An Roinn Sláinte
Department of Health

National Clinical Effectiveness Committee

Standards for Clinical Practice Guidance

May 2025 | Version 2

A manual to provide standards for healthcare professionals developing evidence-based clinical practice guidance, including clinical policies, procedures, protocols, and guidelines for healthcare.

National Patient Safety Office
Oifig Náisiúnta um Shábháilteacht Othar

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

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These standards will be reviewed and updated by the NCEC as required. The current version is available on https://www.gov.ie/en/publication/90221b-clinical-effectiveness/. Further information on NCEC Clinical Effectiveness is available at https://www.gov.ie/en/collection/74f29c-national-clinical-effectiveness-committee/.

Citation text

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Acronyms

CEU	Clinical Effectiveness Unit
CMO	Chief Medical Officer
CPG	Clinical Practice Guidance
DoH	Department of Health
DoHC	Department of Health and Children
HIQA	Health Information and Quality Authority
HR	Human Resources
HRB-CICER	Health Research Board - Centre in Ireland for Clinical guideline support and Evidence Reviews (CICER)
HSE	Health Service Executive
HSE NCCA	HSE National Centre for Clinical Audit
HTA	Health Technology Assessment
IT	Information Technology
MHC	Mental Health Commission
NCEC	National Clinical Effectiveness Committee
NPSO	National Patient Safety Office
PPPG	Policies, Procedures, Protocols and Guidelines
RCSI	Royal College of Surgeons in Ireland

1 National Clinical Effectiveness Committee

Clinical effectiveness is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes, promotes healthcare that is up to date, effective and consistent. Clinical effectiveness processes include guidelines, audit, and clinical practice guidance.

The National Clinical Effectiveness Committee (NCEC) is a multidisciplinary committee established as part of the Patient Safety First Initiative in September 2010 to provide oversight for the national clinical effectiveness agenda, and to optimise patient and service user care. The NCEC is supported by the Clinical Effectiveness Unit (CEU) in the Department of Health (DoH). In the early years of the NCEC, the focus was on establishing the NCEC National Clinical Guideline function. In 2015, with the establishment of the CEU, this work expanded and the functions relating to NCEC National Clinical Audit and National Standards for Clinical Practice Guidance commenced development. The CEU was subsumed into the new structure created by the establishment of the National Patient Safety Office (NPSO) in the DoH in December 2016. The NPSO focuses on leading key patient safety policy initiatives, aiming to support high quality health services by using patient safety data, preparing legislation, promoting evidence-based clinical care and publishing reports about the performance of the health service. The NPSO also work to promote the appropriate use of antibmicrobials through Antimicrobial Resistance policy.

The current NCEC Terms of Reference are to:

1. Provide strategic leadership for the national clinical effectiveness agenda.
2. Contribute to national patient safety and quality improvement agendas.
3. Publish Standards for Clinical Practice Guidance.
4. Publish guidance for National Clinical Guidelines and National Clinical Audit.
5. Prioritise and quality-assure National Clinical Guidelines and National Clinical Audit.
6. Commission National Clinical Guidelines and National Clinical Audit.
7. Align National Clinical Guidelines and National Clinical Audit with implementation levers.
8. Report periodically on the implementation and impact of National Clinical Guidelines and the performance of National Clinical Audit.
9. Establish sub-committees for NCEC work-streams.
10. Publish an Annual Report.

Further information on the NCEC, the framework, and NCEC documentation including endorsement and quality assurance criteria for National Clinical Guidelines and National Clinical Audit is available at: https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/.

2 NCEC Standards for Clinical Practice Guidance – background

Clinical practice guidance (CPG) is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate health care for specific clinical circumstances. Such clinical guidance includes, but is not limited to, clinical policies, procedures, protocols, and guidelines. Care pathways, clinical decision aids/tools, care bundles, flowcharts, checklists and algorithms can form components of policies, procedures, protocols or guidelines. The type of clinical practice guidance chosen is determined by evidence-based criteria and clinical requirements.

The *NCEC Standards for Clinical Practice Guidance* emanated from a request by the Minister for Health that NCEC would develop standards for clinical practice guidance following the Report of the CMO into Portlaoise Perinatal Deaths (2014), as outlined in the box below. The development of the *Standards for Clinical Practice Guidance* complements existing frameworks such as *Safer Better Healthcare* (HIQA 2024), *Building a Culture of Patient Safety* (DoHC 2008) and the *National Quality Framework: Driving Excellence in Mental Health Services* (MHC 2023).

Clinical Effectiveness			
	Recommendation	**Responsible body**	
R.19	The National Clinical Effectiveness Committee should develop standards for clinical practice guidance.	NCEC	Standard definitions and criteria should be developed in relation to the various forms of clinical practice guidance such as guidelines, checklists, procedures, clinical guidance, clinical protocols etc. This will ensure consistency of approach and utilisation of appropriate methodology to develop clinical practice guidance nationally.

Box 1: *Extract from HSE Midland Regional Hospital, Portlaoise Perinatal Deaths (2006- date). (Department of Health 2014)*

The *NCEC Standards for Clinical Practice Guidance* were originally published by the NCEC in 2015, informed by a systematic literature review, advice from an Expert Advisory Group and feedback from a public consultation process. At the time of the development of the standards, the NCEC sought to establish the extent and quality of the evidence internationally on clinical practice guidance in terms of effectiveness, rigour of development, and quality assurance processes. A systematic literature review to support a framework for the development of standards for clinical practice guidance was completed in March 2015[1].

[1] https://assets.gov.ie/11684/d3c73d26cd744d8fbcef1382a40debda.pdf

The key messages from the 2015 literature review included:

- There is a lack of standardisation of terminology, methodology and quality assurance of clinical practice guidance development, implementation and evaluation internationally.
- There is a lack of evidence relating to cost effectiveness and clinical effectiveness of clinical practice guidance internationally.
- Clinical practice guidance must be evidence-based.
- Multi-stakeholder involvement is a key requirement for the effective development of guidance.
- The literature revealed barriers and facilitators at the patient, healthcare professional, team, organisational and health system level.
- Improvements to clinical guidance can be secured if barriers are tracked and a systems approach is taken to the development, implementation and evaluation of guidance.

A summary of the literature search strategy and results are outlined in Appendix A.

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 of an updated literature review to examine evidence since the original literature review and assess whether there has been a material change in approaches, and to capture innovation as driven by the COVID-19 pandemic and other advances in using evidence to determine guidance content.
- Conduct a consultation with key stakeholders, including guidance developers, healthcare professionals, and patients, 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.

A scoping review, carried out by Health Research Board (HRB) funded Centre in Ireland for Clinical guideline support and Evidence Reviews (CICER) and published in January 2024, identified that the 2015 NCEC Standards for Clinical Practice Guidance remain relevant and applicable when compared with current international guidance development processes. However, several advances since 2015 were identified. These included the additional core component of health equity in CPG development. 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 executive summary of the literature review can be found in appendix B.

A targeted stakeholder consultation was carried out by a team from the Royal College of Surgeons in Ireland (RCSI) in late 2023 and early 2024. Participants in the stakeholder consultation spoke to the importance of the core components outlined in the existing NCEC Standards. There was emphasis on the need to have clear governance, in particular robust audit processes, robust methodology, an implementation plan, and clear communication plans. Many participants recognised the value of having standards for CPG development and expressed limited familiarity with specific documents such as the NCEC Standards. Some participants reported confusion related to ambiguity in the use of CPG terminology and which type of guidance is required/takes precedence in various healthcare scenarios or settings. The need for more resources for CPG development in general was a recurring theme throughout the analysis.

An expert advisory group was established to provide advice and information to the NCEC in the development and update of the standards. The members of the 2024 group are listed in table 1. Members of the 2015 expert advisory group can be found in Appendix E.

The information derived from these three inputs to the project was used to inform an update of the standards and culminated in the publication of version 2 of the document in May 2025.

Expert advisory group

Name	Title/Affiliation
Ms Margaret Brennan	Assistant National Director, Dublin North-East Health Region, HSE.
Ms Elaine Brown	Portfolio Manager, Office of the National Clinical Advisor and Group Lead, HSE
Ms Marion Cullinan (Chair)	Clinical Effectiveness Unit, Department of Health
Ms Róisín Cunniffe	Patient Safety Legislation & Advocacy Unit, Department of Health
Ms Majella Daly	Assistant National Director, HSE National Centre for Clinical Audit (NCCA)
Ms Louise Hendrick	HSE National Office of Quality & Patient Safety
Ms Anne Horgan	General Manager, Clinical Design & Innovation, Office of the Chief Clinical Officer, HSE
Mr Gavin O'Dowd	Patient Safety Surveillance and Performance Unit, Department of Health
Ms Shelley O'Neill	Deputy Director HTA Directorate, Health Information and Quality Authority
Dr Eve O'Toole	Head of Evidence and Quality Hub, National Cancer Control Programme
Dr Karina Reynolds	Group Clinical Effectiveness Lead, Private Hospitals Association
Ms Emma Roche (to August 2024)	Research and Policy Manager, Mental Health Commission
Mr Pawel Stepala (from August 2024)	Head of Regulatory Practice and Standards, Mental Health Commission

Table 1: Members of the 2024 Expert Advisory Group for the update of the 2015 NCEC Standards for Clinical Practice Guidance.

3 National Context – other regulatory and policy frameworks

The Health Information and Quality Authority (HIQA) developed *National Standards for Safer Better Healthcare* in 2012 to describe what a high quality, safe service looks like. Version 2 of the Standards were published in September 2024. These standards are an important driver for the implementation of clinical guidance as they set out the need for clinical decisions to be based on best available evidence and information; "*to drive improvements in the quality and safety of healthcare it is important that decisions, including clinical decisions, are based on the best available evidence and information*". The document also describes that it is recognised internationally that the setting and implementation of standards and monitoring compliance with them are important levers in driving improvements in quality and safety in healthcare. "*Standards help to set public, provider and professional expectations and enable everyone involved in healthcare to play a vital part in safeguarding patients and delivering continuous improvement in the quality of care provided. Standards promote responsibility and accountability for the quality and safety of services provided. By incorporating national and international best available evidence, standards also promote healthcare that is up to date, effective and consistent. Importantly, standards for healthcare provide a basis for planning and managing services and measuring improvements as well as identifying and addressing gaps and deterioration in the quality and safety of the services provided.*"

The report of the Commission on Patient Safety and Quality Assurance, *Building a Culture of Patient Safety* (DoHC 2008) and the *National Quality Framework: Driving Excellent in Mental Health Services* (MHC 2023) also recommend the development of evidence-based standards.

Extracts of existing regulatory and policy frameworks encompassing the development, implementation and monitoring stages of clinical practice guidance and are summarised in the box below:

National Standards for Safer Better Healthcare (HIQA, 2024)	
Standard 1.1 The planning, design and delivery of services are informed by service users' identified needs and preferences.	
1.1.1	Proactive and systematic identification of service users' collective needs and preferences.
1.1.2	Formal consideration is given to service users' collective priorities, needs and preferences in the planning, design and delivery of services.
1.1.3	Involvement of service users at key stages in the planning and design of healthcare services. Service users are kept informed of key decisions during this process and how their needs and preferences have been considered.
1.1.4	Provision of services at a time and place which takes into account the expressed preferences of service users, where this provision can be achieved safely, effectively and efficiently.
Standard 1.4 Service users are enabled to participate in making informed decisions about their care.	
1.4.1	Provision of accessible, clear, timely and relevant information to service users about their condition, treatment options and the services available to them.
1.4.2	Active facilitation of individual service users as much as possible to exercise choice in the ongoing planning and delivery of their care and treatment.

Standard 2.1. Healthcare reflects national and international evidence of what is known to achieve best outcomes for service users.

2.1.1 Healthcare that is delivered according to policies, guidelines, protocols and care pathways that are based on best available evidence.

2.1.2 Use of National Clinical Guidelines and nationally agreed protocols, care bundles and care pathways where available.

2.1.3 Regular reviews of National Clinical Guidelines to determine what is relevant to the care and treatment provided and taking steps to address any identified gaps to ensure guidelines are implemented.

2.1.4 A clearly documented risk assessment when services are unable to fully implement National Clinical Guidelines and appropriate action taken to ensure the quality and safety of services.

2.1.5 Modification of National Clinical Guidelines for use in local practice and consideration of these guidelines when assessing and planning an individual service user's care.

2.1.6 An evidence-based process for the development of policies, guidelines, protocols and care pathways.

2.1.7 Support for, and facilitation of, the workforce in making decisions based on the best available evidence.

2.1.8 Support for healthcare professionals in making clinical decisions based on evidence which will maximise benefits to service users and minimise unnecessary treatment and care.

Standard 2.6. Care is provided through a model of service designed to deliver high quality, safe and reliable healthcare.

2.6.2 Delivery of care using high quality, safe and reliable models of service delivery that have the required clinical services, meet legislative requirements and take into account best available evidence, national policies, National Clinical Guidelines if available, local population health needs and available resources.

Standard 7.2. Service providers have arrangements in place to achieve best possible quality and safety outcomes for service users for the money and resources used.

Building a Culture of Patient Safety (DoHC, 2008) (See appendix C for full text of recommendation)

5.5: Organisational performance indicators and targets in the area of safety and quality.

5.16: Mandatory standards and key performance indicators.

5.19: Strong emphasis on safety and quality in the training and education of healthcare professionals.

6.6: Licensing should be linked to compliance with stated standards.

6.9: HIQA should progress urgently the development of standards on safety and quality.

6.11: The regulations that determine the criteria for obtaining a license should include implementation of evidence-based practice.

7.1 Production of evidence-based information and guidance for use in policy making, system reform and individual patient and professional interactions.

7.2 Evidence based service frameworks covering the major health conditions.

7.3 Evidence based national standards should be developed, with multidisciplinary input, in both primary and secondary care settings, and for the transition between care settings.

National Quality Framework: Driving Excellence in Mental Health Services (MHC 2023)

Theme 1: Ensuring quality through clinical and corporate leadership and governance within mental health services to deliver evidence-based care and quality improvement.

Standard 1.1: The mental health service delivers quality throughout all aspects of the service, underpinned by effective clinical and corporate leadership and governance.

Criteria:

1.1.2: The mental health service has clear standards for clinical and corporate governance that are outcome rather than process driven.

1.1.3: Services are designed, delivered, and evaluated in accordance with any relevant legislative requirements and national or international standards as appropriate.

1.1.8: Policies, procedures, protocols, and guidelines are in place that relate to the standards and criteria of the National Quality Framework.

Standard 1.2: The mental health service delivers quality throughout all aspects of the service, underpinned by evidence informed policies and practices.

Criteria:

1.2.1: The mental health service uses best research evidence to inform and improve service planning and delivery.

1.2.2: The mental health service uses audit, benchmarking, and other data to inform and improve service planning and delivery.

1.2.6: The mental health service shares service innovations with other providers to encourage further innovation and to avoid duplication.

1.2.7: The mental health service has an up-to-date repository of policies, procedures, protocols, and guidelines that is accessible by service providers.

1.2.8: The mental health service ensures that all service providers act in accordance with policies, procedures, protocols, and guidelines

Standard 1.3: The mental health service values and actively seeks feedback from service users.

Criteria:

1.3.4: The mental health service incorporates evidence from service users, families and carers into its policies, procedures, protocols, guidelines, and education programmes.

Box 2: *Summary of regulatory and policy frameworks encompassing the development, implementation and monitoring stages of clinical practice guidance in Ireland.*

4 Purpose of the 'Standards for Clinical Practice Guidance' document

The purpose of this document is to provide standards for healthcare professionals developing evidence-based clinical practice guidance for healthcare.

What is Clinical Practice Guidance?

Clinical practice guidance (CPG) is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate health care for specific clinical circumstances. Such clinical guidance includes, but is not limited to, clinical policies, procedures, protocols, and guidelines. Care pathways, clinical decision aids/tools, care bundles, flowcharts, checklists and algorithms can form components of policies, procedures, protocols or guidelines. The type of clinical practice guidance chosen is determined by evidence-based criteria and clinical requirements. See also glossary of terms for further information.

Different types of clinical guidance vary in complexity and scope. For example, clinical practice guidance can be a comprehensive overarching National Clinical Guideline or a more specific clinical protocol. Regardless of the variation in scope and focus, it is important that the development of all clinical practice guidance is underpinned by core standards using an evidence-based approach. The core elements that all CPG should encompass are shaded in yellow within this document. The additional elements which apply only to the more complex forms of CPG are marked with '**as required, complex CPG's**', and shaded in pink.

Does Clinical Practice Guidance improve patient care?

Clinical effectiveness is a key component of patient safety and quality. The integration of best evidence in service provision, through clinical effectiveness processes, such as clinical practice guidance, promotes healthcare that is up to date, effective and consistent. Through consistency in approach and reduction in duplication, variation in practice can be reduced.

The vision of the *Standards for Clinical Practice Guidance* is quality improvement for patient safety. The added value of standards for clinical practice guidance for policy, health system, public and patients can include:

- Improving, optimising, and prioritising patient outcomes
- Facilitating evidence-based practice
- Reduction of variation in clinical practice
- Standardisation of approach, for consistency and avoidance of duplication
- Facilitation of audit: provides parameters for audit
- Consistency of nomenclature
- Improvement of methodological rigour.

5 Scope

The Scope of the *Standards for Clinical Practice Guidance* includes Clinical Practice Guidance in healthcare, spanning the full multidisciplinary team. This includes all healthcare providers in Ireland, both publicly funded and private facilities. The standards are applicable to healthcare in all settings e.g. acute care, social care, mental health, care of the elderly, primary care, disabilities.

	Scope of the Standards for Clinical Practice Guidance
All healthcare settings	• Clinical policies
	• Clinical procedures
	• Clinical protocols
	• Clinical guidelines
	The following can form components of policies / procedures / protocols / guidelines: • Care pathways, clinical decision aids/tools, care bundles, flowcharts (Organisation of care; to support systems of care) • Checklists, algorithms (Implementation)

Box 3: *Scope of the Standards for Clinical Practice Guidance*

The scope of the *Standards for Clinical Practice Guidance* includes **clinical** policies, procedures, protocols, and guidelines. Care bundles, care pathways and clinical decision aids can form part of the approach to organisation of care for clinical guidance. Checklists and algorithms can form part of the guidance implementation toolbox. These are included as components of policies, procedures, protocols and guidelines, rather than stand-alone clinical practice guidance. Models of care are also informed by the standards.

There are existing regulatory frameworks which encompass requirements in relation to the development, implementation, and monitoring stages of clinical practice guidance, such as the *National Standards for Safer Better Healthcare* (HIQA, 2024), the *National Quality Framework: Driving Excellence in Mental Health Services* (MHC, 2023), and individual standards and professional codes of clinicians, as relevant. The *Standards for Clinical Practice Guidance* are intended to support and complement these existing processes. See also section 3, 'National Context'.

It is expected that the HSE and all organisations will develop new and updated guidance in line with these standards. Where clinical practice guidance is already in place, a plan to review this guidance should be made, with key patient safety areas prioritised. Review of existing guidance is recommended every 3 years, or sooner if required by law or new evidence, audit or information indicates required change. The HSE have developed a HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs) to support service providers in developing and implementing PPPGs within the HSE. This document is reviewed periodically, and the most recent version should always be consulted. See https://www2.healthservice.hse.ie/organisation/national-pppgs/.

Outside scope

The *Standards for Clinical Practice Guidance* are applicable to healthcare processes which assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances. **These standards are not intended to cover operational or non-clinical processes**, e.g. specimen transport, clinical waste management, HR policies etc. The HSE has published a guide entitled "*How to Develop HSE National Policies, Procedures, Protocols and Guidelines*", which may be helpful for readers developing non-clinical PPPG. This document is reviewed periodically, and the most current version should always be consulted. See https://www2.healthservice.hse.ie/organisation/national-pppgs/

Interim clinical guidance

Where interim clinical guidance is required on an emergency basis (e.g. public health emergencies, hazards, and emerging infectious threats such as Ebola virus, COVID), evidence-based processes should be followed as much as is practicable. In exceptional circumstances, guidance should be developed by experts, based on the best available evidence, and documented. If sustained as guidance following the initial emergency, this interim guidance should be reviewed and further developed, as required, using the standards.

6 Development of Clinical Practice Guidance

Different types of clinical guidance will vary in complexity and scope, with the choice of clinical practice guidance model determined by evidence-based criteria and clinical requirements. Not all clinical practice guidance requires the same pathway of development as more complex forms of CPG such as National Clinical Guidelines (e.g. NCEC National Clinical Guidelines or HSE National Clinical Guidelines). Note, within this document, the core elements that all CPG should encompass are shaded in yellow. The **additional** elements which apply only to the more complex forms of CPG are marked with '(**as required, complex CPG's**)', and shaded in pink.

However, regardless of the variation in scope and focus, it is important that the development of all clinical guidance is underpinned by an evidence-based approach and quality assurance measures to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances. Further information is available in the *NCEC Guideline Developers Manual*, available at https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/. This document is reviewed periodically, and the most current version should always be consulted.

These standards aim to promote consistency of clinical practice guidance across the country and avoid duplication. Synergies should be maximised across departments/organisations to optimise value for money and use of staff time and expertise. It is not in the interests of patient safety for individual organisations/units to develop or implement different guidance for similar clinical circumstances. Where feasible and appropriate, organisations should promote and utilise national clinical practice guidance developed in line with these standards, to avoid any unnecessary duplication, encompassing any local implementation requirements as required.

Prior to commencing the development of clinical practice guidance, the following should be considered (proportional to the complexity of the clinical practice guidance being developed):

Existing CPGs	Has a change in practice or a change in the environment prompted the need to develop or update the CPG? Is evidence-based CPG (local, national, or international) already available for this topic/clinical question? Is the existing CPG up-to-date, peer reviewed with rigorous methodology, and generalisable to target population? If local or national clinical practice guidance is already available for this topic, consider where your proposed CPG fits in relation to this existing guidance. Factors that may need to be considered include whether any permissions are required in your organisation to produce a new CPG on this topic, whether your new CPG is intended to replace or complement existing CPG, will your proposed CPG contradict existing CPG, or does retirement of existing CPG need to be planned for? If the existing CPG is international, is it applicable to Ireland?
Adapt/adopt	Is this CPG being developed *de novo* or being adapted/adopted from an up to date, rigorous, existing guidance nationally/internationally? Are permissions required?

Coverage/ geography	Is this CPG being developed as national, regional (i.e. for an individual Health Region) or local guidance? Will the proposed CPG be relevant for use in a wider geographical area or wider clinical area? If so, wider collaboration needs to be considered. In general, clinical practice guidance should not vary by location, although the mechanism for local implementation may differ.
Multidisciplinary	Does the CPG development group membership include all relevant stakeholders and professional groupings, to ensure integrated care for the service user? Health equity – have underrepresented groupings been included in the CPG development group or consulted as stakeholders?
Governance	Has a governance model been established for the development, approval, dissemination, implementation, monitoring, audit, updating and repository of Clinical Practice Guidance in your organisation? In addition to the Standards outlined in this document, developers of CPG should follow the templates and governance requirements laid down in their individual organisation for development of CPG, including obtaining corporate or management support, as necessary.
Model	What type of guidance is required for this topic/clinical question? E.g. policy, procedure, protocol, guideline, based on the clinical requirements.
Evidence base	Have you established access to a library or clinical librarian (see below)? Have you established links with an academic partner/third level institution/ research unit, if necessary?

Box 4: *Factors to consider prior to developing CPG*

Library Service

The HSE provides library services through Health Library Ireland (HLI). HLI aims to provide an integrated and high-quality national Library service to ensure that the best available evidence underpins patient care, decision making, education and research in the health service. HLI works to achieve this vision by providing access to:

- an extensive online library available to HSE, authorised users, Section 38s and other partners
- well-resourced physical libraries throughout the country
- the expertise of professional Librarian staff
- core services, including an evidence request service, information skills training, research digests and open access publishing.

Level of complexity

Clinical practice guidance may require different levels of developmental input, proportionate to the type of guidance, and any governance requirements in an individual organisation. For example, an NCEC National Clinical Guideline will require a full budget impact analysis and possibly a Health Technology Assessment (HTA), whereas a protocol may only require consideration of the resources required to develop and implement the protocol. It is expected that all clinical practice guidance will meet all the minimum standards, whereas more complex guidance may require additional rigour. The standards differentiate between minimum standards (shaded yellow) which apply to all CPG, and more rigorous additional requirements for complex guidance (shaded pink and annotated '**as required, complex CPG**'). While there is no standardised definition of 'complex' versus 'non-complex' CPG, it would be expected that NCEC National Clinical Guidelines, or other National Clinical Guidelines (such as a HSE National Clinical Guideline), would be considered as 'complex' CPG. Thereafter, there exists a continuum of complexity that requires a level of commissioner and developer interpretation. Groups developing CPG should document their decision-making approach as to the type of clinical practice guidance chosen, and the standards applied.

Decision-making process

The group developing the clinical practice guidance should document the consideration given to type of clinical practice guidance chosen (based on clinical requirements), and whether the type of clinical practice guidance was determined to be 'complex', or otherwise. This documentation of decision-making should be carried out according to local operational or governance models and templates and does not necessarily always need to be contained in full detail within the body of the clinical practice guidance itself.

7 Standards for Clinical Practice Guidance

Core components

A number of core components form the basis for high quality evidence-based clinical practice guidance, which can be grouped into the four categories of: governance, methodology, planning and implementation, and communications.

Governance	Governance model
	Audit, monitoring, review & evaluation process
	Service user and stakeholder involvement
	Knowledge management

Methodology	Clarity of scope and purpose
	Evidence-based
	Health equity

Planning & Implementation	Resource implications
	Planning & Implementation

Communications	Communications
	Clarity of presentation

A checklist of criteria for each of these components to assist in the development of clinical practice guidance is provided below. All clinical practice guidance should meet the minimum standards (shaded yellow), while some will be developed to a higher standard as required (denoted 'complex CPG's' below, shaded pink). The description of core components in this document provides a useful checklist for monitoring and audit.

1. Governance model[2]

Formal governance arrangements for the commissioning, development, and approval of clinical practice guidance within the organisation 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, complex CPG's**).	

2. Audit, monitoring, review & evaluation process

A process for monitoring is documented.	☐
A process for evaluation of implementation and clinical effectiveness is specified.	☐
Audit criteria and an audit process/plan are specified.	☐
A documented process for revisions/updating and review of the CPG, including timeframe, is provided.	☐

3. Service user and stakeholder involvement[3]

Stakeholder identification and involvement: The guidance development group includes individuals from, or consultation occurs with, all relevant stakeholders, staff, and professional groups.	☐
Guidance is informed by the identified needs and priorities of service users and stakeholders.	☐
The views, values, and preferences of patients and the target population have been sought and taken into consideration in formulating the CPG (**as required, complex CPGs**).	
The guidance development group composition is multidisciplinary and heterogenous in terms of discipline, skills, experience, geography, and diversity (including gender) (**as required, complex CPG's**).	
There is service user/lay representation on guidance development group (**as required, complex CPG's**).	

4. Knowledge management (accessibility/sharing of best practice)

The clinical guidance is easily accessible by all users e.g. CPG repository, smartphone accessibility.	☐
Documented process for version control is provided.	☐
Copyright and permissions are sought and documented, where applicable.	☐

[2] There are existing regulatory frameworks which encompass requirements in relation to the development, implementation and monitoring stages of clinical practice guidance. The Standards for Clinical Practice Guidance are intended to support and complement these existing processes. See also section 8, Monitoring, Implementation, and Audit.

[3] See appendix C for further resources on patient and public involvement (PPI) in CPG development.

5. Clarity of scope and purpose

The decision-making approach relating to type of guidance required (policy, procedure, protocol, guideline) is documented, and coverage of the guidance (national, regional, local) and applicable settings is 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 (e.g. 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.	☐

6. Evidence-based

Methods used to search for evidence, proportional to the complexity of the CPG being developed, are documented and reproducible.	☐
Methodology is appraised and documented for CPGs which are adapted/adopted from international guidance.	☐
Critical appraisal/analysis of 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.	☐
A systematic literature review has been undertaken[4] (**as required, complex CPG's**).	
A Health Technology Assessment (HTA) has been undertaken, where determined necessary (**as required, complex CPG's**).	

7. Health Equity

Health equity[5] has been considered and documented in the development of recommendations from evidence (**as required, complex CPG's**).	

[4] A literature search strategy, including databases searched, search terms and timeframe, should be documented and available.

[5] Groups to consider include older patients, members of the Travelling Community, disadvantaged populations, such as sex workers, drug users, and migrant workers, while factors such as age, disability, sexual orientation, time-dependent situations, and relationships should also be considered.

8. Resource implications

Resources required to develop and implement the CPG have been considered, including identification of available resources across departments/organisations to optimise value for money and use of staff time and expertise.	☐
Relevant existing CPG have been searched for and considered, to avoid duplication of effort in CPG development.	☐
Literature review of cost effectiveness is documented (**as required, complex CPG's**).	
The potential resource implications and budget impact of developing and implementing the guidance are identified and documented e.g. equipment, communications, education & training, staff time and research (**as required, complex CPG's**).	

9. Planning and Implementation[6]

Written implementation plan is provided with timelines, identification of responsible persons/ units and integration into service planning process.	☐
Barriers and facilitators for implementation are identified and aligned with implementation levers.	☐
Information and support are available for staff on the development of evidence-based clinical practice guidance.	☐
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated patient care.[7]	☐
Education and training is provided for the guidance development group on the development and implementation of evidence-based clinical practice guidance (**as required, complex CPG's**).	

10. Communications

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.	☐

11. Clarity of presentation/accessibility

Guidance content and recommendations are specific, unambiguous and use simple, clear language.[8]	☐
The CPG is produced in a format that is easily accessible to the end user . Visual elements such as tables, algorithms, pictures, and graphics have been used where appropriate.[9]	☐
A plain language of the guidance to help patients better understand the goals of the treatment, the different treatment options and the benefits and risks of each option has been prepared (**as required, complex CPG's**)[10].	

[6] See appendix C for further resources on implementation science.

[7] Stakeholders should be identified at the initiation of CPG development, including those that will be involved in the implementation phase, and that these stakeholders should be involved/ collaborated with at appropriate stages of the CPG development.

[8] Consider the number of elements, number of steps within each recommendation and number of conditional factors influencing performance.

[9] Factors such as smartphone accessibility may need to be considered.

[10] See appendix C for further resources on development of lay summaries.

8 Monitoring, Implementation, and Audit

Organisations should put processes in place to facilitate implementation of these standards. It is important that the *NCEC Standards for Clinical Practice Guidance* are aligned with other national standards, initiatives, and levers for implementation (see also section 3, 'National Context'). Users of these Standards should consult their own local and national organisational documentation and procedures in relation to governance, document management, and quality management, in conjunction with these Standards.

Formal governance arrangements for clinical practice guidance at local, regional, and national level should be established and documented by healthcare providers. This governance process should clearly outline quality assurance mechanisms, specific roles and responsibilities, accountability, and authority. Clear processes for developing, approving, disseminating, implementing, monitoring, auditing, and updating clinical practice guidance within the organisation needs to be clearly outlined and available for staff.

Following monitoring, evaluation or audit, a Quality Improvement Plan with actions should be developed, implemented and communicated within governance arrangements.

The HSE work on PPPGs complements and supports the implementation of the *NCEC Standards for Clinical Practice Guidance* through a shared vision for evidence-based practice that reduces variation and duplication in clinical practice. The HSE has established a National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs) to improve the quality of health care provided by the HSE and to enhance organisational effectiveness, aligning the NCEC standards with the stages in the PPPG development cycle. The HSE has also launched the HSE National Central Repository as a single source for accessing, storage and document control of HSE National policies, procedures, protocols, guidelines and clinical guidelines. Further information is available on the HSE website at https://www2.healthservice.hse.ie/organisation/national-pppgs/.

Helpful resources for implementation, monitoring, and audit, can be found in appendix C.

Implementation

The *Standards for Clinical Practice Guidance* provide a framework for assessment and audit. It is expected that the health system regulators will assess the corporate assurance arrangements in place to ensure effective implementation of these standards.

Implementation should follow a clear dissemination plan, to include a mechanism or process that makes guidance easily accessible at the point of care. CPG can only improve patient outcomes and care processes when effectively disseminated (Wang et al, 2015; Panteli et al, 2019). Dissemination strategies should be underpinned by six basic principles (IOM 1990; Fervers et al 2011):

1. CPG is not self-implementing;
2. Effectiveness in achieving intended objectives must be assessed, validated, verified and not assumed;
3. Implementation and evaluation considerations are built into the development process of CPG;
4. Success depends on engagement of all relevant stakeholders;
5. Dissemination is an ongoing process and extends to future iterations and updates;

6. Implementation must be "living", iterative and evolving, as emergent improved evidence-informed clinical practice approaches or methods are identified.

An evaluation framework can assist to determine achievement of objectives, impact and sustainability of a CPG.

Clinical Audit

"Clinical audit" means a clinically-led quality improvement process in healthcare (a) for the purpose of improving patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and taking action to improve care when clinical standards or clinical guidelines are not met, and (b) which selects aspects of the structure, processes and outcomes of care for systematic evaluation against explicit specific clinical standards or clinical guidelines[11]. Following clinical audit, improvements, if required should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements. It is noted that clinically-led includes the breadth of clinical professionals working in health and social care services.

The HSE National Centre for Clinical Audit (NCCA) was established within the National Quality and Patient Safety Directorate (NQPSD) in 2022, following publication of the HSE National Review of Clinical Audit Report, 2019. Establishing the HSE NCCA marks an important step in the HSE's continued efforts to improve the quality and safety of healthcare for patients. This will strengthen the development of an end-to-end process for clinical audit in accordance with the recommendations in the report and meet the needs of clinical audit service providers and multidisciplinary stakeholders. The NCCA is primarily responsible for implementing the *HSE National Review of Clinical Audit Report* recommendations under five key pillars:

- National Governance of Clinical Audit
- Local Governance of Clinical Audit
- Clinical Audit Training
- Clinical Audit Education Resources
- Legislative Changes affecting Clinical Audit (i.e. GDPR and Data Protection)

The *National Review of Clinical Audit Report* 2019 identified the importance of developing guidance for Clinical Audit. The HSE NCCA aims to support and improve the consistency and quality of clinical audit across the health service and enable the planning and management of high-quality healthcare. The HSE NCCA "Clinical Audit – a Practical Guide" is available on the HSE NCCA website. The NCCA also provide a range of resources to support clinical audit on their webpage, including a Clinical Audit toolkit and a Clinical Audit Nomenclature glossary of terms. These documents are reviewed periodically, and the most recent version should always be consulted.

[11] Definition from Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Glossary of Terms

Algorithm	Algorithms can form a component of Clinical Practice Guidance and provide an evidence-based step-by-step visual interpretation of the decision making and/or associated actions relating to a particular guidance area. Notably the steps within an algorithm are more narrowly defined than in a guideline.
Clinical Practice Guidance	Clinical Practice Guidance is an umbrella term to cover several forms of clinical guidance. It is defined as systematically developed statements or processes to assist clinician and patient decisions about appropriate health care for specific clinical circumstances, with the type of clinical practice guidance determined by evidence-based criteria and clinical requirements. Such clinical guidance includes, but is not limited to, clinical policies, procedures, protocols, and guidelines. It is often represented by the acronym PPPG, or 3PG.
Clinical Guideline	Clinical Guidelines are a subset of Clinical Practice Guidance and are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.
NCEC National Clinical Guideline	NCEC National Clinical Guidelines are a subset of Clinical Practice Guidance. They are a suite of guidelines that meet specific prioritisation and quality assurance criteria and that have been recommended by the National Clinical Effectiveness Committee (NCEC) for endorsement by the Chief Medical Officer, and the Minister of Health. Once a National Clinical Guideline is endorsed by the Minister for Health, it supersedes any other guidelines on that topic.
Clinical Audit	"Clinical audit" means a clinically-led quality improvement process in healthcare (a) for the purpose of improving patient care and outcomes through systematic review of care against explicit specific clinical standards or clinical guidelines and taking action to improve care when clinical standards or clinical guidelines are not met, and (b) which selects aspects of the structure, processes and outcomes of care for systematic evaluation against explicit specific clinical standards or clinical guidelines[12]. Following clinical audit, improvements, if required should be implemented at an individual, team, or organisation level and then the care re-evaluated to confirm improvements. It is noted that clinically-led includes the breadth of clinical professionals working in health and social care services.
Clinical Decision Support	Clinical Decision Supports can form components of Clinical Practice Guidance and refer to the provision of clinical knowledge and patient specific information to help clinicians and patients make decisions that enhance patient care.

[12] Definition from Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

Clinical Policy	A Clinical Policy is a subset of Clinical Practice Guidance and is a written operational statement of intent which helps staff to make appropriate decisions and take actions, consistent with the aims of the service provider and in the best interests of service users.
Clinical Procedure	A Procedure is a subset of Clinical Practice Guidance and is a written set of instructions that describes the approved and recommended steps for a particular act or sequence of events.
Clinical Protocol	A Clinical Protocol is a subset of Clinical Practice Guidance and is an agreed statement about a specific clinical issue, with a precise sequence of activities to be adhered to, with little scope for variation. Clinical Protocols are usually based on guidelines and/or organisational consensus.
Care Bundle	A Care Bundle can form a component of Clinical Practice Guidance and is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes.
Care Pathway	A Care Pathway can form a component of Clinical Practice Guidance and is a multidisciplinary care plan that outlines the main clinical interventions that are carried out by different healthcare practitioners for service users with a specific condition or set of symptoms. They are usually locally agreed, evidence-based plans that can incorporate local and national guidelines into everyday practice
Checklist	A Checklist can form a component of Clinical Practice Guidance and is a tool that condenses a large volume of information and allows for systematic verification of steps or practices.
Clinician	A Clinician is a health professional involved in clinical practice.
Flowchart	A Flowchart can form a component of Clinical Practice Guidance and is a diagram of the sequence of movements or actions of people or things involved in a complex system or activity.
Health Outcome Descriptors	Health Outcome Descriptors 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 (Baldeh et al, 2020).
Health equity	Health equity is a measure of the degree to which health policies distribute well-being fairly. It is the absence of systematic or potentially remediable differences in health status, access to healthcare and health-enhancing environments, and treatment in one or more aspects of health across populations or population groups defined socially, economically, demographically, or geographically. Health inequity results from a gap in health status and in access to health services between different social classes, ethnic groups, and between populations in different geographical areas.

Model of care	A Model of Care can form a component of Clinical Practice Guidance and is a multifaceted concept, which broadly defines the way health services are delivered. A model of care outlines best practice patient care delivery through the application of a set of service principles across identified clinical streams and patient flow continuums. The broad objective of developing a model of care is ensuring people get the right care, at the right time, by the right team and in the right place.
Standard	A Standard is a definable measure against which existing structures, processes or outcomes can be compared.
Clinical Standard[13]	"Clinical standard" means a statement which— (a) specifies a level of healthcare outcome that is required to contribute to patient quality and safety, (b) sets out the care that patients should, having regard to a specific clinical condition, be offered by, or receive from, a health practitioner or healthcare provider (or both) for— (i) such specific clinical condition, or (ii) the treatment and prevention of different diseases and conditions, (c) is consistent with current evidence-based best practice, and (d) is measurable, and includes any such statement that is agreed for use, from time to time, at a national level or in respect of any region or other specific geographical area.

[13] Definition from Patient Safety (Notifiable Incidents and Open Disclosure) Act 2023

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Appendix A: Systematic literature review

Key databases and grey literature sources were searched for evidence which evaluated guidance (guidance, pathway, policy, protocol, bundle, standard, algorithm, checklist, decision aid, model of care), development, implementation and evaluation processes. A total of 49 papers were included in this systematic review (Table 2). Owing to the lack of level one evidence (i.e. RCTs, meta-analysis, systematic reviews of RCTs) and heterogeneity of methodologies and outcomes, definitive conclusions could not be made as to the effectiveness of the various guidance types reviewed. However, the analysis of papers within the systematic review surmised that the implementation of guidance had a positive effect on patient outcomes and on the processes of care.

Table 2: Systematic review - Category of papers for each type of guidance

		Algorithms	Bundles	Chekclists	Pathways	Policy	Protocols	Standars of Care	TOTAL
1	SR of SRs, MAs & primary studies	1							**1**
2	Meta –analysis (MAs)		2		2				**4**
3	SRs & MA	1	1		2				**4**
4	SRs of SRs				1				**1**
5	SR of primary studies	6	1	3	8	8	7	1	**34**
6	SR & expert opinion	1							**1**
7	Papers on developing guidance inc. SRs			1		1	1	1	4
Total		**9**	**4**	**4**	**13***	**9**	**8**	**2**	**49**

SR = systematic review; MA = meta-analysis
*Note: 15 papers reviewed on pathways but three papers related to the same body of evidence (Rotter et al., 2009; 2010; 2012)

Source: Hegarty, J., Savage E., Cornally, N., Byrne S., Henn P, Flynn M, McLoughlin K, Fitzgerald S, (2015). A systematic literature review to support a framework for the development of standards for clinical practice guidance. Department of Health; Dublin. Available at: https://assets.gov.ie/11684/d3c73d26cd744d8fbcef1382a40debda.pdf

At a national level, evidence-based guidance can be provided through: statements which assist clinical decision making (clinical guidelines); statements of intent (policy), and the articulation of national standards against which practice can be benchmarked. The implementation of guidance in clinical practice can be supported through the use of implementation tools: protocols, algorithms and checklists. In terms of national approaches to the organisation and provision of evidence-based care, these can include clinical care pathways and care bundles.

Specific review questions were included in the research objectives for the systematic review including; definitions of clinical practice guidance, core elements, decision criteria, quality criteria, impact, resources, updating processes, expertise required, format, strengths and weaknesses, barriers and facilitators. Table 2 summarises the papers reviewed for each of these areas.

Table 2: Number of papers providing data on each question addressed in the systematic literature review

		Algorithms (n=9)	Bundles (n=4)	Checklists (n=4)	Pathways (n=15)*	Policy (n=9)	Protocols (n=7)	Standards of care (n=2)	TOTAL
Q 1	Definitions	2	3	2	10	2	5	0	24
Q 2	Core elements	2	2	0	11	4	1	2	22
Q 3	Decision criteria	7	0	4	2	3	5	2	23
Q 4	Methodological processes**	8	1	1	6	6	6***	1	29
Q 5	Quality criteria**** (for 4 above)	7	0	0	3	1	2	0	13
	&/or assessment of quality of studies in review paper	1	2	1	10	3	4	0	21
Q 6	(i) Impact i.e. outcomes	4	4	2	12	1	5	1	29
	(ii) Method of impact validation	0	0	0	0	0	1	0	1
	(iii) Implementation audit incl. outcome of implementation	1	1	0	0	0	4	0	6
Q 7	Resource implications (time/ cost)	3	0	3	5	1	3	1	16
Q 8	Updating processes	1	0	0	1	1	1	0	4
Q 9	Expertise needed	5	0	3	8	6	3	1	26
Q 10	Layout/format	4	0	3	4	4	5	0	20
Q 11	(i) Strengths	4	0	4	11	1	0	1	21
	(ii) Weaknesses	6	0	3	3	0	1	0	13
Q 12	Barriers	3	2	3	6	4	1	2	21
Q 13	Facilitators	5	0	3	7	7	6	3	31

*Pathways: Three of these papers relate to one body of evidence (Rotter 2009, 2010, 2011), presented as one paper in table.
**Methodological processes: Most papers addressed development processes, some of which also reported on implementation & evaluation.
***Protocols: One paper on protocols reported only on implementation process.
****Quality criteria: This includes use of a grading system to assess the quality of evidence relevant to the development of guidance type.

Source: Hegarty, J., Savage E., Cornally, N., Byrne S., Henn P, Flynn M, McLoughlin K, Fitzgerald S, (2015). A systematic literature review to support a framework for the development of standards for clinical practice guidance. Department of Health; Dublin. Available at: http://health.gov.ie/patient-safety/ncec/clinical- practice-guidance/

Appendix B: Literature review 2024 – Executive Summary

The full text of the literature review can be found at https://www.hiqa.ie/reports-and-publications/hrb-cicer-national-clinical-guideline-support/updating-standards-clinical.

Executive Summary: Advances in the development of clinical practice guidance: A scoping review Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews

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.

Appendix C: Examples of National and International resources

Methodology and General

National Clinical Effectiveness Committee: Resources and learning
https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

Health Improvement Scotland: Methodology toolkit
Improvement Resources | Healthcare improvement Scotland - Improvement resources (ihub.scot)

Australian Commission on Safety and Quality in Health Care: Clinical care standards
https://www.safetyandquality.gov.au/our-work/clinical-care-standards/

National Institute for Health and Care Excellence (NICE), UK;

- NICE guidance: https://www.nice.org.uk/guidance
- NICE standards and indicators: https://www.nice.org.uk/standards-and-indicators
- The National Institute for Health and Care Excellence (NICE). Developing NICE guidelines: the manual: NICE; 2023: https://www.nice.org.uk/process/pmg20

AGREE - international tool to assess the quality and reporting of practice guidelines
http://www.agreetrust.org/agree-ii/

McMaster University – McMaster GRADE Centre
Home - McMaster GRADE Centre

Guidelines International Network (GIN) – Resources
https://g-i-n.net/get-involved/resources

Scottish Intercollegiate Network (SIGN) – Methodology
https://www.sign.ac.uk/what-we-do/methodology/

World Health Organization – Guideline Adoption
Strengthening countries' capacities to adopt and adapt evidence-based guidelines: a handbook for guideline contextualization: https://apps.who.int/iris/handle/10665/372275

Accessibility/Plain Language

National Adult Literary Agency (NALA) – Plain English Service
https://www.nala.ie/plain-english/

National Office for Research Ethics Committees – Guidance on developing a Plain English Summary
https://www.nrecoffice.ie/wp-content/uploads/Plain-English-Summary-Guidance-V1.0-02.02.2022-1.pdf

Guidelines International Netwok (GIN) – Patient information
https://g-i-n.net/chapter/patient-information

Governance and Implementation

NCEC Implementation Guide and Toolkit
https://www.gov.ie/en/collection/cd41ac-clinical-effectiveness-resources-and-learning/

Guidelines International Network (GIN) – Implementation resources
https://g-i-n.net/wp-content/uploads/2021/04/Guideline-Implementation-Planning-Checklist.pdf

HSE National HSE National Framework for developing Policies, Procedures, Protocols and Guidelines (PPPGs)
https://www2.healthservice.hse.ie/organisation/national-pppgs/

Audit

HSE National Centre for Clinical Audit - Resources
https://www2.healthservice.hse.ie/organisation/ncca/

Healthcare Quality Improvement Partnership
https://www.hqip.org.uk/

Public and Patient Involvement

National Clinical Effectiveness Committee - Public Involvement Framework
https://www.gov.ie/en/collection/70a20b-public-involvement-framework/

PPI Ignite Network - Public and patient involvement (PPI)
https://ppinetwork.ie/

HSE Better Together: The Health Services Patient Engagement Roadmap
https://www.hse.ie/eng/about/who/national-services/partnering-with-patients/resourcesqid/hse-better-together-patient-engagement-roadmap-book.pdf

Appendix D: Building a Culture of Patient Safety

The report of the Commission on Patient Safety and Quality Assurance, Building a Culture of Patient Safety (DoHC 2008) recommends the development of evidence-based standards:

Leadership and accountability	
R5.1	Key leadership roles must be assigned to designated professionals and agencies at national level for the purpose of providing strong clinical leadership to the system in the area of patient safety and quality. Such leadership roles must include advocacy for safety and quality, the development and dissemination of patient safety knowledge and learning and the promotion of good practice.
R5.5	Organisational codes of governance must be implemented which clearly identify safety and quality as a core objective and which specify the processes by which these objectives will be achieved. Organisational performance in these areas should be monitored, through, for example, the setting of specific organisational performance indicators and targets in the area of safety and quality and the requirement for regular reports via internal and external accountability mechanisms on delivery against those targets. Patients should be provided with an accessible opportunity to contribute to such accountability mechanisms.
R5.16	The Board must review, on a regular basis, the systems of governance, including risk management and audit, relating to healthcare safety, quality and performance. This should include: mandatory standards and key performance indicators.
R5.19	There should be a strong emphasis on safety and quality in the training and education of healthcare professionals. All bodies responsible for the training and continuing development of healthcare professionals should review their curricula to ensure that patient safety and quality, including technical and human factors, is incorporated into the modules.
Organisational and Professional Regulatory Framework	
R6.6	Licencing should be linked to compliance with stated standards, enforceable through inspection and imposition of sanctions if necessary. The sanctions should range from warnings, with time limits for compliance, up to withdrawal of licence either for a specific service within the hospital or the hospital itself if required.
R6.9	In advance of the introduction of legislation providing for licensing, HIQA should progress urgently the development of standards on safety and quality to be applied to hospitals and all future licensed healthcare facilities. HIQA should also be asked to commence work immediately on standards in respect of any area where a high and intermediate risk to the health and/or welfare of patients or the public is identified. Subject to current legal provisions, arrangements should be put in place by which private healthcare providers would voluntarily adhere to such standards, agree to be monitored and the resulting reports published. Private health insurers should require all private healthcare facilities to adhere to the standards set by HIQA where such standards exist.
R6.11	The regulations that determine the criteria for obtaining a licence should include; implementation of evidence-based practice.
Quality Improvement and Learning Systems	
R7.1	A leadership role in relation to the analysis of international evidence and research, and to the production of evidence-based information and guidance for use in policy making, system reform and individual patient and professional interactions should be developed.
R7.2	A rolling programme should be developed by the Department of Health, HIQA and the HSE to deliver evidence-based service frameworks covering the major health conditions within the public healthcare system, similar to the National Service Frameworks model in the UK. Such frameworks should be reviewed periodically to encompass new evidence on effectiveness and performance.
R7.4	Evidence-based national standards should be developed, with multidisciplinary input, in both primary and secondary care settings, and for the transition between care settings.

Appendix E: Expert Advisory Group for version 1 of the NCEC Standards for Clinical Practice Guidance (2015)

Organisation / Division (nominated by)	Nominee
Clinical Effectiveness Unit, Department of Health	Dr Niamh O'Rourke (Chair)
HSE Quality Improvement Division (Dr Philip Crowley)	Ms Brid Boyce
HSE Mental Health Division (Ms Anne O'Connor)	Ms Margaret Brennan
HSE Quality Assurance Verification (QAV) Division (Mr Patrick Lynch)	Dr Edwina Dunne
Independent Hospital Association of Ireland (Ms Catherine Whelan)	Dr Stephen Frohlich
HSE Social Care Division (Mr Pat Healy)	Dr Siobhan Kennelly
HSE Clinical Strategy and Programmes Division (Dr Áine Carroll)	Ms Aveen Murray
HSE Acute Hospitals Division (Mr Liam Woods)	Ms Deirdre O'Keeffe
HSE Primary Care Division (Mr John Hennessy)	Ms Virginia Pye

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