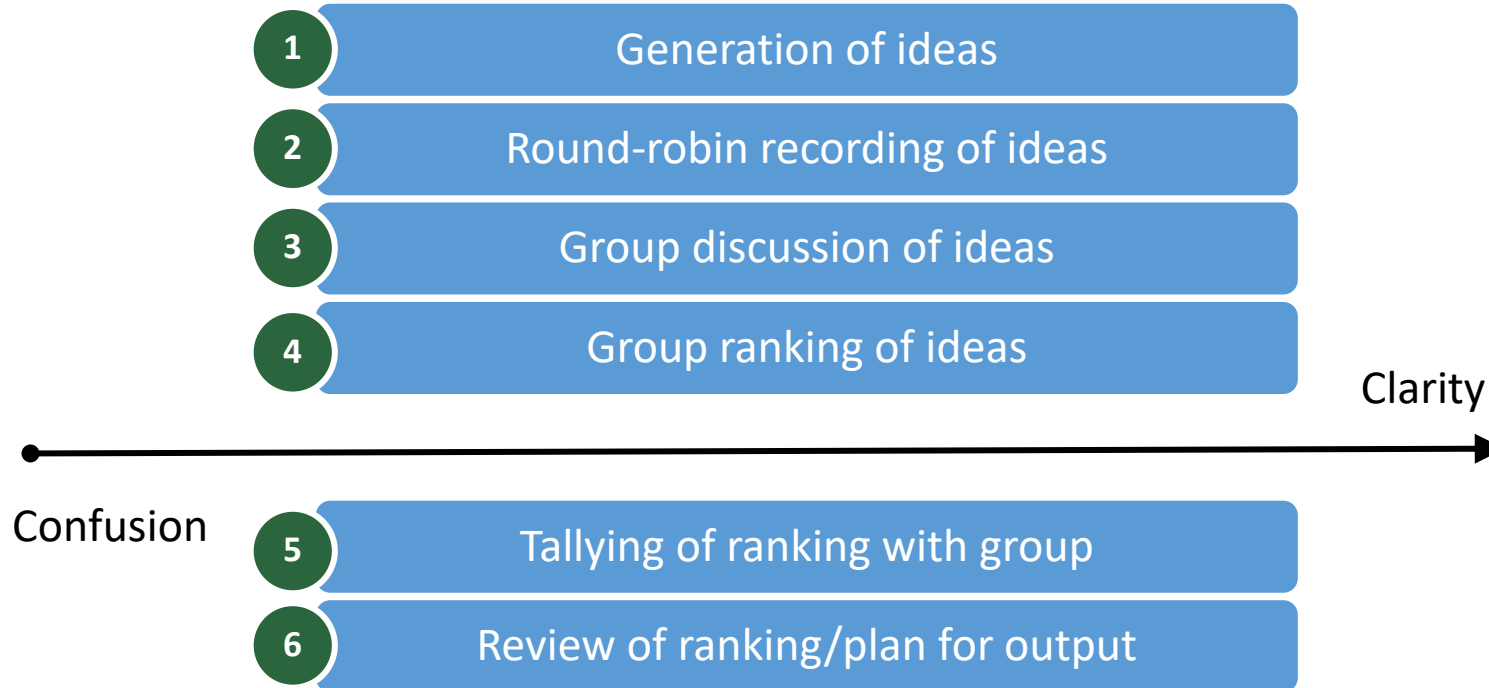
Equity

Consistency

Preparation



The Nominal Group Technique (NGT)



“



Originating in the US

Systematic and iterative

Aggregate opinions from
diverse experts

Preserves anonymity

**Many treatment or
management guidelines
have been developed
using the Delphi method.**

Delphi consensus is robust, credible & widely accepted

Delphi consensus is a recognised approach already **applied regularly to healthcare situations**

“Addresses complex healthcare issues where research based evidence is incomplete or unobtainable”

International Journal of Pharmacy Practice



BSG consensus guidelines on the management of Inflammatory Bowel Disease in adults

September 2019

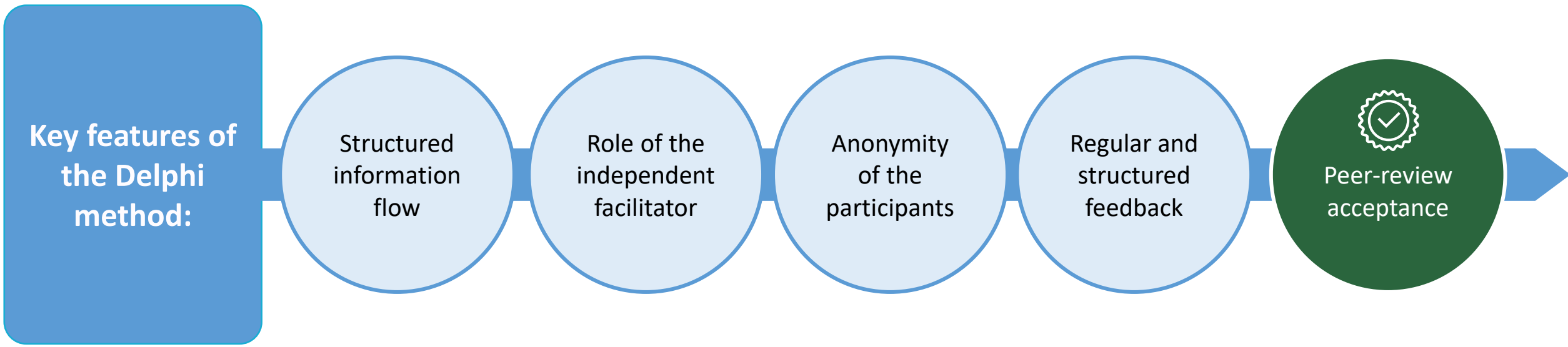


Association of Anaesthetists

Consensus guidelines for managing the airway in patients with COVID-19

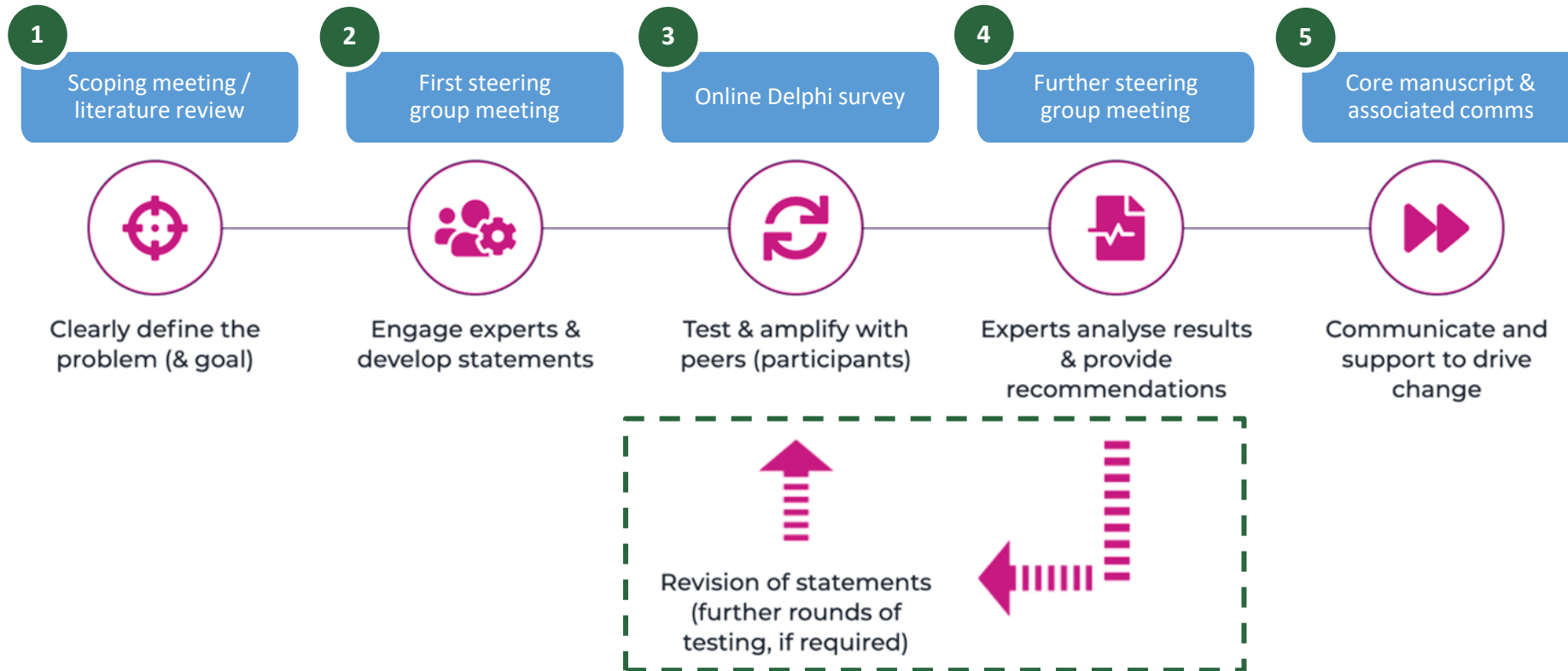
March 2021

Delphi consensus is well recognised and credible



Delphi consensus approach

Insightful, iterative, interactive & amplifying approach



Delphi consensus anticipated benefits

Validated outputs from Delphi consensus studies can be readily developed into a wider communication campaign and support the objective



What can be achieved

- ✓ **Data (Evidence Level 4) to robustly support the core argument**
- ✓ **Content for medical education, communication & campaigning via PR activities**
- ✓ **Credible basis & strong platform to mobilise advocacy in support of behaviour change needed**

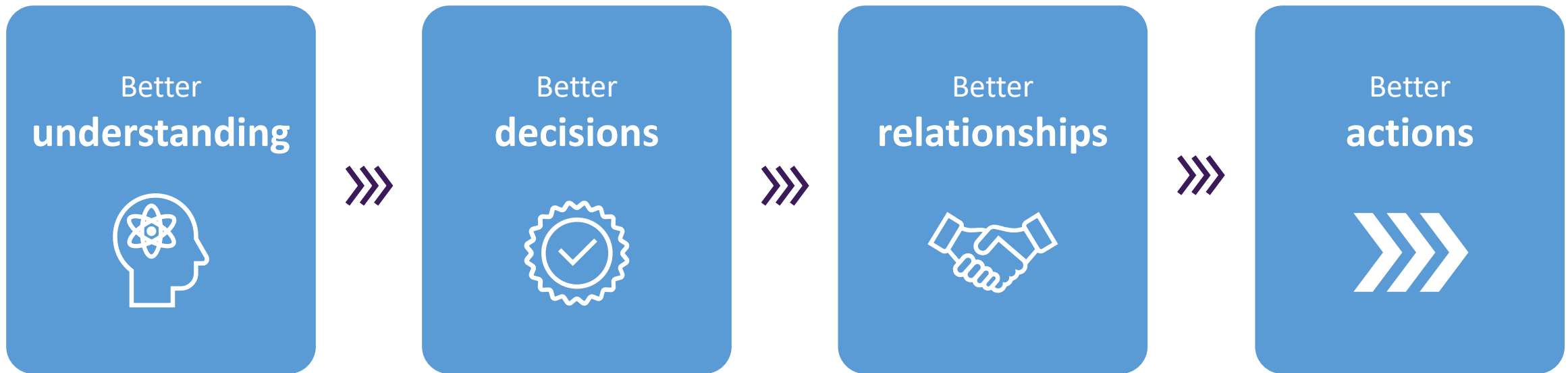
The types of opportunities for this approach are:



Case studies at triducive.com

Delphi is a robust, powerful & applicable communication & research approach

It is not suitable in all healthcare situations , but any situation requiring...



...must be assessed so that the feasibility for Delphi communications can be expertly explored.

Better decisions, actioned... ...the benefit of Consensus



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The development and structure of the ACCORD checklist

Niall Harrison

Background: why ACCORD?



Group consensus
more reliable than
individual opinions
and experiences¹⁻³



Reporting of studies
using consensus
methods is often of
poor quality⁴⁻⁷

A comprehensive reporting tool is needed because numerous methods are used to assess consensus.

1. Kurvers RH, et al. Proc Natl Acad Sci U S A. 2016;113(31):8777-82.
2. Surowiecki J. The wisdom of crowds. New York, USA: Anchor; 2004.
3. Woolley AW, et al. Science. 2010;330(6004):686-8.
4. van Zuuren EJ, et al. BMJ Open. 2022;12(9):e065154.
5. Blazey P, et al. Br J Sports Med. 2022;56(6):306-7.
6. Diamond IR, et al. J Clin Epidemiol. 2014;67(4):401-9.
7. Gupta UG. Technol Forecast Social Change. 1996;53(2):185-211.

How it started

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?



Niall Harrison

Posted 02-05-2021 11:21

Hi all -- has anyone ever come across generalised guidance / a checklist for writing up and report a... on the difference between "consensus", "international consensus", "international therapy-area-specific guidelines, but nothing generalised?"

I don't think this exists, and I think the reason is that consensus implies certain requirements for the resulting publication.

So -- any suggestions?

Niall Harrison

Quality assessment of guidelines/recommendations developed using Delphi methodology

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

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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†}
- The method follows a structured process; sequential rounds of questionnaire are completed anonymously by invited experts. The opinions from each round are reported back to the panel and rounds continue until consensus is achieved.^{2†}
- There is no single standard Delphi method and modifications to the "classical" method are common (Figures 3)^{3†}
- At present there are a lack of standard, validated reporting guidelines for publications reporting the results of Delphi panel studies.^{4†}
- 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 26th February, 2020, identified relevant studies published between 2009–2020.
- Publications were screened according to pre-defined eligibility criteria (Figure 2).
- A 20-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†}
- 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

	Classical Delphi panel	Modified Delphi panel options†
Aim	To achieve consensus on a series of statements	To make decisions and agree future actions
Form/questionnaire	Open-ended questions	Fixed-choice questions Fixed choices
Round(s)	2 or more rounds	One via email then 2 rounds
Distribution method	Self via post	Via email or online survey, via tablet app from 10 experts in the same room
Feedback	Researchers analyse results and share summary with experts	Automatic analysis e.g. using word cloud software
Ending consensus	Rounds continue until consensus is achieved	Consensus reached in 1st round with experts in the same room

†Other modifications to the key features of a Delphi panel are possible

Figure 2. Inclusion criteria and PRISMA diagram



Box 1

What is the Delphi method?

The Delphi method is a structured, iterative technique that can be used to achieve consensus opinion in an anonymous way.



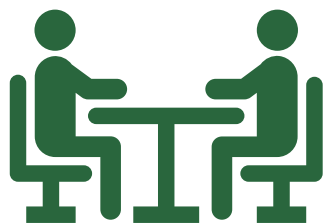
Experts in the field are invited

↓

Experts provide opinion on a series of statements or questions

The objective of ACCORD

- Develop a reporting guideline relevant for ...



All types of consensus
methods



All areas of health
research



Researchers anywhere in
the world

Project overview and timeline: protocol

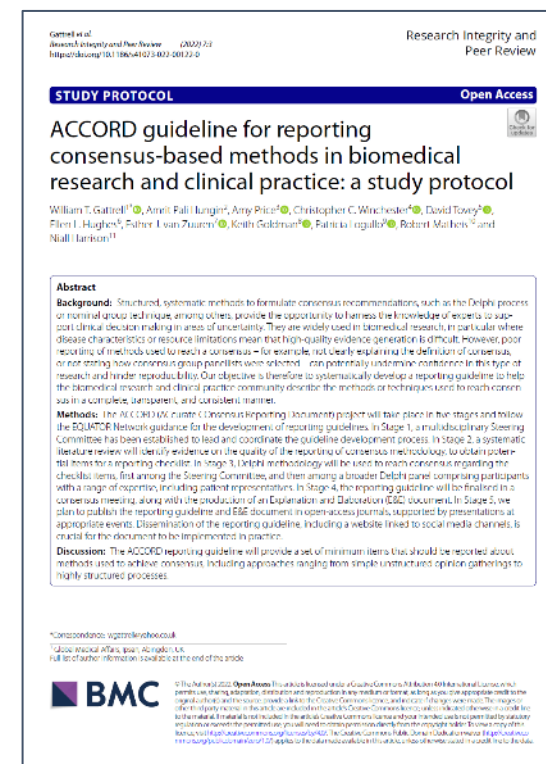


EQUATOR and OSF registration

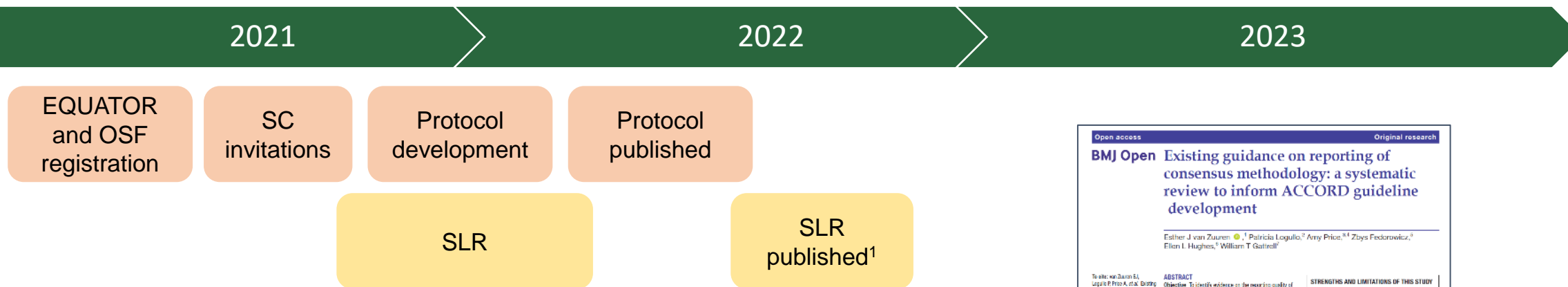
SC invitations

Protocol development

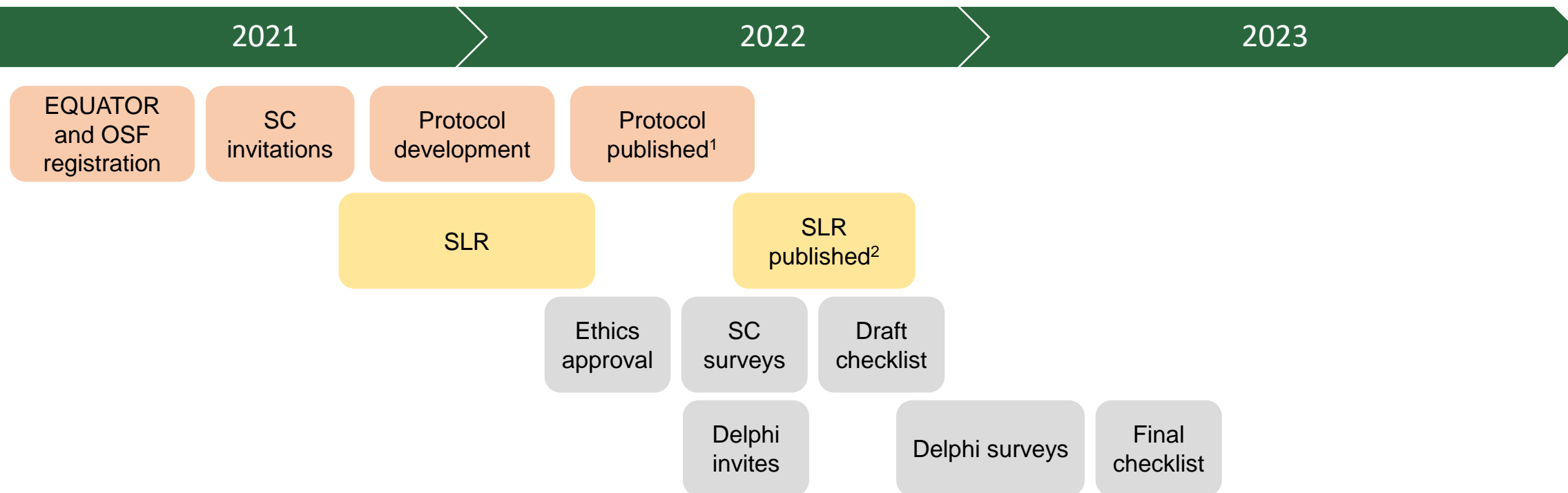
Protocol published¹



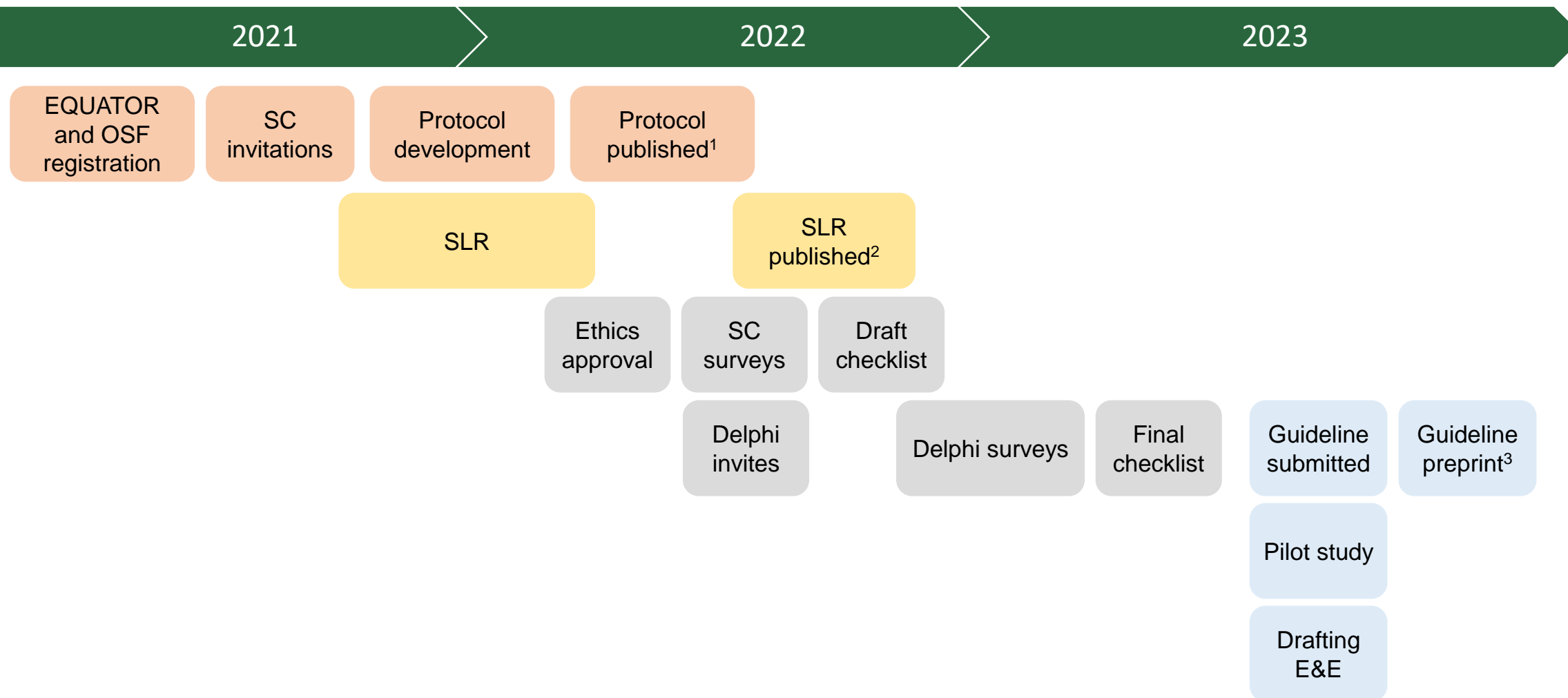
Project overview and timeline: SLR



Project overview and timeline: checklist



Project overview and timeline: publication



Self-identified Delphi panel demographics

Characteristic	Round 1 (n=58) 21 October–4 November 2022	Round 2 (n=54) 21 December 2022–16 January 2023	Round 3 (n=51) 10–27 Feb 2023
Gender, n (%)			
Female	31 (53.4)	28 (51.9)	28 (54.9)
Male	27 (46.6)	25 (46.3)	22 (43.1)
Non-binary	0	1 (1.9)	0
Prefer not to say	0	0	1 (2.0)
Geographic location of current primary residence and work, n (%)			
Africa	3 (5.2)	3 (5.6)	2 (3.9)
Asia	4 (6.9)	4 (7.4)	4 (7.8)
Europe	31 (53.4)	28 (51.9)	26 (51.0)
North America	16 (27.6)	15 (27.8)	15 (29.4)
Oceania	1 (1.7)	1 (1.9)	1 (2.0)
South America	3 (5.2)	3 (5.6)	3 (5.9)
Background*, n (%)			
Clinician	16 (27.6)	14 (25.9)	13 (25.5)
Journal editor	8 (13.8)	6 (11.1)	8 (15.7)
Patient partner [†]	6 (10.3)	6 (11.1)	5 (9.8)
Policymaker	3 (5.2)	3 (5.6)	4 (7.8)
Publications professional	17 (29.3)	17 (31.5)	15 (29.4)
Researcher	29 (50.0)	29 (53.7)	24 (47.1)
Other [‡]	11 (19)	6 (11.1)	8 (15.7)

Addressing gaps identified by the SLR

Panel composition

M3. Explain the criteria for panellist inclusion and the rationale for panellist numbers. State who was responsible for panellist selection.

M4. Describe the recruitment process (how panellists were invited to participate).

Definition of consensus

M12. State the definition of consensus (for example, number, percentage, or categorical rating, such as 'agree' or 'strongly agree') and explain the rationale for that definition.

R4. Report the final outcome of the consensus process as qualitative (for example, aggregated themes from comments) and/or quantitative (for example, summary statistics, score means, medians and/or ranges) data.

Roles and responsibilities

M2. Describe the role(s) and areas of expertise or experience of those directing the consensus exercise.

M5. Describe the role of any members of the public, patients or carers in the different steps of the study.

M19. State if the steering committee was involved in the decisions made by the consensus panel.

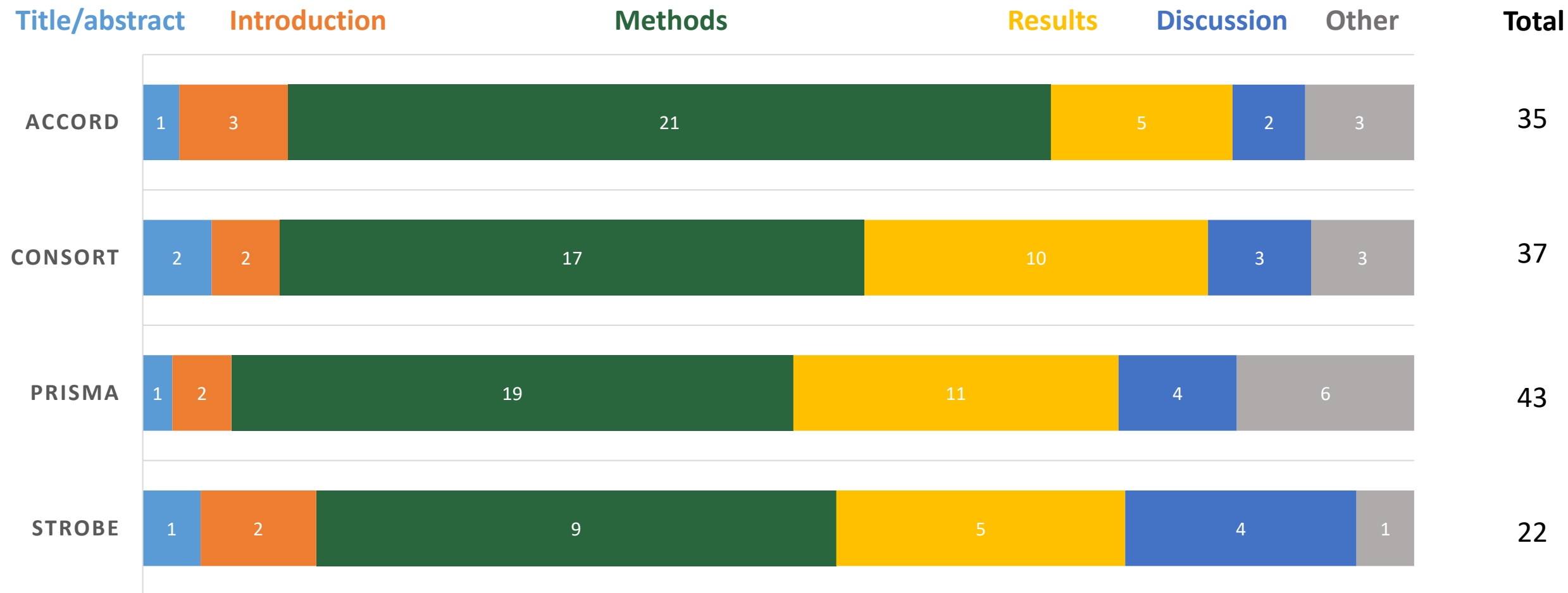
Conflicts of interest

O1. List any endorsing organisations involved and their role.

O2. State any potential conflicts of interests, including among those directing the consensus study and panellists. Describe how conflicts of interest were managed.

O3. State any funding received and the role of the funder.

Comparison with other checklists



Summary

- ACCORD is the first reporting guideline applicable to all consensus-based studies
- ACCORD provides authors with a tool to improve the completeness and transparency of reporting consensus exercise
- Reporting consensus studies with greater clarity and transparency may enhance trust in the recommendations made by consensus panels



Examples of good consensus reporting

Patricia Logullo

Exercise!

Forensics of a reporting guideline checklist
How to make sure a paper is adhering — complete

**M3. Explain the criteria for panellist inclusion and the rationale for panellist numbers.
State who was responsible for panellist selection.**

M3. Explain the criteria for panellist inclusion and the rationale for panellist numbers. State who was responsible for panellist selection.

What are the pieces of information that need to be reported?

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Criteria for the composition
Explanation of the numbers
Who selected

M3. Explain the **criteria for panellist inclusion and the rationale for panellist **numbers**. State **who** was responsible for panellist selection.**

- Criteria
- Numbers
- Who

M3. Explain the **criteria for panellist inclusion and the rationale for panellist **numbers**. State **who** was responsible for panellist selection.**

“In consultation with GA²LEN, 32 experts from 9 European countries (Austria, Finland, France, Germany, Italy, Spain, Sweden, Switzerland and the UK) were invited to participate in the current Delphi process, on the basis of (1) a proven track record of relevant research published in high-ranking peer-reviewed journals, (2) participation in the development of relevant treatment guidelines and involvement with peer-reviewed journals and scientific congress committees, or (3) a commitment to advancing asthma management in clinical practice.”

Bousquet et al. 2012 PMID: 22056555

M3. Explain the **criteria for panellist inclusion and the rationale for panellist **numbers**. State **who** was responsible for panellist selection.**

*“In consultation with GA²LEN, **32 experts** from 9 European countries (Austria, Finland, France, Germany, Italy, Spain, Sweden, Switzerland and the UK) **were invited** to participate in the current Delphi process, **on the basis of** (1) a proven track record of relevant research published in high-ranking peer-reviewed journals, (2) participation in the development of relevant treatment guidelines and involvement with peer-reviewed journals and scientific congress committees, or (3) a commitment to advancing asthma management in clinical practice.”*

Bousquet et al. 2012 PMID: 22056555

M3. Explain the **criteria for panellist inclusion and the rationale for panellist **numbers**. State **who** was responsible for panellist selection.**

“The four co-chairs (J.V.L., A.B., A.K. and A.E.-M.) identified a core group of 40 academic, health, NGO, government and policy experts from 25 countries and territories. Selection by the co-chairs was primarily based on publication record and engagement on COVID-19 issues as well as online biographies. Twenty-nine of these experts were well known to the chairs while seven were suggested through snowball sampling to result in geographical and gender equity among the core group of 40. ... In proposing experts, co-chairs focused on identifying at least one representative from at least 100 countries. One co-chair (J.V.L.) took responsibility for reviewing the suggestions, with support from a research assistant who shared recent publications and a professional biography for every proposed co-author. Many initial suggestions were of leading experts with whom the co-chairs had previously collaborated.”

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*“The **four co-chairs (J.V.L., A.B., A.K. and A.E.-M.)** identified a core group of **40** academic, health, NGO, government and policy experts from 25 countries and territories. Selection by the co-chairs was primarily **based on** publication record and engagement on COVID-19 issues as well as online biographies. Twenty-nine of these experts were well known to the chairs while seven were suggested through snowball sampling to result in geographical and gender equity among the core group of 40. ... In proposing experts, co-chairs focused on identifying at least one representative from at least 100 countries. One co-chair (J.V.L.) took responsibility for reviewing the suggestions, with support from a research assistant who shared recent publications and a professional biography for every proposed co-author. Many initial suggestions were of leading experts with whom the co-chairs had previously collaborated.”*

R5. List any items or topics that were modified or removed during the consensus process. Include why and when in the process they were modified or removed.

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S1 Table: Noteworthy changes in ARRIVE 2.0, compared to the original ARRIVE guidelines published in 2010

Use Tables and Figures!
Use Supplementary!

ARRIVE 2.0	Original ARRIVE	Reason for change
All items	All items	We reordered items and split them in two sets based on their importance to assess the reliability of the study. There is no ranking within each set, items are ordered logically.
ARRIVE Essential 10		
Item 1 – Study design	Item 6 – Study design	We removed the reference to steps taken to minimise the effects of bias (formerly subitem 6b). All information about randomisation is now in item 4 and all information about blinding is now in item 5.
Item 2 – Sample size	Item 10 – Sample size	We clarified that the number of experimental units might be different from the number of animals. Independent replications are now mentioned with the results (item 10) to prevent any confusion with biological replicates.
Item 3 – Inclusion and exclusion criteria	Item 15 – Numbers analysed	We added a new subitem on <i>a priori</i> inclusion and exclusion criteria, evidence shows that ad hoc exclusion of data can lead to false positive results [1]. We clarified that the N number in each analysis might be different from the number of animals. We renamed the item to better reflect content.
Item 4 – Randomisation	Item 11 – Allocating animals to experimental groups	All references to randomisation were consolidated in this item for clarity. We reworded the text to include the randomisation procedure which was covered separately in the study design (formerly item 6). We clarified that experimental units are allocated to group, rather than animals.

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“Ultimately, four indicative questions were excluded due to being answered by past research. The questions pertained to (1) what interventions are most effective for reducing post-traumatic symptoms among survivors of sexual violence/abuse, (2) the relationship between experiencing sexual violence/abuse and having addiction issues, (3) whether exposure to sexual violence/abuse leads to short-term and/or long-term mental health problems other than PTSD, and (4) the relationship between experiencing sexual violence/abuse and having eating disorders and/or obesity. (...) Before rankings were finalised, a vote was conducted to merge two thematically related questions concerning how physical healthcare and mental health services could become more ‘trauma informed’ (see questions ranked as ‘7’ in online supplemental material 3).”

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Discussion

All



Summary and close

William Gattrell

Today's conclusions

Reporting guidelines provide a minimum list of information needed to ensure a study can be understood, replicated, and used

A range of consensus methods, including more and less rigorous approaches, are used to support healthcare decision-making

ACCORD is the first reporting guideline applicable to all types of consensus methods, and can be used in combination with other reporting tools