CICER
Collaboration in Ireland for Clinical Effectiveness Reviews

Advances in the development of clinical practice guidance: A scoping review

January 2024

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

HRB Health Research Board

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

About HRB-CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews) to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, HIQA was awarded research funding spanning the period from 2017 to 2024 to produce the evidence to support the development of National Clinical Guidelines and National Clinical Audits. The HRB-CICER team comprises a dedicated multidisciplinary research team supported by staff from the Health Technology Assessment team in HIQA, the Discipline of Public Health and Primary Care in the School of Medicine at Trinity College Dublin (TCD), as well as national and international clinical and methodological experts.

With regard to clinical guidelines, the role of the HRB-CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups (GDGs), of National Clinical Guidelines for the NCEC. The HRB-CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The HRB-CICER team also works closely with the GDGs and provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaption to Ireland; and supports the development of evidence-based recommendations informed by the evidence produced by HRB-CICER within the National Clinical Guidelines.

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Membership of the evaluation team

Members of the HRB-CICER Evaluation Team were Dr Niamh Merriman (Project Lead), Ms Shibu Shrestha, Mr Barrie Tyner, Dr Tom Lynch, Mr Fearghal Comaskey, Ms Marie Carrigan, Dr Daniela Rohde, Dr Karen Cardwell, Dr Melissa Sharp, Dr Barbara Clyne, Ms Michelle O'Neill, Prof Susan Smith and Dr Máirín Ryan.

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Executive Summary

Background

Clinical practice guidance (CPG) is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances, with the type of CPG determined by evidence-based criteria and clinical requirements. In 2015, the National Clinical Effectiveness Committee (NCEC) published the NCEC Standards for Clinical Practice Guidance, referred to as the NCEC CPG Standards in this review. This identified a number of core components, which can be grouped together into four categories.

- Governance
  - governance model
  - audit, monitoring, review and evaluation process
  - service user and stakeholder involvement
  - knowledge management.
- Methodology
  - clarity of scope and purpose
  - evidence-based.
- Planning and implementation
  - resource implications
  - planning and implementation.
- Communications
  - communications.

The purpose of the current scoping review was to support the NCEC in considering updates to the current NCEC Standards for Clinical Practice Guidance. The review aimed to address three research questions (RQs):

- RQ1: What are the core components of the various types of clinical practice guidance?
- RQ2: What quality assurance or appraisal criteria are available to examine the robustness of the methodological process utilised to develop the various types of clinical practice guidance?
- RQ3: What are the key innovations since 2015 in the development and implementation of clinical practice guidance?

RQ1 and RQ2 are updates of the RQs addressed in the initial systematic review. RQ3 is a new research question.

Methods

Scoping review guidance was followed. International methodological handbooks and peer-reviewed articles published since 2015 were eligible for inclusion. Disease-specific and non-English guidance were excluded.

Results

Study characteristics

In total, 12 handbooks from 11 organisations were identified. Ten handbooks contained information relating to the core components (RQ1), three described an additional core component (RQ1), two described quality measures or criteria (RQ2), and eight handbooks described key innovations (RQ3).

A total of 55 peer-reviewed articles were identified from the database search, of which 20 articles described additional core components (RQ1), 10 articles described quality measures and or criteria (RQ2) and 25 articles described key innovations in the development of CPG (RQ3).

RQ1: Core components of clinical practice guidance

Three organisational handbooks (Australian National Health and Medical Research Council, National Institute for Health and Care Excellence – England and Wales and the US Preventive Services Task Force (USPSTF)) and six peer-reviewed articles consistently identified consideration of health equity as an additional core component of CPG. Consideration of health equity is inherent to many existing EtD frameworks used to formulate recommendations, (for example, the GRADE EtD framework). However, explicit consideration of health equity throughout all phases of guidance and rapid guidance development is now encouraged, especially in relation to populations such as older adults, patients with multiple chronic conditions, and marginalised groups. Gender equity was addressed in one handbook, the USPSTF, and two peer-reviewed articles, which reported an underrepresentation of women across most roles in guideline development groups, while the USPSTF also focused on gender equity in guideline end users.

Additional core components relating to clarity of presentation, health outcome descriptors and quality indicators were identified in the peer-reviewed articles but not in the organisational handbooks.

RQ2: Quality assurance or appraisal criteria to examine the methodological robustness of clinical practice guidance

Thirteen quality assurance or appraisal criteria to examine methodological robustness of clinical practice guidance development were identified in two handbooks (Estonian Health Insurance Fund and the World Health Organization) and ten peer-reviewed articles. Four of the tools (G-TRUST, PANELVIEW tool, NEATS and IGEST) identified in the peer-reviewed

articles were developed to examine the quality of the guidelines or the guideline development process. Six tools (RIGHT statement, RIGHT-Ad@pt checklist, RIGHT for INT, GIN-McMaster Guideline Development Checklist extension for rapid guideline recommendation development, AGREE reporting checklist and AGREE-REX) were designed to be used as reporting statements or reference tools to guide the development and reporting of the guideline.

The G-TRUST tool was developed for clinicians to identify useful guidelines. The NEATS[(2)] tool was developed to assess the extent to which guidelines adhered to the standards developed by the Institute of Medicine (now the National Academy of Medicine). The AGREE Reporting Checklist was designed to improve the quality of reporting practice guidelines. The structure and content of the checklist aligns with the AGREE II quality appraisal tool. The AGREE-REX tool was designed to evaluate the quality of clinical practice guideline recommendations as a complement to the AGREE II tool. The PANELVIEW tool, designed to assess the quality of the guideline development processes from the perspective of the GDG members, was identified in both the WHO handbook and a peer-reviewed article. The RIGHT statement and the RIGHT Ad@pt checklist were described in the EHIF and the WHO handbooks. These checklists are not intended to assess the quality of the guideline but instead to be used in conjunction with the AGREE ll tool to assess the quality of reporting in a clinical practice guideline. While these tools were also identified in three peer-reviewed articles, these papers did not include any evaluation of the tools, nor did we identify any evaluation in the peer-reviewed literature. Other non-evaluated tools identified in the peer-reviewed articles included IGEST, RIGHT for INT and the GIN-McMaster Guideline Development Checklist extension for rapid guideline recommendation development.[(3)] The Quality Assessment with Diverse Studies (QuADS) tool was used to assess the quality of peer-reviewed articles that described quality measures and or criteria to examine methodological robustness of CPG development. The QuADS tool comprises 13 questions to assess methodological quality, with each question scored between 0 (not at all) and 3 (complete). Higher scores indicate better methodological quality. The article which described the development of G-TRUST tool achieved the highest score of 3 across ten criteria and a moderate score of 2 across two criteria. The article describing the AGREE Reporting Checklist achieved the highest score of 3 across six criteria, a moderate score of 2 across four criteria and a score of 1 across three criteria.

RQ3: Key innovations

Four unique innovations were identified across eight handbooks and six peer reviewed articles, published since 2015. One innovation related to contextualisation of guidance (GRADE-ADOLOPMENT approach), one related to living guidance, one to rapid guidance and one to a technological innovation (use of the GRADEpro Guideline Development Tool). The GRADE-ADOLOPMENT approach was designed to facilitate transparent, inclusive and systematic guideline development that accounts for local contextual considerations and maximises trust and implementation. Living guidelines involve the continuous updating of

individual recommendations as new evidence emerges, without the need for the entire guideline to be updated. The rapid guidance approach could be used in the context of public health emergencies and or other situations where there is an urgent need for guidance. The GRADEpro Guideline Development tool facilitates the development of summary of findings tables, GRADE tables and the EtD framework, allowing users to work collaboratively online when developing recommendations.

Six further key innovations were identified and evaluated within 25 peer-reviewed articles. These related to evidence and or guidance translation (such as, patient versions of clinical practice guidance), and technological innovations. Technological innovations included the integration of multiple clinical practice guidelines within a clinical decision support system, an automated approach to citation retrieval, the development of an electronic template for clinical practice guidance documents, the development of pragmatic search strategies to update clinical guidance recommendations and machine learning approaches for article screening in systematic reviews.

Other examples of key innovations not evaluated across the remaining 13 peer-reviewed articles included the adaptation of guidelines, use of technology such as online platforms,[4-6] decision trees to facilitate decision-making, consideration of qualitative evidence synthesis, and colloquial evidence and realist reviews in guideline development.

Conclusion

This review identified that the 2015 NCEC Standards for Clinical Practice Guidance remain relevant and applicable when compared with current international guidance development processes. However, a number of advances since 2015 have been identified. These included the additional core component of health equity in CPG development, three tools to assess the quality and or methodological robustness of CPG (that is, the RIGHT statement, The RIGHT AD@PT reporting checklist and the PANELVIEW tool), and four unique key innovations identified across organisational handbooks. In addition, 20 peer-reviewed articles detailed additional core components of CPG, ten described the development of quality measures and or criteria to assess the methodological robustness of CPG and 25 described key innovations in CPG. The findings of this review will inform updates to the current NCEC Standards for Clinical Practice Guidance to ensure they reflect innovations and current best practice.

List of abbreviations that appear in this report

ACP	American College of Physicians
AGREE	Appraisal of Guidelines for Research and Evaluation
AGREE-REX	Appraisal of Guidelines for Research and Evaluation- Recommendations Excellence
BC	British Columbia
CDSS	Clinical Decision Support System
CEAP	Clinical Efficacy Assessment Project
CPG	Clinical practice guidance
COMET	Comorbidity Ontological Modeling and ExecuTion
EtD	Evidence to decision
EHIF	Estonian Health Insurance Fund
GRADE	Grading Recommendations Assessment and Development Evidence
GDG	Guideline development group
GIN	Guidelines International Network
GPAC	Guidelines and Protocols Advisory Committee of Estonia
G-TRUST	Guideline Trustworthiness, Relevance and utility Scoring Tool
HAS	Haute Autorité de santé [French National Authority for Health]
HIQA	Health Information and Quality Authority
HIS	Health Improvement Scotland
HOD	Health outcome descriptor
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
HTA	Health technology assessment
IGEST	International Guideline Evaluation Screening Tool
KCE	Kenniscentrum Centre d'Expertise [Belgian Health Care Knowledge Centre]
KNGF	Koninklijk Nederlands Genootschap voor Fysiotherapie [Royal Dutch Society for Physiotherapy]
NEATS	National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards
NCEC	National Clinical Effectiveness Committee
NHMRC	Australian National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
PICO	Population, intervention, comparator, outcome
PPPG	Policies, procedures, protocols and guidelines
PPGDs	Policies, procedures, guidelines and directives documents
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR	Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews

PROGRESS-Plus	Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status, or Social capital, also including personal characteristics associated with discrimination, features of relationships, and time-dependent relationships
QuADS	Quality Assessment for Diverse Studies
RIGHT	Reporting Items for practice Guidelines in HealTHcare
RQs	Research Questions
SIGN	Scottish Intercollegiate Guidelines Network
UK	United Kingdom
US	United States
USPSTF	US Preventive Services Task Force
WHO	World Health Organization

1 Background

1.1 Description of Standards for Clinical Practice Guidance development in Ireland

Clinical practice guidance (CPG) is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances, with the type of CPG determined by evidence-based criteria and clinical requirements.[1] CPG includes clinical policies, procedures, protocols and guidelines (PPPG). Care pathways, clinical decision aids and or tools, care bundles, flowcharts, checklists and algorithms can form components of PPPG.[1]

In 2014, the National Clinical Effectiveness Committee (NCEC) was requested by the Minister for Health to develop standards for CPG. The NCEC Standards for Clinical Practice Guidance (hereafter, also referred to as the NCEC CPG Standards in this review) were published in 2015.[1] They were informed by a systematic literature review,[7] an Expert Advisory Group and public consultation. Their aim is to provide standards for healthcare staff developing evidence-based CPG for healthcare settings, ensure consistency of approach and minimise duplication in CPG.

Within the NCEC CPG Standards, nine core components form the basis for high quality evidence-based CPG. These are grouped into four categories:

- governance
- methodology
- planning and implementation
- communications.

Figure 1 provides an overview of the current core components and criteria to assist in the development of CPG.

Figure 1 Core components – Standards for evidence-based clinical practice guidance

Governance	Governance model
	Audit, monitoring, review & evaluation process
	Service user and stakeholder involvement
	Knowledge management
Methodology	Clarity of scope and purpose
	Evidence-based
Planning & Implementation	Resource implications
	Planning & Implementation
Communications	Communications

Source: NCEC Standards for Clinical Practice Guidance, Department of Health (Ireland), 2015[(1)]

1.2 Description of updating the Standards for Clinical Practice Guidance in Ireland

The Clinical Effectiveness Unit in the National Patient Safety Office in the Department of Health has responsibility for leading the clinical effectiveness policy function, including supporting the NCEC, and for promotion of evidence-based healthcare through quality assured National Clinical Guidelines, National Clinical Audits, and CPG. The Terms of Reference for the NCEC include publication of the NCEC Standards for Clinical Practice Guidance.[(8)] As it is eight years since the publication of the original standards, it is timely to review and potentially update these standards to take account of, and incorporate, any relevant developments in the intervening years.

In October 2022, the NCEC agreed that work should commence on a review to inform a potential update of the Standards. The following approach was approved:

- Commission an updated literature review to examine evidence since the original literature review and whether there has been a material change in approaches, and to capture innovation as driven by the COVID-19 pandemic and other reforms in using evidence to determine guidance content.
- Conduct a consultation with key stakeholders, including guidance developers, to determine if (and how) the standards can better support CPG development and implementation and whether the original scope is still appropriate.
- Establish an Expert Advisory Group.

1.3 Purpose of this systematic review

The purpose of this scoping review was to support the NCEC in considering updates to the current NCEC Standards for Clinical Practice Guidance through capturing new and updated CPG methodologies, particularly taking into account innovations (such as, living guidelines and rapid reviews) that were widely used during the COVID-19 pandemic, where the emphasis was on development and implementation of strategies to manage the rapidly evolving evidence base in response to a public health emergency.

2 Methods

In reporting this scoping review we have adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) criteria.[9] The protocol for this systematic review was agreed by the NCEC in April 2023 and published on the HIQA website.

This scoping review aligns with the guidance for conducting a scoping review when needing to examine key characteristics or factors related to a concept.[10]

2.1 Protocol deviations

Backward citation searching did not take place due to the volume of returned records. Minor rewording of RQ2 to aid clarity.

2.2 Criteria for considering publications for this review

The aim of this scoping review was to answer the following research questions (RQs):

1. What are the core components of the various types of clinical practice guidance? (update of Research Question 2 from the 2015 systematic review)[7]

2. What quality assurance or appraisal criteria are available to examine the robustness of the methodological process utilised to develop the various types of clinical practice guidance? (update of Research Question 5 from the 2015 systematic review)[7]

3. What are the key innovations since 2015 in the development and implementation of clinical practice guidance? (new Research Question)

The remaining 11 Research Questions covered in the original systematic review will be updated by the NCEC through a targeted consultation with key stakeholders.

The review questions were formulated in line with the PICO (Population, Intervention, Comparison, Outcome) framework, as presented in Table 1.

Table 1 Population, Intervention, Comparison, Outcome for all three Research Questions

Population	▪ Publications regarding clinical practice guidance for any patient and or population group, excluding disease-specific publications.
Intervention	▪ Clinical practice guidance, including guidelines, pathways, policies, protocols, care bundles, standards of care, algorithms, checklists, decision aids.
Comparison	▪ Alternative methods to produce clinical practice guidance or no comparator (for articles considering the evaluation of methods).
Outcome	▪ RQ1: Description of core components of clinical practice guidance. ▪ RQ2: Description of quality assurance or appraisal criteria to examine methodological robustness of clinical practice guidance development. ▪ RQ3: Description of key innovations since 2015 in the development and implementation of clinical practice guidance.

The types of publications eligible for inclusion were:

- methodological handbooks that provide information relating to any of the following: core components, quality measures and or criteria, or key innovations in the development and or implementation of CPG.

- peer-reviewed articles that describe any of the following: additional core components of CPG (that is, core components not already included in the NCEC CPG Standards), quality measures and or criteria, or key innovations in the development and or implementation of CPG.

Core components refer to the nine core components as described in the NCEC CPG Standards,[1] which can be grouped together into four categories:

- Governance
  - governance model
  - audit, monitoring, review and evaluation process
  - service user and stakeholder involvement
  - knowledge management.
- Methodology
  - clarity of scope and purpose
  - evidence-based.
- Planning and implementation
  - resource implications
  - planning and implementation.
- Communications
  - communications.

Living guidance, modular and or partial updates, and changes in governance procedures for tracking when guidance is due for updating were the key innovations of interest. Other innovations identified by the review were also included.

Only publications from 2015 onwards were considered for inclusion, due to availability of the systematic review,[7] conducted in 2015, to inform the development of the NCEC Standards for Clinical Practice Guidance.

2.3 Exclusion criteria

The following exclusion criteria were applied:

- disease-specific publications, as standards for CPG are intended to be generic across all conditions
- editorials/commentaries/opinion pieces
- abstracts only
- animal studies
- non-English language publications due to the complexity of the data being extracted.

2.4 Search methods for identification of studies

Data for this review were identified from methodological handbooks that detailed the core components, quality measures and or criteria, or key innovations in the development and or implementation of CPG used by international or national groups who provide methods guidance for developing CPG. A systematic literature review published in 2015[7] informed the development of the current NCEC CPG Standards.[1] This systematic review was considered an index document, from which forward citation searches of relevant included documents was conducted.[7] Additionally, data from 2015 to 2023 were gathered through a grey literature search (see sections 2.4.1 and 2.4.2). The overall search span for this scoping review was from 2015 to 2023.

Data were also sourced from peer-reviewed articles which described additional core components of CPG (that is, core components not already included in the NCEC CPG Standards), quality measures and or criteria, or key innovations in the development and or implementation of CPG. For peer-reviewed articles, data from 2015 to 2023 were gathered through a database search (see section 2.4.3).

2.4.1 Organisations

Websites of the organisations listed in Appendix A, Table A1 were searched for relevant methodological handbooks. The organisations were chosen based on guidance being available in English and identification of the organisation from previous systematic reviews on this topic (that is, the systematic review published in 2015 to inform the NCEC CPG Standards[7] and the HRB-CICER systematic review of update processes for clinical guidelines).[11] Other sources of grey literature, listed in Table 2, were searched for relevant methodological handbooks.

Table 2 Grey literature searched for relevant methodological handbooks

Other literature sources	URL
Research Rabbit	www.researchrabbitapp.com
PubMed 'Similar Articles' feature	www.pubmed.ncbi.nlm.nih.gov
Lights Database	www.lights.science

2.4.2 Databases

The following databases (used in the original systematic review) were searched for peer-reviewed articles using the search strategy defined in Appendix A, Table A2:

- Medline (EBSCO)
- CINAHL (EBSCO)
- The Cochrane Library (Wiley).

2.5 Data collection and analysis

2.5.1 Selection of eligible publications

Methodological handbooks were identified through searching the websites of eligible organisations (see Appendix A, Table A1). This was done by one reviewer and relevant handbooks were imported into Endnote (Version X20), these were reviewed by a second reviewer to confirm their eligibility.

All citations identified from the collective search strategy (see Appendix A, Table A2) were exported to EndNote (Version X20) for reference management, where duplicates were identified and removed. Using Covidence (www.covidence.org), two reviewers independently reviewed the titles and abstracts of the remaining citations to identify those for full-text review. The full texts were obtained and independently evaluated by two reviewers applying the defined inclusion and exclusion criteria. Where disagreements occurred, discussions were held to reach consensus and where necessary, a third reviewer was involved. Citations excluded during the full-text review stage were documented alongside the reasoning for their exclusion and included in the PRISMA-ScR flow diagram.

2.5.2 Data extraction and management

Data were extracted from methodological handbooks and peer-reviewed articles by one reviewer and checked for accuracy and omissions by a second. Where disagreements occurred, discussions were held to reach consensus and where necessary, a third reviewer was involved. Data extraction was conducted in Microsoft Word, using a data extraction form. The data extraction form was piloted and refined to include a section on the category of

evidence (as defined by the NCEC, see section 2.5.3) and the addition of a summary section relating to each included handbook and or peer-reviewed article.

2.5.3 Quality appraisal

Methodological handbooks were not quality appraised.

Peer-reviewed studies employed a diverse range of methods and a number of studies either did not report or did not fully report the methods used. As such, only peer-reviewed articles relating to quality assurance or appraisal criteria that had been evaluated were quality appraised, as the methodologies employed were typically described in a way that permitted quality appraisal. Quality appraisal was conducted independently by two reviewers using the Quality Assessment for Diverse Studies (QuADS).[12] Any disagreements were resolved by deliberation or, if necessary, a third reviewer.

In line with the original 2015 systematic review,[7] a two-step hierarchal evidence grading system was used. According to this system, peer-reviewed articles were first graded using the following criteria:

- **Grade A:** Evidence from a meta-analysis of randomised controlled trials (RCTs), or from at least one RCT.
- **Grade B:** Evidence based on one controlled trial without randomisation, a quasi-experimental study, or extrapolated from RCTs.
- **Grade C:** Evidence from comparative studies, correlation studies, case control studies or extrapolated from Grade A or B.
- **Grade D:** Evidence from expert committees, reports or opinions, the clinical experience of respected authorities, and the conclusions of the GDG.

Then additionally, graded according to the utility of the evidence in practice:

- **Grade 1:** Most common recommended practice according to the retrieved literature for clinical practice guidance development.
- **Grade 2:** Less common recommended practice according to the retrieved literature clinical practice guidance development.

2.5.4 Data synthesis

Since the primary data extracted for this review was descriptive in nature, a narrative synthesis was undertaken. Methodological handbooks served as the primary data source, while peer-reviewed articles constituted a secondary data source.

As mentioned in section 2.2, the NCEC CPG Standards describe nine core components. These are supplemented by a checklist detailing 37 subcomponents in total. These core components and subcomponents were used to guide RQ1.

In addressing RQ1, which focused on the core components of CPG, data from methodological handbooks published since 2015 were synthesised and described according to the NCEC CPG Standards core components and subcomponents. Any additional core components identified which were not included in the NCEC CPG Standards, were also synthesised and described.

For RQ2 and RQ3, quality assurance or appraisal criteria used to examine the methodological robustness of CPG (RQ2) and key innovations in the development of CPGs (RQ3), not included in the NCEC CPG Standards, were described. For the purpose of this review the following terms were defined:

Quality assurance is a process step during the finalisation phase of the development of CPGs, involving the assessment of draft CPGs against specific set standards, criteria or guidance to ensure that the CPGs meet a consistently high-quality standard. For example, the NCEC developed a pre-requisite assurance criteria for the Irish context in 2015 in the Framework for Endorsement of National Clinical Guidelines.[13]

Appraisal criteria, on the other hand, involves applying a set of criteria to evaluate a CPG for specific purposes. These might include assessing the quality of reporting within a CPG or determining its suitability for adaptation to a particular setting. Such tools are typically used during the planning or development stages of a CPG. In some cases, they also serve to enhance the quality assurance process. An example of this is the AGREE II tool, which can be used to evaluate a CPG's suitability for adaptability but also can supplement the quality assurance stage.

RQ2 focuses on identifying quality assurance or appraisal criteria that are not currently included within the NCEC pre-requisite assurance criteria or that could complement these criteria.

Key innovations were practices, tools or ideas that would assist in guidance development process that are currently not included in the NCEC CPG Standards. Examples of these include, living guidelines, partial updates and changes in governance procedure for guidance development. Where identified, relevant peer-reviewed articles that included evaluations are described in full. Peer-reviewed articles that did not include an evaluation were listed and or only briefly described in the main report. Data extraction tables for all handbooks and peer-reviewed articles are presented in the Appendices B and C, respectively.

Evaluation has been defined as the systematic assessment of the merit of methodologies relating to CPG development and or implementation to inform decision-making. This

definition included both formative (such as, process and or implementation evaluations) and summative evaluations (such as, outcome and or impact evaluations).[14]

3 Results

The results are presented in three main sections as follows:

- Research question 1: Core components of CPG:
    - Core components (as defined by the NCEC CPG Standards) identified in methodological handbooks and additional core components identified.
    - Additional core components identified in peer-reviewed articles.
- Research question 2: Quality assurance or appraisal criteria to examine methodological robustness of CPG development
    - Quality assurance or appraisal criteria identified in methodological handbooks.
    - Quality assurance or appraisal criteria identified in peer-reviewed articles.
- Research question 3: Key innovations in the development and implementation of CPG
    - Key innovations identified in methodological handbooks.
    - Key innovations identified in peer-reviewed articles.

3.1 Organisation search results (handbooks)

Eight handbooks were identified from seven of the 25 pre-defined organisations (see Appendix A, Table A1). The grey literature search identified a further four handbooks from four organisations. In total, 12 handbooks[15-26] from 11 organisations were eligible for inclusion; these organisations are listed below.

- Australian National Health and Medical Research Council (NHMRC)[21]
- Belgian Health Care Knowledge Centre (KCE)[20]
- Clinical Guidelines Committee of the American College of Physicians (ACP)[22]
- Estonian Health Insurance Fund (EHIF)[17]
- French National Authority of Health (HAS)[19]
- Guidelines and Protocols Advisory Committee of British Columbia (GPAC)[18]
- National Institute for Health and Care Excellence (NICE)[25]
- Royal Dutch Society for Physiotherapy (KNGF)[15]
- Scottish Intercollegiate Guidelines Network (SIGN)[23, 24]
- US Preventive Services Task Force (USPSTF)[16]
- World Health Organization Regional Office for Europe (WHO).[26]

An overview of the organisations included in this review is provided in Table 3.

Table 3 Overview of the organisations included in this report

Organisation Country Date founded	Funding	Remit
Clinical Guidelines Committee of the American College of Physicians (ACP)[22] US 1981	▪ Funding of the ACP comes from the ACP and from interested individuals and organisations. ▪ Beginning in 1986, ACP has accepted contributions to the Clinical Efficacy Assessment Project from interested individuals and organisations.	▪ Its purpose is to help physicians practice high-quality, more efficient, and cost-effective medicine. ▪ ACP recommendations are intended to provide physicians with current information and guidelines regarding the use of tests, procedures, and therapies and the rationale for such recommendations founded on both the literature and broad-based expert opinion.
Estonian Health Insurance Fund (EHIF)[17] Estonia 2001	▪ EHIF is funded through social taxation.	▪ The purpose of the EHIF is to organise national health insurance to provide insured people with access to necessary healthcare services, medicines, medical equipment and cash benefits. ▪ The EHIF, in cooperation with the Guideline Advisory Board and the University of Tartu, are tasked with methodological supervision of the guidelines being developed.
Guidelines and Protocols Advisory Committee (GPAC)[18] British Columbia (BC), Canada 1993	▪ Funding for GPAC is made available through the Physician Master Agreement; an agreement between the Doctors of BC, Medical Services Commission and the Minister of Health which outlines funding through social taxation.	▪ The GPAC mandate is to support both the effective utilisation of medical services and high quality, appropriate patient care. This is achieved through the development, publication and promotion of clinical practice guidelines and protocols.
French National Authority for Health (HAS)[19] France 2005	▪ HAS is an independent public body with financial autonomy. ▪ Finance is provided by the Government of France through social taxation.	▪ It is mandated by law to carry out specific projects on which it reports to Government and Parliament. ▪ It defines recommendations for good clinical practice, public health recommendations, medico-economic studies, management guides, intended for professionals but also patients.
Belgian Health Care Knowledge Centre (KCE)[20] Belgium 2003	▪ KCE is funded by the federal authorities (78% from the National Insurance for Health and Disability Insurance and 22% from the Federal Public Service "Public Health" and "Social Security" combined).	▪ KCE is an independent research centre that provides advice to policymakers on decisions relating to healthcare and health insurance on the basis of scientific and objective research. ▪ This includes the production of clinical practice guidelines which are disseminated through the Belgian network of Evidence-Based Practice.
Royal Dutch Society for Physiotherapy (KNGF)[15] The Netherlands 1998	▪ Funding comes from its members. ▪ The KNGF also works in collaboration with other professional societies.	▪ The KNGF represents the professional, social, and economic interests of over 20,000 members. ▪ The KNGF develops a large number of evidence-based products including clinical guidelines for use in the Dutch and other European countries.

Organisation Country Date founded	Funding	Remit
National Health and Medical Research Council (NHMRC)[21] Australia 1936	▪ The NHMRC is funded by the Government of Australia via the Department of Health through social taxation.	▪ NHMRC is an independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing, operating under the *National Health and Medical Research Council Act 1992* (NHMRC Act) since 1 July 2006. ▪ NHMRC develops and supports high quality guidelines for clinical practice, public health, environmental health and ethics.
National Institute for Health and Care Excellence (NICE)[25] England and Wales 1999	▪ NICE is funded by and accountable to the Department of Health and Social Care. ▪ NICE is a national advisory body established as an executive non-departmental public body. ▪ NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government, and Northern Ireland Executive.	▪ To improve outcomes for people using the NHS and other public health and social care services. ▪ To produce evidence-based guidance and advice for health, public health and social care practitioners. ▪ To develop quality standards and performance metrics for those providing and commissioning health, public health and social care services. ▪ To provide a range of information services for commissioners, practitioners and managers across health and social care.
Scottish Intercollegiate Guidelines Network (SIGN)[23] Scotland 1993	▪ SIGN is part of the Evidence Directorate of Health Improvement Scotland and core funding supports the SIGN guideline programme. SIGN is editorially independent from HIS and the Scottish Government which funds HIS.	▪ To improve the quality of healthcare for patients in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence.
US Preventive Services Task Force (USPSTF)[16] US 1984	▪ The USPSTF is funded, staffed, and appointed by the US Department of Health and Human Services via the Agency for Healthcare Research and Quality.	▪ USPSTF is an independent group of national experts in prevention and evidence-based medicine that work to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counselling services, or preventive medications.
World Health Organization Regional Office of Europe (WHO)[26] Denmark 1948	▪ Member States contribute almost 60% of the programme budget directly, a further 14% comes indirectly from national governments through other organisations in the United Nations system, partnerships and development banks. ▪ 10% of the WHO's funds come from philanthropic foundations.	▪ The WHO's official mandate is to promote health and safety while helping the vulnerable worldwide. ▪ It provides technical assistance to countries, sets international health standards, collects data on global health issues, and serves as a forum for scientific or policy discussions related to health.

Key: ACP - American College of Physicians; BC – British Columbia; EHIF - Estonian Health Insurance Fund; GPAC - Guidelines and Protocols Advisory Committee; HAS - Haute

Autorité de Santé [High Authority for Health]; KCE - Belgian Health Care Knowledge Centre; KNGF - Koninklijk Nederlands Genootschap voor Fysiotherapie [Royal Dutch Society for Physical Therapy]; NHMRC - National Health and Medical Research Council; NHS – National Health Service; NICE - National Institute for Health and Care Excellence; SIGN - Scottish Intercollegiate Guidelines Network; USPSTF - US Preventive Services Task Force; WHO – World Health Organization.

3.1.1 Characteristics of included handbooks

Twelve handbooks from eleven organisations published from 2015 to 2023 were included in this scoping review.[15-26] Three were developed by organisations based in the UK, two handbooks by SIGN[23, 24] and one by NICE.[25] Two handbooks were developed by organisations in the US (ACP and USPSTF)[16, 22] and one each by the EHIF in Estonia,[17] GPAC in British Columbia, Canada,[18] HAS in France,[19] KCE in Belgium,[20] KNGF in the Netherlands[15] and NHMRC in Australia.[21] One handbook was developed by the European regional office of the WHO.[26]

Ten handbooks (ACP; KCE; EHIF; HAS; GPAC; NICE; NHMRC; KNGF; SIGN; and USPSTF) included processes for developing *de novo* clinical guidelines,[15-23, 25] six of which (ACP, EHIF, KCE, NHMRC, NICE, and SIGN) included considerations for adapting and adopting recommendation(s) from existing high-quality clinical guidelines.[17, 20-23, 25] The GPAC handbook also covers the development of clinical protocols.[18] Two handbooks (SIGN and WHO) described novel approaches to guideline development.[24, 26] The SIGN handbook outlined the methodology used for developing rapid guidelines. This handbook supplements the main handbook by SIGN and reports only the processes that differ from non-rapid guidelines.[24] The handbook produced by the WHO Europe focused solely on the process of contextualisation.[26] Contextualisation is a structured and transparent process for modifying or adding to recommendations identified in existing guidelines that are developed for one setting and optimised for implementation to another.[26]

Each handbook included varying levels of detail on the description of core components (section 3.3.1), quality measures and or appraisal criteria (section 3.4.1), and key innovations used (section 3.5.1). Table 4 provides an overview of the characteristics of the included handbooks the complete data extraction tables are in Appendix B.

Table 4 Characteristics of included handbooks

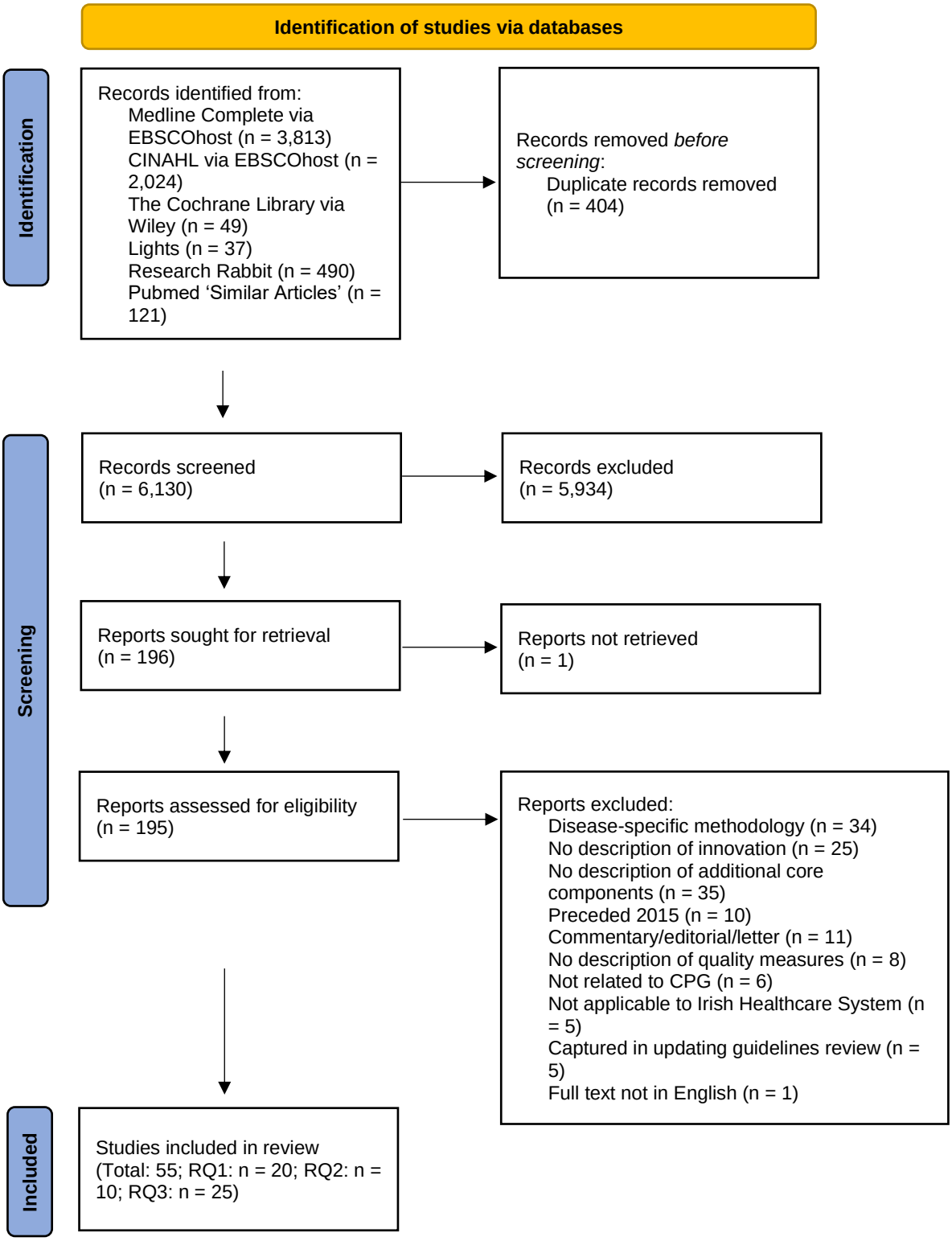
Organisation (Country)	Name of handbook	Year	Jurisdiction
ACP (US)[22]	Development of Clinical Guidelines and Guidance Statements by the Clinical Guidelines Committee of the American College of Physicians: Update of Methods	2019	National
EHIF (Estonia)[17]	Estonian Handbook for Guidelines Development	2020	National
GPAC (British Columbia - Canada)[18]	Guidelines and Protocols Advisory Committee Handbook	2017	Provincial
HAS (France)[19]	Development of good practice guidelines "Clinical practice guidelines" Method	2020	National
KCE (Belgium)[20]	KCE Process Book	2021	National
KNGF (The Netherlands)[15]	KNGF guideline methodology	2019	National
NHMRC (Australia)[21]	Standards for guidelines	2016	National
NICE (UK)[25]	Developing NICE guidelines: the manual (PMG20)	2020	National
SIGN (Scotland)[23]	A guideline developer's handbook	2019	National
SIGN Rapid (Scotland)[24]	Rapid guideline methodology	2021	National
USPSTF (US)[16]	Procedure Manual	2021	National
WHO (Europe)[26]	Strengthening countries' capacities to adopt and adapt evidence-based guidelines: a handbook for guideline contextualization	2023	Regional

Key: ACP - American College of Physicians; BC – British Columbia; EHIF - Estonian Health Insurance Fund; HAS - Haute Autorité de Santé [High Authority for Health]; KCE - Belgian Health Care Knowledge Centre; KNGF - Koninklijk Nederlands Genootschap voor Fysiotherapie [Royal Dutch Society for Physical Therapy]; NHMRC - National Health and Medical Research Council; NICE - National Institute for Health and Care Excellence; SIGN - Scottish Intercollegiate Guidelines Network; USPSTF - US Preventative Services Task Force; WHO– World Health Organization.

3.2 Database search results (peer-reviewed articles)

The search of electronic databases (see Appendix A, Table A2), from 1 January 2015 to 25 May 2023, identified a total of 6,534 citations. After the removal of duplicates, 6,130 records were screened. A total of 195 full-text articles were assessed for eligibility according to the inclusion and exclusion criteria; 140 were excluded (see Appendix A, Table A3). This resulted in 55 articles being eligible for inclusion in this review: 20 articles related to the additional core components of CPG, 10 articles related to quality measures and or criteria to determine the robustness of the methodologies used for CPG development, and 25 articles related to key innovations in CPG since 2015. The PRISMA flow chart (outlining the flow of studies through this scoping review) is presented in Figure 2.

Figure 2 PRISMA flow diagram of included studies



3.2.1 Characteristics of peer-reviewed articles

A total of 55 peer-reviewed articles were identified in this scoping review, of which 20 articles[27-46] described additional core elements, 10 articles described quality assurance or appraisal criteria,[2, 3, 47-54] and 25 described key innovations related to CPG.[4-6, 55-76] The study characteristics of these papers are described below.

Thirty-seven articles were developed in international settings, that is they were developed by authors from two or more countries.[3, 5, 27-32, 34, 36, 39, 40, 42-44, 46-48, 50, 52, 54, 55, 57, 62-64, 66-76] Eight[2, 37, 38, 51, 56, 58, 59, 61] articles were developed in North America (four[2, 56, 58, 61] in the US and four[37, 38, 51, 59] in Canada), five[6, 33, 41, 45, 49, 60, 65] were conducted in Europe (one[33] in the Netherlands, two[41, 45] in Germany, one[6] in Spain, one[49] in Italy) and two[60, 65] in the UK. Two of the articles[4, 35] were conducted in Australia and one[53] in China.

Out of 55 studies, 42[2, 3, 5, 6, 29-33, 35, 37-40, 42-44, 47-57, 60, 64-76] studies were related to clinical practice guidelines; one[34] study referred to both clinical practice guidelines and rapid policy; five studies[42-46] referred to guideline-based quality indicators; one[41] study referred to quality indicators in clinical pathways; two studies[4, 58] referred to guidance documents including protocols, policies, guidelines, directives standards and quality indicators; two studies[59, 62] referred to clinical pathways and two studies[61, 62]referred to flowchart and or algorithms.

Twenty-six of the 55 studies used a mixed methods study design.[2, 3, 5, 27, 29-32, 34, 38, 42-44, 48-51, 53, 54, 56, 58, 62, 72, 74-76] Nine studies used literature review methodology, [36, 37, 40, 41, 46, 59, 61, 64, 66, 68] out of which four studies used systematic review, [36, 40, 46, 66] four studies used narrative review[41, 61, 65, 68] and one study used realist review.[37] Seven studies employed consensus methodology[28, 33, 47, 52, 69-71] of which five used a nominal group technique design,[28, 33, 69-71] one used a Delphi design[52] and one used a modified Delphi design.[47] Eleven studies used a descriptive study design, [6, 35, 39, 45, 57, 59, 60, 63, 64, 67, 73] five of which used a cross-sectional study design,[6, 35, 63, 64, 67] three studies used a qualitative study design,[39, 45, 73] two used an evaluation design[57, 59] and one used a user study design.[60] One used an experimental study design[55] and one other was protocol for a descriptive study. [4]

Overall, 11[2, 47, 48, 50, 51, 55-60] studies included an evaluation of the quality measure and or criteria, or key innovations described within that study. Consideration of evaluation within peer-reviewed articles was not applicable to studies that identified additional core components as these studies were descriptive in nature.

According to the grading system used in the original systematic review,[7] studies were graded according to the level of evidence (Grade A to D) and the utility of the evidence in practice (grade 1 or 2). For level of evidence:

- one[42] study was graded B (that is, evidence based on one controlled trial without randomisation, a quasi-experimental study, or extrapolated from RCTs)
- thirty-seven[2, 3, 5, 29-32, 35-40, 42-46, 48, 49, 51, 53-58, 60, 62, 66, 67, 72-76] studies were graded C (evidence from comparative studies, correlation studies, case control studies or extrapolated form category A or B)
- seventeen[4, 6, 28, 33, 34, 41, 47, 52, 59, 61, 63-65, 68-71] studies were graded D (evidence from expert committees, reports or opinions, the clinical experience of respected authorities and the conclusions of the guideline development group).

For utility of the evidence in practice see section 3.3.3 (RQ1), section 3.4.2 (RQ2) and section 3.5.2 (RQ3).

Table 5 Characteristics of included peer-reviewed articles

Author	Country	Study design	Guidance type applicable to	Category of evidence	Utility of evidence in practice
Peer-reviewed articles describing additional core components					
Akl (2017a)[31]	International	Mixed methods	Guideline	C	1
Baldeh (2020)[27]	International	Mixed methods	Guideline	C	2
Bohren (2019)[36]	Australia, Switzerland	Systematic review	Guideline	C	2
Brouwers (2015)[38]	Canada	Mixed methods	Guideline	C	1
Dewidar (2022)[34]	International	Mixed methods	Guideline; Rapid policy	D	1
Kastner (2015)[37]	Canada	Realist review	Guideline	C	1
Langendam (2020)[46]	International	Systematic review	Quality indicators - guideline-based	C	1
Nothacker (2016)[44]	International	Mixed methods	Quality indicators - guideline-based	C	1
Nothacker (2021)[45]	Germany	Descriptive study - qualitative	Quality indicators - guideline-based	C	1
Piggott (2021)[42]	International	Mixed methods	Quality indicators - guideline-based	B	1
Piggott (2023)[43]	International	Mixed methods	Quality indicators - guideline-based	C	1
Pottie (2017)[32]	International	Mixed methods	Guideline	C	1
Richter (2016)[41]	Germany	Narrative Review	Quality indicators in clinical pathways	D	1
Santesso (2022)[39]	Poland, Canada	Descriptive study - qualitative	Guideline	C	1
Shalit (2023)[35]	Australia	Descriptive study - cross-sectional	Guideline	C	2
Schipper (2015)[40]	Switzerland, The Netherlands	Systematic review	Guideline	C	1
van Munster (2017)[33]	The Netherlands	Nominal group technique	Guideline	D	1
Welch (2017a)[29]	International	Mixed methods	Guideline	C	1
Welch (2017b)[30]	International	Mixed methods	Guideline	C	1
Wiercioch (2021)[28]	International	Nominal group technique	Guideline	D	2
Peer-reviewed articles describing quality assurance or appraisal criteria (evaluation included within the article)					
Brouwers (2016)[51]	Canada	Mixed methods	Guideline	C	1
Brouwers (2020)[48]	International	Mixed methods	Guideline	C	1
Jue (2019)[2]	US	Mixed methods	Guideline	C	1
Shaughnessy (2017)[47]	Canada, USA	Modified Delphi	Guideline	D	1

Author	Country	Study design	Guidance type applicable to	Category of evidence	Utility of evidence in practice
Wiercioch (2020)[50]	International	Mixed methods	Guideline	C	1
Peer-reviewed articles describing quality assurance or appraisal criteria (no evaluation within the article)					
Chen (2017)[52]	International	Delphi study	Guideline	D	2
D'Angelo (2022)[49]	Italy	Mixed methods	Guideline	C	2
Morgan (2018)[3]	International	Mixed methods	Guideline	C	2
Song (2022)[54]	International	Mixed methods	Guideline	C	2
Zhou (2022)[53]	China	Mixed methods	Guideline	C	2
Peer-reviewed articles describing key innovations (evaluation included within the article)					
Abidi (2017)[59]	Canada	Descriptive study - evaluation	Clinical pathway	D	1
Bui (2015)[56]	US	Mixed methods	Guideline	C	1
Corey (2018)[58]	US	Mixed methods	Guidance (protocols, policies, guidelines, and directives)	C	1
Fearns (2016)[60]	UK	Descriptive study - user study	Guideline	C	1
Martínez García (2015)[57]	International	Descriptive study - evaluation	Guideline	C	1
Yamada (2020)[55]	Japan, UK, USA	Experimental study	Guideline	C	1
Peer-reviewed articles describing key innovations (no evaluation within the article)					
Akl (2017b)[68]	International	Narrative Review	Guideline	D	2
Akl (2021)[75]	International	Mixed methods	Guideline	C	2
Ardito (2020)[63]	International	Descriptive study – cross-sectional	Clinical pathway	D	2
Brennan (2016)[65]	UK	Narrative Review	Guideline	D	2
Djulbegovic (2018)[61]	US	Narrative Review	Flowchart/algorithm	D	2
Downe (2019)[69]	International	Nominal group technique	Guideline	D	2
Garritty (2017)[76]	Canada, Croatia, Switzerland	Mixed methods	Guideline	C	2
Girgis (2018)[62]	Australia, UK	Mixed methods	Algorithm	C	2
Glenton (2019)[71]	International	Nominal group technique	Guideline	D	2
Haby (2016)[74]	International	Mixed methods	Guidance	C	2
Heen (2021)[5]	Norway, Canada, US	Mixed methods	Guideline	C	2
Lewin (2019)[70]	International	Nominal group technique	Guideline	D	2

Author	Country	Study design	Guidance type applicable to	Category of evidence	Utility of evidence in practice
Quesada-Martínez (2018)[6]	Spain	Descriptive study – cross-sectional	Guideline	D	2
Schünemann (2017)[72]	International	Mixed methods	Guideline	C	2
Sharma (2015)[66]	Denmark, UK	Systematic review	Guideline	C	2
Song (2021)[73]	International	Descriptive study - qualitative	Guideline	C	2
Wagner (2017)[67]	International	Descriptive study - cross-sectional	Guideline	C	2
Wiles (2016)[4]	Australia	Protocol - descriptive study	Guidance (standards and quality indicators)	D	2
Wilk (2017)[64]	Canada, Poland, US	Descriptive study – cross-sectional	Guideline	D	2

Key: US – United States; UK – United Kingdom.

Category of evidence:[7] Grade A – evidence from a meta-analysis of randomised controlled trials (RCTs), or from at least one RCT; Grade B – evidence based on one controlled trial without randomisation, a quasi-experimental study, or extrapolated from RCTs; Grade C – evidence from comparative studies, correlation studies, case control studies or extrapolated from Grade A or B; Grade D – evidence from expert committees, reports or opinions, the clinical experience of respected authorities, and the conclusions of the GDG.
Utility of evidence in practice:[7] Grade 1 – most common recommended practice according to the retrieved literature for clinical practice guidance development; Grade 2 – less common recommended practice according to the retrieved literature clinical practice guidance development.

3.3 Research Question 1: Core components of clinical practice guidance

3.3.1 Core components (as defined by the NCEC CPG Standards) identified in methodological handbooks

Ten handbooks (ACP; KCE; EHIF; HAS; GPAC; NICE; NHMRC; KNGF; SIGN; and USPSTF)[15-23, 25] provided data relating to at least one of the nine NCEC core components of CPG,[1] as outlined in sections 2.2 and 2.5.4. See Table 6 for a high-level summary of the core components and subcomponents identified within the 10 included handbooks. A more detailed table of the core components is presented in Table B in Appendix B.

Clarity of scope and purpose

The NCEC core component of 'Clarity of scope and purpose' comprises the following six subcomponents:

- The decision-making approach relating to type of guidance required (policy, procedure, protocol, guideline), coverage of the guidance (national, regional, local) and applicable settings are described.
- The overall objective(s) of the clinical guidance are specifically described.
- The clinical question(s) covered by the guidance are specifically described.
- The target users and the population/patient group to whom the guidance is meant to apply are specifically described.
- The potential for improved health is described (for example, clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).
- The scope of the CPG is clearly described, specifying what is included and what lies outside the scope of the CPG.[1]

Nine of the 10 included handbooks described the core component 'Clarity of scope and purpose', of which six handbooks (ACP, EHIF, HAS, KNGF, NHMRC, NICE, SIGN and USPSTF)[15-17, 19, 22, 23] considered all of the subcomponents within this core component. One handbook[18] by the GPAC addressed some subcomponents and the KCE handbook[20] did not cover any areas relating to clarity of scope and purpose. See Table 6 for an overview of the core components and subcomponents of each core component described by the handbooks included in this review.

Governance model

The NCEC core component 'Governance model' comprises the following three subcomponents:

- Formal governance arrangements for clinical practice guidance at local, regional and national level are established and documented.
- Conflict of interest statements from all members of the guidance development group are documented, with a description of mitigating actions if relevant.
- The guidance has been reviewed by independent experts prior to publication as required (for example, in complex CPGs).[1]

All ten handbooks described this core component, of which seven handbooks addressed all subcomponents of this core component (EHIF, GPAC, HAS, NHMRC, NICE, SIGN and the USPSTF).[16-19, 21, 23, 25] Three handbooks (ACP, KCE and KNGF) described some of the subcomponents.[15, 20, 22] See Table 6.

Communications

The NCEC core component 'Communications' comprises the following two subcomponents:

- A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.
- Plan and procedure for dissemination of the CPG is described.[1]

Nine handbooks described the core component 'Governance,' of which eight handbooks (ACP, EHIF, GPAC, KNGF, NHMRC, NICE, SIGN and USPSTF) addressed all subcomponents within this element.[15-18, 21-23, 25] The handbook[19] by HAS partially described this core component and the handbook by KCE did not describe this core component.[20] See Table 6.

Service user and stakeholder involvement

The NCEC core component 'Service user and stakeholder involvement' comprises the following four subcomponents:

- Stakeholder identification and involvement: The guidance development group includes individuals from all relevant stakeholders, staff and professional groups.
- Guidance is informed by the identified needs and priorities of service users and stakeholders.

- The views and preferences of the target population have been sought and taken into consideration (as required).
- There is service user and or lay representation on the guidance development team (as required).[1]

Ten handbooks described the core component 'Service user and stakeholder involvement.' Six handbooks (ACP, EHIF, KNGF, NHMRC, NICE and SIGN)[15, 17, 21-23, 25] addressed all subcomponents within this element and four handbooks partially addressed this core component (GPAC, HAS, KCE and USPSTF).[16, 18-20] See Table 6.

Evidence based

The NCEC core component 'Evidence based' comprises the following six subcomponents:

- Systematic methods used to search for evidence are documented (for CPGs which are adapted and or adopted from international guidance, their methodology is appraised and documented).
- Critical appraisal and or analysis of the evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).
- The health benefits, side effects and risks have been considered and documented in formulating the guidance.
- There is an explicit link between the clinical guidance and the supporting evidence.
- The guidance and or recommendations are specific and unambiguous.
- A systematic literature review and Health Technology Assessment (HTA) has been undertaken as required (for example, in complex CPGs).[1]

Ten handbooks described the core component 'Evidence based,' of which seven handbooks (EHIF, KCE, KNGF, NHMRC, NICE, SIGN and USPSTF) addressed all related subcomponents.[15-17, 20, 21, 23, 25] The handbooks by ACP, GPAC and HAS described some of the subcomponents of this core component.[18, 19, 22] See Table 6.

Knowledge management

The NCEC core component of 'Knowledge management (accessibility and or sharing of best practice)' comprises the following three subcomponents:

- The clinical guidance is easily accessible by all users, for example, CPG repository.

- Documented process for version control is provided.
- Copyright and permissions are sought and documented.[1]

Ten handbooks described the core component 'Knowledge management,' of which only one (NHMRC) addressed all relevant subcomponents;[21] nine handbooks (ACP, EHIF, GPAC, HAS, KCE, KNGF, NICE, SIGN and USPSTF) addressed at least one subcategory.[15-20, 22, 23, 25] See Table 6.

Resource implications

The NCEC core component 'Resource implications' comprises the following four subcomponents:

- The potential resource implications of developing and implementing the guidance are identified, for example, equipment, education and training, staff time and research.
- Synergies are maximised across departments and or organisations to avoid duplication and to optimise value for money and use of staff time and expertise.
- Budget impact analysis is documented as required (for example, in complex CPGs).
- Literature review of cost effectiveness is documented as required (such as, for complex CPGs).[1]

Eight handbooks described the core component 'Resource implications,' of which three handbooks (EHIF, NICE and SIGN) addressed all subcomponents.[16, 17, 25] Five handbooks (ACP, KCE, KNGF, NHMRC, USPSTF) described some of the subcomponents of this core component;[15, 16, 20-22] two handbooks (GPAC, HAS) did not describe any of the subcomponents.[18, 19] See Table 6.

Planning and implementation

The NCEC core component 'Planning and implementation' comprises the following five subcomponents:

- Written implementation plan is provided with timelines, identification of responsible persons and or units and integration into service planning process.
- Barriers and facilitators for implementation are identified, and aligned with implementation levers.
- Information and support is available for staff on the development of evidence-based CPG.

- There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated patient care.
- Education and training is provided for staff on the development and implementation of evidence-based CPG as required (for example, in complex CPGs).[1]

Eight handbooks described the core component 'Planning and implementation,' of which five handbooks address all subcomponents (EHIF, KNGF, NHMRC, NICE and SIGN).[15, 17, 21, 23, 25] The handbooks by ACP, GPAC and USPSTF partially describe this core component.[16, 18, 22] The handbooks by HAS and KCE did not describe this core component.[19, 20] See Table 6.

Audit, monitoring, review and evaluation

The NCEC core component 'Audit, monitoring, review and evaluation' comprises the following subcomponents:

- Process for monitoring and continuous improvement is documented.
- Audit criteria and audit process and or plan are specified.
- Documented process for revisions and or updating and review, including timeframe is provided.[1]

Nine handbooks described the core component 'Audit, monitoring, review and evaluation,' of which five addressed all subcomponents (EHIF, KNGF, NHMRC, NICE and SIGN).[15, 17, 21, 23, 25] The handbooks by ACP, GPAC and USPSTF partially describe this core component.[16, 18, 22] The KCE handbook did not describe this core component.[20] See Table 6.

Table 6 NCEC core components and subcomponents identified in organisational handbooks

What core components and subcomponents are described		ACP - US[22]	EHIF - Estonia[17]	GPAC - BC[18]	HAS - France[19]	KCE - Belgium[20]	KNGF - The Netherlands[15]	NHMRC - Australia[21]	NICE - England[25]	SIGN - Scotland[23]	USPSTF - US[16]
Clarity of scope and purpose	Decision making	✓	✓	✓	✓	N/R	✓	✓	✓	✓	✓
	Objective of CPG	✓	✓	N/R	✓	N/R	✓	✓	✓	✓	✓
	Clinical question	✓	✓	✓	✓	N/R	✓	✓	✓	✓	✓
	Target user and patient	✓	✓	N/R	✓	N/R	✓	✓	✓	✓	✓
	Potential improvement	✓	✓	N/R	✓	N/R	✓	✓	✓	✓	✓
	Scope	✓	✓	✓	✓	N/R	✓	✓	✓	✓	✓
Governance	Governance in place	N/R	✓	✓	✓	N/R	N/R	✓	✓	✓	✓
	Conflict of interest	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Independent review	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Communication	Communication plan for all stakeholders	✓	✓	✓	N/R	N/R	✓	✓	✓	✓	✓
	Plan and procedure for dissemination	✓	✓	✓	✓	N/R	✓	✓	✓	✓	✓
Service user and stakeholder involvement	Relevant stakeholders on GDG	✓	✓	✓	✓	N/R	✓	✓	✓	✓	✓
	Needs and priorities inform CPG	✓	✓	✓	✓	N/R	✓	✓	✓	✓	N/R
	Opinions of target population sought and considered	✓	✓	✓	N/R	✓	✓	✓	✓	✓	✓
	Service user representation on GDG	✓	✓	N/R	✓	✓	✓	✓	✓	✓	✓
Evidence-based	Systematic methods for searching	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Critical appraisal of evidence	✓	✓	N/R	✓	✓	✓	✓	✓	✓	✓
	Benefits and harms	✓	✓	N/R	N/R	✓	✓	✓	✓	✓	✓
	Link between CPG and supporting evidence	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Recommendations are unambiguous	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

What core components and subcomponents are described		ACP - US[22]	EHIF - Estonia[17]	GPAC - BC[18]	HAS - France[19]	KCE - Belgium[20]	KNGF - The Netherlands[15]	NHMRC - Australia[21]	NICE - England[25]	SIGN - Scotland[23]	USPSTF - US[16]
	Systematic review undertaken	N/R	✓	N/R	✓	✓	✓	✓	✓	✓	✓
Knowledge management	CPG easily accessible	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Version control	N/R	N/R	✓	N/R	N/R	N/R	✓	✓	✓	N/R
	Copyright/permission sought	N/R	✓	N/R	N/R	N/R	N/R	✓	N/R	N/R	N/R
Resource implications	Potential implications identified	✓	✓	N/R	N/R	✓	N/R	✓	✓	✓	✓
	Synergies are maximised	N/R	✓	N/R	N/R	N/R	✓	✓	✓	✓	
	Budget impact analysis	N/R	✓	N/R	N/R	✓	N/R	N/R	✓	✓	N/R
	Cost effectiveness	N/R	✓	N/R	N/R	✓	✓	✓	✓	✓	✓
Planning and Implementation	Written plan provided	N/R	✓	✓	N/R	N/R	✓	✓	✓	✓	N/R
	Barriers and facilitators identified	N/R	✓	N/R	N/R	N/R	✓	✓	✓	✓	N/R
	Information and support is available	✓	✓	N/R	N/R	N/R	✓	✓	✓	✓	N/R
	Collaboration across all stakeholders		✓	N/R	N/R	N/R	✓	✓	✓	✓	✓
	Education and training	✓	✓	N/R	N/R	N/R	✓	✓	✓	✓	N/R
Audit, monitoring, review and evaluation	Continuous improvement	N/R	✓	N/R	✓	N/R	✓	✓	✓	✓	N/R
	Evaluation of implementation	N/R	✓	N/R	N/R	N/R	✓	✓	✓	✓	N/R
	Audit criteria and process/plan	N/R	✓	N/R	✓	N/R	✓	✓	✓	✓	N/R
	Process for revisions/updating	✓	✓		✓	N/R	✓	✓	✓	✓	✓

Key: ACP - American College of Physicians; BC – British Columbia; CPG – clinical practice guidance; EHIF - Estonian Health Insurance Fund; GDG – guideline development group; HAS - Haute Autorité de Santé [High Authority for Health]; KCE - Belgian Health Care Knowledge Centre; KNGF - Koninklijk Nederlands Genootschap voor Fysiotherapie [Royal Dutch Society for Physical Therapy]; NHMRC - National Health and Medical Research Council; NICE - National Institute for Health and Care Excellence; SIGN - Scottish Intercollegiate Guidelines Network; SIGN Rapid - Scottish Intercollegiate Guidelines Network rapid guideline methodology; USPSTF - US Preventative Services Task Force; WHO/Europe – World Health Organization European regional office.

3.3.2 Additional core components identified (methodological handbooks)

Three of the included handbooks (NHMRC, NICE and USPSTF) described an additional core component (that is, equity in CPG development) not included in the NCEC Standards for Clinical Practice Guidance.[1, 16, 21, 25] All three handbooks highlighted the need to expand considerations relating to health inequities and marginalised groups. For the USPSTF handbook, pilot testing approaches is ongoing since 2021.[16] See Table 7 for more information on the additional core components identified.

Table 7 Additional core components identified in methodological handbooks

Organisation	Additional core component	Notes
NHMRC[21]	Equity Considerations	Approach: 1. Identify equity issues relevant to the guideline. 2. Engage with communities affected by inequity. 3. Ensure appropriate evidence is sought, identified and considered. 4. Understand the impact of guideline recommendations on disadvantaged populations. 5. Identify areas where research is needed on equity and disadvantaged populations.
NICE (UK)[25]	Equality and diversity considerations	▪ Equality and diversity considerations should be included where relevant: o Any equality criterion specified in the review protocol should be included in the evidence tables. o Review inclusion and exclusion criteria should take the relevant groups into account, as specified in the review protocol. o Equalities and health inequalities should be considered during the drafting of the evidence reviews, including any issues documented in the equality and health inequalities assessment. o The data extraction process should be recorded in the committee discussion section. o Equalities and health inequalities should be considered during surveillance and updating. o All searches should be inclusive, capturing evidence related to health inequalities or impacts on equality relevant to the guideline topic. For example, if the population group is 'older people' a search should pick up sub-populations such as 'disabled older people' or 'black and minority ethnic older people'. o Similarly, if the setting is 'communities and religious places', the search terms should cover all relevant faith settings (such as 'church', 'temple' and 'mosque').
USPSTF (US)[16]	Approach to addressing inequities (pilot testing is ongoing since 2021)	▪ The USPSTF is developing inclusive approaches to addressing sex and gender in recommendation development. Additional approaches include a taxonomy to categorise evidence gaps and inform future research addressing health inequities. As these changes crystallise, they will be reflected in updates to the USPSTF Procedure Manual. ▪ The USPSTF will continue to pilot test the inclusion of evidence on variation in benefits and harms as well as implementation

Organisation	Additional core component	Notes
		barriers by population groups. This process will inform the development of a health equity framework. ▪ The approach to addressing inequities is exemplified in the recent update of the USPSTF lung cancer screening recommendation. o The updated recommendation was informed by new trial evidence and simulation modelling that allowed the USPSTF to identify the most efficient screening strategies, particularly among Black people, who have a greater burden of lung cancer. o On the basis of simulation modelling, the 2021 recommendation, which decreased the starting age from 55 to 50 years and the smoking criterion from ≥30 to ≥20 pack-years, would increase the relative percentage of adults eligible for screening by 78% in non-Hispanic White persons, 107% in non-Hispanic Black persons, and 112% in Hispanic and Latino persons.

Key: NHMRC – National Health and Medical Research Council; NICE - National Institute for Health and Care Excellence; USPSTF - US Preventative Services Task Force.

3.3.3 Additional core components identified (peer-reviewed articles)

Five additional core components were identified across 20 peer-reviewed articles, they were: clarity of presentation,[37-40] gender equity,[35, 36] health equity,[29-34] health outcome descriptors (HODs),[27, 28] and quality indicators.[41-46] According to the evidence grading system,[7] the most commonly recommended practices according to the retrieved literature (grade 1) were: clarity of presentation, health equity and quality indicators. Less commonly recommended practices for CPG development were gender equity and health outcome descriptors, which were grade 2.

These additional core components are described below and in Table 8; full data extraction tables are presented in Appendix C.

Clarity of presentation

Four articles described clarity of presentation.[37-40] Two articles advised that the guideline content and recommendations be specific, unambiguous and use simple, clear and persuasive language.[37, 38]

Santesso et al.[39] described the development of a template that provided guidance to guideline developers when developing Plain Language Recommendations.

Schipper et al.[40] recommended developing a lay version of the recommendations to help patients better understand the goals of the treatment, the different treatment options and the benefits and risks of each option (See Table 8).

Gender equity

Two articles[35, 36] focused on gender equity in the guideline development panel composition. Both studies found underrepresentation of women across most roles in guideline panels (See Table 8).[35, 36]

Health equity

Six articles described the consideration of health equity in guidance development processes.[29-34] Four of the six articles were part of a series and described different aspects of health equity in guideline development.[29-32] Three of the six articles recommended consideration of health equity throughout different phases of guideline development, specifically during question formulation, scope definition, group membership, evidence assessment and development of recommendations from evidence.[29, 31, 34]

Welch et al.[30] further described consideration of health equity when using the Grading Recommendations Assessment and Development Evidence (GRADE) approach in guideline development. Similarly, Pottie et al.[32] also suggested two approaches to the incorporation of health equity within the GRADE Evidence to Decision (EtD) framework. The first of these was assessment of the potential impact of interventions on equity, and the second was incorporation of equity considerations when judging or weighing each of the EtD criteria. One study[33] focused on methodologies to increase the focus on older people in the development of guidelines. This article recommended assessment of the extent to which a specific focus on older people was required or desirable within a guideline. Additionally, this article advised considering any coincident comorbidity or multimorbidity that might affect the primary condition addressed by the guideline, when developing guidelines for older people; see Table 8.

Health outcome descriptors

Two articles suggested the consideration of health outcome descriptors (HODs) as part of the standards for clinical practice guidance.[27, 28] HODs define health outcomes based on the experiences of affected individuals and or patients, and provide a reference point for guideline panel members throughout the guideline development process.[27] Within these studies, HODs were developed using a template that described symptoms, time horizon, testing, treatment and consequences.[27, 28] See Table 8.

Quality indicators

Six articles provided information on quality indicators.[41-46] Quality indicators are defined as a 'measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change in the quality, of care provided'.[45] The definition and selection of an appropriate set of quality indicators for a healthcare organisation depend on the how they are intended to be used and could include, for example, certification or internal objectives.[41]

Two articles focused on quality assurance and improvement in guideline development.[42, 43] Both articles suggested the use of a number of quality indicators;[42, 43] these are outlined in Table 8 below. Nothacker et al.[44] developed a reporting standard for guideline-based performance measures with nine criteria, which are also described in Table 8.

Nothacker et al.[45] conducted a qualitative study to describe the development process of guideline-based quality indicators. The study recommended a designated person or team in the guideline organisation (and or a collaborating organisation) be responsible for the development of a guideline-based quality indicator. It was also recommended that the guideline organisation work with partners in quality improvement, and that they adapt the quality indicator process according to the availability of resources.

Langendam et al.[46] conducted an extension and update of a previous systematic review to identify approaches to the integrated development of guidelines and related quality indicators. The study found that guidelines were a source to inform the quality indicator development in most approaches.

Only one article focused on the potential of integrating and utilising quality indicators in clinical pathways (see Table 8).[41]

Table 8 Additional core components identified in peer reviewed articles

Author	Objective	Summary of additional core component
Clarity of presentation		
Brouwers (2015)[38]	To create a comprehensive and evidence-informed model of guideline implementability.	▪ Authors recommended the use of simple, clear and persuasive language in guidelines. ▪ For formatting, the authors recommended developing tailored versions in different modalities (electronic and non-electronic) and document types. ▪ In terms of presentation, it was recommended to consider visual elements and length for the layout of the document. ▪ The document should be structured to align with the real world system and sections to be grouped or ordered. ▪ For information visualisation, the authors recommended the use of tables, algorithms, pictures and graphics and to consider the framing, vividness, depth of field and extent to which the content can be evaluated. ▪ See Appendix C Table C1.
Kastner (2015)[37]	To identify factors associated with the implementability of clinical practice guidelines and recommendations through a comprehensive and multidisciplinary perspective.	▪ Guideline messages should be simple, clear and persuasive. ▪ Simplicity for recommendations can be attained by limiting the number of elements, number of steps within each recommendation and number of conditional factors influencing performance. ▪ For maintaining clarity, the authors recommended using specific, unambiguous language and using a direct style of writing, using short sentences and bullet lists to convey points. It was also recommended to avoid unnecessary jargon. ▪ For persuasiveness, the authors recommended framing messages in terms of potential gains so that the advantage of one approach over others is clear. ▪ In terms of formatting, the authors suggested the development of multiple versions of the guideline such as research-based, information-gathering, analytical tool, brief guide for clinical education, short version for point-of-care clinical use, lay versions. ▪ For presentation of information, the authors recommended considering the layout of the full document, sequential bundling of different sections, and visualisation of information. ▪ See Appendix C Table C2.
Santesso (2022)[39]	To test a patient-focused template for communicating recommendations.	The Plain Language Recommendations template included the following components: ▪ the recommendation and its strength ▪ list of people, populations or individuals to whom the recommendation applied ▪ a rationale for the strength of the recommendation ▪ discussion about additional considerations for using the recommendation ▪ description of the possible benefits and harms ▪ a link to the summary of findings ▪ an explanation of the implications of the guideline

Author	Objective	Summary of additional core component
		▪ topics and or questions that should be discussed with the doctor. ▪ See Appendix C Table C3.
Schipper (2015)[40]	To assess what dissemination strategies are feasible to inform and educate patients about recommendations or guidelines.	The study recommended developing a lay version of the recommendations to help patients better understand the goals of the treatment, the different treatment options and the benefits and risks of each option. The study suggested aspects to consider when developing lay versions. These included: ▪ customisation of the message to the target audience ▪ ensuring the information is relevant, consistent, unambiguous, credible, readable and simple ▪ signposting to where detailed information can be found ▪ using familiar words of one or two syllables, active voice, short sentences of 15 words or less, and short paragraphs of ten lines or less ▪ translation of international guidelines into different languages through forward translation, back translation and patient testing. ▪ See Appendix C Table C4.
Gender equity		
Bohren (2019)[36]	To assess the gender composition of guideline contributors for all WHO guidelines published from 2008-2010.	▪ Among all the WHO guideline contributors from 2008-2018, 45.6% of the GDG members were female. Only 39.5% of females were chair of GDGs and 63.5% had contributed as guideline methodologists. ▪ See Appendix C Table C5.
Shalit (2023)[35]	To assess the composition by gender of Australian clinical practice guideline development panels.	▪ In the Australian clinical practice guideline panels, 44.8% of the guideline contributors were women, 41.1% of the guideline members were women and 42.1% of guideline panel chairs were women. ▪ The proportion of female guideline panel members was smaller than 40% for 179 of 335 guidelines (53%). ▪ The proportion was smaller for NHMRC-approved guidelines (17 of 59, 29%), and larger in some health areas (for example, cardiology, 80%; nephrology, 67%) than others (for example, women's health, 12%; paediatric medicine, 31%). ▪ See Appendix C Table C6.
Health equity		
Akl (2017a)[31]	To provide guidance for guideline developers on how to consider equity at key stages of the guideline development process.	During the guideline development process, equity should be considered in the following ways: ▪ dedicating whole or part of the research towards the care of disadvantaged populations, such as sex workers, drug users, migrant workers ▪ including disadvantaged group members in guideline groups and seeking support from methodologists familiar with equity issues ▪ engagement of disadvantaged population groups in identifying the target audience ▪ considering equity during development of the PICO elements ▪ engaging disadvantaged population representatives in determining the importance of outcomes and

Author	Objective	Summary of additional core component
		interventions ▪ searching literature specific to disadvantaged populations such as unpublished reports of organisations involved with disadvantaged populations, literature from fields other than health of and seeking evidence specific to such groups ▪ considering the PROGRESS-plus elements in evidence synthesis o PROGRESS is an acronym that can help guideline panels when considering health equity issues. It includes: place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status or social capital. "Plus" refers to other relevant characteristics such as age, disability, sexual orientation, time-dependent situations and relationships need. ▪ using PRISMA-equity statements to report systematic reviews ▪ developing specific recommendations for clarity in how it applies to disadvantaged populations ▪ producing tools to facilitate implementation and use among disadvantaged populations. ▪ See Appendix C Table C7.
Dewidar (2022)[34]	To provide guidance for the consideration of equity in rapid reviews through examples of published COVID-19 rapid reviews.	In rapid reviews conducted to inform rapid policy decisions and guideline development, equity can be incorporated in the following areas: ▪ engaging relevant stakeholders in conducting, designing and interpreting the rapid review ▪ reflecting on equity in the rapid review research team values and composition ▪ developing research questions to assess health inequities ▪ conducting searches in relevant inter-disciplinary databases ▪ collecting data on equity (for example, sample characteristics such as context and population demographics that interact with other contextual elements and influence health inequities, information on retention and attrition across populations experiencing inequities) ▪ analysing evidence on equity ▪ evaluating the applicability of the findings to populations experiencing inequities (for example, racialised communities, indigenous population) ▪ adhering to reporting guidelines for communicating review findings. ▪ See Appendix C Table C8.
Pottie (2017)[32]	To provide guidance on the incorporation of health equity into the GRADE evidence to decision process.	Two approaches to incorporating equity considerations are: ▪ assessing the potential impact of interventions on equity ▪ incorporate equity considerations when judging or weighing each of the evidence to decision criteria. ▪ See Appendix C Table C9.
van Munster (2017)[33]	To develop a methodology to increase the focus on older people in the development of guidelines.	Adoption of the following steps was recommended: ▪ assessing the extent to which a specific focus on older people is required or desirable within a guideline ▪ assessing older people-specific evidence through systematic reviews ▪ identifying similar guidelines or using the expertise of subject matter experts

Author	Objective	Summary of additional core component
		▪ considering the occurrence of interfering comorbidity or multimorbidity when developing guidelines for older people ▪ considering participation of a specialist in aged care and organisations for older people in guideline development working groups ▪ considering the beliefs, values and preferences of older people ▪ ensuring any literature searches conducted capture evidence relevant to older people, (for example, using "patient preferences," "patient satisfaction," "patient experiences," "patient participation," "physician-patient relations," and "shared decision making" in the search strategy) ▪ considering outcome measures such as quality of life, hospitalisation, cognitive functioning, functional status and treatment burden ▪ checking clinical studies produce evidence for elderly people ▪ considering absolute benefits and absolute risk of interventions, medicine interactions, drug-disease interactions, treatment burden, physical, mental and emotional capacity of a patient, prognosis and the values and preferences of patients when formulating recommendations. ▪ See Appendix C Table C10.
Welch (2017a)[29]	To describe the methodology and rationale for the consideration of health equity throughout the guideline development process.	During the guideline development process, equity can be considered in the following areas: ▪ identifying the priorities of disadvantages groups and or populations and ensuring these are reflected in the key question of the guideline ▪ considering analysis of differences of effect, targeted interventions and quality assessment of directness ▪ considering the balance of health equity and other factors (such as, baseline risk, resource use) when developing guideline recommendations. ▪ See Appendix C Table C11.
Welch (2017b)[30]	To describe a conceptual framework for how to consider health equity in the GRADE guideline development process.	The authors suggested the following considerations regarding health equity using the GRADE approach: ▪ include health equity as an outcome ▪ consider patient-important outcomes relevant to health equity ▪ assess differences in the magnitude of effect in relative terms between disadvantaged and more advantaged individuals or populations ▪ assess differences in baseline risk and hence the differing impacts on absolute effects for disadvantaged individuals or populations ▪ assess indirectness of evidence to disadvantaged populations and or settings. ▪ See Appendix C Table C12.
Health outcome descriptors		
Baldeh (2020)[27]	To determine the aspects of development, content and use of health outcome descriptors that	The authors proposed a concise template for health outcome descriptors. The template should be completed at a Grade 8 reading level from the viewpoint of healthcare recipient.

Author	Objective	Summary of additional core component

	are valuable to guideline developers.	The template for describing health outcome descriptors has been listed below.
		
		<u>Name of health outcome - importance rating</u>
		▪ Symptoms
		  ○ list the most common symptoms.
		▪ Time horizon
		  ○ describe how long the symptoms will persist for and how they might change over time.
		  ○ describe the approximate timing of relevant healthcare.
		▪ Testing and treatment
		  ○ describe the relevant healthcare or interventions.
		▪ Consequences
		  ○ describe the relevant consequences resulting from the health outcome or relevant healthcare.
		▪ See Appendix C Table C13.

Wiercioch (2021)[28]	To describe methods for developing health outcome descriptors in the real-world context, describe how the approach facilitated prioritising and rating of health outcomes and how it was incorporated in decision-making by guideline panels.	The template developed had the following components:
		
		<u>Health outcome descriptor title, including lay health outcome descriptor title</u>
		▪ Symptoms
		  ○ common symptoms due to the health state
		  ○ note that the grade of severity can be labelled mild, moderate or severe and will be used as a descriptor of the health outcome descriptor, not as part of the symptom.
		▪ Time horizon
		  ○ within which timeframe does the health state occur.
		▪ Testing and treatment
		  ○ which tests and treatments are commonly applied for this health state.
		▪ Consequences
		  ○ including prognosis and side effects.
		
		Health outcome descriptors could also be used in EtD frameworks to facilitate panel's judgements and decision making. This helped to ensure that panellists were considering the same outcome in their discussions.
		▪ See Appendix C Table C14.

Quality indicators		
Langendam (2020)[46]	To identify and describe approaches used to develop guideline recommendations and quality indicators.	Quality indicators are used to monitor guideline adherence. The development of quality indicators should be incorporated into the guideline development process. This will help link the quality indicators with the recommendations.

Author	Objective	Summary of additional core component
		The study found that guidelines were a source to inform the quality indicator development in most approaches. There were also wide variation in the criteria to select recommendations (for example, level of evidence or strength of the recommendation) and to generate, select and assess quality indicators. The study also found 30 articles describing integrated development of guidelines and related quality indicators. However, the approaches stated in the papers were not based on well-established conceptual frameworks and lacked full integration of quality indicators development into the guideline development process. ▪ Appendix C Table C15
Nothacker (2016)[44]	To develop and agree a set of core methodological standards for guideline-based performance measures with an associated rationale.	The authors developed a reporting standard for guideline-based performance measures with nine criteria: ▪ **Guideline selection:** State the currency of the guideline that is used for the development of a guideline-based performance measure, and also describe the quality of the guideline using a validated quality appraisal tool. ▪ **Selection of guideline recommendations:** State the strength of evidence or grade of recommendation. ▪ **Selection process of performance measures from guideline recommendations:** Describe the methods used to develop the performance measures from the supporting clinical guideline recommendations. ▪ **Core attributes of performance measures:** Describe whether guideline performance measures (specifically, relevance, scientific and feasibility) were considered in the development process. ▪ **Specification of performance measures:** State the reporting detail in which numerator and denominator of the guideline-based performance measure are described. ▪ **Intended use of performance measure:** State whether there is a description on the intended use of the performance measure and what level of health system (local, regional or national) it should be used in. ▪ **Practice test of performance measures:** Provide a description of the piloting of the performance measure. ▪ **Review and re-evaluation of performance measures:** State the currency of the performance measure and the criteria used for deciding to change or stop the use of the performance measure. ▪ **Composition of the panel deciding on guideline-based performance measures:** Describe the composition of the panel with details on participation of multidisciplinary experts, stakeholders in the field, experts in quality measurement, and patient representatives. ▪ Appendix C Table C16.

Nothacker (2021)[45]	To explore the processes in the development of a guideline-based quality indicator.	Quality indicators are defined as a 'measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change the quality, of care provided'.
		
		The main aspects of the quality indicator development process and suggested approaches were:
		▪ Organisation and or context of the guideline and quality indicator development process
		  ○ have a designated person or team in the guideline organisation (and or collaborating organisation) who is responsible for the development of the guideline-based quality indicator
		  ○ work with partners in quality improvement

Author	Objective	Summary of additional core component
		○ adapt the quality indicator process according to the availability of resources. ▪ Panel composition and decision making ○ train the quality indicator development team concerning quality indicator methodology, possibilities and limitations ○ discuss patient perspective and patient relevance of guideline-based quality indicator in the beginning of the quality indicator process as well as patient participation ○ if GRADE is used in the guideline quality indicator can be linked to prioritised patient relevant outcomes ○ instruct patients participating in the quality indicator process and methodology as part of the panel. ▪ Quality indicator selection criteria ○ use explicit evidence-based guidelines for quality indicator development with transparent evidence base for each recommendation ○ assess the need of a quality indicator through the assessment of regional and or national quality gaps using healthcare data and expert consensus when data are not available ○ pilot the quality indicator with users ○ align the new quality indicator with an existing quality indicator and consider resource use and expense for clinicians when assessing feasibility. ▪ Intended use and implementation ○ ensure guideline-based quality indicators are available to decision makers in charge of quality indicators ○ pilot to ensure quality indicator is suitable for the intended use for implementation of quality indicator. ▪ See Appendix C Table C17.
Piggott (2021)[42]	To identify key issues and provide solutions on the integration of guidelines and quality assurance.	The authors identified seven key themes as key considerations for integrating guideline and quality assurance schemes: ▪ evidence-based integrated guideline and quality assurance framework ▪ transparency in clearly documenting the source and rationale for quality indicators ▪ declaring interests and managing conflicts for participants in an integrated guideline and quality assurance scheme ▪ refining selection processes and criteria for quality indicators ▪ retirement of quality indicator if it no longer addresses a quality gap ▪ risk mitigation of an integrated guideline and quality assurance group ▪ extension of the GIN-McMaster Guideline Development Checklist to incorporate quality assurance considerations.

Author	Objective	Summary of additional core component
		See Appendix C Table C18
Piggott (2023)[43]	To develop an extension of the GIN-McMaster Guideline Development Checklist and Tool for the integration of quality assurance and improvement (QAI) schemes with guideline development	The authors stated that credible quality indicators should have the following characteristics: ▪ Certainty in the evidence: High certainty in the quality indicator indicates that the supporting evidence is at low risk of bias, precise, relevant, consistent and without publication bias. ▪ Measuring change: The indicator should be sensitive to change. ▪ Feasibility: The indicator should be feasible to measure, implement and monitor. The GIN Mc-Master Checklist extension for quality assurance and quality improvement comprised 40 items across 19 domains; of which 18 domains are from the GIN-McMaster Guideline Development Checklist and one additional domain is specific to quality assurance indicator. ▪ See Appendix C Table C19.
Richter (2016)[41]	To analyse the potential of the integration and utilisation of quality indicators in clinical pathways.	Use of quality indicators in clinical pathways ensure easier monitoring and assessment of care provision and progress of a patient as well. The study suggested the following framework for source, integration and utilisation of quality indicators in clinical pathway. ▪ Quality indicator source and or quality scheme o Define and select quality indicators for healthcare institution based on their intended use. o If the source of quality indicators include new or revised indicators, the implementation scheme should be adapted accordingly. The quality indicator scheme then needs to be integrated into the clinical pathway of a healthcare institution. ▪ Management and operation level o Document, monitor, control and evaluate the use of quality indicators. o Conduct continuous monitoring and formative evaluation. Develop internal and external quality reports, budget planning, benchmarking, healthcare network (that is, coordinated care across healthcare disciplines and institutions) quality assessment, feedback to GDG and evidence for research. ▪ See Appendix C Table C20.

Key: EtD – evidence to decision; GDG – guideline development group; GIN – Guidelines International Network; GRADE – Grading Recommendations Assessment and Development Evidence; PICO – Population/patients, Intervention, Comparison, Outcome; NHMRC – National Health and Medical Research Council; PRISMA – Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROGRESS-Plus – PROGRESS (Place of residence, Race/ethnicity/culture/language, Occupation, Gender/sex, Religion, Education, Socioeconomic status or Social capital) Plus (personal characteristics associated with discrimination, features of relationships, time-dependent relationships); WHO – World Health Organization.

3.4 Research Question 2: Quality assurance or appraisal criteria to examine methodological robustness of clinical practice guidance development

3.4.1 Quality assurance or appraisal criteria identified (methodological handbooks)

Quality assurance or appraisal criteria to examine the methodology for development of clinical practice guidance development were identified in two handbooks (EHIF and the WHO).[17, 26] Further details are described in Table 9 and the full data extraction tables are available in Appendix B.

The WHO handbook recommended using the PANELVIEW tool when following the GRADE-ADOLOPMENT approach to guideline development. This tool is designed to assess guideline processes, methods, and outcomes from the perspective of the participating guideline panellists and group members, to support the quality assurance process. The PANELVIEW tool was evaluated and is described in more detail in section 3.4.2.

The EHIF handbook stated the importance of compliance with the reporting checklist of the Essential Reporting Items for Practice Guidelines in Healthcare (RIGHT) statement or the RIGHT AD@PT reporting checklist (in instances where guideline recommendations have been adapted) as part of their criteria used during the quality assurance process.[17, 52, 54] Importantly, the RIGHT checklist tools are intended to complement existing quality assessment tools, such as the AGREE ll. Similarly, the WHO handbook recommended compliance with the RIGHT-AD@PT reporting checklist in addition to adhering to the 15 steps outlined in the handbook as part of the overall quality assurance process.[26]

Table 9 Quality assurance or appraisal tool and or criteria identified in organisational handbooks

Quality measures and or criteria	Additional information	Handbook(s) that featured quality measures and or criteria
PANELVIEW[50]	▪ The PANELVIEW tool is used to evaluate the processes, methods, and outcomes from the development of a guideline from the perspective of those who involved in its development.	WHO
RIGHT[52]	▪ RIGHT checklist is used to assess the reporting quality of clinical practice guideline and can be used by guideline development groups to ensure essential items are reported in the proposed guideline. ▪ It includes 22 items that cover essential items covers all stages of guideline development. ▪ It is not intended to assess the quality of the guideline (such as the AGREE II reporting checklist)	EHIF
RIGHT-AD@PT[54]	▪ RIGHT-Ad@pt is an extension of the RIGHT checklist for the reporting of adapted guidelines that include recommendations that have been adopted, adapted, or developed de novo.	EHIF and WHO

Key: AGREE – Appraisal of Guidelines Research and Evaluation; EHIF – Estonian Health Insurance Fund; EtD – evidence to decision; GRADE - Grading of Recommendations Assessment, Development and Evaluation; RIGHT – Reporting Items for practice Guidelines in Healthcare; WHO – World Health Organization.

3.4.2 Quality assurance or appraisal criteria identified (peer-reviewed articles)

Ten tools (that is, a quality assurance or appraisal tool and or criteria) developed to examine the aspects relating to the methodological robustness of clinical practice guidance development were identified in ten peer-reviewed articles.[2, 3, 47-54]

Two tools were designed for quality assurance of CPG development process. The National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards (NEATS),[2] assesses the rigor of development and transparency of reporting. It is intended to accompany CPGs listed on National Guideline Clearing House to help inform a website user's judgement about a guideline's suitability for use. The PANELVIEW tool[50] assesses the quality of the processes used to develop a CPG as perceived by those involved in its development.

Three tools were designed to appraise the quality of the CPG, check the suitability of the document and appraise the quality of recommendations provided in CPG.[47-49] The Guideline Trustworthiness, Relevance- and Utility Scoring Tool (G-TRUST) is intended for use by clinicians to identify suitable and trustworthy guidelines to follow.[47] The International Guideline Evaluation Screening Tool (I-GEST) was designed as a screening tool for guideline developers to rapidly assess the suitability of a CPG for adaption to a local context.[49] Additionally, the Appraisal of Guidelines Research and Evaluation Recommendations Excellence (AGREE-REX) is designed to be used by guideline developers, clinicians and policy makers to evaluate the quality of CPG recommendations.[48]

Five tools were designed to be used as reporting statements or reference tools to guide the development and reporting of the guideline.[3, 51-54] These included the Appraisal of Guidelines Research and Evaluation (AGREE) Reporting Checklist,[51] RIGHT statement,[52] RIGHT-Ad@pt checklist,[54] RIGHT for INT[53] and GIN-McMaster Guideline Development Checklist extension for rapid guideline recommendation development.[3] These reporting checklists and reference tools can also be included as a supplementary file to the final guideline.

Five of the ten tools identified (IGEST, RIGHT statement, RIGHT-Ad@pt checklist, RIGHT for INT and GIN-McMaster Guideline Development checklist extension for rapid guideline recommendation development) did not include an evaluation of the tool within the article.[3, 49, 52-54] These non-evaluated tools were assessed as grade 2, the less commonly recommended practices according to the retrieved literature.[7] The full data extraction tables for these are detailed in Appendix C Tables C21 to C25.

Of the ten tools identified, five (G-TRUST, NEATS, PANELVIEW, AGREE Reporting Checklist and AGREE-REX)[2, 47, 48, 50, 51] included an evaluation of the tool within the article. These evaluated tools were grade 1,[7] the most commonly recommended practices according to the retrieved literature. Each of these tools are described below and in Table 10. The full data extraction tables can be found in Appendix C Tables C26 to C30.

Quality assurance tools that have been evaluated

The NEATS tool[2] assesses the extent to which guidelines adhere to the standards developed by the Institute of Medicine (now the National Academy of Medicine). The tool comprises 15 items. These items cover eight domains:

- disclosure of the funding source
- disclosure and management of financial conflicts of interest
- GDG composition
- use of a systematic review of evidence
- evidence foundations for rating the strength of recommendations
- specific and unambiguous articulation of recommendations
- external review
- updating.

The NEATS tool[2] was evaluated for external validity and inter-rater reliability and field tested among 10 external stakeholders. The NEATS tool was reported to have good external validity and inter-rater reliability. The NEATS tool provides consolidated information on transparency, completeness of documentation, and rigour of development, which helps a user judge whether a guideline is suitable for use. The tool was created for use by the National Guideline Clearinghouse staff and was not designed or tested for wider application. As such, it may have limited generalisability outside the National Guideline Clearinghouse. See Table 10 and Appendix C Tables C27.

The PANELVIEW tool,[50] also referred to in section 3.4.1, was designed to assess guideline processes, methods and outcomes from the perspective of the participating GDGs. It comprises 15 domains and 34 items which are scored using a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The domains of the tool cover the following aspects of guideline development:

- administration (organisational support for guideline project, meetings and meeting agenda, time for task completion)
- training
- panel chair (ability of the panel chair to provide clinical and methodological guidance and skills to manage group process)

- conflict of interest (appropriate management of conflict of interest and potential bias in panel members' interpretation of evidence)
- scoping of the guideline
- methodology and process
- considering the evidence and contributing through expertise
- formulating the recommendations
- group composition
- group roles
- group interaction
- implementation and dissemination plan
- writing guideline
- incentive
- overall satisfaction.

The PANELVIEW tool[50] was initially pilot tested with one GDG and, following minor revisions, it was tested with eight GDGs that consisted of 94 members in total. There was high internal consistency in the rating of satisfaction and appropriateness of the process across the eight groups, with Cronbach's α coefficient[77] (that is, a measure of internal consistency, or reliability, of a set of survey items) ranging from 0.85 to 0.98.[50]

The PANELVIEW tool[50] focuses on the transparency of the guideline-development process, allowing organisations responsible for guideline development to refine their quality-improvement efforts. See Table 10 and Appendix C Table C28.

Tools to support quality appraisal that have been evaluated

The G-TRUST [47] was developed for clinicians to identify useful guidelines. It comprises an 8-item checklist categorised into three categories, *relevance threats*, *evidence threats* and *interpretation threats*. Items on the checklist are scored on a 3-point scale ranging from 'useful' to 'may not be useful' to 'not useful'. Items relating to *relevance threats* assess the relevance of recommendations on improving patient oriented outcomes and the clarity and actionability of the recommendations. It also weighs the relevance of the patient population and condition to the clinical setting. Items relating to *evidence threats* assess whether the guideline is based on a systematic review of the research data and the recommendations

based on graded evidence. These items also assess the composition of the GDG to check if methodologists (such as, a statistician or epidemiologist) were part of the process. Items relating to *interpretation threats* assess the disclosure of financial conflicts of interest, funding sources and the inclusion of all relevant stakeholders such as patients, payer organisations, and public health entities. One of the strengths of the tool is that different items have different weights of importance. Items are categorised as major and minor and an overall score for the guideline quality is calculated. The authors of G-TRUST evaluated the ability of the tool to identify low quality guidelines. Using AGREE II scores as reference, G-TRUST was able to identify 92% of low-quality guidelines. Using G-TRUST, many guidelines rated as high quality based on AGREE II were disqualified because G-TRUST had a more strict definition of trustworthiness. See Table 10 and Appendix C Table C26.

The AGREE-REX tool[48] was designed to evaluate the quality of clinical practice guideline recommendations. It was developed to complement the AGREE II tool.[78] It comprises 9 items clustered under three domains:

- Domain 1. Clinical applicability
    - evidence
    - applicability to target users
    - applicability to patients and or populations.
- Domain 2. Values and preferences
    - values and preferences of target users
    - values and preferences of patients and or populations
    - values and preferences of policy and or decision-makers
    - values and preferences of guideline developers.
- Domain 3. Implementability
    - purpose
    - local application and adoption.

The tool uses a 7-point scale (from 1-strong disagreement to 7-strong agreement) and asks appraisers to consider whether the criteria were addressed in the clinical practice guideline and if they influenced the recommendations.[48] The AGREE-REX tool[48] was developed by a multidisciplinary international research team and engaged 322 international representative participants involved in the development of clinical practice guidelines. While the

measurement properties and usability surveys were performed with the penultimate draft version of this tool, the authors stated that decisions for modifications made were informed by evidence.[48] See Table 10 and Appendix C Table C30.

Reporting statements or reference tools

The AGREE Reporting Checklist,[51] was designed to improve the quality of reporting practice guidelines. The structure and content of the checklist aligns with AGREE II, which is a widely used standard for assessing the methodological quality of practice guidelines.[78] The checklist comprises six domains and 23 items which align with specific reporting criteria. The domains and items are:

- Domain 1: Scope and purpose
    - objectives
    - questions
    - population.
- Domain 2: Stakeholder involvement
    - group membership
    - target population preferences and views
    - target users.
- Domain 3: Rigour of development
    - search methods
    - evidence selection criteria
    - strengths and limitations of the evidence
    - formulation of recommendations
    - consideration of benefits and harms
    - link between recommendations and evidence
    - external review
    - updating procedure.
- Domain 4: Clarity of presentation

  - specific and unambiguous recommendations
  - management options
  - identifiable key recommendations.

- Domain 5: Applicability
  - facilitators and barriers to application
  - implementation advice and or tools
  - resource implications
  - monitoring and or auditing criteria.

- Domain 6: Editorial independence
  - funding body
  - competing interests.

The AGREE reporting checklist[51] was developed based on a comprehensive literature review and consensus among practice guideline stakeholders. The checklist comprises domains and items along with check boxes that users can check off. The checklist could be used both prospectively and retrospectively in guideline development process. Prospectively, the checklist can be used during drafting and editing in the final stage to ensure inclusion of all relevant information. The checklist can also be used retrospectively after the guideline is completed as a quality assurance step. See Table 10 and Appendix C Table C29.

Table 10 Quality assurance or appraisal criteria identified in peer-reviewed articles

Tool	Objective of the tool	Domains addressed by the tool	Strengths and limitations as reported by the authors	Description of the evaluation conducted within the article
Quality assurance tools				
NEATS[2]	To assess the extent to which guidelines adhered to the standards developed by the Institute of Medicine (now the National Academy of Medicine).	Eight domains covered: ▪ disclosure of the funding source ▪ disclosure and management of financial conflicts of interest ▪ GDG composition ▪ use of a systematic review of evidence ▪ evidence foundations for rating the strength of recommendations ▪ specific and unambiguous articulation of recommendations ▪ external review ▪ updating.	**Strengths** ▪ Good external validity and good inter-rater reliability across trained reviewers. ▪ Offers consolidated information on transparency, completeness of documentation, and rigor of development to inform a user's judgement about a guideline's suitability for use. ▪ Developed through a federally funded contract and hence is in the public domain. **Limitations** ▪ No summative evaluation of appraisal tool, that is, not evaluated for effectiveness against existing gold standard. ▪ In assessing the tool's external validity, authors were limited by time, budget, and the constraints of the Paperwork Reduction Act to surveying only nine persons who were not federal employees (one represented a federal clinical practice guideline developer) ▪ NEATS was created for use by the National Guideline Clearinghouse staff and was neither designed nor tested	The tool was field tested among 10 external stakeholders who were experts in guideline development. These experts reviewed a guideline using the NEATS tool and provided feedback on the tool. The majority of those surveyed (90%) agreed that that the output of the NEATS provided useful information to identify the extent to which a guideline adhered to Institute of Medicine standards. For 14 out of the 15 items, respondents showed agreement that the items should be included in the tool.

			for wider application, hence its generalisability outside NGC maybe limited.	
PANELVIEW tool[50]	To assess guideline processes, methods and outcomes from the perspective of the participating GDGs.	The domains of the tool cover the following aspects: ▪ administration (organisational support for guideline project, meetings and meeting agenda, time for task completion) ▪ training ▪ panel chair (ability of the panel chair to provide clinical and methodological guidance and skills to manage group process) ▪ conflict of interest (appropriate management of conflict of interest and potential bias in panel members' interpretation of evidence) ▪ scoping of the guideline ▪ methodology and process ▪ considering the evidence and contributing through expertise ▪ formulating the recommendations ▪ group composition ▪ group roles ▪ group interaction ▪ implementation and dissemination plan ▪ writing guideline ▪ incentive ▪ overall satisfaction.	**Strengths** ▪ Focused on the transparency of the guideline-development process and allows organisations responsible for guideline development to monitor their quality-improvement efforts. ▪ Followed best practice for tool development. ▪ Tested successfully with GDGs from international guideline organisations. **Limitations** ▪ No summative evaluation of the tool, that is, not evaluated for effectiveness against existing gold standard. ▪ During the tool development process, authors did not conduct systematic searches of the non-medical literature in the areas of business, education and policy-making to identify relevant items for the tool.	The tool was pilot tested with 1 GDG consisting of 12 members. After minor revisions, the tool was then tested by eight GDGs consisting of 94 members. The group members individually completed the PANELVIEW survey. The scoring was based on a 7-point Likert scale ranging from 1 (strongly disagree) to 7 (strongly agree). The group members also provided feedback on the tool. There was high internal consistency in the rating of satisfaction and appropriateness of the process across the eight groups, with Cronbach's α ranging from 0.85 to 0.98. On an individual respondent level, the tool distinguished between responses and that there was no end-of-scale aversion. The item-total correlation values by individual raters ranged from 0.40 to 0.80, indicating that the items measured different aspects of the guideline process.
Tools to support quality appraisal				
AGREE-REX[48]	To describe the development of AGREE-REX (Appraisal of Guidelines Research and	AGREE-REX comprised 9 items clustered into three domains: ▪ Domain 1. Clinical applicability ○ evidence	**Strengths** ▪ A usable, reliable, and valid tool to evaluate clinical	The draft version of AGREE-REX was tested among clinical practice guideline developers, researchers and or trainees using a cross-sectional survey design.

	Evaluation-Recommendations Excellence), a tool designed to evaluate the quality of clinical practice guideline recommendations.	○ applicability to target users ○ applicability to patients and or populations. ▪ Domain 2. Values and preferences ○ values and preferences of target users ○ values and preferences of patients and or populations ○ values and preferences of policy and or decision-makers ○ values and preferences of guideline developers. ▪ Domain 3. Implementability ○ purpose ○ local application and adoption.	practice guidelines recommendations. ▪ Use of methodological standards of measurement design in its development ▪ Use of multidisciplinary literature as a basis for the concepts underpinning AGREE-REX. ▪ Developed by a multidisciplinary international research team and engagement of 322 internationally representative participants involved in the development of clinical practice guidelines. **Limitations** ▪ No summative evaluation of the appraisal tool, that is, not evaluated for effectiveness against existing gold standard. ▪ The measurement properties and usability surveys were performed with the penultimate draft version of the tool and not the final version.	Participants read a clinical practice guideline and evaluated the recommendations using the draft AGREE-REX and completed the AGREE-REX usability survey. The participants were asked to rate the items, the instructions, the response scale, their ability to apply the tool and its usefulness using a 7-point scale. The results of the survey indicated high internal consistency (Cronbach α=0.94) The correlation between the overall AGREE-REX score and implementability score was 0.81 while the correlation between the overall AGREE-REX score and clinical credibility score was 0.76.
G-TRUST[47]	To develop the Guideline Trustworthiness, Relevance and Utility Scoring Tool (G-TRUST) for clinicians to identify useful clinical practice guidelines	The checklist comprises three domains: ▪ relevance threats ▪ evidence threats ▪ Interpretation threats.	**Strengths** ▪ More stringent than AGREE II in handling conflicts of interest and in the requirement for broad representation of the GDG. It also states that an independent research analyst	Two authors assessed the quality of 26 low-quality and 9 high-quality guidelines with G-TRUST to determine concurrent validity and to develop a scoring system. These guidelines were previously assessed by others using AGREE tool. Items evaluating clinical relevance of the recommendations

			or methodologist should be part of the process. ▪ Individual items on the checklist are weighted according to importance (that is, major and minor) and overall quality of the guideline is then determined (useful, may not be useful, not useful). **Limitations** ▪ No summative evaluation, that is, not evaluated for effectiveness against existing gold standard. ▪ Uses a conservative cut-off score, which may result in some guidelines being rated as "may not be useful" that would otherwise be rated as high quality using AGREE.	were excluded from G-TRUST as they were not included in AGREE or AGREE II. For each item, the assessors marked whether the criterion was met, not met or could not be determined. The authors evaluated G-TRUST against AGREE scores as reference standard when appraising guidelines and found that G-TRUST was able to identify almost all (92%) low-quality guidelines. Using G-TRUST, many guidelines rated as high quality based on AGREE II were disqualified because G-TRUST had a more strict definition of trustworthiness.
Reporting statements or reference tools				

AGREE Reporting Checklist[51]	To describe the development of the AGREE Reporting Checklist	The AGREE Reporting Checklist comprises the six quality domains and 23 key items listed below.
		▪ Domain 1: Scope and purpose
		  ○ objectives
		  ○ questions
		  ○ population.
		▪ Domain 2: Stakeholder involvement
		  ○ group membership
		  ○ target population preferences and views
		  ○ target users.
		▪ Domain 3: Rigour of development
		  ○ search methods
		  ○ evidence selection criteria
			Strengths
			▪ The structure and design of the checklist aligns with AGREE II.
			▪ The checklist can be used prospectively in the drafting and editing stage and also retrospectively as a quality assurance step.
			
			Limitations
			N/R
				A total of 15 people with experience in guideline development evaluated the AGREE Reporting Checklist. On a five point scale (score of 1 indicating low level of agreement and score of 5 indicating higher level of agreement), the participants agreed that the structure of the checklist was logical (mean=4.6), the layout ensured easy application (mean=4.3) and included the most important information in reporting of practice guidelines (mean=4.6).
				
				Out of 15 participants, 13 reported that

		○ strengths and limitations of the evidence ○ formulation of recommendations ○ consideration of benefits and harms ○ link between recommendations and evidence ○ external review ○ updating procedure. ▪ Domain 4: Clarity of presentation ○ specific and unambiguous recommendations ○ management options ○ identifiable key recommendations. ▪ Domain 5: Applicability ○ facilitators and barriers to application ○ implementation advice and or tools ○ resource implications ○ monitoring and or auditing criteria. ▪ Domain 6: Editorial independence ○ funding body ○ competing interests.		they would use the AGREE Reporting Checklist, 14 agreed that the appropriate level of detail had been included in the items and 13 reported that it would be useful to both new and experienced guideline developers. Most of the respondents also reported that the checklist would act as a reminder in terms of what details to include in their documents.

Key: AGREE- Appraisal of Guidelines Research and Evaluation; AGREE-REX- Appraisal of Guidelines Research and Evaluation–Recommendations Excellence; GDG – guideline development group; G-TRUST- Guideline Trustworthiness, Relevance, and Utility Scoring Tool; NEATS- National Guideline Clearinghouse Extent of Adherence to Trustworthy Standards; N/R – not reported.

3.4.3 Quality appraisal of peer-reviewed articles that described quality measures and or criteria (only evaluated studies)

The Quality Assessment with Diverse Studies (QuADS) tool was used to assess the quality of peer-reviewed articles that described quality measures and or criteria to examine methodological robustness of CPG development.[12] The QuADS tool allows for the quality appraisal of studies that employ or combine a range of methods. It has substantial inter-rater reliability and content and face validity. The QuADS tool comprises 13 quality criteria, these assess different dimensions of methodological and evidence quality. Each criterion is scored from 0 to 3, with overall scores of 0 to 39. A score of 0 indicates no information provided, a score of 1 indicates very limited information or brief details provided, a score of 2 indicates a basic or moderate level of information provided, and a score of 3 indicates detailed information provided. Higher scores indicate better methodological quality.

Only the five articles that included an evaluation in the peer-reviewed article were quality appraised using the QuADS tool.[2, 47, 48, 50, 51] See Table 11.

Taking each quality criterion in turn, all of the five articles[2, 47, 48, 50, 51] scored 2 for theoretical or conceptual underpinning. All articles[2, 47, 48, 50, 51] provided detailed information on the research aims, description of research setting and target population, rationale for choice of data collection tools and appropriateness of the method of analysis. One[51] of the five articles scored 2 for the description of research setting and target population as it did not provide specific details; the remaining four studies[2, 47, 48, 50] scored 3 for this criterion. Four articles[2, 48, 50, 51] scored 3 for appropriateness of the study design and one study[47] scored 2 as the article could have used alternative designs such as a systematic review in addition to the Delphi process.[47]

For appropriateness of sampling, two articles scored 3[47, 48] and one study[2] scored 2 as it did not provide details on the characteristics of the sample. Two articles[50, 51] scored 1 as the sample characteristics were not described with reference to the research aims and objectives. Four articles[47, 48, 50, 51] scored 3 for appropriateness of the data collection tool, and one article[2] scored 2 as the article only provided sparse information on the Delphi process. In terms of the description of the data collection procedure, two articles [47, 50] scored 3 as details on each stage of data collection process were mentioned distinctly and three articles[2, 48, 51] scored 2 as they provided limited details on some stages of the data collection process. One article[47] provided detailed information on recruitment and scored 3, another article[48] provided moderate details about recruitment and scored 2. Three articles[2, 50, 51] provided minimal information on recruitment and scored 1.

Two articles[48, 51] scored 3 on the justification for analytic method selected as detailed justifications were provided, and three articles[2, 47, 50] scored 2. In terms of consideration of

research stakeholders in research design, two articles[47, 50] scored 3 and three articles[2, 48, 51] scored 2 as they did not provide details on the involvement of public stakeholders. Four of the articles explicitly stated the strengths and limitations and were scored 3;[2, 47, 48, 50] one article provided limited information on the limitations and was scored 1.[51]

Overall, the article by Shaughnessy et al.,[47] which described the development of G-TRUST tool, achieved the highest score of 3 across ten criteria and a moderate score of 2 across two criteria. The article describing the AGREE Reporting Checklist[78] achieved the highest score of 3 across six criteria, a moderate score of 2 across four criteria and a score of 1 across three criteria.[51]

Table 11 Quality appraisal of peer-reviewed articles relating to quality measures and or criteria to examine methodological robustness of clinical practice guidance (for studies that included an evaluation)

QuADS Criteria	Shaughnessy (2017)[47] (G-TRUST)	Wiercicoh (2020)[50] (PANELVIEW)	Jue (2019)[2] (NEATS)	Brouwers (2016)[51] (AGREE)	Brouwers (2020)[48] (AGREE-REX)
Theoretical or conceptual underpinning	2	2	2	2	2
Research/aims	3	3	3	3	3
Description of research setting and target population	3	3	3	2	3
Appropriateness of the study design	2	3	3	3	3
Appropriateness of sampling	3	1	2	1	3
Rationale for choice of data collection tool/s	3	3	3	3	3
Appropriateness of the data collection tool	3	3	2	3	3
Description of data collection procedure	3	3	2	2	2
Recruitment data provided	3	1	1	1	2
Justification for analytic method selected	2	2	2	3	3
Appropriateness of the method of analysis	3	3	3	3	3
Consideration of research stakeholders in research design	3	3	2	2	2
Strengths and limitations	3	3	3	1	3
Overall quality score	**36**	**33**	**31**	**29**	**35**

Key: QuADS – Quality Assessment with Diverse Studies.
Scoring: 0 – no information provided; 1 – very limited information or brief details provided; 2 – basic or moderate level of information provided; 3 – indicates detailed information provided.

3.5 Research Question 3: Key innovations in the development and implementation of clinical practice guidance

3.5.1 Key innovations identified (methodological handbooks)

Key innovations were defined as practices, ideas or tools that would assist in the guidance development process that are currently not included in the NCEC CPG Standards.

Four unique key innovations since 2015 were identified in eight handbooks[17, 20-26] by seven organisations (ACP, EHIF, KCE, NHMRC, NICE, SIGN and WHO/Europe). The key innovations related to GRADE-ADOLOPMENT,[26] living guidance innovations,[21-23, 25] rapid guidance innovations[20, 24] and technological innovations.[17] Each key innovation is described in turn below; a summary is provided in Table 12 and the full data extractions are available in Appendix B.

GRADE-ADOLOPMENT

The European regional office of the WHO recently published a handbook on contextualisation.[26] The handbook describes a 15-step approach to adopt or adapt existing recommendations, or develop de novo recommendations, based on the GRADE-ADOLOPMENT approach. This approach was designed to facilitate transparent, inclusive and systematic guideline development that accounted for local contextual considerations and maximised trust and implementation.[72]

Living guidance

Living guidelines were discussed in four handbooks (ACP, NHMRC, NICE, SIGN).[21-23, 25] However, only those handbooks by SIGN and NICE provided methodological guidance for the development of living guidelines.[23, 25] NICE is currently pilot testing a living guidelines approach on a select number of topics.[25] SIGN has completed one living guideline on the management of asthma.[79] The ACP and NHMRC handbooks stated that methodological guidance on living guidelines is currently in development.[21, 22] Notably, where guidance was available, the process for updating a living guideline was largely the same as that for non-living guidelines. The main difference related to the surveillance of new evidence at regular intervals in order to continually update living recommendations.[23, 25] NICE has stated that it is piloting the use of a surveillance decision framework, followed by a multi-criteria decision framework, to assess if an update is needed, with the aim of updating recommendations on key topics within three to six months of new, practice-changing evidence emerging (see Appendix B Table B8 for more details on these frameworks). Likewise for SIGN, living guidelines are developed on a rolling programme of regular updates, normally annual or biennial, or more frequent depending on the rate of new evidence emerging.

Rapid guidance

Rapid guidelines is an approach outlined by SIGN in a standalone methodological guidance handbook.[24] This approach could be used in the context of public health emergencies and or other situations where there is an urgent need for guidance. Criteria for deciding whether this approach is warranted include the existence of an emergent and dangerous situation or the identification of new evidence that would result in a change in recommendations.

The handbook by KCE included detailed methodology for conducting rapid reviews to facilitate evidenced-based decision-making in a short time frame.[20] Such as, in emergency situations or when new, urgent evidence was identified that would result in a change in a recommendation. The handbook listed the dimensions of a standard systematic review that may be altered in a rapid review. This includes limiting the scope, the number of databases searched, the study types included, single screening of studies and single data extraction. The methods adopted during a rapid review vary based on the project. Notably, in a rapid review, the dimensions relating to evidence synthesis (such as risk of bias assessments, GRADE assessments and conducting quantitative or qualitative analysis, where applicable) should continue to be undertaken as per standard systematic review methods.

Technological innovations

Since 2020, EHIF conducted the entire guideline development process online using the GRADEpro Guideline Development Tool.[17] This tool facilitated the development of summary of findings tables, GRADE tables and the Evidence to Decision (EtD) framework, allowing users to work collaboratively online when developing recommendations. The software permits online editing, commenting and voting. Additional software used by EHIF to facilitate collaborative guideline development includes the use of Doodle for scheduling meetings, Skype for attending meetings, PanelVoice for input and voting on recommendations, and OneDrive for file sharing between collaborators.

Table 12 Key innovations since 2015 identified in organisational handbooks

Organisation	Innovation	Additional information
GRADE-ADOLOPMENT		
WHO (European region)[26]	GRADE-ADOLOPMENT	▪ The GRADE-ADOLOPMENT approach to guideline production uses the adoption, adaptation, and/or de novo development of context-relevant recommendations with GRADE methodology. The approach is designed to promote the use of existing high-quality guidelines and their recommendations in the development of new guidelines, while also ensuring that the guidelines are relevant and appropriate for the local context. The process is reported to ensure transparency and trust. ▪ For guidelines to be implemented, they must be relevant and responsive to the needs, values and preferences of the target populations and or individuals affected by the recommendations and their individual risks for the outcomes of interest. In addition, guidelines also need to be suitable for the available resources and organisational contexts. Contextualisation is a process by which efficient implementation can be achieved on different levels when using existing guidelines developed by other organisations.
Living guidance		
ACP (US)[22]	Living systematic reviews and clinical guidelines (methodological guidance currently in development)	▪ Since the last update to the ACP handbook, a living guideline by ACP was published in February 2023 on non-pharmacologic and pharmacologic interventions as initial and second-line treatments during the acute phase of a major depressive disorder episode. ▪ The ACP plan to maintain this topic as a living guideline given that the topic is a priority for clinical care and there is active and ongoing research in this field: o Literature surveillance is conducted on a quarterly basis. o Systematic reviews and clinical recommendations will be updated based on evidence identified through the literature search, when deemed necessary. ▪ The ACP may choose to retire this topic from living status if it is no longer deemed a priority for decision-making, if there is confidence that conclusions are unlikely to change with new evidence, or if it is improbable that new evidence will emerge.
NHMRC (Australia)[21]	Living evidence and guidelines (methodological guidance currently in development)	No further information currently available.
NICE (UK)[25]	Living guideline recommendations (currently being tested on a select number of topics)	▪ During COVID-19, NICE created a suite of living guidelines. According to the NICE 2021 to 2026 strategy, the aim is to recreate this 'living guideline' approach across the topic portfolio. ▪ NICE plans to update some recommendations as soon as new evidence becomes available to provide useable content to users. ▪ Interim principles for methods and processes that are used to develop NICE's living guideline recommendations have been published. This is a living document that is reviewed on a quarterly basis. ▪ After review, these interim principles will be updated and, following the usual consultation process for

Organisation	Innovation	Additional information
		manual updates, they will become part of the main methods and processes in *Developing NICE guidelines: the manual*.
SIGN (Scotland)[23]	Living guidelines	▪ Living guidelines are developed on a rolling programme of regular updates and the process for updating a living guideline is largely the same as that for non-living guidelines. They seek to update and build on the evidence base used in the original guideline and subsequent updates. ▪ The frequency of updating will depend on the rate at which new evidence is emerging, but will normally be annual or biennial. ▪ To date, SIGN has developed one living guideline, the British guideline on the management of asthma in collaboration with the British Thoracic Society.
Rapid guidance		
KCE (Belgium)[20]	Rapid reviews	▪ Implemented to support urgent and emergent decisions related to procurement, clinical practice, and policy. Dimensions of standard systematic review that may be altered in a rapid review as per the KCE handbook: ▪ Scope o Limit the type of questions (for example, efficacy only, new technology only, single technology only): Yes o Limit number of questions: Yes o Limit the number of studies that can be included: Yes ▪ Comprehensiveness o Limit the search strategy (for example, number of databases, grey literature, date, setting, language): Yes o Limit the study types included (for example, existing systematic reviews only, RCTs only): Yes o Limit the textual analysis (for example, no full-text review, limit the number of extracted items): Limit number of extracted items ▪ Rigour/quality control o Eliminate dual study selection: Yes o Eliminate dual data extraction: Yes o Limit or eliminate internal or external review of final product (for example, peer review): Limit to internal review ▪ Synthesis o Limit or eliminate the risk of bias/quality assessment of individual studies: No o Limit or eliminate either quantitative or qualitative analysis: No o Limit or eliminate strength/quality of evidence assessments (for example, the GRADE approach): No ▪ Conclusions

Organisation	Innovation	Additional information
		○ Simplify or eliminate any conclusive statements about the direction of the evidence: No
SIGN (Scotland)[24]	Rapid guideline methodology	▪ SIGN states that rapid guidelines may be necessary to provide important evidence-based guidance in times of urgency and emergency. Criteria used when considering this approach are, does the topic relate to: ▪ emergent and dangerous situations (for example, an epidemic of an infectious disease) ▪ new, urgent and recommendation-changing evidence about: o patient safety o efficacy that could change current knowledge or practice o cost-effectiveness. ▪ People with lived experience are recruited according to the usual process. If the circumstances of rapid guideline development make this difficult SIGN approach patient organisations to provide representatives so that we get a wide range of views on the guideline topic. ▪ When developing a rapid guideline, it may not be possible to carry out a systematic review and in these circumstances a rapid review will be more appropriate.
Technological innovations		
EHIF (Estonia)[17]	Entire process conducted using GRADEpro Guideline Development Tool	▪ EHIF use an online authoring platform for developing and implementing guidelines called GRADEpro Guideline Development Tool. ▪ Additional software is used to facilitate online collaborative working. This includes Doodle (scheduling meetings), Skype (attending meetings), GRADEpro and PanelVoice (input and voting on recommendations), and OneDrive (file sharing).

Key: ACP - American College of Physicians; EHIF - Estonian Health Insurance Fund; EtD – evidence to decision; GDG – guideline development group; GRADE - Grading of Recommendations Assessment, Development and Evaluation; KCE - Belgian Health Care Knowledge Centre; NHMRC - National Health and Medical Research Council; NICE - National Institute for Health and Care Excellence; RCT – randomised controlled trial; RIGHT – Reporting Items for practice Guidelines in Healthcare; SIGN - Scottish Intercollegiate Guidelines Network; USPSTF - US Preventative Services Task Force; WHO – World Health Organization.

3.5.2 Key innovations identified (peer-reviewed articles)

A range of different innovations related to CPG were identified across 25 peer-reviewed articles,[4-6, 55-76] of which 19[4-7, 61-76] did not include a summative or formative evaluation. These studies[4-7, 61-76] were deemed to be Grade 2 level of evidence according to the NCEC grading criteria of the most commonly recommended practices according to the retrieved literature. Full data extraction tables for studies that did not include an evaluation are presented in Appendix C. These non-evaluated studies related to innovations in:

- evidence and or guidance translation
    - GRADE–ADOLOPMENT framework to inform context appropriate guideline recommendations[72] (see Appendix C Table C31)
    - adaptation of clinical guidelines[73] (see Appendix C Table C32).
- evidence synthesis
    - qualitative evidence synthesis in guideline development[69, 70] (see Appendix C Table C33 and C34)
    - qualitative evidence synthesis in guideline implementation[71] (see Appendix C Table C35)
    - use of colloquial evidence in guideline development[66] (see Appendix C Table C36)
    - use of realist review methodology to explore barriers and facilitators to guideline implementation[65] (see Appendix C Table C37).
- rapid guidance
    - criteria for the development of trustworthy recommendations during urgent responses[75] (see Appendix C Table C38)
    - rapid review methodology to inform guideline development[67, 76] (see Appendix C Table C39 and C40)
    - rapid response programmes[74] (see Appendix C Table C41).
- living guidance
    - living guidelines and recommendations[68] (see Appendix C Table C42).

- technological innovations
    - inclusion of automated decisional algorithms to aid decision-making in clinical pathways[61-63](see Appendix C Tables C43 to C45)
    - inclusion of automated decisional algorithms to aid decision-making in patients with more than one chronic condition[64] (see Appendix C Table C46)
    - online-platform for the development of standards and quality indicators[4] (see Appendix C Table C47)
    - online-platform for the integration of practical issues that are of importance to patients[5] (see Appendix C Table C48)
    - computer-interpretable guidelines for use as clinical decision aids[6] (see Appendix C Table C49).

Six[55-60] of the 25 studies included a summative or formative evaluation and as such were deemed to be grade 1 level of evidence according to the 2015 systematic review.[7] These studies related to technological innovations and innovations in evidence and or guidance translation. A summary of extracted data relating to the key innovations identified in these studies is presented in Table 13; full data extraction tables are presented in Appendix C Tables C50 to C55. These studies are described in more detail below.

Evidence and or guidance translation

Fearns et al.[60] described the user-testing of a patient version of a SIGN clinical guideline for people with a diagnosis of glaucoma or non-professional carers of a person with glaucoma. Patient versions of clinical guidelines helped patients to understand what to expect when receiving an intervention in terms of standards of care and helped them to participate more actively in the decision-making process. The authors concluded that patient versions of guidelines should be uncluttered, colourful (that is, include colour associations that patients are familiar with, for example, green for go and red for stop, when describing recommendations), have simple language of an appropriate font size, simple diagrams, as well as icons and or headings to indicate clear recommendations. The patient version should also be kept simple while providing sufficient information to maintain the creditability of the guideline and facilitate shared decision-making and the empowerment of patients. See Appendix C Table C50.

Technological innovation

Abidi et al.[59] described the innovative integration of multiple clinical practice guidelines within a clinical decision support system. The clinical practice guideline integration

framework, COMET (Comorbidity Ontological Modeling and ExecuTion), comprised a knowledge management approach to model, computerise and integrate multiple clinical practice guidelines to develop evidence-based recommendations for the treatment of patients with co-morbidities. Multiple clinical practice guidelines corresponding to co-morbid diseases were inputted into the framework. The co-morbid clinical pathway recommended clinical actions that were compliant with conditions of co-morbid patients while avoiding adverse interactions that might arise when prescribing for a patient according to multiple single-condition clinical practice guidelines. The authors also recommended considering safe methods for integrating multiple disease-specific clinical practice guidelines and balancing risks and benefits of a care plan for patients with co-morbidities. See Appendix C Table C51.

Bui et al.[56] described an automated approach to retrieving relevant and high-quality citations from PubMed through innovative query expansion and citation ranking approaches. The aim was to improve the traditional searching methods used in systematic reviews and guideline development. The results showed that the innovative query expansion outperformed the default PubMed query expansion in terms of recall (80.2% versus 51.5%, mean difference 28.7%) and seeding recall (90% versus 63.5%, mean difference 26.5%), with a loss in precision (0.6% versus 0.4%, p=0.09) that was not statistically significant. Similarly, the innovative citation ranking approach outperformed the PubMed 'most recent' ranking, PubMed 'most relevant' ranking and a generic machine learning classifier (for identification of high quality studies from Medline) in terms of precision (7.0% versus 0.5%, 0.9% and 2.1%, respectively). See Appendix C Table C52.

Martínez García et al.[57] evaluated two restrictive search strategies to identify signals for updating recommendations and compared them to an exhaustive search strategy using a random sample of recommendations from a cohort of clinical guidelines from a Spanish national guideline development programme. The first restrictive search strategy used PubMed Clinical Queries filters in the MEDLINE database. This approach provided a feasible and efficient method for guideline developers to identify new studies that were likely to trigger a recommendation update. The second restrictive search strategy was to only search using the PLUS database. This approach was suboptimal and needed topic-specific tailoring due to the limited number of journals contained within that database. See Appendix C Table C54.

Corey et al.[58] described the development of a standardised electronic template for clinical practice guidance documents, such as policies, procedures, guidelines and directives documents (PPGDs) within the Critical Care Practice Manual of a US-based level one trauma academic medical centre. The template comprised the following sections: standardised purpose statement, table of contents, policy statements, clinical indications and contraindications, equipment, room entry procedure, procedure title, patient monitoring and care with rationale and considerations, nursing documentation, considerations and additional education, appendix, document history, key words and references. Ninety-five percent of the

PPGDs were converted to the new electronic format and subsequently evaluated for usability through a survey of critical care nurse specialists. The survey found that all respondents (n=106) accessed the PPGDs at least once a month. Only 24% of the respondents reported that PPGDs were difficult to find. Additionally, results indicated that the respondents agreed or strongly agreed that the PPGDs provided guidance (85%), reflected current practice (76%), were clear and concise (75%), and were evidence-based (73%). The authors noted the challenges involved in engaging with electronic guidance formats for individuals who may be unfamiliar with technology. See Appendix C Table C53.

Yamada et al.[55] investigated the use of a machine learning system, Concept Encoder, to reduce workload and accelerate the systematic review process. Concept Encoder is an artificial intelligence engine used to screen studies returned by a systematic review search, that is to semi-automatically exclude irrelevant studies. In this study, described as a validation study, Concept Encoder was used to screen the primary search results returned by the published search strategy of five recent clinical guidelines, published in the US. Concept Encoder achieved a ten-fold reduction in the screening workload. The authors concluded that Concept Encoder could facilitate the acquisition of evidence for clinical guidelines. See Appendix C Table C55.

Table 13 Key innovations in peer-reviewed articles since 2015 in the development and implementation of clinical practice guidance that have been evaluated

Author	Objective and innovation	Evaluation and results of evaluation	Authors' conclusions
Evidence and or guidance translation			
Fearns (2016)[60]	**Objective** To user-test a patient version of a SIGN clinical guideline that was designed based on preliminary work for the DECIDE project. **Innovation** Patient version of guidelines.	**Evaluation** The patient versions of guidelines were user-tested and themes relating to usefulness, usability, credibility, guideline aesthetics, accessibility and findability documented. **Results of evaluation** Thirteen user testing sessions were completed. Key facilitators of desirability and usability identified included clear branding of the patient version as well as a clearly described purpose, audience and contents page. Other useful facilitators included use of a 'friendly' tone achieved through use of colour, quotes, icons, simple language, charts and brief chunked text (that is, splitting information into small pieces or "chunks" to make reading and understanding faster and easier). Patients were often disappointed at the lack of information on treatments in the patient versions.	Guideline producers need to strike a balance between keeping the patient version simple and providing sufficient information to facilitate shared decision-making and empower the public.
Technological innovation			
Abidi (2017)[59]	**Objective** To describe the integration of multiple disease-specific clinical practice guidelines in order to manage co-morbidities within a computerised CDSS. **Innovation** The COMET framework, integrates multiple disease-specific clinical practice guidelines in order to manage co-morbidities within a computerised CDSS.	**Evaluation** A usability framework was used to guide evaluation. The formative evaluation question was to ascertain if the COMET computerised CDSS met the functional goals and usability needs of general practitioners managing patients who have comorbid chronic heart failure and atrial fibrillation. Both qualitative and quantitative evaluations were conducted. **Results of evaluation** The results found that General Practitioners were usually receptive to the use of the COMET tool in	While integrating multiple disease clinical practice guidelines within a computerised CDSS, it is important to consider how to safely integrate multiple disease-specific clinical practice guidelines and balance the risks and benefits of a care plan when considering patients living with multiple conditions or comorbidities.

Author	Objective and innovation	Evaluation and results of evaluation	Authors' conclusions
		clinical practice. However, the qualitative analysis identified specific usability issues related to the need to enter demographic information manually and the insufficient breadth of dropdown options available on the patient history and examination screen.	
Bui (2015)[56]	**Objective** To improve the traditional literature search which, despite modern technology, article screening is often conducted manually. **Innovation** An automated approach to citation retrieval was developed which utilised query expansion and citation ranking methods.	**Evaluation** The automated approach to citation retrieval was compared with baseline PubMed expansion. **Results of evaluation** The query expansion algorithm's recall was 80.2%. In comparison with a recall of 51.5% for the PubMed expansion approach. There was a minor drop off in the query expansion algorithm's accuracy in comparison to the PubMed expansion approach (0.4% versus 0.6%), though this was not statistically significant. The algorithm was able to find all citations used to support a larger number of guideline recommendations than the baseline PubMed expansion approach (64.5% versus 37.2%, $p < 0.001$). In terms of citation ranking, the innovative approach recall was 66.2% compared with the performance of PubMed's 'sort by Relevance' (51.4%), 'sort by Most Recent' (45.1%) and a generic machine-learning classifier (62%). The difference was significant to $p < 0.001$ across all comparisons.	The automated citation retrieval methods showed improved recall over standard PubMed query expansion and rankings, and a general-purpose machine learning classifier. The proposed approach could be used to aid the systematic search and screening process in the development of systematic reviews and clinical guidelines.
Corey (2018)[58]	**Objective** To update the Critical Care Practice Manual of a level one trauma and academic medical centre in the US and to ensure alignment of clinical practice with the best available evidence. The aim was to design a new template for PPGD	**Evaluation** On-going feedback was provided during the development process. Furthermore, the efficacy of changes made in the process and formatting of PPGDs was evaluated through a survey of nurse clinicians.	The proposed online template restored and enhanced the standardisation of PPGDs. However, frustrations arose for users who were not comfortable with IT.

Author	Objective and innovation	Evaluation and results of evaluation	Authors' conclusions
	using available technology to optimise the presentation and usability of these documents. **Innovation** Standardised electronic template for clinical practice guidance including standard practice elements (quality indicators).	**Results of evaluation** On the basis of the survey results, nurses at the medical centre accessed a PPGD at least once a month. The overall results indicated that the majority of respondents agreed or strongly agreed that the PPGDs provided guidance, reflected current practice, were clear and concise, and were evidence-based. Under a quarter of those surveyed experienced challenges locating PPGDs.	
Martínez García (2015)[57]	**Objective** To evaluate the efficiency and feasibility of two new approaches to identify the need to update clinical guidelines recommendations: the development of search strategies using PubMed Clinical Queries for MEDLINE and the use of the PLUS (McMaster Premium Literature Service) database. **Innovation** Pragmatic search strategies to update clinical guideline recommendations.	**Evaluation** The pragmatic restrictive search strategies were evaluated against standard exhaustive database searches. **Results of evaluation** The restrictive search approach retrieved 68.1% less references than the exhaustive search approach (12,486 versus 39,136). However, the restrictive search approach identified 89.9% (62/69) of the key references and 88.0% (22/25) of the recommendation updates. The use of PLUS (McMaster Premium Literature Service) retrieved 88.5% fewer references than the exhaustive approach (4,486 versus 39,136) and identified fewer key references 26.1% (18/69) and fewer recommendation updates 40.0% (10/25).	The proposed method of developing restrictive search strategies provided a feasible and efficient method for guideline developers to identify significant new studies that are likely to trigger a recommendation update. There is also a need for additional methodological research in this field.
Yamada (2020)[55]	**Objective** To investigate whether a machine learning system could improve efficiency when conducting systematic reviews. **Innovation** Machine learning for use as part of article screening in systematic reviews.	**Evaluation** The machine learning performance was compared with manual practice. **Results of evaluation** Eight reviews were included. The use of a machine learning system reduced literature screening six-fold in comparison to manual	The machine learning system achieved a ten-fold reduction of the screening workload for conducting a systematic review after learning from two randomly selected studies on the topic of interest. The machine learning system could facilitate the acquisition

Author	Objective and innovation	Evaluation and results of evaluation	Authors' conclusions
		screening. If the machine learning system was initially given two correct articles, then a ten-fold reduction in workload was observed in comparison to manual screening.	of evidence for clinical guidelines.

Key: CDSS- Clinical Decision Support System; COMET – Comorbidity Ontological Modelling and ExecuTion DECIDE - Developing and Evaluating Communication Strategies to support Informed Decision and practice based on Evidence; IT – information technology; PPGD – protocols, policies, guidelines and directives; SIGN – Scottish Intercollegiate Guideline Network.

4 Discussion

4.1 Summary of findings

We identified 12 methodological handbooks that had been published or updated since the last review was conducted.[15-26] These were from 11 organisations that provided data on the core components of CPG, as predefined by the NCEC Standards in Clinical Practice Guidance, additional core components of CPG, quality assurance or appraisal criteria to assess the methodological robustness of CPG, and key innovations in the development of CPG.[15-26] Additionally, 55 peer-reviewed articles where eligible for inclusion, of which 20 detailed additional core components of CPG,[27-46] ten described the development of quality measures and or criteria to assess the methodological robustness of CPG[2, 3, 47-54] and 25 described key innovations in CPG.[4-6, 55-76]

4.1.1 Core components of clinical practice guidance

Of the handbooks included, all provided some information on at least one subcategory of the nine core components as described in the NCEC Standards for Clinical Practice Guidance. The most comprehensive information was obtained from four handbooks (EHIF,[17] the NHMRC,[21] NICE[25] and SIGN),[23] with these handbooks addressing 36 of the 37 core components and subcomponents defined in the NCEC CPG Standards.

4.1.2 Additional core components of clinical practice guidance

Three organisational handbooks (NHMRC,[21] NICE[25] and the USPSTF)[16] and six peer-reviewed articles[29-34] consistently identified health equity as an additional core component of CPG. Consideration of health equity is inherent to many existing EtD frameworks used to formulate recommendations,[80] (for example, the GRADE EtD framework).[81] However, explicit consideration of health equity throughout all phases of guidance[29-32] and rapid guidance development[34] is now encouraged, especially in relation to populations such as older adults, patients with multiple chronic conditions, and marginalised groups.[21, 25, 33]

One handbook, the USPSTF,[16] and two peer-reviewed articles[35, 36] addressed gender equity. Both studies[35, 36] reported an underrepresentation of women across most roles in guideline development groups, while the USPSTF[16] focused on gender equity in guideline end users, highlighting its intention to develop inclusive approaches for addressing sex and gender in recommendation development.

While additional core components relating to clarity of presentation,[37-40] health outcome descriptors[27, 28] and quality indicators[41-46] were identified in the peer-reviewed articles, these components were not identified in the organisational handbooks. Although, it is

possible that these components may yet be incorporated into handbooks as core components for CPG development.

4.1.3 Quality assurance or appraisal criteria to examine methodological robustness of clinical practice guidance development

Three tools to examine methodological robustness of CPG development were identified in two handbooks (EHIF[17] and the WHO[26]) for use as part of a quality assurance process. The PANELVIEW tool,[50] designed to assess the quality of the guideline development processes from the perspective of the GDG members, was identified in both the WHO[26] handbook and a peer-reviewed article which also described an evaluation of the tool.[50] The RIGHT statement[52] and the RIGHT Ad@pt checklist[54] were described in the EHIF[17] and the WHO[26] handbooks. Similar to the PANELVIEW tool, the RIGHT statement and the RIGHT Ad@pt checklist were recommended for use in supplementing the quality assurance process. However, it is important to note that the latter two are not intended to assess the quality of the guideline but are rather reporting checklists to be used in conjunction with quality appraisal tool such as the AGREE ll tool.[78] The PANELVIEW tool, RIGHT statement and the RIGHT Ad@pt checklist were also identified in three peer-reviewed articles.[50, 82] However, only the PANELVIEW tool was evaluated, with the article demonstrating a high internal consistency in the rating of satisfaction and appropriateness of the process by a range of users.[50]

Four other tools were identified from peer-reviewed articles that included an evaluation within the article, namely, G-TRUST,[47] NEATS,[2] AGREE Reporting Checklist[51] and AGREE-REX.[48] Other non-evaluated tools identified in the peer-reviewed articles included IGEST,[49] RIGHT for INT[53] and the GIN-McMaster Guideline Development Checklist extension for rapid guideline recommendation development.[3]

4.1.4 Key innovations in clinical practice guidance

Four unique innovations were identified across eight handbooks[17, 20-26] published by seven organisations (ACP, EHIF, KCE, NHMRC, NICE, SIGN and WHO/Europe) since 2015. One innovation related to contextualisation of guidance, one related to living guidance, one related to rapid guidance and one related to a technological innovation (namely, the GRADEpro Guideline Development Tool). Two key innovations identified in the handbooks (that is, contextualisation of guidance through the GRADE–ADOLOPMENT framework[72] and rapid and or living guidance innovations)[67, 68, 74-76] were also identified across the peer-reviewed articles. These innovations were implemented largely due to the urgency connected with the COVID-19 pandemic. However, these innovations had not been evaluated within the articles.

Six key innovations were identified within 25 peer-reviewed articles; these key innovations were also evaluated within the article. Key innovations related to evidence and or guidance translation (such as, patient versions of clinical practice guidance),[60] and technological innovations. Technological innovations included the integration of multiple clinical practice guidelines within a clinical decision support system,[59] an automated approach to citation retrieval,[56] the development of an electronic template for clinical practice guidance documents,[58] the development of pragmatic search strategies to update clinical guidance recommendations[57] and machine learning approaches for article screening in systematic reviews.[55]

Other examples of non-evaluated key innovations across the remaining 13 peer-reviewed articles included the adaptation of guidelines,[73] use of technology such as online platforms,[4-6] and decision trees[61-64] to facilitate decision making, consideration of qualitative evidence synthesis,[69-71] colloquial evidence[66] and realist reviews[65] in guideline development.

4.2 Findings in the context of previous research

The development of CPG comprises multiple non-linear stages. These stages were identified in the previous systematic review[7] conducted to support the 2015 Standards for CPGs, and outlined in the NCEC CPG Standards.[1] The 12 organisational handbooks[15-26] published since 2015, included processes that were largely representative of those included in the NCEC CPG Standards.[1]

Since the NCEC CPG Standards were published in 2015, there have been developments relating to the explicit consideration of health equity across the guidance development process evidenced by both organisational handbooks[16, 21, 25] and peer-reviewed articles.[29-34] CPG has the potential to either reduce or unintentionally worsen existing health inequities among disadvantaged groups, such as poorer health outcomes or higher disease burden depending on their ability to consider evidence for clinical effectiveness alongside evidence related to guidance implementation, acceptability, feasibility and capacity to lessen health inequalities.[83] However, consideration of health equity throughout the CPG development process remains challenging as there is, as yet, no widely accepted standard for reporting quality relating to health equity, nor do available quality appraisal tools and reporting checklists currently include health equity as a consideration for guidance development.[83]

The PROGRESS-Plus framework[84] has been recommended by NICE[25] and the GRADE Working Group[31] for consideration of equity at the planning stage of CPG development. Specifically, the PROGRESS-Plus framework provides health equity criteria for use when developing data extraction tables[25] and synthesising available evidence.[31] These health equity criteria are age, sex, sexual orientation, disability, ethnicity, religion, place of residence, occupation, education, socioeconomic position and social capital. A recent scoping review[83] of health equity considerations suggested a number of recommendations for incorporation

of health equity best practice across the four phases of guideline development (that is, guideline planning, evidence review, guideline development and guideline dissemination). The review authors also included a topic relating to the assessment of equity within guidelines, where they suggested the use of the International Clinical Epidemiology Network (INCLEN) equity lens.[85] INCLEN equity lens comprises five criteria to determine how well guidelines address equity. However, due to the complexities inherent in health equity, balancing the advantages and disadvantages of different strategies to promote the consideration of health equity remains a challenge for organisations that produce CPG.[86]

Similar to the NCEC CPG Standards, six[17, 20, 22, 23, 25, 26] of the included organisational handbooks referenced adherence to the internationally accepted quality criteria outlined in the AGREE II quality appraisal tool.[78] While the AGREE II tool was not discussed in this scoping review as it was developed before 2015, the tool remains international best practice for appraisal of the methodological robustness of CPG. Developments in quality assurance or appraisal criteria for CPG since 2015 include the AGREE Reporting checklist,[51] which is recommended to be used in conjunction with the AGREE II tool. This approach has been used for the development of guidance related to spinal cord injury management.[87] However some GDGs have used the AGREE Reporting checklist in isolation.[88] Similarly, the AGREE-REX tool[48] was developed as an accompaniment to the AGREE II tool, and used by a number of GDGs to assess the quality of clinical practice guideline recommendations and methodology, respectively.[89-91]

While not explicitly a quality appraisal tool, the RIGHT statement[52] was described in the EHIF[17] and the WHO[26] handbooks and used during quality assurance. The EHIF handbook used the RIGHT statement to supplement the AGREE II tool.[78] The checklist contains 22 items considered essential for good reporting of clinical practice guidelines. Although we did not identify an evaluation of the RIGHT statement[52] during this scoping review, this checklist has been successfully used as an accompaniment to the GIN-McMaster Guideline Development Checklist in the development of international guidelines.[92]

Further developments related to rapid evidence syntheses and rapid guidelines are increasingly being used to communicate guidance in response to public health emergencies[93, 94] and new evidence that would lead to a change in a recommendation.[3, 20] These processes were outlined in the handbooks by KCE[20] and SIGN.[24] Rapid evidence syntheses and rapid guidelines involve limiting or removing some of the steps involved in standard systematic reviews[20] and guideline development,[3] respectively. In a qualitative study by Clyne et al.,[94] rapid evidence syntheses were found to be invaluable in informing national policy and patient care in response to the COVID-19 pandemic.

Living guidelines are also novel and unique in that individual recommendations are continually updated (using rigorous methods, such as GRADE) as new evidence emerges, without the need for the entire guideline to be updated.[95] In this scoping review, four eligible

handbooks (ACP,[22] NHMRC,[21] NICE,[25] and SIGN[23]) described their approach to living guidelines. However, as living guideline methodology is still emerging, only the handbooks by SIGN and NICE provided methodological guidance for the development of living guidelines;[23, 25] methodological guidance on living guidelines from the ACP and NHMRC is currently in development.[21, 22] SIGN has completed one living guideline on the management of asthma,[79] and a living guideline approach is currently being piloted by NICE on a select number of topics.[25] The main difference between standard guidelines and living guidelines relates to the surveillance of new evidence.[23, 25] In order to continually update living recommendations based on the best available evidence, living guideline developers must conduct surveillance of new evidence at regular intervals.[23, 25, 95] However, the resources required for continual surveillance of new evidence has resulted in the discontinuation of some living guidelines.[96, 97]

The European regional office of the WHO recently published a handbook on contextualisation of recommendations, through use of the GRADE-ADOLOPMENT approach.[26] GRADE ADOLOPMENT involves a series of steps for adoption or adaptation of an existing guideline and or de novo development, thus capitalising on the benefits of pre-existing, high-quality clinical practice guidelines while ensuring recommendations are appropriate to the local context. Similarly, the RIGHT Ad@pt checklist[54] was described in the EHIF[17] and the WHO[26] handbooks and can used to inform the reporting of adapted guidelines, including the rigour of the adaptation process and adapted recommendations. Although we did not identify an evaluation of the GRADE-ADOLOPMENT approach[26] or the RIGHT Ad@pt checklist[54] during this scoping review, GRADE-ADOLOPMENT has been reportedly used for developing various clinical guidelines implemented in a range of national health systems and is said to be a feasible approach in the consideration of local contexts.[98] These include Australia,[99] the Asia-Pacific region,[100] Mexico,[101] the Eastern Mediterranean region,[102] Pakistan,[103] Saudi Arabia,[72] Tunisia[104] and the UK.[105] The RIGHT Ad@pt checklist[54] has been found to be a feasible tool for use in adapting existing guidelines across a number of countries, including India and Egypt.[106, 107]

Although the GRADEpro Guideline Development Tool (GDT)[108] has been available to healthcare decision makers and GDGs since 2013, only one handbook (produced by the EHIF[17]) reported that the GRADEpro GDT has been used for all guideline development processes since 2020. The GRADEpro GDT provides an integrated web-based platform to, facilitate the decision-making process, develop recommendations (including question formulation), generate and prioritise outcomes, facilitate teamwork, manage potential conflicts of interest, and present results through summary of findings tables.

Technical innovations to support CPG development such as machine learning algorithms and restrictive search strategies to support systematic reviewing were identified in the peer-reviewed articles during this scoping review. With the broader adoption of artificial

intelligence, innovations such as these are becoming more prevalent and will serve to increase the efficiency of systematic review screening.[109]

4.3 Strengths and limitations of this review

This scoping review adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) criteria.[9] The protocol was published in July 2023 on the HIQA website.[110] We conducted an exhaustive search that included three electronic databases (Medline, CINAHL and the Cochrane Library), three grey literature databases (Research Rabbit, PubMed's 'similar articles' feature and Lights), and 29 organisational websites. However, there are some limitations. It is possible that we did not identify all relevant handbooks because some are not publicly available. Moreover, due to resource constraints, we restricted inclusion to English language only and did not search for, or include, disease-specific handbooks. It is possible that we did not identify all potentially eligible peer-reviewed articles and handbooks from the database search and organisations' websites. While the identification of changes in governance procedures for tracking when guidance is due for updating was of particular interest to the NCEC, we were unable to identify data relating to innovations in governance procedures for CPG development.

4.4 Implications for practice based on review findings

As demonstrated by this review, the NCEC Standards for Clinical Practice Guidance are comprehensive and are largely representative of the guideline development standards currently in practice internationally. However, since 2015 one additional core component has entered guideline development practice as described in both the handbooks and peer-reviewed articles. This component relates to extending considerations for health equity to all phases of guidance development. Currently, the NCEC CPG Standards requires the consideration of health equity during recommendation formulation only.

When updating the NCEC Standards for Clinical Practice Guidance, the following areas for consideration were noted:

- Use of the PANELVIEW tool[50] to assess the CPG development process in addition to assessing the quality of the CPG methodology.
- Use of complementary tools such as the AGREE-REX[48] and AGREE Reporting checklist[51] to assess specific components of CPG.
- Development of patient versions of guidelines to assist patients in understanding and adhering to guideline recommendations.[60]
- A number of innovations identified in the peer-reviewed articles have not been evaluated and their effectiveness is unclear at the present time.

4.5 Knowledge gaps in the research

We were unable to identify peer-reviewed evaluation studies pertaining to the RIGHT statement, RIGHT Ad@pt checklist or GRADE ADOLOPMENT, which may reflect that they have been developed relatively recently.[52, 54, 98] Future research should attempt to evaluate these measures.

Currently, evaluations of most of the key innovations identified in this review are limited. Future research is needed to evaluate the effectiveness of these innovations, such as innovations in technology, evidence and or guidance translation, rapid evidence syntheses and rapid and or living reviews in order to support their inclusion in updated standards for CPG development and implementation.

4.6 Conclusions

This review identified that the NCEC Standards for Clinical Practice Guidance remain relevant and applicable when compared with the guidance development processes identified internationally since 2015. However, some innovations were identified in this scoping review. In particular, an additional core component of equity in CPG development was identified in three methodological handbooks from NHMRC, NICE and USPSTF, not currently included in the NCEC Standards for Clinical Practice Guidance.[1] Also, three tools were identified that are used as part of the quality assurance process (that is, the RIGHT statement, The RIGHT AD@PT reporting checklist and the PANELVIEW tool), in handbooks from the WHO and EHIF. Four unique key innovations were identified across seven handbooks. These included GRADE-ADOLOPMENT, living guidance innovations, rapid guidance innovations and a technological innovation related to use of the GRADEpro Guideline Development Tool. Fifty-five peer-reviewed articles were identified that detailed additional core components of CPG, quality assurance or appraisal criteria to assess the methodological robustness of CPG and key innovations in CPG. However, the evaluation for quality assurance or appraisal criteria and key innovations are limited, indicating a need for further research around usability and effectiveness.

The NCEC Standards for Clinical Practice Guidance provides standards for healthcare staff developing evidence-based CPG for healthcare settings. This helps to ensure that there is a consistency of approach, reduction in duplication and optimisation of health service resources and expertise. The findings of this review will inform updates to the current NCEC Standards for Clinical Practice Guidance to ensure they reflect innovations and current best practice.

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99. Okely AD, Ghersi D, Loughran SP, Cliff DP, Shilton T, Jones RA, et al. A collaborative approach to adopting/adapting guidelines. The Australian 24-hour movement guidelines for children (5-12 years) and young people (13-17 years): An integration of physical activity, sedentary behaviour, and sleep. International Journal of Behavioral Nutrition and Physical Activity. 2022;19(1):2. 10.1186/s12966-021-01236-2.
100. Loo BKG, Okely AD, Pulungan A, Jalaludin MY. Asia-Pacific Consensus Statement on integrated 24-hour activity guidelines for children and adolescents. British Journal of Sports Medicine. 2022;56(10):539-45. 10.1136/bjsports-2021-104527.
101. Coronado-Zarco R, Olascoaga-Gómez de León A, Faba-Beaumont MG. Adaptation of clinical practice guidelines for osteoporosis in a Mexican context. Experience using

methodologies ADAPTE, GRADE-ADOLOPMENT, and RAND/UCLA. Journal of Clinical Epidemiology. 2021;131:30-42. https://doi.org/10.1016/j.jclinepi.2020.10.022.

102. Darzi A, Harfouche M, Arayssi T, Alemadi S, Alnaqbi KA, Badsha H, et al. Adaptation of the 2015 American College of Rheumatology treatment guideline for rheumatoid arthritis for the Eastern Mediterranean Region: an exemplar of the GRADE Adolopment. Health and Quality of Life Outcomes. 2017;15(1):183. 10.1186/s12955-017-0754-1.
103. Martins RS, Masood MQ, Mahmud O, Rizvi NA, Sheikh A, Islam N, et al. Adolopment of adult diabetes mellitus management guidelines for a Pakistani context: Methodology and challenges. Frontiers in Endocrinology. 2023;13. 10.3389/fendo.2022.1081361.
104. Kahale LA, Ouertatani H, Brahem AB, Grati H, Hamouda MB, Saz-Parkinson Z, et al. Contextual differences considered in the Tunisian ADOLOPMENT of the European guidelines on breast cancer screening. Health Research Policy and Systems. 2021;19(1):80. 10.1186/s12961-021-00731-z.
105. Reilly JJ, Hughes AR, Janssen X, Hesketh KR, Livingstone S, Hill C, et al. GRADE-ADOLOPMENT Process to Develop 24-Hour Movement Behavior Recommendations and Physical Activity Guidelines for the Under 5s in the United Kingdom, 2019. Journal of Physical Activity and Health. 2020;17(1):101-8. 10.1123/jpah.2019-0139.
106. Sengar M, Pramesh CS, Mehndiratta A, Shah S, Munshi A, Vijaykumar DK, et al. Ensuring quality in contextualised cancer management guidelines for resource-constraint settings: using a systematic approach. BMJ Global Health. 2022;7(8):e009584. 10.1136/bmjgh-2022-009584.
107. Moustafa B, El-Kersh MM, Shalaby S, Salam NA, Moselhy S, Soliman GT, et al. Egyptian evidence -based pediatric clinical practice adapted guidelines for management of [1] steroid sensitive nephrotic syndrome (EPG/SSNS 2022). Egyptian Pediatric Association Gazette. 2023;71(1):13. 10.1186/s43054-022-00119-w.
108. Brozek J, Akl E, Falck-Ytter Y, Kunstman P, Meerpohl J, Mustafa R, et al. P307 Guideline Development Tool (GDT) – Web-Based Solution For Guideline Developers And Authors Of Systematic Reviews. BMJ Quality & Safety. 2013;22(Suppl 1):82-. 10.1136/bmjqs-2013-002293.248.
109. van de Schoot R, de Bruin J, Schram R, Zahedi P, de Boer J, Weijdema F, et al. An open source machine learning framework for efficient and transparent systematic reviews. Nature Machine Intelligence. 2021;3(2):125-33. 10.1038/s42256-020-00287-7.
110. Health Information and Quality Authority (HIQA). Advances in the development of clinical practice guidance: A scoping review protocol: 2023 [updated 05 Jul 2023; cited 14 Aug 2023]. Available from: https://www.hiqa.ie/reports-and-publications/hrb-cicer-national-clinical-guideline-support/updating-standards-clinical.

Appendix A

Table A1: List of organisations searched

Organisation name	Organisation URL
Agency for Healthcare Research and Quality (AHRQ), USA	https://www.ahrq.gov/
Appraisal of Guidelines for Research and Evaluation (AGREE) Advancing the science of practice guidelines	https://www.agreetrust.org/resource-centre/
Association of the Scientific Medical Societies (AWMF), Germany	https://www.verwaltung.awmf.org/en/awmf.html
Australian National Health and Medical Research Council (NHMRC), Australia	https://www.nhmrc.gov.au/
Belgian Health Care Knowledge Centre (KCE), Belgium	https://kce.fgov.be/en/
Canadian Agency for Drugs and Technologies in Health (CADTH), Canada	https://www.cadth.ca/
Clinical Guidelines Committee of the American College of Physicians (ACP), USA	https://www.acponline.org/
Estonian Health Insurance Fund, Estonia	https://www.tervisekassa.ee/en
European Network for Health Technology Assessment (EUnetHTA)	https://www.eunethta.eu/
Finnish Institute for Health and Welfare (THL), Finland	https://thl.fi/fi/
Guidelines International Network (GIN)	https://g-i-n.net/
Health Council of the Netherlands, The Netherlands	https://www.healthcouncil.nl/
Institute for Clinical Systems Improvement	https://www.icsi.org/
National Academy of Medicine, USA	https://nam.edu/about-the-nam/
McMaster GRADE centre, Canada	https://cebgrade.mcmaster.ca/
Monash University Centre for Clinical Effectiveness	https://monashhealth.org/health-professionals/cce/
National Institute for Health and Care Excellence (NICE), UK	https://www.nice.org.uk/
Ravijuhend, Estonia	https://www.ravijuhend.ee/
Scottish Intercollegiate Guidelines Network (SIGN), Scotland	https://www.sign.ac.uk/
National Board of Health and Welfare, Sweden	https://www.socialstyrelsen.se/en/regulations-and-guidelines/national-guidelines/
Public Health Agency of Sweden (PHAS), Sweden	https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/
Swiss Centre for International Health, Switzerland	https://www.swisstph.ch/en/
The Best Practice Advocacy Centre New Zealand, (bpac^{nz}), New Zealand	https://bpac.org.nz/guidelines/
US Preventive Services Task Force (USPSTF), USA	https://uspreventiveservicestaskforce.org/uspstf/
World Health Organization (WHO)	https://www.who.int/

Table A2: Search strategy

Database: Medline (EBSCO) Run: 25/05/2023			
#	Query	Limiters/Expanders	Results
S1	(MH "Critical Pathways/ST")	Expanders - Apply equivalent subjects	946
S2	(MH "Clinical Protocols/ST")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	3,749
S3	(MH "Patient Care Bundles/ST")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	166
S4	(MH "Algorithms")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	301,398
S5	(MH "Checklist/ST")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	781
S6	(MH "Health Policy/ST") or (MH "Standard of Care+/ST")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	899
S7	AB ((standard* OR methodolog*) N3 (guideline* OR guidance CPGs OR pathway* OR policy OR policies OR bundl* OR algorithm* OR checklist* OR "standards of care")) OR TI ((standard* OR methodolog*) N3 (guideline* OR guidance OR CPGs OR pathway* OR policy OR policies OR bundl* OR algorithm* OR checklist* OR "standards of care"))	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	35,213
S8	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	339,570
S9	(MH "Guidelines as Topic+") OR (MH "Evidence-Based Medicine/ST/MT")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	179,802
S10	S8 AND S9	Limiters - Date of Publication: 20150101-; English Language Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	2,499
S11	(MH "Guidelines as Topic+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	172,701
S12	S7 OR S11	Expanders - Apply equivalent subjects	204,265

		Search modes - Boolean/Phrase	
S13	((((((((((JN "Implementation science: IS [Implement Sci] NLMUID: 101258411")) OR (JN "BMC medical research methodology [BMC Med Res Methodol] NLMUID: 100968545")) OR (JN "International journal of evidence-based healthcare [Int J Evid Based Healthc] NLMUID: 101247063")) OR (JN "PloS one [PLoS One] NLMUID: 101285081")) OR (JN "Journal of clinical epidemiology [J Clin Epidemiol] NLMUID: 8801383")) OR (JN "F1000Research [F1000Res] NLMUID: 101594320")) OR (JN "BMJ open [BMJ Open] NLMUID: 101552874")) OR (JN "BMJ: British medical journal / British Medical Association [BMJ] NLMUID: 8900488")) OR (JN "PLoS medicine [PLoS Med] NLMUID: 101231360")) OR (JN "Journal of evaluation in clinical practice [J Eval Clin Pract] NLMUID: 9609066") OR (JN "BMC health services research [BMC Health Serv Res] NLMUID: 101088677")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	437,356
S14	MH "Systematic Review" OR MH "Meta Analysis" OR PT "Meta-Analysis" OR PT "Systematic Review" OR TI systematic* N1 (review* OR overview*) OR AB systematic* N1 (review* OR overview*) OR TI "meta analys*" OR TI "meta analyz*" OR AB "meta analys*" OR AB "meta analyz* OR TI literature N2 (review* OR overview*) OR AB literature N2 (review* OR overview*)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	774,693
S15	S12 AND S13 AND S14	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	791
S16	S10 OR S15	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	3,251
S17	AB ((appraisal OR quality) N3 (guideline* OR guidance CPGs OR pathway* OR policy OR policies OR bundl* OR algorithm* OR checklist* OR "standards of care")) OR TI ((appraisal OR quality) N3 (guideline* OR guidance OR CPGs OR pathway* OR policy OR policies OR bundl* OR algorithm* OR checklist* OR "standards of care"))	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	20,763
S18	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S17	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	326,961
S19	(MH "Quality Indicators, Health Care")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	17,342

S20	(MH "Quality Assurance, Health Care+/ST")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	28,047
S21	AB "quality indicator*" OR TI "quality indicator*"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	10,244
S22	AB "quality criteri*" OR TI "quality criteri*"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	5,432
S23	TI "quality measure*" OR AB "quality measure*"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	9,567
S24	AB process N1 assessment OR TI process N1 assessment	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	5,469
S25	AB (quality N2 (assessment OR evaluation OR assurance OR appraisal)) OR TI (quality N2 (assessment OR evaluation OR assurance OR appraisal))	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	93,823
S26	TI "appraisal tool*" OR AB "appraisal tool*"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	3,125
S26	S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	159,417
S27	S9 AND S18 AND S26	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	2,026
S28	S11 OR S17	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	190,449
S29	S26 AND S28	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	21,218
S30	((((((((((JN "Implementation science: IS [Implement Sci] NLMUID: 101258411")) OR (JN "BMC medical research methodology [BMC Med Res Methodol] NLMUID: 100968545")) OR (JN "International journal of evidence-based healthcare [Int J Evid Based Healthc] NLMUID: 101247063")) OR (JN "PloS one [PLoS One] NLMUID: 101285081")) OR (JN "Journal of clinical epidemiology [J Clin Epidemiol] NLMUID: 8801383")) OR (JN "F1000Research [F1000Res] NLMUID: 101594320")) OR (JN "BMJ open [BMJ Open]	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	439,928

	NLMUID: 101552874")) OR (JN "BMJ: British medical journal / British Medical Association [BMJ] NLMUID: 8900488")) OR (JN "PLoS medicine [PLoS Med] NLMUID: 101231360")) OR (JN "Journal of evaluation in clinical practice [J Eval Clin Pract] NLMUID: 9609066") OR (JN "BMC health services research [BMC Health Serv Res] NLMUID: 101088677") OR (JN "International journal for quality in health care: journal of the International Society for Quality in Health Care / ISQua [Int J Qual Health Care] NLMUID: 9434628")		
S31	S29 AND S30	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	1,020
S32	S27 OR S31	Limiters - Date of Publication: 20150101-; Human Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	1,249
S33	S16 OR S32	Limiters - Date of Publication: 20150101-; English Language Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	3,811

Table A3: Studies excluded after full text review

Peer-reviewed article		Reason for exclusion
1	Afzal M, Hussain M, Ali T, Hussain J, Khan WA, Lee S, Kang BH. Knowledge-based query construction using the CDSS knowledge base for efficient evidence retrieval. Sensors. 2015 Aug 28;15(9):21294-314.	No description of innovation
2	Ako-Arrey DE, Brouwers MC, Lavis JN, Giacomini MK, Agree HS Team. Health system guidance appraisal—concept evaluation and usability testing. Implementation Science. 2015 Dec;11:1-3.	No description of quality measures
3	Ako-Arrey DE, Brouwers MC, Lavis JN, Giacomini MK, AGREE-HS Team. Health systems guidance appraisal—a critical interpretive synthesis. Implementation Science. 2015 Dec;11:1-20.	Not related to clinical guidance
4	Alla K, Oprescu F, Hall WD, Whiteford HA, Head BW, Meurk CS. Can automated content analysis be used to assess and improve the use of evidence in mental health policy? A systematic review. Systematic Reviews. 2018 Dec;7(1):1-6.	Disease-specific
5	Alper BS, Tristan M, Ramirez-Morera A, Vreugdenhil MM, Van Zuuren EJ, Fedorowicz Z. RAPADAPTE for rapid guideline development: high-quality clinical guidelines can be rapidly developed with limited resources. International Journal for Quality in Health Care. 2016 Jun 1;28(3):268-74.	Disease-specific
6	Alvarez E, Lavis JN, Brouwers M, Schwartz L. Developing a workbook to support the contextualisation of global health systems guidance: a case study identifying steps and critical factors for success in this process at WHO. Health research policy and systems. 2018 Dec;16:1-1.	No description of innovation
7	Amer YS, Elzalabany MM, Omar TI, Ibrahim AG, Dowidar NL. The 'Adapted ADAPTE': an approach to improve utilization of the ADAPTE guideline adaptation resource toolkit in the Alexandria Center for Evidence-Based Clinical Practice Guidelines. Journal of evaluation in clinical practice. 2015 Dec;21(6):1095-106.	Not applicable to Irish healthcare system
8	Becker M, Breuing J, Nothacker M, Deckert S, Steudtner M, Schmitt J, Neugebauer E, Pieper D. Guideline-based quality indicators—a systematic comparison of German and international clinical practice guidelines: protocol for a systematic review. Systematic reviews. 2018 Dec;7:1-5.	No description of innovation
9	Benmarhnia T, Huang JY, Jones CM. Lost in translation: Piloting a novel framework to assess the challenges in translating scientific uncertainty from empirical findings to WHO policy statements. International journal of health policy and management. 2017 Nov;6(11):649.	No description of additional core components
10	Benzon HT, Joshi GP, Gan TJ, Vetter TR. Development, reporting, and evaluation of clinical practice guidelines. Anesthesia & Analgesia. 2019 Dec 1;129(6):1771-7.	Preceded 2015
11	Bianco L, Raffa S, Fornelli P, Mancini R, Gabriele A, Medici F, Battista C, Greco S, Croce G, Germani A, Petrucci S. From Survey Results to a Decision-Making Matrix for Strategic Planning in Healthcare: The Case of Clinical Pathways. International Journal of Environmental Research and Public Health. 2022 Jun 25;19(13):7806.	No description of innovation
12	Bjurling-Sjöberg P, Wadensten B, Pöder U, Jansson I, Nordgren L. Struggling for a feasible tool–the process of implementing a clinical pathway in intensive care: a grounded theory study. BMC health services research. 2018 Dec;18(1):1-5.	No description of additional core components
13	Bravi F, Di Ruscio E, Frassoldati A, Cavallesco GN, Valpiani G, Ferrozzi A, Wienand U, Carradori T. Patient and health care professional perspectives: a case study of the lung cancer integrated care pathway. International Journal of Integrated Care. 2018 Oct;18(4).	Disease-specific
14	Brignardello-Petersen R, Carrasco-Labra A, Guyatt GH. How to interpret and use a clinical practice guideline or recommendation: users' guides to	No description of additional core

Peer-reviewed article		Reason for exclusion
	the medical literature. Jama. 2021 Oct 19;326(15):1516-23.	components
15	Brouwers MC, Ako-Arrey D, Spithoff K, Vukmirovic M, Florez ID, Lavis JN, Cluzeau F, Permanand G, Bosch-Capblanch X, Chen Y, AGREE-HS Research Team Andy Haines Carmen Mihaela Dolea Fadi El-Jardali Jillian Ross Luis Gabriel Cuervo Mike Wilson Mita Giacomini Pablo Perel Padraig Warde Pierre Ongolo-Zogo Sheila McNair Ulysses Panisset. Validity and usability testing of a health systems guidance appraisal tool, the AGREE-HS. Health research policy and systems. 2018 Dec;16:1-9.	Not related to clinical guidance
16	Brouwers MC, Lavis JN, Spithoff K, Vukmirovic M, Florez ID, Velez M, Kibria M, Sekercioglu N, Kamler E, Halladay J, Sandhu J. Assessment of health systems guidance using the Appraisal of Guidelines for Research and Evaluation–Health Systems (AGREE-HS) instrument. Health Policy. 2019 Jul 1;123(7):646-51.	Not related to clinical guidance
17	Browman GP, Somerfield MR, Lyman GH, Brouwers MC. When is good, good enough? Methodological pragmatism for sustainable guideline development. Implementation Science. 2015 Dec;10(1):1-5.	Commentary/editorial/letter
18	Buccheri RK, Sharifi C. Critical appraisal tools and reporting guidelines for evidence-based practice. Worldviews on Evidence-Based Nursing. 2017 Dec;14(6):463-72.	No description of quality measures
19	Bush SH, Marchington KL, Agar M, Davis DH, Sikora L, Tsang TW. Quality of clinical practice guidelines in delirium: a systematic appraisal. BMJ open. 2017 Mar 1;7(3):e013809.	Disease-specific
20	Butow P, Shaw J, Shepherd HL, Price M, Masya L, Kelly B, Rankin NM, Girgis A, Hack TF, Beale P, Viney R. Comparison of implementation strategies to influence adherence to the clinical pathway for screening, assessment and management of anxiety and depression in adult cancer patients (ADAPT CP): study protocol of a cluster randomised controlled trial. BMC cancer. 2018 Dec;18:1-2.	Disease-specific
21	Checkland K, Hammond JO, Allen P, Coleman A, Warwick-Giles L, Hall A, Mays N, Sutton M. Road to nowhere? A critical consideration of the use of the metaphor 'care pathway'in health services planning, organisation and delivery. Journal of Social Policy. 2020 Apr;49(2):405-24.	No description of additional core components
22	Comin E, Catalan-Ramos A, Iglesias-Rodal M, Grau M, Del Val JL, Consola A, Amado E, Pons A, Mata-Cases M, Franzi A, Ciurana R. Impact of implementing electronic clinical practice guidelines for the diagnosis, control and treatment of cardiovascular risk factors: A pre-post controlled study. Atencion primaria. 2017 Aug 1;49(7):389-98.	No description of innovation
23	Coombs MA, Davidson JE, Nunnally ME, Wickline MA, Curtis JR. Using qualitative research to inform development of professional guidelines: a case study of the society of critical care medicine family-centered care guidelines. Critical care medicine. 2017 Aug 1;45(8):1352-8.	No description of innovation
24	Cooper K, Kirkpatrick P, Florida-James S. Incorporating qualitative evidence in clinical practice guidelines: a Scottish perspective. JBI Evidence Implementation. 2019 Jun 1;17:S6-8.	No description of innovation
25	Coronado-Zarco R, de León AO, Faba-Beaumont MG. Adaptation of clinical practice guidelines for osteoporosis in a Mexican context. Experience using methodologies ADAPTE, GRADE-ADOLOPMENT, and RAND/UCLA. Journal of Clinical Epidemiology. 2021 Mar 1;131:30-42.	Disease-specific
26	Dannenberg MD, Durand MA, Montori VM, Reilly C, Elwyn G. Existing evidence summarization methods cannot guarantee trustworthy patient decision aids. Journal of Clinical Epidemiology. 2018 Oct 1;102:69-77.	No description of additional core components
27	Darzi A, Abou-Jaoude EA, Agarwal A, Lakis C, Wiercioch W, Santesso N, Brax H, El-Jardali F, Schünemann HJ, Akl EA. A methodological survey	No description of innovation

Peer-reviewed article		Reason for exclusion
	identified eight proposed frameworks for the adaptation of health related guidelines. Journal of clinical epidemiology. 2017 Jun 1;86:3-10.	
28	Darzi A, Harfouche M, Arayssi T, Alemadi S, Alnaqbi KA, Badsha H, Al Balushi F, Elzorkany B, Halabi H, Hamoudeh M, Hazer W. Adaptation of the 2015 American College of Rheumatology treatment guideline for rheumatoid arthritis for the Eastern Mediterranean Region: an exemplar of the GRADE Adolopment. Health and Quality of Life Outcomes. 2017 Dec;15:1-3.	Disease-specific
29	Dijkers MP, Ward I, Annaswamy T, Dedrick D, Feldpausch J, Moul A, Hoffecker L. Quality of rehabilitation clinical practice guidelines: an overview study of AGREE II appraisals. Archives of physical medicine and rehabilitation. 2020 Sep 1;101(9):1643-55.	Disease-specific
30	Dizon JM, Machingaidze S, Grimmer K. To adopt, to adapt, or to contextualise? The big question in clinical practice guideline development. BMC research notes. 2016 Dec;9(1):1-8.	Not applicable to Irish healthcare system
31	Djulbegovic B, Hozo I, Lizarraga D, Guyatt G. Decomposing clinical practice guidelines panels' deliberation into decision theoretical constructs. Journal of Evaluation in Clinical Practice. 2023 Apr;29(3):459-71.	Disease-specific
32	Dreesens D, Kremer L, van der Weijden T. The Dutch chaos case: a scoping review of knowledge and decision support tools available to clinicians in the Netherlands. Health Policy. 2019 Dec 1;123(12):1288-97.	No description of additional core components
33	El-Harakeh A, Lotfi T, Ahmad A, Morsi RZ, Fadlallah R, Bou-Karroum L, Akl EA. The implementation of prioritization exercises in the development and update of health practice guidelines: a scoping review. PLoS One. 2020 Mar 20;15(3):e0229249.	Captured in updating guidelines review
34	El-Harakeh A, Morsi RZ, Fadlallah R, Bou-Karroum L, Lotfi T, Akl EA. Prioritization approaches in the development of health practice guidelines: a systematic review. BMC health services research. 2019 Dec;19:1-0.	Captured in updating guidelines review
35	Elliott MJ, Gil S, Hemmelgarn BR, Manns BJ, Tonelli M, Jun M, Donald M. A scoping review of adult chronic kidney disease clinical pathways for primary care. Nephrology Dialysis Transplantation. 2017 May 1;32(5):838-46.	Disease-specific
36	Ernstzen DV, Louw QA, Hillier SL. Clinical practice guidelines for the management of chronic musculoskeletal pain in primary healthcare: a systematic review. Implementation Science. 2017 Dec;12(1):1-3.	Disease-specific
37	Fang Y, Yao L, Sun J, Zhang J, Li Y, Yang R, Yang K, Tian L. Appraisal of clinical practice guidelines on the management of hypothyroidism in pregnancy using the Appraisal of Guidelines for Research and Evaluation II instrument. Endocrine. 2018 Apr;60:4-14.	Disease-specific
38	Florez ID, Amer YS, McCaul M, Lavis JN, Brouwers M. Guidelines developed under pressure. The case of the COVID-19 low-quality “rapid” guidelines and potential solutions. Journal of Clinical Epidemiology. 2022 Feb 1;142:194-9.	Commentary/editorial/letter
39	Florez ID, Brouwers MC, Kerkvliet K, Spithoff K, Alonso-Coello P, Burgers J, Cluzeau F, Férvers B, Graham I, Grimshaw J, Hanna S. Assessment of the quality of recommendations from 161 clinical practice guidelines using the Appraisal of Guidelines for Research and Evaluation–Recommendations Excellence (AGREE-REX) instrument shows there is room for improvement. Implementation Science. 2020 Dec;15(1):1-8.	No description of quality measures
40	Franco JV, Arancibia M, Meza N, Madrid E, Kopitowski K. Clinical practice guidelines: concepts, limitations and challenges. Medwave. 2020 Apr 30;20(3).	Commentary/editorial/letter

Peer-reviewed article		Reason for exclusion
41	Freund M, Zucca A, Sanson-Fisher R, Milat A, Mackenzie L, Turon H. Barriers to the evaluation of evidence-based public health policy. Journal of Public Health Policy. 2019 Mar 6;40:114-25.	No description of quality measures
42	Gambito ED, Gonzalez-Suarez CB, Grimmer KA, Valdecañas CM, Dizon JM, Beredo ME, Zamora MT. Updating contextualized clinical practice guidelines on stroke rehabilitation and low back pain management using a novel assessment framework that standardizes decisions. BMC Research Notes. 2015 Dec;8(1):1-2.	Disease-specific
43	García LM, Pardo-Hernandez H, de Guzman EN, Superchi C, Ballesteros M, McFarlane E, Penman K, Posso M, i Figuls MR, Sanabria AJ, Selva A. Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol. BMJ open. 2017 Aug 1;7(8):e017226.	Captured in updating guidelines review
44	Grimmer K, Louw Q, Dizon JM, Brown SM, Ernstzen D, Wiysonge CS. A South African experience in applying the adopt–contextualise–adapt framework to stroke rehabilitation clinical practice guidelines. Health Research Policy and Systems. 2019 Dec;17(1):1-4.	Not applicable to Irish healthcare system
45	Grimmer K, Louw Q, Dizon JM, van Niekerk SM, Ernstzen D, Wiysonge C. Standardising evidence strength grading for recommendations from multiple clinical practice guidelines: a South African case study. Implementation Science. 2018 Dec;13(1):1-8.	Disease-specific
46	Grimmer K, Machingaidze S, Dizon J, Kredo T, Louw Q, Young T. South African clinical practice guidelines quality measured with complex and rapid appraisal instruments. BMC Research Notes. 2016 Dec;9(1):1-8.	Preceded 2015
47	Haby MM, Chapman E, Clark R, Barreto J, Reveiz L, Lavis JN. What are the best methodologies for rapid reviews of the research evidence for evidence-informed decision making in health policy and practice: a rapid review. Health research policy and systems. 2016 Dec;14(1):1-2.	Not related to clinical guidance
48	Haile ZT. Critical appraisal tools and reporting guidelines. Journal of Human Lactation. 2022 Feb;38(1):21-7.	No description of quality measures
49	Hoffman AS, Sepucha KR, Abhyankar P, Sheridan S, Bekker H, LeBlanc A, Levin C, Ropka M, Shaffer V, Stacey D, Stalmeier P. Explanation and elaboration of the Standards for UNiversal reporting of patient Decision Aid Evaluations (SUNDAE) guidelines: examples of reporting SUNDAE items from patient decision aid evaluation literature. BMJ quality & safety. 2018 May 1;27(5):389-412.	No description of additional core components
50	Hoffmann-Eßer W, Siering U, Neugebauer EA, Brockhaus AC, McGauran N, Eikermann M. Guideline appraisal with AGREE II: online survey of the potential influence of AGREE II items on overall assessment of guideline quality and recommendation for use. BMC health services research. 2018 Dec;18(1):1-9.	No description of quality measures
51	Hollon SD, Teachman BA. Advantages of developing clinical practice guidelines using international standards. Psychotherapy. 2019 Sep;56(3):340.	Preceded 2015
52	Hoste P, Vanhaecht K, Ferdinande P, Rogiers X, Eeckloo K, Blot S, Hoste E, Vogelaers D, Vandewoude K. Care pathways for organ donation after brain death: guidance from available literature?. Journal of advanced nursing. 2016 Oct;72(10):2369-80.	Disease-specific
53	Hurtado MM, Nogueras EV, Cantero N, Gálvez L, García-Herrera JM, Morales-Asencio JM. Development of a guideline for the treatment of generalized anxiety disorder with the ADAPTE method. International Journal for Quality in Health Care. 2020 Jul 20;32(6):356-63.	Disease-specific
54	Iannone P, Costantino G, Montano N, Podda GM, Minardi M, Doyle J,	Commentary/editorial/l

Peer-reviewed article		Reason for exclusion
	Cartabellotta A. Wrong guidelines: how to detect them and what to do in the case of flawed recommendations. BMJ Evidence-Based Medicine. 2017 Mar 1;22(1):4-8.	etter
55	Ierano C, Ayton D, Peel T, Marshall C, Thursky K. Evaluating the implementability of Antibiotic Surgical Prophylaxis guidelines. Infection, Disease & Health. 2020 Feb 1;25(1):11-21.	Disease-specific
56	Irving G. The AGREE Reporting Checklist is useful for assessing the quality of clinical practice guideline development. BMJ. 2016 Apr 12;353.	Commentary/editorial/letter
57	Jafarpour B, Abidi SR, Abidi SS. Exploiting semantic web technologies to develop OWL-based clinical practice guideline execution engines. IEEE journal of biomedical and health informatics. 2014 Dec 18;20(1):388-98.	Preceded 2015
58	JJ GD, Rodríguez-Padial L. Implementation of clinical practice guidelines: Wishful thinking or reality. Decision algorithm. Clinica e Investigacion en Arteriosclerosis: Publicacion Oficial de la Sociedad Espanola de Arteriosclerosis. 2021 May 1;33:33-9.	Full text not in English
59	Kent K, Jessup B, Marsh P, Barnett T, Ball M. A systematic review and quality appraisal of bereavement care practice guidelines. Journal of Evaluation in Clinical Practice. 2020 Jun;26(3):852-62.	Disease-specific
60	Khalid AF, Grimshaw JM, Parakh ND, Charide R, Rab F, Sohani S. Decision-makers' experiences with rapid evidence summaries to support real-time evidence informed decision-making in crises: a mixed methods study. BMC Health Services Research. 2023 Mar 25;23(1):282.	No description of innovation
61	Kneale D, Thomas J, O'Mara-Eves A, Wiggins R. How can additional secondary data analysis of observational data enhance the generalisability of meta-analytic evidence for local public health decision making?. Research synthesis methods. 2019 Mar;10(1):44-56.	No description of innovation
62	Koc EM, Aksoy H, Ayhan Baser D, Baydar Artantas A, Kahveci R, Cihan FG. Evaluation of clinical practice guideline quality: comparison of two appraisal tools. International Journal for Quality in Health Care. 2020 Dec 1;32(10):663-70.	Preceded 2015
63	Lewin S, Glenton C, Munthe-Kaas H, Carlsen B, Colvin CJ, Gülmezoglu M, Noyes J, Booth A, Garside R, Rashidian A. Using qualitative evidence in decision making for health and social interventions: an approach to assess confidence in findings from qualitative evidence syntheses (GRADE-CERQual). PLoS medicine. 2015 Oct 27;12(10):e1001895.	No description of innovation
64	Lewin S, Glenton C. Are we entering a new era for qualitative research? Using qualitative evidence to support guidance and guideline development by the World Health Organization. International journal for equity in health. 2018 Dec;17(1):1-5.	Commentary/editorial/letter
65	Li H, Xie R, Wang Y, Xie X, Deng J, Lu C. A new scale for the evaluation of clinical practice guidelines applicability: development and appraisal. Implementation Science. 2018 Dec;13:1-9.	Not applicable to Irish healthcare system
66	Lukersmith S, Hopman K, Vine K, Krahe L, McColl A. A new framing approach in guideline development to manage different sources of knowledge. Journal of evaluation in clinical practice. 2017 Feb;23(1):66-72.	Disease-specific
67	Lunny C, Ramasubbu C, Gerrish S, Liu T, Salzwedel DM, Puil L, Mintzes B, Wright JJ. Impact and use of reviews and 'overviews of reviews' to inform clinical practice guideline recommendations: protocol for a methods study. BMJ open. 2020 Jan 1;10(1):e031442.	No description of innovation
68	Machluf Y, Tal O, Navon A, Chaiter Y. From population databases to research and informed health decisions and policy. Frontiers in Public Health. 2017 Sep 21;5:230.	No description of innovation

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69	Makkar SR, Gilham F, Williamson A, Bisset K. Usage of an online tool to help policymakers better engage with research: Web CIPHER. Implementation Science. 2015 Dec;10:1-1.	No description of innovation
70	Marriott RD. Process mapping–the Foundation for effective quality improvement. Current problems in pediatric and adolescent health care. 2018 Jul 1;48(7):177-81.	Commentary/editorial/letter
71	Marx N, Rydén L, Brosius F, Ceriello A, Cheung M, Cosentino F, Green J, Kellerer M, Koob S, Kosiborod M, Nedungadi P. Proceedings of the Guideline Workshop 2019–Strategies for the optimization of guideline processes in diabetes, cardiovascular diseases and kidney diseases. diabetes research and clinical practice. 2020 Apr 1;162:108092.	Disease-specific
72	McDonald S, Elliott JH, Green S, Turner T. Towards a new model for producing evidence-based guidelines: a qualitative study of current approaches and opportunities for innovation among Australian guideline developers. F1000Research. 2019;8.	No description of innovation
73	McGowan J, Muratov S, Tsepke A, Issina A, Slawecki E, Lang ES. Clinical practice guidelines were adapted and implemented meeting country-specific requirements—the example of Kazakhstan. Journal of clinical epidemiology. 2016 Jan 1;69:8-15.	Disease-specific
74	Miguel RT, Silvestre MA, Imperial ML, Ho BL, Dans LF. Appraisal of the methodological quality of clinical practice guidelines in the Philippines. The International Journal of Health Planning and Management. 2019 Oct;34(4):e1723-35.	Not applicable to Irish healthcare system
75	Moleman M, Jerak-Zuiderent S, van de Bovenkamp H, Bal R, Zuiderent-Jerak T. Evidence-basing for quality improvement; bringing clinical practice guidelines closer to their promise of improving care practices. Journal of Evaluation in Clinical Practice. 2022 Dec;28(6):1003-26.	No description of quality measures
76	Montero-Odasso MM, Kamkar N, Pieruccini-Faria F, Osman A, Sarquis-Adamson Y, Close J, Hogan DB, Hunter SW, Kenny RA, Lipsitz LA, Lord SR. Evaluation of clinical practice guidelines on fall prevention and management for older adults: a systematic review. JAMA network open. 2021 Dec 1;4(12):e2138911-.	Disease-specific
77	Moreno-Casbas T, González-María E, Albornos-Muñoz L, Grinspun D. Getting guidelines into practice: Lessons learned as Best Practice Spotlight Organization host. JBI Evidence Implementation. 2019 Jun 1;17:S15-7.	Preceded 2015
78	O'Caoimh R, Weathers E, Hally R, O'Sullivan R, FitzGerald C, Cornally N, Svendrovski A, Healy E, O'Connell E, O'Keeffe G, Warren PL. The Community Assessment of Risk and Treatment Strategies (CARTS): An integrated care pathway to manage frailty and functional decline in community dwelling older adults. InInformation and Communication Technologies for Ageing Well and e-Health: First International Conference, ICT4AgeingWell 2015, Lisbon, Portugal, May 20-22, 2015. Revised Selected Papers 1 2015 (pp. 3-18). Springer International Publishing.	Disease-specific
79	O'Connor AM, Tsafnat G, Thomas J, Glasziou P, Gilbert SB, Hutton B. A question of trust: can we build an evidence base to gain trust in systematic review automation technologies?. Systematic reviews. 2019 Dec;8(1):1-8.	No description of innovation
80	Odlum A, James R, Mahieu A, Blanchet K, Altare C, Singh N, Spiegel P. Use of COVID-19 evidence in humanitarian settings: the need for dynamic guidance adapted to changing humanitarian crisis contexts. Conflict and Health. 2021 Dec;15(1):1-6.	No description of innovation
81	Oliver KA, de Vocht F. Defining 'evidence'in public health: a survey of policymakers' uses and preferences. The European Journal of Public Health. 2017 May 1;27(suppl_2):112-7.	No description of innovation

Peer-reviewed article		Reason for exclusion
82	Oyinlola JO, Campbell J, Kousoulis AA. Is real world evidence influencing practice? A systematic review of CPRD research in NICE guidances. BMC Health Services Research. 2016 Dec;16:1-2.	No description of innovation
83	Parmelli E, Langendam M, Piggott T, Adolfsson J, Akl EA, Armstrong D, Braithwaite J, Brignardello-Petersen R, Follmann M, Leś Z, Meerpohl JJ. Guideline-based quality assurance: a conceptual framework for the definition of key elements. BMC Health Services Research. 2021 Dec;21:1-8.	No description of additional core components
84	Peterson K, Floyd N, Ferguson L, Christensen V, Helfand M. User survey finds rapid evidence reviews increased uptake of evidence by Veterans Health Administration leadership to inform fast-paced health-system decision-making. Systematic Reviews. 2016 Dec;5(1):1-2.	No description of innovation
85	Piggott T, Langendam MW, Parmelli E, Adolfsson J, Akl EA, Armstrong D, Braithwaite J, Brignardello-Petersen R, Brozek J, Follmann M, Kopp I. Integrating quality assurance and quality improvement with guidelines: systematic stakeholder-driven development of an extension of the Guidelines International Network–McMaster guideline development checklist. Annals of Internal Medicine. 2022 May;175(5):735-9.	Commentary/editorial/letter
86	Pokharel S, Spencer C, McArdle D, Archer F. Global consensus frameworks, standards, guidelines, and tools: their implications in international development policy and practice. Prehospital and disaster medicine. 2019 Dec;34(6):644-52.	Not related to clinical guidance
87	Porgo TV, Ferri M, Norris SL. Common issues raised during the quality assurance process of WHO guidelines: a cross-sectional study. Health Research Policy and Systems. 2018 Dec;16(1):1-6.	No description of additional core components
88	Porgo TV, Norris SL, Salanti G, Johnson LF, Simpson JA, Low N, Egger M, Althaus CL. The use of mathematical modeling studies for evidence synthesis and guideline development: A glossary. Research synthesis methods. 2019 Mar;10(1):125-33.	No description of innovation
89	Rego de Sousa MJ, Albuquerque M, Ribeiro R, Cruz G, Mateus P, de Sousa J, de Sousa G. Evaluation of Noninvasive Prenatal Testing (NIPT) guidelines using the AGREE II instrument. The Journal of Maternal-Fetal & Neonatal Medicine. 2020 Feb 1;33(3):455-63.	Disease-specific
90	Robertson-Malt S, Norton-Westwood D. Framework of care: communicating the structure and processes of care. JBI Evidence Implementation. 2017 Sep 1;15(3):82-9.	Commentary/editorial/letter
91	Saunders GH, Christensen JH, Gutenberg J, Pontoppidan NH, Smith A, Spanoudakis G, Bamiou DE. Application of big data to support evidence-based public health policy decision-making for hearing. Ear and hearing. 2020 Sep;41(5):1057.	No description of innovation
92	Scharpf J. The challenge of guideline development when evidence is sparse. Otolaryngology–Head and Neck Surgery. 2017 Sep;157(3):383-4.	Commentary/editorial/letter
93	Schünemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R, Ventresca M, Brignardello-Petersen R, Laisaar KT, Kowalski S, Baldeh T. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. Cmaj. 2014 Feb 18;186(3):E123-42.	Preceded 2015
94	Semlitsch T, Blank WA, Kopp IB, Siering U, Siebenhofer A. Evaluating guidelines: a review of key quality criteria. Deutsches Ärzteblatt International. 2015 Jul;112(27-28):471.	Preceded 2015
95	Seys D, Bruyneel L, Deneckere S, Kul S, Van der Veken L, Van Zelm R, Sermeus W, Panella M, Vanhaecht K. Better organized care via care pathways: A multicenter study. PloS one. 2017 Jul 3;12(7):e0180398.	No description of quality measures

Peer-reviewed article		Reason for exclusion
96	Shepherd HL, Geerligs L, Butow P, Masya L, Shaw J, Price M, Dhillon HM, Hack TF, Girgis A, Luckett T, Lovell M. The elusive search for success: defining and measuring implementation outcomes in a real-world hospital trial. Frontiers in Public Health. 2019 Oct 18;7:293.	Disease-specific
97	Siebenhofer A, Semlitsch T, Herborn T, Siering U, Kopp I, Hartig J. Validation and reliability of a guideline appraisal mini-checklist for daily practice use. BMC Medical Research Methodology. 2016 Dec;16(1):1-1.	Preceded 2015
98	Smith H, Varshoei P, Boushey R, Kuziemsky C. Use of simulation modeling to inform decision making for health care systems and policy in colorectal cancer screening: protocol for a systematic review. JMIR Research Protocols. 2020 May 13;9(5):e16103.	No description of innovation
99	Subramaniam A, Reddy MP, Kadam U, Zubarev A, Lim Z, Anstey C, Bihari S, Haji J, Luo J, Mitra S, Ramanathan K. Development and validation of a tool to appraise guidelines on SARS-CoV-2 infection control strategies in healthcare workers. Australian Critical Care. 2022 Jul 1;35(4):415-23.	Disease-specific
100	Sultan S, Siedler MR, Morgan RL, Ogunremi T, Dahm P, Fatheree LA, Getchius TS, Ginex PK, Jakhmola P, McFarlane E, Murad MH. An international needs assessment survey of guideline developers demonstrates variability in resources and challenges to collaboration between organizations. Journal of general internal medicine. 2021 Sep 20:1-9.	No description of additional core components
101	Trepanier L, Reyes A, Stamoulos C, Beauchamp S, Dagenais C, Ciquier G, Drapeau M. Can We Develop Evidence-Based Guidelines Without Research Expertise?. Administration and Policy in Mental Health and Mental Health Services Research. 2021 Feb 12:1-5.	No description of additional core components
102	Trollope H, Leung JP, Wise M, Farquhar C, Sadler L. An evaluation of the objective quality and perceived usefulness of maternity clinical practice guidelines at a tertiary maternity unit. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2018 Dec;58(6):660-6.	Disease-specific
103	Tugwell P, Knottnerus JA. Global Evidence. Journal of clinical epidemiology. 2017 Mar 1;83:1-2.	Commentary/editorial/letter
104	Tyagi NK, Dhesy-Thind S. Clinical practice guidelines in breast cancer. Current Oncology. 2018 Jun;25(s1):151-60.	Disease-specific
105	Van Remoortel H, De Buck E, Dieltjens T, Pauwels NS, Compernolle V, Vandekerckhove P. Methodologic quality assessment of red blood cell transfusion guidelines and the evidence base of more restrictive transfusion thresholds. Transfusion. 2016 Feb;56(2):472-80.	Disease-specific
106	van Zuuren EJ, Logullo P, Price A, Fedorowicz Z, Hughes EL, Gattrell WT. Existing guidance on reporting of consensus methodology: a systematic review to inform ACCORD guideline development. BMJ open. 2022 Sep 1;12(9):e065154.	Not related to clinical guidance
107	Verdolini N, Hidalgo-Mazzei D, Del Matto L, Muscas M, Pacchiarotti I, Murru A, Samalin L, Aedo A, Tohen M, Grunze H, Young AH. Long-term treatment of bipolar disorder type I: A systematic and critical review of clinical guidelines with derived practice algorithms. Bipolar disorders. 2021 Jun;23(4):324-40.	Disease-specific
108	Vernooij RW, Alonso-Coello P, Brouwers M, Martinez Garcia L, CheckUp Panel. Reporting items for updated clinical guidelines: checklist for the reporting of updated guidelines (CheckUp). PLoS medicine. 2017 Jan 10;14(1):e1002207.	Captured in updating guidelines review
109	Vernooij RW, Martínez García L, Florez ID, Hildago Armas L, Poorthuis MH, Brouwers M, Alonso-Coello P. Updated clinical guidelines experience major reporting limitations. Implementation Science. 2017 Dec;12(1):1-0.	Captured in updating guidelines review

Peer-reviewed article		Reason for exclusion
110	Versloot J, Grudniewicz A, Chatterjee A, Hayden L, Kastner M, Bhattacharyya O. Format guidelines to make them vivid, intuitive, and visual: use simple formatting rules to optimize usability and accessibility of clinical practice guidelines. JBI Evidence Implementation. 2015 Jun 1;13(2):52-7.	No description of additional core components
111	Wainberg SK, Santos NC, Gabriel FC, de Vasconcelos LP, Nascimento JS, de Godoi Rezende Costa Molino C, de Melo DO. Clinical practice guidelines for surgical antimicrobial prophylaxis: Qualitative appraisals and synthesis of recommendations. Journal of Evaluation in Clinical Practice. 2019 Aug;25(4):591-602.	Disease-specific
112	Wan KR, Zeng GQ, Li Y, Wu JW, Zou BY, Liang HR, Jiang M. Quality changes of clinical practice guidelines for respiratory diseases in China: A systematic review. The Clinical Respiratory Journal. 2021 Sep;15(9):983-91.	Disease-specific
113	Wang YY, Liang DD, Lu C, Shi YX, Zhang J, Cao Y, Fang C, Huang D, Jin YH. An exploration of how developers use qualitative evidence: content analysis and critical appraisal of guidelines. BMC Medical Research Methodology. 2020 Dec;20(1):1-28.	No description of innovation
114	Weld-Blundell IV, Grech L, Learmonth YC, Marck CH. Lifestyle and complementary therapies in multiple sclerosis guidelines: Systematic review. Acta Neurologica Scandinavica. 2022 Apr;145(4):379-92.	Disease-specific
115	Wieringa S, Dreesens D, Forland F, Hulshof C, Lukersmith S, Macbeth F, Shaw B, Van Vliet A, Zuiderent-Jerak T. Different knowledge, different styles of reasoning: a challenge for guideline development. BMJ evidence-based medicine. 2018 Jun 1;23(3):87-91.	No description of additional core components
116	Williamson A, Makkar SR, Redman S. How was research engaged with and used in the development of 131 policy documents? Findings and measurement implications from a mixed methods study. Implementation Science. 2019 Dec;14(1):1-5.	No description of additional core components
117	Wilson MG, Lavis JN, Gauvin FP. Developing a rapid-response program for health system decision-makers in Canada: findings from an issue brief and stakeholder dialogue. Systematic reviews. 2015 Dec;4(1):1-1.	No description of innovation
118	Woiski MD, van Vugt HC, Dijkman A, Grol RP, Marcus A, Middeldorp JM, Mol BW, Mols F, Oudijk MA, Porath M, Scheepers HJ. From postpartum haemorrhage guideline to local protocol: A study of protocol quality. Maternal and Child Health Journal. 2016 Oct;20:2160-8.	Disease-specific
119	Yoshida M, Kinoshita Y, Watanabe M, Sugano K. JSGE clinical practice guidelines 2014: standards, methods, and process of developing the guidelines. Journal of Gastroenterology. 2015 Jan;50(1):4-10.	Preceded 2015
120	Armstrong MJ, Rueda J-D, Gronseth GS, Mullins CD. Framework for enhancing clinical practice guidelines through continuous patient engagement. Health expectations : an international journal of public participation in health care and health policy. 2017;20(1):3-10.	No description of additional core components
121	Blackwood J, Armstrong MJ, Schaefer C, Graham ID, Knaapen L, Straus SE, et al. How do guideline developers identify, incorporate and report patient preferences? An international cross-sectional survey. BMC health services research. 2020;20(1):458.	No description of additional core components
122	Blume LHK, Busari JO, van Weert NJHW, Delnoij DMJ. Exploring the solutions to the inherent perils of (the multitude of) guidelines - a focus group study of stakeholders' perceptions. BMC health services research. 2019;19(1):395.	No description of additional core components

Peer-reviewed article		Reason for exclusion
123	Flores EJ, Mull NK, Lavenberg JG, Mitchell MD, Leas BF, Williams A, et al. Using a 10-step framework to support the implementation of an evidence-based clinical pathways programme. BMJ Quality & Safety. 2019;28(6):476-85.	No description of additional core components
124	Gagliardi AR, Alhabib S. Trends in guideline implementation: a scoping systematic review. Implementation science : IS. 2015;10:54.	No description of additional core components
125	Gagliardi AR, Marshall C, Huckson S, James R, Moore V. Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice. Implement Sci. 2015;10:19.	No description of additional core components
126	Gartner J-B, Abasse KS, Bergeron F, Landa P, Lemaire C, Côté A. Definition and conceptualization of the patient-centered care pathway, a proposed integrative framework for consensus: a Concept analysis and systematic review. BMC Health Services Research. 2022.	No description of additional core components
127	Lotfi T, Hajizadeh A, Moja L, Akl EA, Piggott T, Kredo T, et al. A taxonomy and framework for identifying and developing actionable statements in guidelines suggests avoiding informal recommendations. Journal of Clinical Epidemiology. 2022;141:161-71.	No description of additional core components
128	Luciana Pereira de V, Daniela Oliveira de M, Airton Tetelbom S, Heráclito Barbosa C. Even High-Quality CPGs Seldom Include Implementation Strategies. Frontiers in Pharmacology. 2021.	No description of additional core components
129	Morciano C, Basevi V, Faralli C, Hilton Boon M, Tonon S, Taruscio D. Policies on Conflicts of Interest in Health Care Guideline Development: A Cross-Sectional Analysis. PloS one. 2016;11(11):e0166485.	No description of additional core components
130	Nieuwlaat R, Wiercioch W, Brozek JL, Santesso N, Kunkle R, Alonso-Coello P, et al. How to write a guideline: a proposal for a manuscript template that supports the creation of trustworthy guidelines. Blood Advances. 2021;5(22):4721-6.	No description of additional core components
131	Pereira VC, Silva SN, Carvalho VKS, Zanghelini F, Barreto JOM. Strategies for the implementation of clinical practice guidelines in public health: an overview of systematic reviews. Health research policy and systems. 2022;20(1):13.	No description of additional core components
132	Peters S, Sukumar K, Blanchard S, Ramasamy A, Malinowski J, Ginex P, et al. Trends in guideline implementation: an updated scoping review. Implementation science : IS. 2022;17(1):50.	No description of additional core components
133	Piggott T, Baldeh T, Akl EA, Junek M, Wiercioch W, Schneider R, et al. Supporting effective participation in health guideline development groups: The Guideline Participant Tool. Journal of Clinical Epidemiology. 2021;130:42-8.	No description of additional core components
134	Selva A, Sanabria AJ, Pequeño S, Zhang Y, Solà I, Pardo-Hernandez H, et al. Incorporating patients' views in guideline development: a systematic review of guidance documents. J Clin Epidemiol. 2017;88:102-12.	No description of additional core components
135	Sharon JW, Zoe R. An integrative approach to improving patient care pathways. International Journal of Health Care Quality	No description of additional core

Peer-reviewed article		Reason for exclusion
	Assurance. 2018.	components
136	Sipilä R, Mäkelä M, Komulainen J. Highlighting the need for de-implementation - Choosing Wisely recommendations based on clinical practice guidelines. BMC health services research. 2019;19(1):638.	No description of additional core components
137	Sonis J, Chen OM. Approval processes in evidence-based clinical practice guidelines sponsored by medical specialty societies. PloS one. 2020;15(2):e0229004.	No description of additional core components
138	Sonyi M, Keller J, Fox M, Hammer HF. Development of a Multinational Clinical Practice Guideline: A Practical Structured Procedure. Digestive diseases (Basel, Switzerland). 2021;39(5):477-87.	No description of additional core components
139	Baxter S, Johnson M, Chambers D, Sutton A, Goyder E, Booth A. Understanding new models of integrated care in developed countries: a systematic review. Health Services and Delivery Research. 2018.	No description of additional core components
140	Tamara K, Susanne B, Shingai M, Taryn Y, Quinette L, Eleanor AO, et al. Guide to clinical practice guidelines: the current state of play. International Journal for Quality in Health Care. 2016.	No description of additional core components