Cochr**A**ne qualitative **ME**thodological Limitati**O**ns Assessment **T**ool (CAMELOT)

A new approach for assessing methodological limitations of qualitative research

25 April 2024

Cochrane Norway & Cochrane Sweden

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On behalf of the CAMELOT Development Group

Declaration of conflict of interest

- No commercial or financial potential or actual conflicts of interest
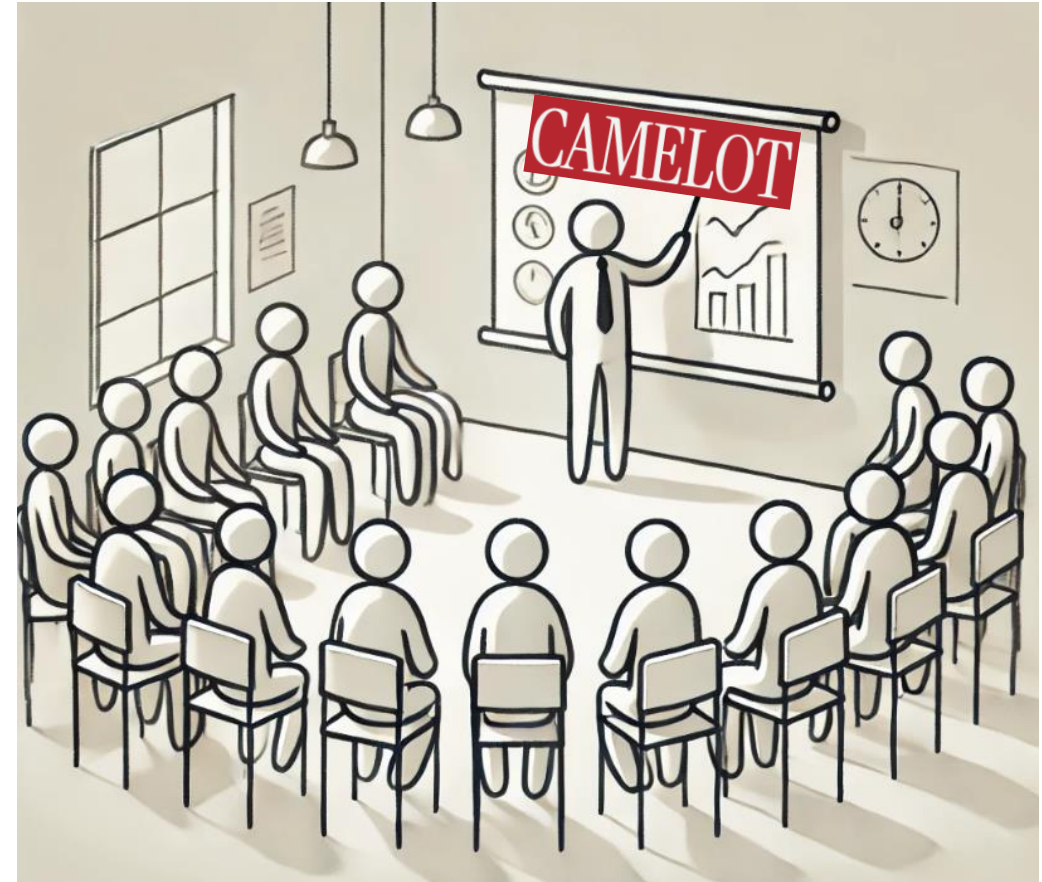- Co-founder and co-coordinator GRADE-CERQual

Agenda

- **Objectives**
- Critical appraisal
- Introduction to GRADE-CERQual
- Introduction to CAMELOT
- Group activity: Applying CAMELOT – data extraction
- Group activity: Applying CAMELOT – fit
- iSoQ
- Wrap-up and Q&A

Objectives

- Become familiar with CAMELOT
- Gain practical experience applying CAMELOT

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Decision makers need evidence about intervention options...

And qualitative evidence is necessary to address many important questions

What *questions and interventions* matter to people?

Is the intervention *effective* and does it have *side-effects*?

How much does the intervention *cost*?

What intervention *outcomes* matter to people?

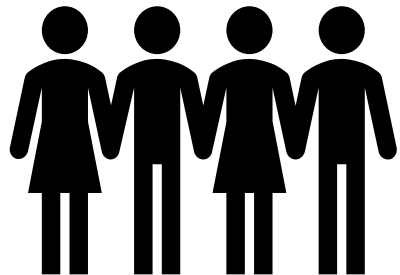Is this intervention *acceptable* to people?

Is this intervention *feasible* to implement?

How could the intervention influence *equity*?

How should we *implement* this intervention?

GRADE CERQual
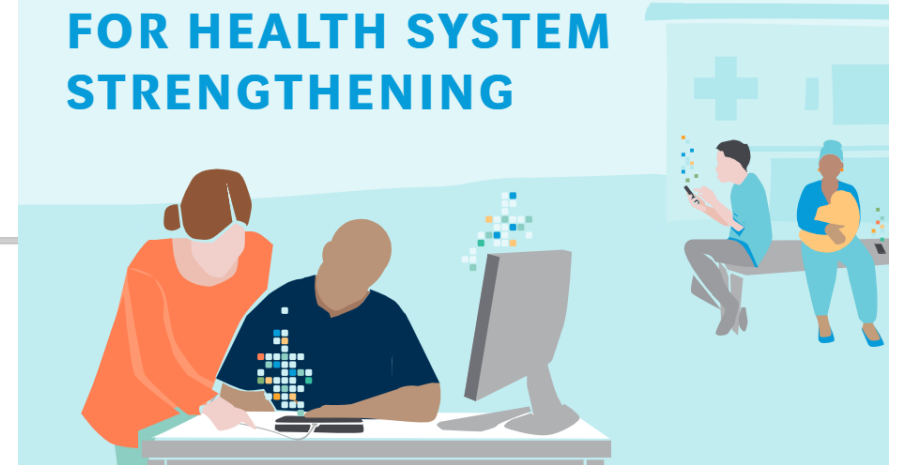
Stages of a qualitative evidence synthesis

- Stage 1: Formulating the question
- Stage 2: Developing inclusion criteria
- Stage 3: Searching for studies
- Stage 4: Including and sampling studies
- **Stage 5: Critically appraising the studies**
- Stage 6: Extracting and synthesising the study data
- Stage 7: Assessing confidence in the findings

Why critical appraisal?

Qualitative research

- Credibility and trustworthiness
- Rigour and appropriateness of methods
- Understanding research context
- Identifying researcher influence (biases and reflexivity)
- Contribution to knowledge
- Ethical issues
- Equity, diversity and inclusion issues

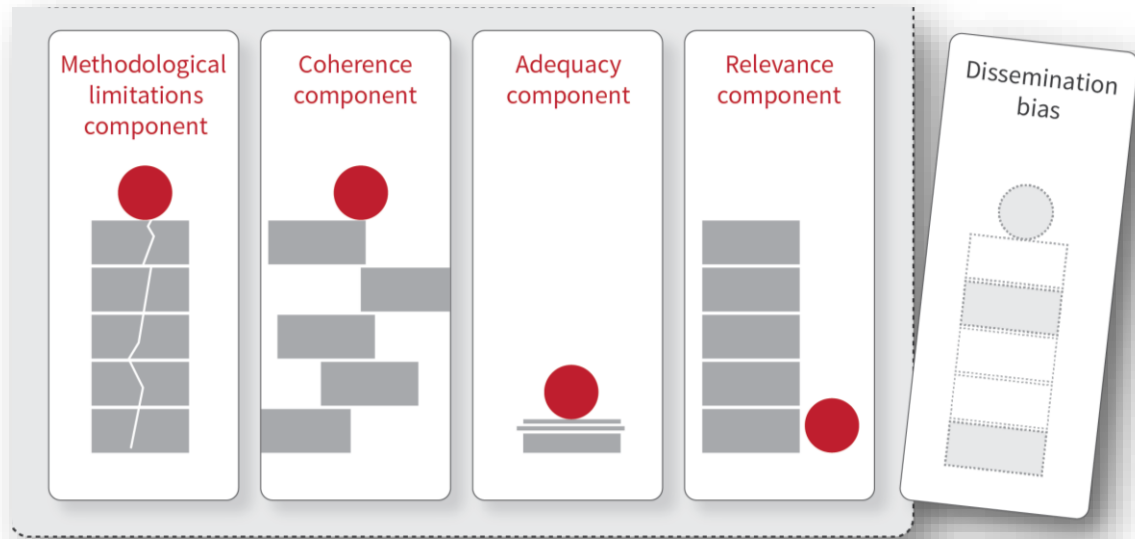# A qualitative approach to critical appraisal

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GRADE-CERQual approach

CERQual: Confidence in the Evidence from Reviews of Qualitative Research

- GRADE-CERQual aims to transparently assess and describe how much confidence to place in findings from qualitative evidence syntheses

- CERQual is part of the range of approaches for assessing confidence in evidence developed by the GRADE Working Group

- A key tool for facilitating the use of qualitative evidence in decision making processes

Lewin, Simon, Andrew Booth, Claire Glenton, Heather Munthe-Kaas, Arash Rashidian, Megan Wainwright, Meghan A. Bohren et al. "Applying GRADE-CERQual to qualitative evidence synthesis findings: introduction to the series." Implementation Science 13 (2018): 1-10.

GRADE CERQual

What do we mean by 'confidence in the evidence'?

The extent to which a review finding is a reasonable representation of the phenomenon of interest

- i.e. the phenomenon of interest is unlikely to be substantially different from the research finding

GRADE-CERQual is applied to *individual* synthesis findings

- In the context of a qualitative evidence synthesis, a finding is…:

...an analytic output that describes a phenomenon or an aspect of a phenomenon

- Findings from qualitative evidence syntheses typically presented as:

    - Themes, categories or theories

    - As both descriptive or more interpretive findings

The GRADE-CERQual approach
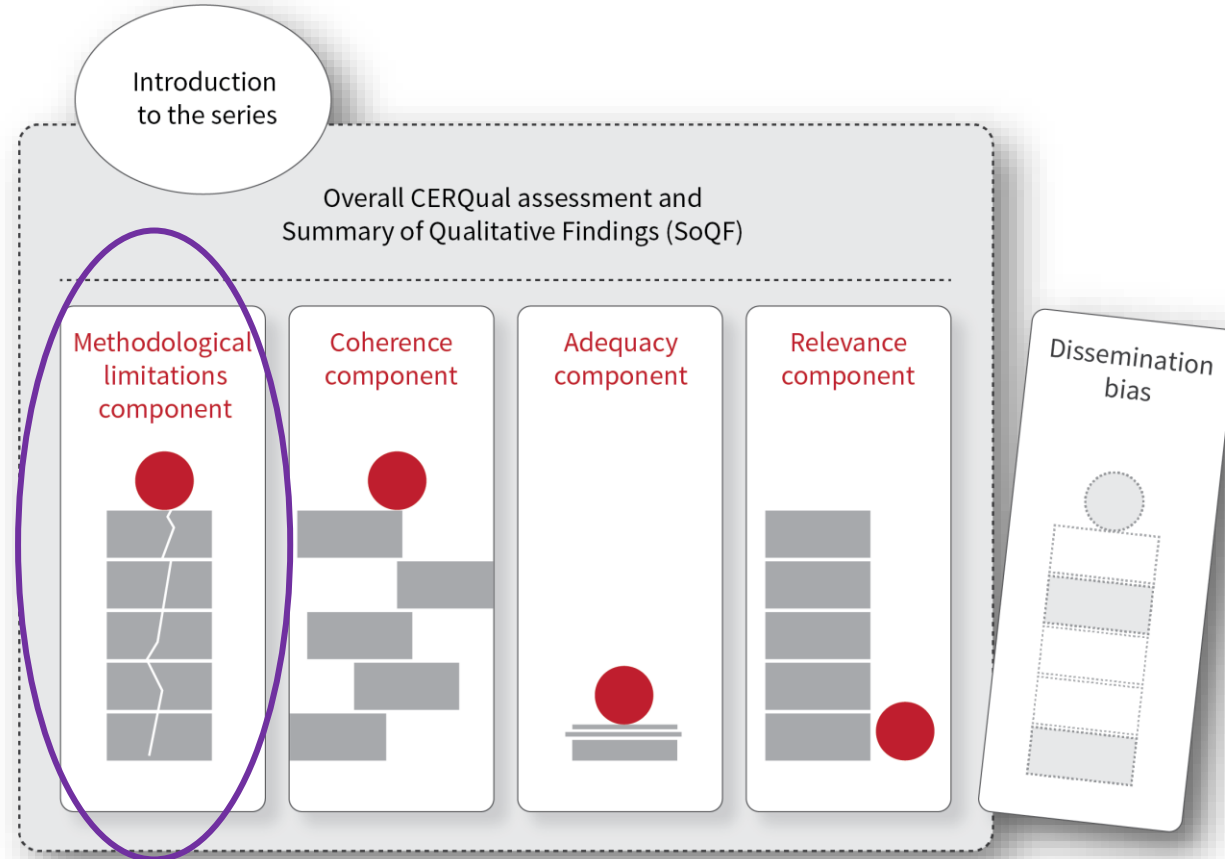
Munthe-Kaas, Heather, Meghan A. Bohren, Claire Glenton, Simon Lewin, Jane Noyes, Özge Tunçalp, Andrew Booth et al. "Applying GRADE-CERQual to qualitative evidence synthesis findings—paper 3: how to assess methodological limitations." Implementation Science 13 (2018): 25-32.

Agenda

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CAMELOT approach

Development of a qualitative approach to critically appraise primary qualitative research

Development methods

o **Systematic review** of existing critical appraisal tools. *(Munthe-Kaas et al. 2019)*

o **Evidence identification** supporting the inclusion of potential domains for CAMELOT. *(2017-2022)*

o **Consensus survey** for inclusion of domains and how to define CAMELOT domains. *(2023)*

o **Human-centered design** to develop and refine CAMELOT. *(2023-2024)*
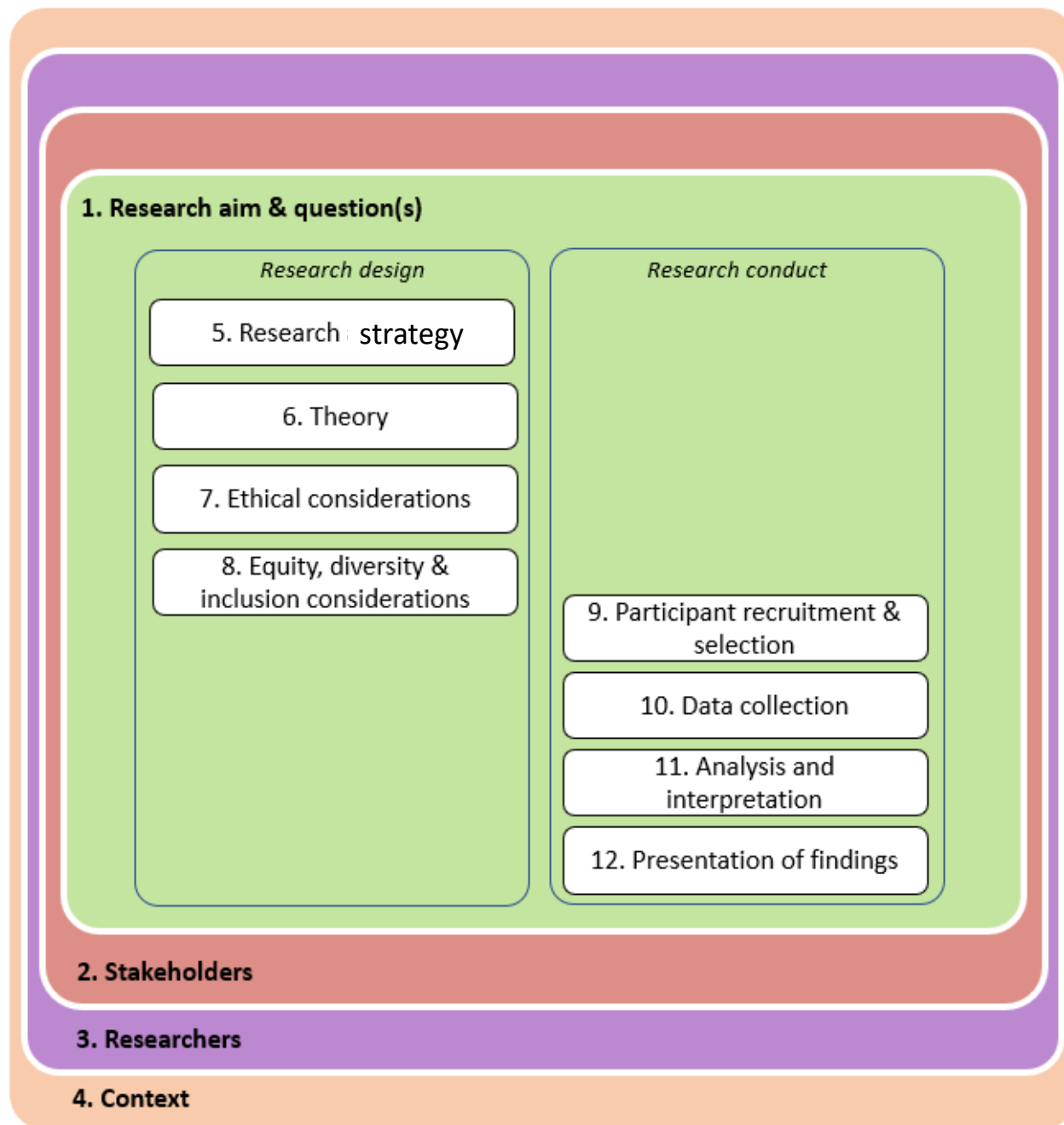
Meta domains

1 Research aim & question(s)

Definition: The purpose of the study and/or what questions the researchers intend to explore.

What to do: Consider the research aim & question(s) and describe (when possible):

- The research aim, the rationale for the research aim and how the aim relates to existing research.
- The research question, the clarity of the research question, and how the research question(s) was/were formed.

2 Stakeholders

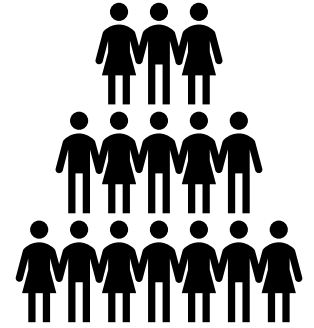**Definition**: Anyone with an interest (financial or otherwise) in the findings of the research study. Stakeholders are not the same as participants in this context. Stakeholders include patient and public participants.

What to do: Extract relevant data for the review question from the primary study related to any, some or all of (but not limited to) the following:

- Whether and how stakeholders were involved in the design, planning, conduct, analysis or interpretation of the study findings
- The type of stakeholders or stakeholder groups (including funders), how they were recruited/selected, who they represent, their relationship to the research question and whether their conflicts of interest have been considered (if relevant).
- How the study was funded and the role of the funding

3 Researchers
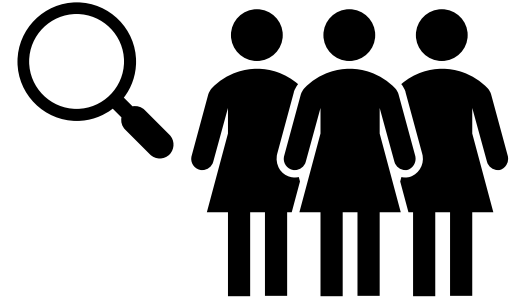
Definition: The investigators who have designed, planned and conducted the study and their relationship to the study question, context and/or participants.

What to do: Extract relevant data for the review question from the primary study related to any, some, or all of (but not limited to) the following:

- The researchers' role, their reflexivity including their relationship to (a) the research question, (b) research context and process, (c) any other decisions they make regarding methodology;
- The researchers' relationship to participants
- The researchers' background and/or epistemological stance, training, experience, affiliation;
- A discussion of how any of the above may influence the design and/or conduct of the study or the interpretation of the findings;
- A discussion of researcher actual or potential conflicts of interest (financial or otherwise).

4 Context
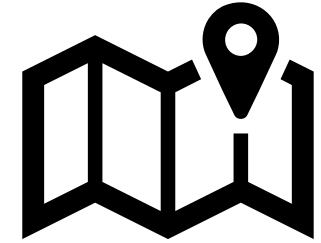
Definition: The local, national or global context that the study was conducted in.

What to do: Extract relevant data for the review question from the primary study related to any, some or all of (but not limited to) the following:

- The context in which the study was conducted, such as geography, climate, culture, when the study was conducted, and/or the legal, political, social, economic, healthcare or welfare systems.

5 Research strategy

Definition: The overall intended plan, proposal or strategy for the study. This domain refers to the overarching roadmap for carrying out the research project (also referred to as research approach, study design, or type of study). This domain does not include issues related to participant recruitment and selection, data collection and analysis and interpretation. These are separate domains.

What to do: Extract relevant data for the review question from the primary study related to some, any or all of (but not limited to) the following:

- The research strategy, including how the study was planned, designed and conducted.
- Availability or description of a research plan or protocol is available, any changes made to the original plan or protocol and rationale for changes
- The overarching methodologies (e.g., ethnography, phenomenology, etc.)
- Appropriate referencing to the methods used

6 Ethical considerations

Definition: How the researchers considered and incorporated ethical principles and standards into decisions related to the design, planning and conduct of the study.
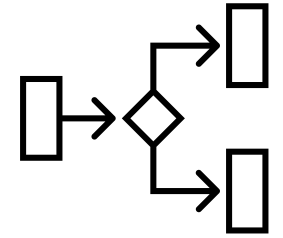
What to do: Extract relevant data for the review question from the primary study related to any, some or all of (but not limited to) the following:

- Appropriate ethical approval
- Ethical issues in the design, planning, conduct, analysis, interpretation or dissemination of the study, selection, recruitment and informed consent of participants
- Discussion of how the study impacted the community, and how researchers considered issues related to maintaining respect and dignity of participants, and
- How the researchers addressed any issues related to ethics
- Data management and protection measures (e.g., data security and storage, etc.)

7 Equity, diversity & inclusion considerations
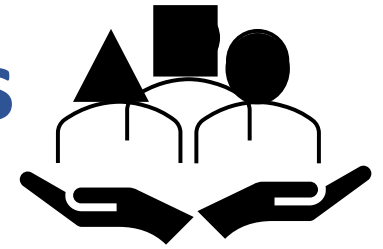
Definition: Whether and how the researchers considered:

- (1) equity – including distribution of power within the research context, whether there was equitable representation and participation in the research process, particularly for underrepresented groups, the possible differential experiences or perspectives of a phenomenon of interest for different populations and whether there was and whether unnecessary or discriminating differences in how people participate in a study

- (2) diversity – including seeking out diverse experiences, perspectives and backgrounds, inclusion of participants with diverse backgrounds and considering how diversity can influence research findings

- (3) inclusion – including the degree to which the research environment was such that all participants felt welcome and valued, whether culturally sensitive and inclusive research methods and communication strategies were employed and whether research materials, locations and processes were accessible for all participants.

What to do: Extract relevant data for the review question from the primary study related to any, some or all (but not limited to) of the following:

- Equity, diversity and inclusion considerations, which could include, but is not limited to Place of Residence, Race/Ethnicity, Visa/Residency status, Occupation, Gender, Religion, Education, Socioeconomic Status, and Social Capital, and Plus represents additional categories such as Age, Disability, and Sexual Orientation (PROGRESS-Plus)1 2. Review authors may consider using an existing framework or checklist to assess equity (e.g., CONSORT Equity extension 3 PRISMA equity extension 4)

- How the researchers addressed any issues related to equity, diversity and inclusion

8 Theory

Definition: Organization of concepts, ideas, literature or principles into systems or frameworks that attempt to describe, explore, explain, understand or predict a phenomenon.

What to do: Extract relevant data for the review question from the primary study related to any, some or all of (but not limited to) the following:

- Whether and how theory or a concept was used (appropriately and consistently) to inform the planning, design, and/or conduct of the study.
- Whether and how theory or a concept was used (appropriately and consistently) to analyze explore and/or contextualize the findings from the study.
- Whether and how a theoretical or conceptual framework was used. Theoretical or conceptual frameworks can be presented as logic models, theories of change, or conceptual model. Theory refers to a collection of concepts or ideas that are organized in a reasonable way to explain a phenomenon in the real world.
- If a theoretical or conceptual framework has not been used, is an appropriate rationale provided?

Method domains
- Research conduct

9 Participant recruitment & selection

Definition: How participants were identified, recruited and selected for the research study.

What to do: Extract relevant data for the review question from the primary study related to any, some or all of (but not limited to) the following:

- • How and why participants were recruited and selected, and who was not recruited and selected

- • Description of participants and non-participants

- • Numbers and reasons for any participant refusal, dropout, who was not included or represented

- • Any incentives provided for participation

10 Data collection
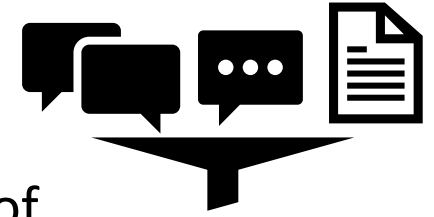
Definition: The process of gathering qualitative information (data) in the form of perspectives, experiences or opinions from participants, and/or observations, prolonged engagement in the filed by researchers in order to explore or answer the research questions and address the research aim.

What to do: Extract relevant data for the review question from the primary study related to any, some or all of (but not limited to) the following:

- Rationale for data collection methods

- Development of data collection materials (e.g., interview guide development and testing)

- What type of data were collected (e.g., recorded interviews, structured observations, field notes, pictures, videos, photos, etc.)

- Data collection methods, including language used when engaging with participants, how long researchers were engaged with participants

- When data were collected, who was present during and physical setting of data collection, the medium through which data were collected (e.g., online or in person or

11 Analysis & intepretation

Definition: The process of systematically examining, exploring and interrogating data gathered during the study in order to identify themes, patterns, lines of argument and if appropriate theories and gain a greater understanding of the phenomenon of interest.

What to do: Extract data from the primary study related to all, some or any of (but not limited to) the following:

- Rationale for choice of analysis
- Analysis and interpretation methods, including plans for data analysis, deviations from the protocol, how analysis, interpretation and if appropriate theory development was conducted, who was involved in data analysis,
- Strategies to improve trustworthiness (e.g., methods of triangulation, participant feedback, multiple observations etc)
- Disconfirming findings and whether researchers challenged their findings
- Data saturation*
- Use of analysis software (including artificial intelligence software)

12 Presentation of findings

Definition: How the findings from the study are organized and communicated and how well they represent the underpinning data.

What to do: Consider the study findings and describe (when possible):

- How closely the study findings represent the data (e.g., how categories and themes , lines of inquiry and theories and author interpretations are derived from the data)

- How clearly findings are articulated

- The adequate reflection of participants' voices and participants' meanings of experiences, perceptions (etc) and, where relevant, inclusion of other forms of supporting evidence (e.g. quotations from an interview, field note entries, etc.)

Extract/code data

Extract or code data from the primary study related to the following domains (some of these domains will not be relevant for some studies):

Meta domains

1. Research aim & question(s)
2. Stakeholders
3. Researchers
4. Context

Method domains

Research design

5. Research strategy
6. Theory
7. Ethical considerations
8. Equity, diversity & inclusion considerations

Research conduct

5. Participant recruitment & selection
6. Data collection
7. Analysis and interpretation
8. Presentation of findings

Step 1

Note any comments regarding each domain. This may include problems or missing information. This step is optional but will act as an audit trail and help to inform the subsequent steps.

Step 2

1 Research aim & question(s)

Definition: The purpose of the study and/or what questions the researchers intend to explore.

What to do: Consider the research aim & question(s) and describe (when possible):

•The research aim, the rationale for the research aim and how the aim relates to existing research.

•The research question, the clarity of the research question, and how the research question(s) was/were formed.

Note that some researchers may only state the research question and not the research aim/objective or vice versa depending on the approach used in the study. This does not necessarily constitute a concern.

Note concerns and where important information is missing.

Tips:

•This information may be found in the Abstract, Introduction or Methods sections of the study report.

•In mixed-methods studies where the qualitative research is one part of the study, consider the Research aim or question(s) related to the qualitative research only. Likewise, in studies where there are multiple research question(s), consider those most relevant for your review question.

Examples*:

Study ID:	Data from primary study	Optional comments (notes to self, including any problems or missing information)
Researchers	The aim of the research project is to explore the difficulties encountered by social workers when assisting adult individuals without homes. To fulfill this purpose, the following goals were set: • To outline policy and laws related to homelessness in a context of a country in the Southern Hemisphere and to characterize homelessness on a worldwide scale. • To detail the assistance offered and obstacles encountered by social workers engaging with adult individuals lacking homes, supported by the ecological viewpoint. • To concretely examine the hurdles social workers encounter in providing services to adult individuals without homes. • To offer conclusions and suggestions derived from the research findings.	Adequate description of aims and objectives.

Characteristics of included studies table

Characteristic	Data	Comments
Author		
Title		
Journal		
Year		
Context		
Research strategy		
Participant recruitment and selection		
Data collection		
Analysis and interpretation		
Theory		
Ethical considerations		

Describe concerns regarding, and make assessment of, fit between domains

- Describe concerns regarding appropriateness of fit between (1) the Research design and conduct domains and each of the Meta domains, and (2) between the research design and research conduct domains.

- Make an assessment using the following categories to describe concerns regarding the fit:
  - Serious concerns
  - Moderate concerns
  - Minor concerns
  - No or minimal concerns
  - Unclear

Step 3

Step 4

Step 5

Step 4. Describe level of concern regarding methodological limitations

Combine these assessments to make an overall assessment of methodological limitations by indicating level of concern using the following categories and provide an explanation for your assessment:

- *No or minimal concerns, minor concerns, moderate concerns, serious concerns*

Step 5. Combine assessments across studies

Combine assessments of fit across studies contributing to a review finding and indicate level of concern regarding methodological limitations using the following categories:

- *No or minimal concerns, minor concerns, moderate concerns, serious concerns*

Describe if you have any concerns about the fit between the following domains	Research design domains and Research aim & question	Research design domains and Stakeholders	Research design domains and Researchers	Research design domains and Context	Research conduct domains and Research aim & question	Research conduct domains and Researchers	Research conduct domains and Stakeholders	Research conduct domains and Context	Research design domains and Research conduct domains
Indicate concerns regarding fit:									

No or minimal concerns

Minor concerns

Moderate concerns

Serious concerns

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Group work

Step 1 & 2

- Code/extract data for «Analysis and interpretation»
- Note any comments or concerns

Article:
https://onlinelibrary.wiley.com/doi/10.1111/jan.15419

CAMELOT Primary table:
https://docs.google.com/spreadsheets/d/1xPMSx_ipjGkoS
T6aFeV-bVvxsj15aU8h1-zVif5mpVk/edit?gid=0#gid=0

JAN | WILEY

'Doing the best we can': Registered Nurses' experiences and perceptions of patient safety in intensive care during COVID-19

Louise Caroline Stayt[1] | Clair Merriman[2] | Suzanne Bench[3] | Ann M. Price[4] | Sarah Vollam[5,6] | Helen Walthall[7] | Nicki Credland[8] | Karin Gerber[9] | Vid Calovski[2]

[1]Oxford Brookes University/Oxford University NHS Trust, Oxford, UK
[2]Oxford Brookes University, Oxford, UK
[3]Guys and St Thomas NHS Foundation Trust, London, UK
[4]Canterbury Christ Church University, Canterbury, UK
[5]Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK
[6]NIHR Oxford Biomedical Research Centre, Oxford, UK
[7]Oxford University Hospitals NHS Foundation Trust and Oxford Biomedical Research Centre, Oxford, UK
[8]University of Hull MMedSci, Hull, UK
[9]Royal Berkshire Hospital, Reading, UK

Correspondence
Louise Caroline Stayt, Oxford Brookes University/Oxford University NHS Trust, Oxford, UK.
Email: lstayt@brookes.ac.uk

Twitter Handle: @lstayt

Abstract

Aims: To explore registered nurses' experiences of patient safety in intensive care during COVID-19.

Design: A qualitative interview study informed by constructivism.

Method: Semi-structured interviews were conducted and audio-recorded with 19 registered nurses who worked in intensive care during COVID-19 between May and July 2021. Interviews were transcribed verbatim and thematically analysed utilizing framework.

Results: Two key themes were identified. 'On a war footing'—an unprecedented situation which describes the situation nurses faced, and the actions are taken to prepare for the safe delivery of care. 'Doing the best we can'—Safe Delivery of Care which describes the ramifications of the actions taken on short- and long-term patient safety including organization of care, missed and suboptimal care and communication. Both themes were embedded in the landscape of Staff Well-being and Peer Support.

Conclusion: Nurses reported an increase in patient safety risks which they attributed to the dilution of skill mix and fragmentation of care. Nurses demonstrated an understanding of the holistic and long-term impacts on patient safety and recovery from critical illness.

Impact: This study explored the perceived impact of COVID-19 on patient safety in intensive care from a nursing perspective. Dilution of skill mix, where specialist critical care registered nurses were diluted with registered nurses with no critical care experience, and the fragmentation of care was perceived to lead to reduced quality of care

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    - Serious concerns
    - Moderate concerns
    - Minor concerns
    - No or minimal concerns
    - Unclear

Step 3

Examples of fit

Concerns regarding fit	Research aim and/or question	Stakeholders
Research design domains	The research aims to explore adolescent pregnancy and education obtainment. The ethnographic approach failed to consider that the phenomenon of interest happened long before the study took place. No discussion of ethical or equity considerations. **Moderate concerns**	Community-based participatory research, but teenagers (main target group) not included in stakeholder group. No discussion of diversity or inclusion issues related to including teenagers with ill mental health. **Serious concerns**
Research conduct domains	The aim of the research was to explore conflict between different community groups. Unclear whether community groups were interviewed separately or together. **Minor concerns**	Interview guide was developed with input from relevant stakeholders. **No or minimal concerns**

Group work

Step 3

Describe and indicate degree of concerns regarding fit between domains

- ○ No or minimal concerns
- ○ Minor concerns
- ○ Moderate concerns
- ○ Serious concerns
- ○ Unclear

CAMELOT TABLE:
https://docs.google.com/spreadsheets/d/1wYCFjHfz8UAqDxyHV7xKrTZeVTAHmS6TKGRXcekIMmY/edit?gid=0#gid=0

'Doing the best we can': Registered Nurses' experiences and perceptions of patient safety in intensive care during COVID-19

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[4]Canterbury Christ Church University, Canterbury, UK
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[6]NIHR Oxford Biomedical Research Centre, Oxford, UK
[7]Oxford University Hospitals NHS Foundation Trust and Oxford Biomedical Research Centre, Oxford, UK
[8]University of Hull MMedSci, Hull, UK
[9]Royal Berkshire Hospital, Reading, UK

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Email: lstayt@brookes.ac.uk

Twitter Handle: @lstayt

Abstract

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Results: Two key themes were identified. *'On a war footing'*—an unprecedented situation which describes the situation nurses faced, and the actions are taken to prepare for the safe delivery of care. *'Doing the best we can'*—Safe Delivery of Care which describes the ramifications of the actions taken on short- and long-term patient safety including organization of care, missed and suboptimal care and communication. Both themes were embedded in the landscape of *Staff Well-being and Peer Support*.

Conclusion: Nurses reported an increase in patient safety risks which they attributed to the dilution of skill mix and fragmentation of care. Nurses demonstrated an understanding of the holistic and long-term impacts on patient safety and recovery from critical illness.

Impact: This study explored the perceived impact of COVID-19 on patient safety in intensive care from a nursing perspective. Dilution of skill mix, where specialist critical care registered nurses were diluted with registered nurses with no critical care experience, and the fragmentation of care was perceived to lead to reduced quality of care

https://onlinelibrary.wiley.com/doi/epdf/10.1111/jan.15419

META domains	Data extracted from primary study	Optional comments (notes to self, including any problems or missing information)
Research aim & question(s)		
Stakeholders		
Researchers		
Context		

METHOD domains

Research design domains

	Data extracted from primary study	Optional comments (notes to self, including any problems or missing information)
Research strategy		
Ethical considerations		
Equity, diversity & inclusion considerations		
Theory		

Research conduct domains

	Data extracted from primary study	Optional comments (notes to self, including any problems or missing information)							
Participant recruitment & selection									
Data collection									
Analysis and interpretation									
Presentation of findings									
Describe if you have any concerns about the fit between the following domains (and indicate concerns using Serious, Moderate, Minor, No or minimal):	Fit between **Research design domains** and **Research aim & question(s)**	Fit between **Research design domains** and **Stakeholders**	Fit between **Research design domains** and **Researchers**	Fit between **Research design domains** and **Context**	Fit between **Research conduct domains** and **Research aim & question(s)**	Fit between **Research conduct domains** and **Stakeholders**	Fit between **Research conduct domains** and **Researchers**	Fit between **Research conduct domains** and **Context**	Fit between **Research design domains** and **Research conduct domains**
OVERALL ASSESSMENT OF LIMITATIONS: (No or minimal, minor, moderate, serious)									
Explanation for overall assessment									

Step 4

Step 4. Describe level of concern regarding methodological limitations

Combine these assessments to make an overall assessment of methodological limitations by indicating level of concern using the following categories and provide an explanation for your assessment:

- *No or minimal concerns, minor concerns, moderate concerns, serious concerns*

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iSoQ Beta version

An online tool for applying the GRADE-CERQual approach to findings of a qualitative evidence synthesis

- Learn more about iSoQ
- Browse

+ Add characteristic

Studies Characteristics

Participants

Authors

Country

CAMELOT Domains

Research question and/or aims

Context

Research strategy

Participant recruitment & selection

Data collection

Analysis & interpretation

Presentation of findings

Theory

Ethical considerations

Equity, diversity & inclusion considerations

Researchers

Stakeholders

Participants

Remove characteristic

Extracted data

Comments

Authors

Remove characteristic

Extracted data

Comments

Country

Remove characteristic

Extracted data

Comments

Meta Domain 1 - Research ⑦

Extracted data

Comments

For each combination, **select the degree of fit** from the following categories: No or Minimal Concerns, Minor Concerns, Moderate Concerns, Serious Concerns, or Unclear. **If concerns exist, describe them** in the text box provided.

Fit assessment	Meta Domains	Research conduct domains

Fit assessment

- 🔵 No or minimal concerns
- ⭕ Minor concerns
- ⭕ Moderate concerns
- ⭕ Serious concerns
- ⭕ Unclear

Explain any concerns you have in your own words

Excellent fit.

Cancel   Save

Meta Domains

1 - Research

Concerns ⌄

The aim of this study was to explore intensive care and redeployed nurses' experiences and perceptions of patient safety in intensive care during the COVID-19 pandemic. Objectives were to identify patient safety issues encountered, and any factors perceived to optimize, inhibit or improve patient safety. The research question was 'What are registered nurses' experiences and perceptions of patient safety in intensive care during COVID-19?'

Extracted data ⌄

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2 - Stakeholders

3 - Researchers

4 - Context

Research conduct domains

Participant recruitment & selection

Concerns ⌄

Purposive and maximum variation sampling, online recruitment. Little description of demographic characteristics of sample (e.g., minority, language, age, number of jobs, full/part time position)

Extracted data ⟩

Data collection

Concerns ⌄

Limited by covid (social distancing)

Extracted data ⟩

Analysis and interpretation

Concerns ⌄

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Agenda

- Objectives
- Critical appraisal (2 mins)
- Introduction to GRADE-CERQual (2 mins)
- Introduction to CAMELOT (5 mins)
- Group activity: Applying CAMELOT – fit (15 mins)
- iSoQ
- Wrap-up and Q&A

THANK YOU

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