



An Roinn Sláinte
Department of Health

How to develop a National Clinical Guideline

A manual for guideline developers



This publication aims to provide guidance and instruction to persons who are considering or planning to develop clinical guidelines for submission to the NCEC. This manual supersedes the 2013 publication.


For guideline development groups, it aims to provide a clear pathway for the development of evidence based clinical guidelines that are implementable in the Irish health services.

While every effort was made to ensure the weblinks are correct, they may over time change or expire.

Suggestions and feedback on this publication are always welcome and should be addressed to ncec@health.gov.ie


Key information is highlighted in this guide using the following colour scheme:

Links to useful resources



Here are supporting information and guidance documents, made easily accessible through weblinks where available.

NCEC procedure and tips



Here the NCEC’s four steps - screening, prioritisation, quality assurance and endorsement are explained. You will also find information about numerous tasks and actions the Guideline Development Group (GDG) need to plan for when developing a guideline and making submissions to the NCEC.

How to use this interactive pdf:

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Published by:
 The Department of Health
 Block 1, Miesian Plaza, 50 – 58 Lower Baggot Street, Dublin 2, D02 XW14
 Tel: (01) 6354000
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Foreword

This manual establishes a framework for guideline development in Ireland. The first edition was published in 2013. It was developed to support guideline development group members to prepare their guidelines and submit to the NCEC for prioritisation, quality assurance and endorsement by the Minister for Health as a National Clinical Effectiveness Committee (NCEC) National Clinical Guideline (NCG). The evidence base supporting guideline development internationally continues to evolve and NCEC processes have been refined and updated.

This second edition provides guidance on:

1. A recommended guideline methodology based on Grading of Recommendations Assessment, Development and Evaluation (GRADE).
2. How to plan, develop and submit a clinical guideline to the NCEC for prioritisation and quality assurance leading to Ministerial endorsement for implementation in the Irish health services.

The NCEC is committed to making guidance available that incorporates the most up-to-date guideline methodology and NCEC processes. During 2017, the NCEC agreed that GRADE is the best approach for future NCGs and this manual is an important enabler to achieving this. The NCEC acknowledge that the introduction of GRADE adds a degree of complexity to the guideline development process, often requiring support from GRADE experts. Provision of GRADE workshops and tailored training will also build capacity among guideline developers in Ireland. Recognising that the use of GRADE is new for guideline development in Ireland, a period of transition is expected. The NCEC will remain flexible to allow workable solutions for current and future guideline developers. Periodically, the NCEC will issue updated guidance.

The Guideline Methodology Subgroup was tasked by the NCEC to revise the 2013 manual and their work under the leadership of Professor Declan Devane is gratefully acknowledged (see appendix 3). To build on existing work in this space, to maximise efficiency and to minimise duplication, this manual adapts two international guideline development handbooks (listed 1 and 2 below) with explicit acknowledgements and permissions from the respective organisations. Adaptation in this context has included; reproduction of sections of text unaltered; and reproduction of sections of text modified to suit the Irish context.

Permissions received from:

1. The WHO permissions team, for the *WHO Handbook for Guideline Development* (2nd edition, 2014). In addition, permission was granted from Prof Holger Schünemann (c/o McMaster University, Canada) for *Chapter 9, Evidence assessment and Chapter 10, Developing recommendations*.
2. The WHO permissions team and the WHO Country Office in Estonia for *The Estonian Handbook for Guidelines Development* (2011).
3. IQ healthcare – for embedding a weblink to: *A tool for project management in guideline development*.
4. The G-I-N Adaptation Working Group to reproduce the figure “Summary of the ADAPTE process” from the *ADAPTE Manual and Resources Toolkit* (2009).
5. The AGREE Scientific Research Office for use of the *AGREE II instrument* and to embed weblinks to the AGREE Enterprise website.

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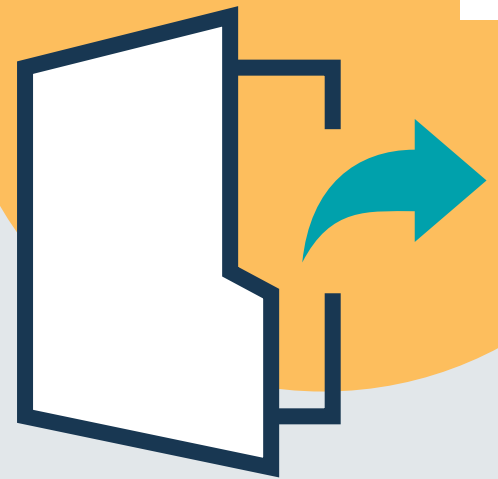
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List of abbreviations

BIA	Budget impact analysis
CEU	Clinical Effectiveness Unit
COI	Conflict of interest
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HIPE	Hospital Inpatient Enquiry
HIQA	Health Information and Quality Authority
HRB	Health Research Board
HSE	Health Service Executive
MDT	Multidisciplinary team
MeSH	Medical Subject Headings
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
NICE	National Institute for Health and Care Excellence
NPSO	National Patient Safety Office
PICO	Population, Intervention, Comparison and Outcomes
PIPOH	Population, Intervention, Professionals, Outcomes and Healthcare settings
RCT	Randomised controlled trial
QA	Quality Assurance
SIGN	Scottish Intercollegiate Guidelines Network

Introduction

The term '**clinical guideline**' has a number of synonyms that are used interchangeably. These include 'guideline', 'health guideline', 'clinical practice guideline', 'evidence-based guideline', 'evidence-based guidance' and 'guidance'.



For the purpose of consistency, the National Clinical Effectiveness Committee (NCEC) utilises the term 'clinical guideline' in its work with the following meaning:

Clinical guidelines 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. Clinical guidelines endorsed by the Minister will be titled 'NCEC National Clinical Guidelines'

(NCEC Framework for Endorsement of National Clinical Guidelines 2015, p. 2).

The National Standards for Safer Better Healthcare (HIQA 2012) highlight that evidence-based healthcare involves the integration of best available evidence from systematic research, healthcare professionals' knowledge and experience, and service users' individual values and preferences. Healthcare that is supported by best available evidence helps assure providers that they are delivering safe, high quality care.

NCEC National Clinical Guidelines (NCGs) provide robust evidence-based guidance to inform health care decisions in the Irish health system. The implementation of clinical guidelines can improve health outcomes for patients, reduce variation in practice and improve the quality of clinical decisions. NCEC NCGs endorsed by the Minister for Health are mandated for implementation in the Irish health system and their implementation is monitored through national and local guideline audits, the HSE Performance Assurance Reports, compliance with HIQAs National Standards for Safer Better Healthcare and through increased alignment with the clinical indemnity scheme.

Additional levers are coming on stream as part of the legislative programme of work of the National Patient Safety Office:

- The Patient Safety Licensing Bill, will introduce a regulatory system for acute hospitals both public and private, and high risk "designated activities" performed in other settings. Applicant service providers are expected to demonstrate how it plans to meet the regulatory requirements in relation to guidelines, clinical standards and audit. This ensures the provision of safe and effective care, a key element of the licensing framework. There will be specific reference to those policies, clinical standards, clinical guidelines and clinical audit processes endorsed by the Minister. Ministerial endorsement requires national implementation. Therefore, a hospital's statement of purpose could be expected to set out how the hospital will take into account the relevant NCEC National Clinical Guidelines (and National Clinical Audit) that are applicable to the services it is providing.

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Other legislation of note:

- The General Scheme of the Patient Safety Bill, approved by Government in July 2018. This new legislation provides for a number of patient safety priorities, including the use of clinical audit to improve patient care and outcomes, the mandatory open disclosure of serious patient safety incidents, the notification of reportable patient safety incidents to the appropriate Regulator, and the extension of HIQA's remit to private hospitals.

The NCEC Framework for Endorsement of National Clinical Guidelines (2015) describes in detail the 4 steps required in order for clinical guidelines to be endorsed by the Minister for Health as a National Clinical Guideline (figure 1). The framework details the roles and responsibilities of the NCEC and the Guideline Development Groups (GDGs), the prioritisation and quality criteria along with submission details. It is strongly recommended that this framework is read and considered by all parties planning to develop a clinical guideline for submission to the NCEC.

Every clinical guideline recommended to the Minister for Health for endorsement as an NCEC National Clinical Guideline must go through a number of steps. The term NCEC National Clinical Guideline is reserved for those that have successfully progressed through all steps of the Framework for Endorsement.

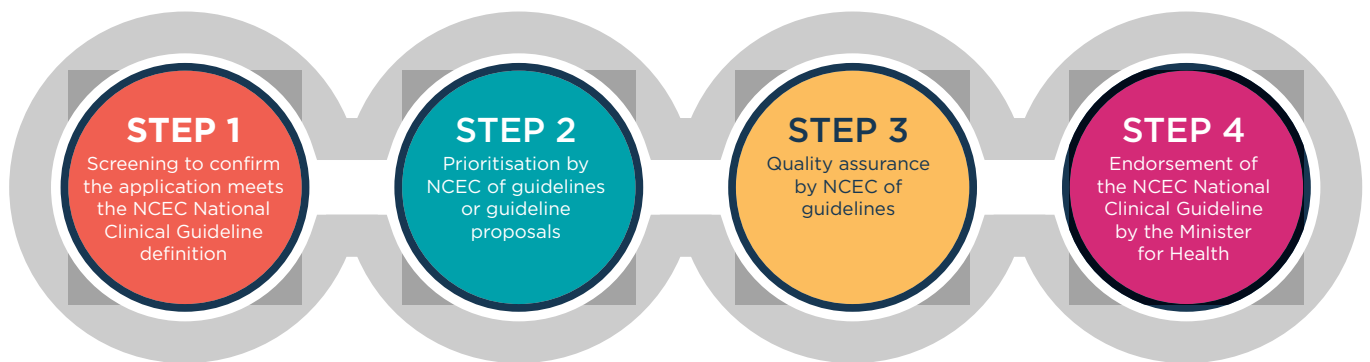


Figure 1: Steps 1-4 in the Framework for Endorsement of NCEC NCGs

➤
Links to useful resources

- [NCEC Framework for Endorsement of National Clinical Guidelines \(2015\)](#)
- [List of published NCEC National Clinical Guidelines](#)
- [List of clinical guidelines in development](#)
- [National Standards for Safer Better Healthcare \(HIQA 2012\)](#)
- NPSO's legislative programme of work [Webpage](#) - for up-to-date information on Patient Safety & Advocacy Policy

Planning a guideline

Before starting to develop a new guideline for the Irish health service, it is important to agree on its purpose, scope and specific objectives and then consider if developing a National Clinical Guideline is the best approach to meeting these needs.



Careful consideration of the issues raised in this chapter and efforts put into developing a thorough and reasoned planning proposal will reduce the time and resources expended on the guideline and will result in a superior, more useful final product. The scoping carried out as part of the planning stage will provide the foundation for the next steps. This is an iterative process and the scoping document may be refined further during subsequent steps in guideline development.

1.1 Is this guideline really needed?

Before starting to develop new guidelines for the Irish health service, it is important to agree on the objectives and desired outcome and to consider if a National Clinical Guideline is the best approach. Furthermore, it is important to ascertain whether a NCEC National Clinical Guideline is required or if a policy, procedure or protocol would be more appropriate.

The more preparation and consultation with key stakeholders at the planning stage, the more efficient the entire process, resulting in a high-quality, useful product (WHO 2014).

Some key questions to consider early include:

What purpose and audience does the guideline serve?

- What will the guideline achieve?
- What are the specific objectives of the guideline?
- Who is the target audience(s) (end-user i.e., those who will apply the guidelines)?
- Who are the recipients (patients and other individuals) whose health and well-being will be affected by the recommended interventions?
- What are the consequences of not producing the guideline?

When is the guideline needed?

- Why now?
- When is the guideline needed and how does this match with the projected timeline for guideline development?
- Is the guideline a response to a situation calling for urgent advice?

Chapter 1: Planning a guideline

Will the recommendations in the guideline be implemented?

- What existing programme of work or health service structure will lead guideline implementation? Can responsible persons/groups and or organisations be identified?
- The implementation period must align with the lifespan of the guideline (currently 3 years).
- What are the barriers and facilitators of implementing the guideline?
- What early input can be made to the HSE service planning and financial estimates process?

Additional considerations

- Are the necessary resources to develop a guideline available for the duration of the guideline development project?
- The sustainability of updating the guideline (every 3 years) needs to be factored in from the outset.
- What level of detail and format of dissemination will your target audience(s) find most useful?

What are the alternatives to NCEC National Clinical Guidelines?

In clinical practice, there are different types of guidance that vary in complexity and scope. For example, guidance can be a comprehensive clinical policy or a more specific clinical protocol or procedure (NCEC Standards for Clinical Practice Guidance, 2015).

1.2 Determining the guideline scope

As part of the preparatory work and before the clinical guideline is proposed for NCEC prioritisation, it is recommended that the scope of the clinical guideline, including overall aim and objectives is determined. Identifying the required impact of the guideline will assist in defining the scope. Scoping is the process of defining what the guideline will and will not include and sets the boundaries and establishes specifically what the group and the clinical guideline seeks to achieve. It is equally important to clarify what the guideline will not cover. The GDG Chair may consult with healthcare professionals and the wider stakeholder community including healthcare users and the public in order to assess values and preferences, clinical or policy needs.

Experience to date has shown that a narrow scope delivers a completed guideline in a timely manner that is implementable within the lifespan of the guideline (currently 3 years). To be practical, the available resources and timelines must be considered and so the GDG must carefully prioritise and focus the scope on areas of the patient pathway where variation occurs rather than the total patient pathway.

The clinical guideline scope should be prepared and set out clearly in a document. This scoping document will assist with the prioritisation process and for project planning for commissioned guidelines. The scoping document should include:

- The title of the proposed clinical guideline
- The areas of practice or policy to which the guideline applies
- Burden of clinical topic – Does the disease/condition/circumstance cause substantial burden to the population and/or the health system?
- Variability in practice – Is there evidence of variability between current practice and best practice?
- Potential for improved health - Is there evidence as to how the clinical guideline can lead to improved healthcare and/or health?
- The intervention or types of intervention to be included or excluded

Chapter 1: Planning a guideline

- The individuals/population (and settings) that will and will not be covered. Who are the relevant patients?
- Economic impact – What are the direct and indirect health costs of both the disease/ condition/circumstance and of implementing the guideline? Is there evidence to indicate that alternative interventions have been considered? Is there potential for cost avoidance/savings if the guideline is implemented? Is there research on cost effectiveness in the literature? What are the economic perspectives on the topic under consideration?
- The professionals whom it is expected will use the guideline and implement its recommendations in full in the Irish health services and how this may inform the membership of the GDG
- Clinical guideline implementation – Is it feasible to implement the guideline? The assessment of implementation readiness (need, fit, capacity to implement, implementation responsibility).

Based on the broad scope, it's useful to prepare:

- A list of draft potential healthcare questions using the PICO or PIPOH format. Note they can be refined again before a search protocol is finalised.
- A list of potentially important outcomes, both benefits and harms, that may result.

As part of the scoping exercise, it is recommended to explore international clinical guidelines, key systematic reviews, current ongoing research, economic papers, information on current practice including patient safety concerns and resources on the topic of interest. Consider also information and views from patients, service users and their families if available and concurrent work being carried out in other parts of the health service.

Librarians can advise and provide assistance in search and retrieval of published and unpublished literature on the topic. While there is no recommended maximum number of healthcare questions per clinical guideline, the larger the number of questions the longer timeframe required to complete the project. This may result in more complex development and implementation. The focus should be on priority elements of clinical care that need to be answered and where changes in practice or policy are required.

After initial drafting and consultation, it is recommended that the final scope is agreed and signed off by the GDG. The final scoping document is helpful as a reference document during the course of the project and can be used to provide background information to relevant stakeholders.

1.3 Proposing a topic and submitting a Notice of Intent to the NCEC

Step 1 of the NCEC Framework for Endorsement is screening (figure 2). Following initial planning and scoping, the next step is to propose a topic for an NCEC National Clinical Guideline. An NCEC Notice of Intent form must be completed and submitted. Submission of a Notice of Intent is an important step as it allows the CEU, on behalf of the NCEC, to identify the lead organisation and to identify if more than one group are working on or proposing to work on the same or similar guidelines. It also allows for planning and managing of multiple proposals and guidelines at various stages of development.

To prepare for this step, GDGs may contact the NCEC by email and a CEU staff member will respond and assist with queries and a meeting may be arranged. All Notices of Intent are screened to ensure that the proposed guideline meets the NCEC definition of a clinical guideline. Successful screening does not infer that the guideline will be prioritised by the NCEC. Screening and agreement of the guideline topic is important because it identifies the disease or condition, the patient population and the setting in which the clinical care will be delivered.

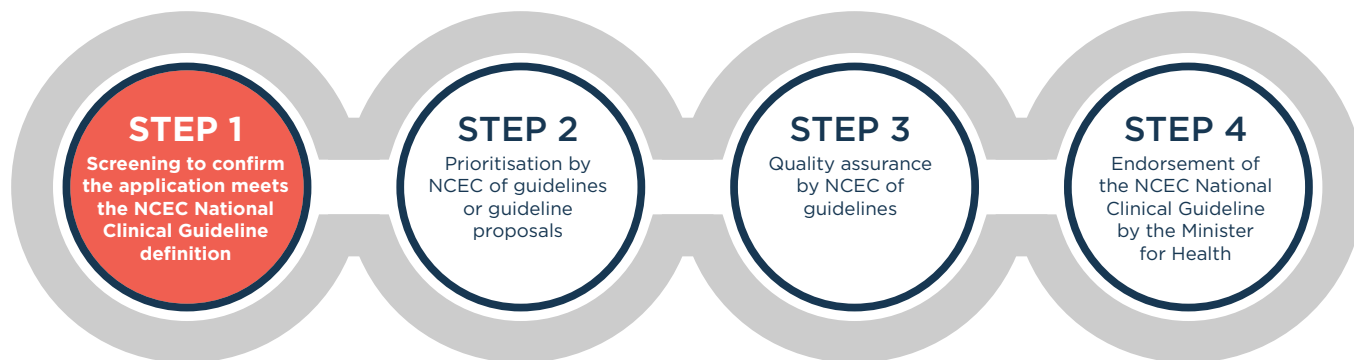


Figure 2: Step 1 on the Framework for Endorsement of NCEC NCGs

Links to useful resources



[NCEC Framework for Endorsement of National Clinical Guidelines \(2015\)](#)

[NCEC Notice of Intent Form - Look up - "Where to start?"](#)

[NCEC List of clinical guidelines in development](#)

HSE Librarian [referral form](#) if relevant

NCEC [Standards for Clinical Practice Guidance \(PPPGs\) \(2015\)](#)

HSE [National Framework](#) for developing policies, procedures, protocols and guidelines (PPPGs)

NCEC procedure and tips



- 1 Guideline developers are invited to contact CEU staff by email: ncec@health.gov.ie
- 2 After the screening exercise, the CEU will contact the Chair or guideline lead and inform them of the decision.
- 3 Following successful screening, the NCEC list of clinical guidelines in development on the website will be updated.
- 4 Guideline developers must prepare a scoping document (see section 1.2).
- 5 Consideration should be given to alignment with the other guidelines in development and/or published NCEC National Clinical Guidelines on related topics.
- 6 It is strongly recommended that the NCEC Prioritisation and QA Criteria are reviewed (appendix 1 and 2).
- 7 In keeping with the [Connecting for Life Strategy and Implementation Plan 2017-2020](#), GDGs are asked to make reference to mental health, suicide and self-harm reduction as appropriate when developing clinical guidelines.

Contributors and their role in guideline development



Guideline development is a complex process and it is essential that the required clinical, methodological, economic, management and administrative skills are available to produce a robust evidence based clinical guideline in the planned timeframe. The GDG should ensure clarity of the roles and responsibilities of their group as well as reporting paths to any oversight committee. There are no rules about the size of the group, but it must include representatives with relevant expertise and experience and a minimum of two public involvement representatives. Other stakeholders who are not represented on the GDG may have input to the clinical guideline development process during the preparatory scoping exercise and later during the consultation and or implementation phases.

It may be effective to establish subgroups to undertake aspects of clinical guideline development, such as searching for, and appraising clinical guidelines or leading on the guideline implementation plan. It is also reasonable to invite professionals with expertise required in one specific area of the clinical guideline to comment on specific sections or attend meetings as required.

2.1 Stakeholder analysis

Stakeholders are people who have a common interest in improving health services. This includes persons responsible for delivering and those who receive services related to the clinical guideline. It is important, therefore, that the whole system is mapped to ensure that all those who have a contribution to make are included in the guideline development and implementation process at appropriate stages. All the relevant connections should be identified and an assessment of impact in different areas should be taken into account. The stakeholders' analysis may be useful at later stages for communication purposes around consultation and dissemination post guideline publication.

Key stakeholders that may be included are:

- patients, carers, the public and their representative groups including voluntary organisations/groups and charities
- healthcare professionals, ensuring primary, secondary and tertiary care, as well as local and national organisations are represented where relevant
- healthcare managers (at Hospital Group, CHO or hospital level), responsible for organisations and budgets, ensuring primary, secondary and tertiary care, as well as local and national organisations are represented if relevant
- voluntary organisations and charities
- education providers
- government e.g. Department of Health
- regulators e.g. HIQA, Mental Health Commission and regulators of individual professions

Chapter 2: Contributors and their role in guideline development

- international organisations who may be in the process or have completed relevant clinical guidelines
- others as appropriate.

2.2 Composition of the GDG

The Chair

There are a variety of ways in which the Chair of the GDG may emerge, i.e. nomination, election or appointment. The Chair should have no relevant conflicts of interest (if possible) and have expertise in chairing groups. A Vice-chair should also be identified to stand in if the chair is absent and to share in the Chair's tasks and responsibilities. Another acceptable option is to have two Co-chairs with equal responsibilities and complementary expertise and perspectives.

Clinical expert representatives

Clinical expert representatives are drawn from professional groups with direct experience in managing the condition or problem across the patient pathway addressed by the guideline. They also have a role in implementing the new recommendations, e.g. members of the full multidisciplinary team, members of clinical specialities with an interest in the clinical topic such as general practitioners.

Methodology expertise

Ideally, at least one of the members should have expertise in the processes and methods for developing evidence-based guidelines. The guideline methodologist should be an expert in evidence synthesis (incl. systematic reviews), GRADE, and the translation of evidence into recommendations. The NCEC acknowledge that the number of experts in Ireland is small and although capacity is growing, it recognises that many GDGs depend on other supports. If possible, methodologists should be identified early in the guideline process so that they can participate in planning, scoping and the development of healthcare questions.

Senior management

Representatives from the relevant services (e.g. HSE Divisions, Hospital Groups, or Community Healthcare Organisations). Local and national representation should be considered.

Research, information and economic expertise

Members may be chosen from disciplines such as librarians, Public Health specialists, epidemiology, biostatistics, healthcare research, bioethics, health economics, health technology and information sciences.

Project management and administrative support

This is essential to ensure the complex process of guideline development is adequately supported and resourced.

Implementation lead

While the implementation plan is the responsibility of the full GDG, a nominated lead person is recommended to ensure that implementation is planned from the outset.

Representatives of the people affected by the recommendations

The NCEC quality assurance criteria require that there are at least two public involvement representatives as members of the GDG. Public involvement representatives have different perspectives on healthcare processes, priorities, and outcomes from those of healthcare professionals, managers and policy makers. They can identify issues that may be overlooked, can highlight areas where their perspective differs from the views of healthcare professionals, and can ensure that the guideline addresses key issues of concern to them.

Engaging public involvement representatives in groups developing guidelines also helps to ensure that:

- key questions are informed by issues that matter to them
- outcome measures they think are important for each key question are identified
- plans for consultation are informed by the perspectives of service users
- areas where their preferences and choices may need to be acknowledged in the guideline are identified
- the clinical guideline is clearly and sensitively worded
- patient information resources are clear and easy to understand.

There are different methods of engaging public involvement representatives and each method will have its own strengths and weaknesses. Utilisation of a variety of methods to engage public representatives is encouraged. See the link in useful resources for the NCEC Public Involvement Framework (2018) for more information.

2.3 Managing an effective GDG

The role of the Chair/Co-chairs and Vice-chair

The Chair plays an essential role in managing the outcome and processes of the GDG. He/she has a key clinical leadership role in the total process from guideline development to successful implementation. Together, the Chair and programme manager/project officer form the core of a successful project.

The Chair's responsibilities are to:

- manage declarations of interest and conflict when it arises
- agree terms of reference and membership ensuring broad stakeholder involvement
- prepare and conform to the agreed project plan including agreed timelines (using a standard project management approach, where possible)
- encourage and lead the project activities as derived from the project plan. This can be achieved by regularly stating the results and emphasising the benefits of implementation of the guideline respecting the diverse stakeholder perspectives
- ensure the guideline is developed using a robust methodology and that each of the stages of the clinical guideline path are addressed
- ensure engagement of all group members in the healthcare question development
- sign off the final drafts and submit to the NCEC for prioritisation and for quality assurance using the NCEC templates and checklists in line with the guidance for submission and the timeframes required.

During meetings, the Chair must ensure that GDG members can present their viewpoints and that all relevant issues are discussed in a respectful and efficient manner. In addition, the Chair should:

- chair the meeting in line with the procedures set out in the Terms of Reference for the GDG
- manage procedures for declaring and managing conflicts of interest in line with the NCEC policy, including providing the opportunity for GDG members to verbally declare any real and/or potential conflicts of interest at the start of each meeting
- set and circulate the agenda of each meeting to members
- establish meeting rules (if appropriate); this may include methods of reaching consensus, voting rights and/ or majority views
- encourage broad participation from members in discussion around the agenda items
- identify and assign tasks including the public representatives where appropriate
- provide additional support and guidance to the two public representatives and other members who may be new to the guideline development process
- identify and oversee the progress of specific subgroups.

After each meeting, the Chair should:

- end each meeting with a summary of decisions and actions
- agree next meeting date (if not already known)
- liaise with an overseeing body/committee as relevant
- liaise with CEU staff and others as appropriate.

The role of guideline development group members is to:

- provide input into the scope of the guideline
- assist with developing the healthcare questions in PICO format
- prioritise the questions
- agree the approach to guideline development i.e. whether to adapt, adopt or develop a new clinical guideline
- agree timelines for meetings and the clinical guideline development process
- review existing policies, guidelines, national and international evidence and best practices, relevant scientific and clinical expert opinion pertaining to the clinical guideline area
- choose and rank priority outcomes that will guide the evidence reviews and focus the recommendations
- examine the Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence profiles or other assessments of the quality of the evidence used to inform the recommendations and provide input
- interpret the evidence, with explicit consideration of the overall balance of benefits and harms
- formulate recommendations taking into account, in a transparent manner, benefits, harms, values and preferences, feasibility, equity, acceptability, resource requirements and other factors, as appropriate; and consult with relevant interested parties and the public
- review and approve the final guideline document before submission to the NCEC
- promote understanding and knowledge of the guideline amongst colleagues and within the healthcare services.

Knowledge and skills of guideline development group members:

- competence in the clinical topic
- competence in one or more stages of the clinical guideline path e.g. implementation. Involvement of a librarian/information specialist, economic expert and researcher is invaluable at key stages of the guideline
- project management skills – ideally there should be a designated project manager to support the guideline development group in identifying and achieving the aims of the project
- interest and enthusiasm for improving healthcare services
- time to commit to the work of the group (e.g. attending meetings, background reading, consultation, reviewing and drafting the guideline)
- willingness to feed in the views of staff/service users/carer groups not represented on the guideline group
- ability to be objective with good communication and team working skills
- willingness to share learning and experience of guideline development.



Links to useful resources

NCEC [Framework for Public Involvement](#) in Clinical Effectiveness Processes (2018)

NCEC [Tools](#) for Public Involvement

[NCEC Resources & learning](#) – The NPSO Learning Zone is a web-based learning platform that hosts a number of resources including the e-learning course ‘Involving the Public when developing a guideline or audit’.



NCEC procedure and tips

- 1 It is recommended to carry out a stakeholder analysis to identify the key contributors and to select the membership of the guideline development group.
- 2 Establish a GDG and ensure clarity in roles and responsibilities to manage the expectations of all members effectively including the two public involvement representatives.
- 3 A terms of reference document should be prepared and agreed before commencement of meetings by the GDG. This will be published in the final guideline to provide information on the meeting process and the governance arrangements.
- 3 All members of GDGs are strongly encouraged to complete the E-learning module: *Involving the public when developing a guideline or audit*.
- 4 It is strongly recommended that the NCEC Prioritisation and QA Criteria on GDG membership and stakeholders are reviewed and are adhered to as appropriate (appendix 1 and 2).

2.4 Managing conflicts of interest

In 2016, the NCEC approved a revised Conflict of Interest Policy and Declarations of Interest Form. As a committee of the Department of Health, the NCEC is expected to maintain high standards of probity in the way it conducts its activities. The NCEC is committed to operating in an open and transparent manner and includes the management of all real and potential conflicts of interest of members, and others involved in National Clinical Guidelines and National Clinical Audit: development, prioritisation and quality assurance. The policy extends to members of the GDG and external reviewers also.

Minimising conflicts of interest in guideline development and ensuring appropriate management is critical to ensuring public and healthcare professionals confidence in the clinical guideline. Conflicts of interest may arise if members of the guideline development group have financial or academic interests in, or work closely with pharmaceutical companies, medical equipment or other commercial companies. These relationships may have an influence on GDG members. All potential conflicts of interest, including those beyond the commercial sector, should be declared e.g. involvement in a professional group that wishes to lead or take over the provision of a particular service.

Links to useful resources



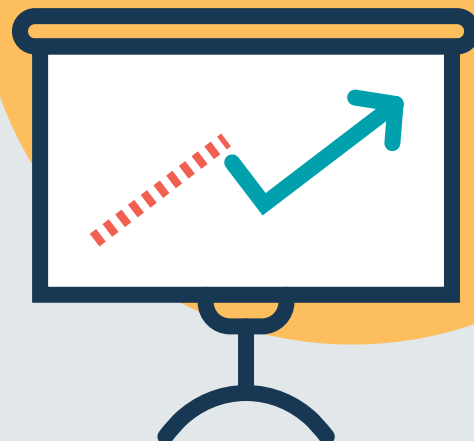
[NCEC Conflict of Interest policy](#) and [declaration of interest form](#)

NCEC procedure and tips



- 1 Every member of the GDG must review and comply with the NCEC Conflicts of Interest policy. A full disclosure/declaration of interests must be made using the declaration of interest form on appointment and annually thereafter.
- 2 Copies of all declarations of interest forms must be included as part of the guideline submission to the NCEC for quality assurance. These will be retained on permanent record in the Department of Health.
- 3 A statement of declared interests (including none) must be made in the published guideline and details of how any declared conflicts were managed (as relevant).
- 4 It is strongly recommended that the NCEC Prioritisation and QA Criteria on conflicts of interest are reviewed and are adhered to as appropriate (appendix 1 and 2).

Project management and support



3.1 Project planning

It is important to be realistic with the number of healthcare questions the guideline will address and the planned timeframe. It is estimated that a high quality NCEC National Clinical Guideline may take up to two years to produce (figure 3); however, timelines are often dependent on the urgency, the available resources, the scope and number of questions within the guideline. A good understanding and use of project management principles and tools will assist to complete on schedule. A useful tool is a simple plan (on Excel or other) that flags key deliverables (milestones) dates and responsible person(s). The GDG must factor in scheduled meeting dates of the NCEC. The NCEC meets 4-5 times throughout the year and these dates are available from the liaison CEU officer and are listed on the Department of Health website.

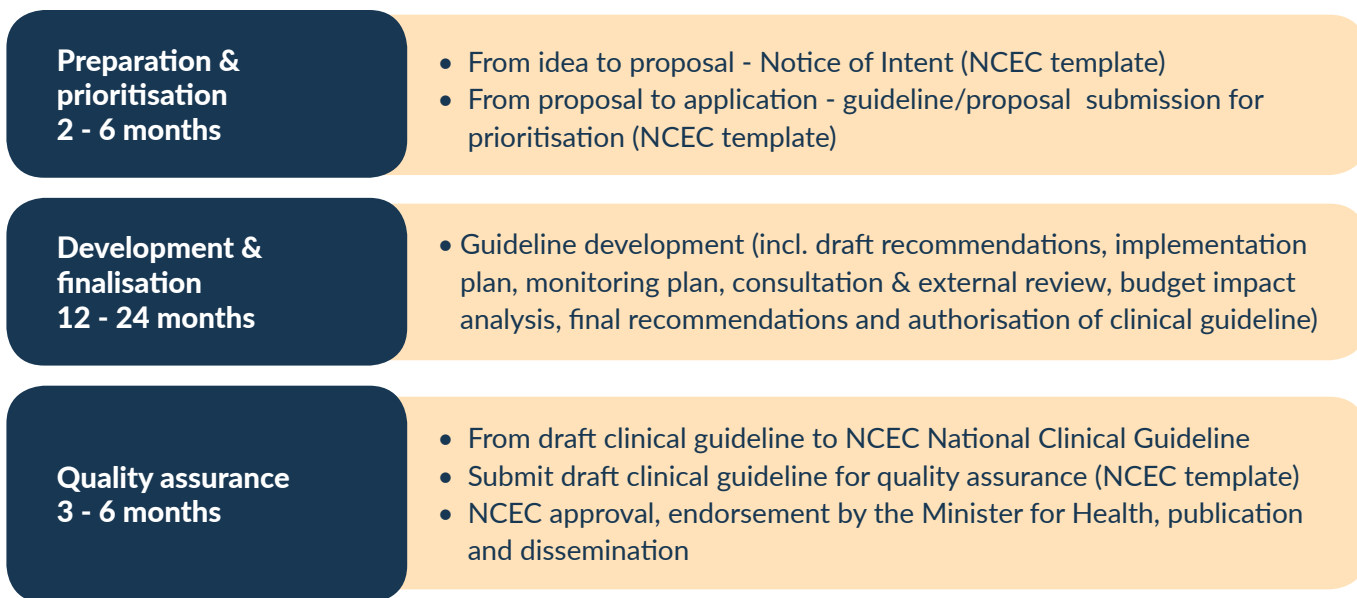


Figure 3: The phases and timelines in the development of NCEC NCGs

Resources. It is important that the resources required to complete the development of the clinical guideline are planned to ensure that the process is as efficient and sustainable as possible. These resources include suitably qualified and multidisciplinary staff, their expertise and time, project management and administrative support, evidence/information searching and retrieving, meeting rooms, printing, conducting or commissioning research if required. The GDG should examine the expertise and resources available to them within the GDG and the wider healthcare system and leverage these early on.

Identifying the resources required, utilising available resources where possible and including others with expertise in the service planning or other relevant processes to access resources can increase the likelihood of timely completion of a high-quality guideline. All relevant organisational stakeholders should be aware of the guideline in development from a service planning and implementation perspective. This includes services not directly affected by the guideline topic, but which may have a knock-on effect e.g. guidelines on screening or diagnosis will have an effect on treatment services.

The source of funding must be documented in the guideline, whether it be internal to the organisation or from an external funding body. The guideline content must not have been influenced by the views of the funding body.

Document control. A robust document control process is essential to manage the guideline during development. To get the most out of the document control procedure, it should communicate the steps necessary to ensure that staff and other users of the organisation's documentation understand what they must do to manage that information effectively and efficiently. Good document control procedure must define:

- How documents are approved prior to use e.g. signed-off final versions
- How to update and re-approve amended documents
- How to identify changes e.g. by date or issue number
- How to ensure that documents are available where and when they are needed
- How to control documents of external origin, if required
- How to prevent the inadvertent use of out of date documents.

Good document control principles

- All clinical guideline draft documents can be easily controlled by using a standard file name with the essential components, e.g. Guideline name, draft version and date (Atrial fibrillation_draft V0.1_Feb22.18).
- When the file name is agreed, it can be added to the footer of the draft guideline during development.
- Every time a draft clinical guideline is changed the version status increments by 0.1. Whole numbers are usually reserved for when the document is shared with persons/bodies external to the group, such as draft for consultation, international reviewers or the NCEC.
- Use of a watermark "DRAFT" can also be considered.
- Clinical guideline documents should not be changed without the approval of the designated person in the GDG.
- Clinical and economic papers, important correspondence, permissions, conflicts of interest forms etc and all other supporting resources should be filed logically in a repository and retained by the GDG, so they are available later if needed.

3.2 Supports from the CEU

Clinical Effectiveness Officer

The GDG will receive support from a member of the CEU team. The CEU is part of the National Patient Safety Office in the Department of Health. Their role is to provide information and guidance on all aspects of the submission process to the NCEC for prioritisation and quality assurance. They will engage and meet GDGs as required during the guideline development process and this assistance will be tailored to meet the needs of the group. It's important to note that they are not members of the guideline group. The CEU provides regular updates to the NCEC on all guidelines in development.

HRB-Collaboration in Ireland for Clinical Effectiveness Reviews (HRB-CICER)

In 2016, the Department of Health requested the Health Research Board (HRB) to fund a dedicated multidisciplinary research group to support the activities of the NCEC. Called HRB-CICER, a five-year contract (2017 to 2022) was awarded following a competitive process to the Principal Investigator Dr Máirín Ryan of the Health Information and Quality Authority (HIQA). The HRB-CICER team comprises a dedicated multidisciplinary research team (including expertise in health economics, qualitative and quantitative research methods and epidemiology) supported by staff from the Health Technology Assessment (HTA) team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodology experts.

HRB-CICER provides independent scientific support to GDGs tailored according to their specific needs. The main role of the HRB-CICER team is to undertake systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines and to estimate the budget impact of implementing the guidelines. Additional support can be provided by HRB-CICER and includes: providing tailored training sessions and working closely with the GDGs to develop clinical questions and search strategies; performing systematic reviews of international clinical guidelines; supporting the assessment of their suitability for adaption to Ireland and assisting in the development of evidence-based recommendations.

HRB-CICER operates under an executive committee and its annual work plan is agreed with the CEU. Access to the HRB-CICER team is coordinated through the CEU and is only considered for NCEC prioritised clinical guidelines (and clinical audit). The range of supports required by the GDG will be assessed, prioritised and agreed by the executive committee according to capacity and work schedule of HRB-CICER for the coming year.

Training resources and tools and templates

There are multiple tools and templates and links to useful resources included as embedded weblinks in the relevant sections of this guide. In addition, the NPSO Learning Zone is a free open access resource for GDGs and persons considering guideline development. Self-registration on the learning zone is required to access the full suite of learning materials.

Feedback reports from NCEC

When guidelines are considered by members of the NCEC during the steps of prioritisation and quality assurance, detailed reports are prepared. These reports are shared with the GDG and offer general guidance and specific instruction regarding guideline development.

Links to useful resources



[Tool for project management in guideline development](#) (Dutch with English language option, provided with permission from IQhealthcare)

Email the CEU team at ncec@health.gov.ie

[NCEC website](#)

NPSO Learning Zone: <http://health.gov.ie/national-patient-safety-office/ncec/resources-and-learning/>

Submitting a guideline for NCEC prioritisation



Step 2 of the NCEC Framework for Endorsement is prioritisation (figure 4). In 2014, the NCEC developed a prioritisation process to assist in identifying key topics for potential NCEC National Clinical Guidelines in the Irish healthcare system. The development of the NCEC prioritisation process was informed by international literature, Irish requirements, NCEC members' considerations and a public consultation. In March 2015, this process was updated, and the resulting prioritisation process provides the NCEC and guideline developers with a transparent prioritisation tool.

The NCEC's prioritisation criteria for clinical guidelines are shown in appendix 1. The seven criteria for prioritisation are:

- Patient safety issue
- Burden of clinical topic
- Evidence analysis
- Economic impact
- Variability in practice
- Potential for addressing health issues
- Clinical guideline implementation.

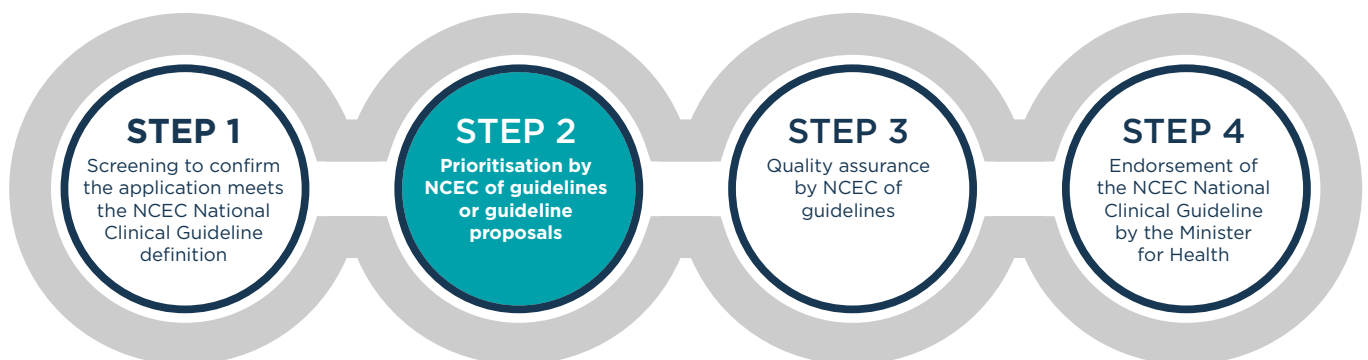


Figure 4: Step 2 on the Framework for endorsement of NCEC NCGs

Chapter 4: Submitting a guideline for NCEC prioritisation



Links to useful resources

[NCEC Prioritisation Process \(2015\)](#)

[NCEC List of guidelines in development](#)

[NCEC National Clinical Guideline Proposal - Template for prioritisation](#)



NCEC procedure and tips

- 1 In accordance with the NCEC prioritisation process, a comprehensive clinical guideline proposal must be prepared using the correct template. The content of the clinical guideline proposal must address all seven prioritisation criteria (see appendix 1).
- 2 In limited cases, a draft clinical guideline can be submitted to undergo prioritisation, but this is the exception rather than the rule. The proposal template is designed to capture all information necessary for the prioritisation exercise. Where a draft guideline is used, it should be checked to ensure information on all criteria is included. The intended guideline development approach should also be included.
- 3 Planning for implementation at an early stage of guideline development will enhance success. It is recommended to identify an implementation lead on the GDG from the beginning. See chapter 6 for more information on the NCEC Implementation Guide and Toolkit and the required Implementation Plan. It may be useful to start developing a logic model at this stage.
- 4 It is recommended that good quality and valid data (e.g. HIPE and others) is used in appropriate sections (e.g. burden of clinical topic) to inform both notices of intent and submissions for prioritisation.
- 5 Following submission, the proposal (or in limited cases a draft clinical guideline) will be assessed by a team of appraisers appointed by the CEU. Each member of the appraisal team completes an individual assessment that is then collated into a composite prioritisation report. A meeting may be held to discuss the assessments and to agree the final prioritisation report.
- 6 The NCEC will consider the prioritisation report at their next meeting.
- 7 The clinical guideline proposal (or in limited cases the draft clinical guideline) must achieve sufficiently high scores across all seven criteria to be prioritised by the committee and be accepted on the NCEC programme of clinical guideline development. The possible outcomes are:
 - a) The clinical guideline proposal (or draft clinical guideline) is successfully prioritised and will be listed on the NCEC schedule of clinical guidelines.
 - b) The clinical guideline proposal (or draft clinical guideline) does not score highly enough against the prioritisation criteria to progress. The NCEC will advise which criteria are not adequately addressed and offer a meeting with the GDG.
- 8 After the appraisal and committee decision, the NCEC Chair will write to the GDG Chair and will refer to areas for review and amendment as relevant. This information, in particular items listed as “key recommendations/amendments required”, must be actioned to assist with the further development and completion of the clinical guideline. A copy of the prioritisation report will also be sent.
- 9 Following successful prioritisation, the NCEC list of clinical guidelines in development on the website will be updated. The GDG may proceed with completion of the clinical guideline and prepare for NCEC quality assurance.

Developing a clinical guideline



GDGs must agree on the approach to be taken to develop their clinical guideline. The most common approaches are (1) adopting an existing guideline; (2) adapting an existing guideline; (3) creating a new clinical guideline (de novo); or (4) a combination of these approaches. GDGs will need to select the approach best suited to address their clinical needs while considering the availability of existing guidance, resources and time available.

Adoption. To adopt a guideline without modification from elsewhere, the group must accept as a whole the external guideline, after its quality, currency and content have been considered (Graham and Harrison 2005). Note: as the Irish healthcare service is different to other countries, the NCEC considers that adopting a complete guideline in its entirety is unlikely to suit the Irish context. However, certain aspects within a guideline may be applicable and adopted following appraisal and relevant permissions.

Adaptation. Adaptation is defined as *“the systematic approach to considering the use and/or modification of (a) guideline(s) produced in one cultural and organizational setting for application in a different context”* (The ADAPTE Collaboration 2009, p. 9).

It is an option to gain time through the adaptation of existing guidelines that are then modified to meet the needs, priorities, legislation, policies and resources of a targeted setting. The ADAPTE process is shown in figure 5. Adapted guidelines should fulfil the criteria for relevance, generalisability and applicability in the Irish setting. Permissions must be obtained in advance of any work commencing and note that a fee may be levied by the guideline authors. It is not the aim of this manual to explain this approach, ADAPTE resources can be found in the G-I-N website.

The ADAPTE Collaboration has developed a manual and resource toolkit to promote the development and use of guidelines through the adaptation of existing guidelines (The ADAPTE Collaboration 2009).

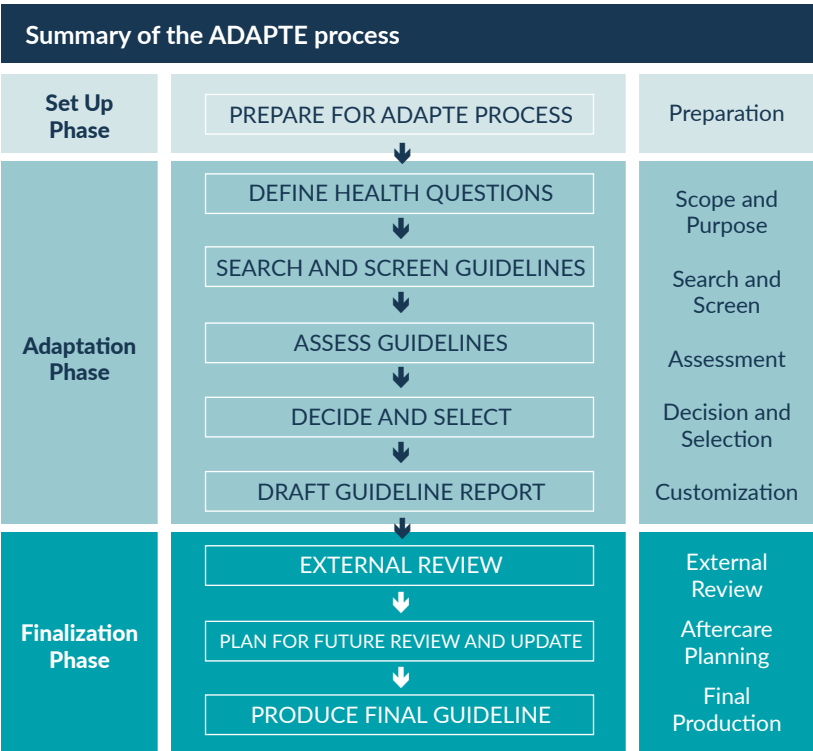


Figure 5: Summary of the ADAPTE process (reproduced with permission from the G-I-N Adaptation Working Group)

Chapter 5: Developing a clinical guideline

Creating a new guideline (de novo). Developing a new clinical guideline in entirety should only be undertaken if an existing guideline of good quality cannot be identified and if sufficient resources, including time and expertise, are available. Where an existing guideline recommendation is out of date due to more recent or more robust evidence becoming available, then specific questions within the clinical guideline may be answered de novo.

Contextualisation of NICE Clinical Guidelines. In 2017, the NCEC and the UK National Institute for Health and Care Excellence (NICE) embarked on a guideline contextualisation pilot. The NCEC agreed to proceed to pilot the contextualisation process with one guideline in 2017/18 and to monitor and evaluate over the lifetime of the project. Whilst remaining true to many of the underlying principles of the ADAPTE process, the NICE contextualisation approach proposes a pragmatic process for guideline adaptation. A useful definition of NICE contextualisation is “the process of changing the UK NICE Guideline recommendations for the UK population area to be applicable to the Republic of Ireland area.”

Its key characteristics include:

- Restricting consideration of relevant guidelines to the NICE library, thereby bypassing a number of early stages of the ADAPTE process;
- Resources are not spent on searching and screening of guidelines, however, a licence fee and costs for service applies;
- As the process for NICE guideline development has been NICE accredited (using AGREE assessment criteria), there is assurance that guidelines have undergone a robust quality assessment and are up-to-date (screened for update every 2 years).

Readers should note that at the time of printing, the NCEC contextualisation pilot is undergoing an evaluation. The NCEC is expected to consider the evaluation report in 2019 and this section will be updated accordingly.

Links to useful resources



Guideline Adaptation - [A Resource Toolkit](#) (The ADAPTE Collaboration, 2009) from the G-I-N website

[GIN-McMaster Guideline Development Checklist](#) - a publicly available and interactive resource from partnership between the Guidelines International Network (G-I-N) and McMaster University

Higgins JPT, Green S (editors). [Cochrane Handbook for Systematic Reviews of Interventions](#) Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011

NCEC procedure and tips



- 1 It is strongly recommended strongly that the NCEC Prioritisation and QA Criteria on guideline methodology are reviewed and are adhered to as appropriate (appendix 1 and 2).
- 2 For commissioned guidelines, all systematic reviews must be registered with the international database [PROSPERO](#). The NCEC strongly suggest that systematic literature reviews for all non-commissioned guidelines would also be registered.

Chapter 5: Developing a clinical guideline

5.1 Formulate the guideline questions

To identify the evidence required to address the topic, it is essential to define one or more healthcare questions that the guideline will address. Each question forms the basis of the search for the evidence that will underpin the recommendations. Because these questions drive the evidence search and form the basis of the recommendations, care should be given to ensure they are clear and focussed.

Clear, focussed questions have greater potential to lead to clear, focussed clinical guideline recommendations. Broad questions will lead to a comprehensive summary of a larger body of evidence and more generalisable findings. On the other hand, a narrow question may be easier to manage, but the evidence may be sparse and the findings less generalisable (WHO 2014).

Questions should be framed in a manner that facilitates a systematic search of the literature. The PICO and PIPOH formats (see below) are useful ways to identify inclusion and exclusion criteria for the body of evidence and for formulating recommendations. The format used should be detailed in the final guideline. The support of an information specialist or guideline or evidence synthesis methodologist and a subject matter expert at an early stage, can help in framing questions.

The PICO items are:

Population	What group or population is targeted by the intervention under consideration? Are there subgroups that need to be considered?
Intervention	What intervention(s) or diagnostic test of interest is under consideration?
Comparator	What alternative(s) to the intervention are being considered? E.g. other interventions or usual care/standard practice?
Outcome	What are the outcomes that matter the most to the patients and populations of the intervention under consideration in the guideline? Outcomes should be considered including patient-centred outcomes, system outcomes and/or public health outcomes? Include both the benefits and harms.

The PIPOH items are:

Population	What group or population is targeted by the intervention under consideration? Are there subgroups that need to be considered?
Intervention	What intervention(s) or diagnostic test of interest is under consideration?
Professional	Who are the professionals targeted in the guideline?
Outcome	What are the outcomes that matter the most to the patients and populations of the intervention under consideration in the guideline? Outcomes should be considered including patient-centred outcomes, system outcomes and/or public health outcomes? Include both the benefits and harms.
Healthcare setting	What is the healthcare setting and context in which the guideline is to be implemented?

Chapter 5: Developing a clinical guideline

The number of questions for a guideline varies and will depend on the complexity and the breadth of the scope. To be practical, the available resources and timeline must be considered seriously. **The GDG must therefore review and prioritise questions to enable completion of the clinical guideline in a timely manner and within realistic implementation parameters.** It is recommended that the GDG generates an initial list of questions based on the agreed scope of the guideline and then review the list to prioritise the questions and the important critical clinical outcomes that will be used to formulate the guideline recommendations.

Selecting outcomes. Selecting the most important outcome(s) is critical in producing a useful guideline. It is widely accepted that different individuals, groups and subgroups can attach different values to an outcome. It is essential to seek the views of all members of the GDG (which should include the public, healthcare professionals, policy makers and health service managers) and wider stakeholders (as appropriate) to identify key outcomes (benefits and harms) that need to be considered.

The most important outcomes should be identified. Generally, no more than seven outcomes (both beneficial and harmful) considered important or critical to the formulation of the recommendations should be selected (Guyatt et al 2013). Too many outcomes can make it difficult to compare across outcomes when balancing the overall benefits and harms of an intervention (WHO 2014).

5.2 Search methodology

NCEC guideline recommendations must be based on the best available evidence. All relevant evidence should be identified, synthesised and presented in a comprehensive and unbiased manner. Therefore, recommendations GDGs make in NCEC guidelines should be based on a systematic review of the evidence, which has been guided by the healthcare questions under consideration.

The Cochrane Collaboration defines a systematic review as *“a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to extract and analyse data from the studies that are included in the review”* (Higgins and Green 2011). If conducted properly, systematic reviews reduce the risk of bias and improve the reliability and accuracy of conclusions based on evidence (WHO 2014).

Based on the healthcare question(s), the next step is to develop a search strategy. The search strategy should be documented explicitly in order that it can be replicated (and will be needed for guideline updating). The dates of the search should be documented clearly. This step is resource intensive and when deciding on the most appropriate search strategy a balance is needed between complexity of the topic and risk of excluding studies. The PICO and/or PIPOH formats discussed earlier can be used to structure a search strategy.

It is practical and efficient to use reviews and recommendations from existing guidelines as the basis for NCEC guideline development and develop recommendations de novo where necessary. Therefore, the hierarchy of sources of evidence to inform NCEC guidance is:

- recommendations developed from published high quality, evidence-based clinical guidelines that were created by independent national authorities (e.g. NICE, SIGN)
- recommendations developed from published clinical guidelines that were created by specialty societies, and that follow internationally-recognised standards of best practice for guideline development and adequate descriptions of the processes used to manage conflicts of interest where appropriate
- recommendations developed from existing systematic reviews
- recommendations developed from de novo systematic reviews.

Chapter 5: Developing a clinical guideline

It is anticipated that from time to time, guideline recommendations may be required when there is truly no high-quality evidence to support a decision. In these situations, the GDG will need to document the reasons for developing the recommendation and the basis for their judgement¹. Such a recommendation may also be the basis for a proposal for research (WHO 2011).

5.2.1 Retrieving and assessing existing guidelines

The initial search for existing guidelines should be broad and without limitation, as guidelines can be difficult to find through electronic citation databases (WHO 2011).

The following sources, in addition to Medline should be searched:

- the US National Guideline Clearinghouse
- the database of the Guidelines International Network (GIN)
- websites of guideline-producing agencies (see resources below)
- websites of specialist medical societies relevant to the topic and scope of the proposed guidelines.

Links to selected guideline resources



The [NPSO Learning Zone](#) - has materials on literature searching and appraisal

Agency for Healthcare Research and Quality ([AHRQ](#)) National Guideline Clearing House

Canadian Agency for Drugs and Technologies in Health ([CADTH](#))

Guidelines International Network (GIN) - [website](#)

Scottish Intercollegiate Guidelines Network (SIGN) - [website](#)

National Institute for Health and Care Excellence (NICE) - [website](#)

Cochrane - [website](#) for repository of high-quality, relevant, up-to-date systematic reviews and other synthesised research evidence to inform health decision making.

AGREE Enterprise - [website](#) The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument was developed to address the issue of variability in the quality of practice guidelines.

World Health Organization Guidelines - [website](#)

The search strategy used should be documented and should specify:

- the details of the sources (databases, websites etc.) searched
- the details of each strategy used, specifying the date on which the search was conducted and/or updated (this description must be included in the final guideline).
- The citation list resulting from the search strategy should be screened to exclude obviously irrelevant publications. Potentially relevant citations should be retrieved as abstracts, if possible, and then further screening should be undertaken to identify possible guideline documents. These should then be retrieved in full text.

¹Avoid using unsystematically gathered, potentially biased beliefs and opinions. Instead obtain observations from GDG members and/or other stakeholders systematically.

Chapter 5: Developing a clinical guideline

Relevant guidelines should then be assessed for the following aspects:

- Are the guidelines based on explicit use of evidence?
 - ✓ If not, they should not be used.
 - ✓ If they are evidence based, are evidence summaries (e.g., GRADE tables, summary of findings tables, or references to systematic reviews) provided?
- Potential or actual conflicts of interest?
 - ✓ All potential conflicts of interest, including those beyond the commercial sector, should be declared e.g. involvement in a professional group that wishes to lead or take over the provision of a particular service. If these are not described adequately, the guidelines should not be used, but there may be relevant systematic reviews or evidence profiles incorporated into them that may be informative.

A summary of the publications assessed, and reasons for the exclusion of any, should be reviewed by the GDG to ensure agreement on exclusions.

- Publications or guidelines that are included following this initial screening need to be assessed in further detail for two aspects:
 - ✓ do the recommendations in the publications correspond to the questions for the proposed guideline?
 - ✓ what is the quality of the guideline, based on the AGREE II rating instrument?

5.2.2 Appraise guideline validity

Determining whether a guideline is valid involves three separate but related assessments:

- a. Appraising the quality of the guideline
- b. Determining its currency
- c. Content analysis - examining guideline recommendations.

All relevant stakeholders must be involved in the appraisal phase. Each guideline should be appraised separately by at least two appraisers. The appraisers should include at least one clinical expert and one guideline methodologist. The conclusions from the appraisal exercise should be discussed and validated by the GDG.

This assessment process should lead to the identification of a list of guidelines that may be used for developing local recommendations or as a source of evidence. The recommendations in these guidelines should be mapped in detail to the questions in the guideline under development.

a. Appraise the overall quality of the guideline

The Appraisal of Guidelines for Research and Evaluation II (AGREE II) is an internationally recognised instrument in quality assessing clinical guidelines. The AGREE II instrument must be applied to all guidelines that have been screened for inclusion. This process provides an explicit method of rating the quality of a guideline. The key questions in the AGREE instrument relevant to quality of a guideline for subsequent consideration are 8-11 and 22-23. It is recommended that two people assess each guideline and the individual ratings be compared. While there is no threshold for acceptable or unacceptable guidelines based on these criteria, the clinical guideline group may decide to include all guidelines above a certain score or to rank guidelines and keep the top few for further assessment through the steps below. For example, if these six questions score a total of 12 or less by each rater, the guideline might be of insufficient quality to be useful.

Guidelines screened as likely being of high quality must next be assessed and interpreted to ensure that any recommendations adopted or adapted from those guidelines are based on evidence, that the evidence supports the recommendations listed and that recommendations are current.

Chapter 5: Developing a clinical guideline

b. Determine the currency of the guideline

Guidelines that meet minimum quality criteria must then be assessed to determine whether they are still current. Methods of checking the currency of guidelines include reviewing the date of release/publication; scanning the bibliography for the dates of the original studies cited; and checking with developers about whether they still consider the guideline to be current or have plans to update it. A search on major medical and allied health databases for systematic reviews and other significant research published, since the release of the guideline, may also be useful.

A guideline that is appraised as being very high quality but out of date may still be of some use, when supplemented with other guidelines or research evidence. Guideline quality and currency could be noted in a matrix (see table 1).

Table 1: Guideline quality and currency matrix

Indicate with a ✓ if key question(s) is included in the Clinical Guideline. Note (a) Quality and (b) Currency of the clinical guideline				
	Clinical Guideline 1	Clinical Guideline 2	Clinical Guideline 3	Clinical Guideline 4
Quality, AGREE II scores				
Currency (year of search)				
Guideline Question 1				
Guideline Question 2				
Guideline Question 3				
etc				

c. Examine the guideline recommendations

The next step is to conduct a content analysis of the recommendations in each guideline. An evidence and recommendations matrix may be drawn up. Each guideline should be associated with an overall AGREE II score as above. Each recommendation within the guideline should be associated with the level of evidence for that recommendation. If the guideline has been appraised as being developed in a robust manner, i.e. scored well within each domain of AGREE II, and each recommendation is associated with a description of the level of evidence on which it is based, it is likely unnecessary to go back to the original evidence. The guideline appraisers can accept the level of evidence contained within the guideline under review. However, if the appraisers have any concerns with the robustness of the evidence and its interpretation, they should either check with the guideline authors or review the source evidence.

5.2.3 Decisions following assessment of guideline validity

When the GDG has identified one, or several guidelines that are high quality, and with modification could meet the needs, priorities, legislation, policies and resources of the Irish setting, the GDG can decide to:

1. Accept the evidence summary of the guideline: Having reviewed the guidelines the GDG accept the description of the evidence but reject the interpretation and recommendations. The GDG will develop their own recommendations based on the evidence description.
2. Modify specific recommendations. See section 5.8 *Develop recommendations*.
3. Accept specific recommendations but not others. The GDG may decide to select recommendations supported by the best evidence from the guidelines under consideration. The other recommendations will have to be developed de novo.

Chapter 5: Developing a clinical guideline

GDGs should ensure that the reason behind choosing options 1, 2 or 3 (and for choosing specific recommendations but not others) is explained clearly in the guideline. If the recommendations and the sources of evidence are the same, the main considerations in deciding to adopt the recommendations will be based on factors of cost, values and preferences, and feasibility (WHO 2011). See section 5.8 *Develop recommendations*.

If there is an absence of high quality, up-to-date guidelines [within 3 years] that make recommendations for a question, it will be necessary to review the evidence summary (systematic reviews and clinical trials) for these recommendations. Pragmatic decisions will have to be made about how to supplement the evidence in existing guidelines with new evidence, if necessary. Advice on this should be obtained from the content experts on the GDG ideally with the support of a methodologist. If it is necessary to search for additional evidence, then it may be practical to limit the search to a period not covered already by searches made for existing guidelines.

If the recommendations in the guidelines that are used vary from each other or if there are no usable existing guidelines or recommendations for a particular question, it is likely that further evidence retrieval will be needed. This will ideally be the retrieval of relevant systematic reviews or, where none are found, the conduct of de novo reviews based on the key questions.

5.2.4 Finding systematic reviews

The first step is to identify relevant systematic reviews for each of the questions, using PubMed or a similar database. The PubMed “Clinical Queries” or “Special Queries” options permit specific searches to be set up to identify systematic reviews of different types of studies identified with MeSH terms (see <http://www.ncbi.nlm.nih.gov/mesh>). This includes searches of the Cochrane Database of Systematic Reviews, which is a key database for searching for high quality (Cochrane only) systematic reviews. The value of a systematic review is that it addresses a clearly formulated question; for example: Can antibiotics help in alleviating the symptoms of a sore throat? In this example, all the existing primary research that meets the criteria is searched and collated. Next the evidence is assessed using stringent guidelines, to establish whether or not there is conclusive evidence about a specific treatment.

As with searches for guidelines, the search strategy for systematic reviews needs to be initially broad, with careful consideration given to the recency of retrieved reviews (i.e., when were they conducted and how likely is it that they retain currency and relevancy).

The search strategy used should be documented. The initial list of citations retrieved should be screened for relevance, and obviously irrelevant citations should be excluded. The remainder should be retrieved in abstract form for further assessment. Then identify a final list of reviews for potential use in developing recommendations that should be retrieved in full.

5.2.5 Performing the primary literature search

If no appropriate guideline has been found, then a search of the primary literature is carried out based on the PICO/PIPOH of the clinical questions identified by the GDG. These searches should be carried out by qualified health librarians. The search strategy should be built around each element of the PICO or PIPOH and include both controlled vocabulary (e.g. MeSH) and free text search terms and synonyms. Databases to be used will depend on the individual question, but at a minimum will include PubMed/Medline, Cochrane, Embase (especially for pharmacology-based questions), and Clinical Trials databases. Depending on the topic, other primary databases should be included e.g. PsycINFO for psychiatry/mental health; PeDRO for physiotherapy etc. Relevant clinical staff can advise on association or member society websites that should be included in the search together with other grey literature sources. Studies are selected based on the hierarchy of evidence. All searches must be documented and saved. Inclusion and exclusion criteria should be specified. If limits are

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applied, the rationale behind these limits should be explained. The initial list of citations retrieved should be screened for relevance, and obviously irrelevant citations should be excluded. The remainder should be retrieved in abstract for further assessment, to identify a final list of papers for potential use in developing recommendations and these should be retrieved in full.

For more detailed background and guidance on conducting a search, see the Cochrane Handbook for Systematic Reviews; Chapter 6: “Searching for studies” (The Cochrane Collaboration, 2011) or CRD’s Guidance for undertaking reviews in health care; Chapter 1: “Core principles and methods for conducting a systematic review of health interventions” (CRD 2009) (see useful resources below).

5.2.6 Assessing the quality of retrieved studies

Once the studies are retrieved, they should be appraised for bias and methodological strength by at least two independent content experts, using the appropriate checklist which can be found at the Centre for Evidence Based Medicine (CEBM) website (see useful resources, p.33).

In addition, they should fulfil the criteria for relevance, generalisability and applicability in the Irish setting. The GRADE, or GRADEpro tool is recommended for evidence synthesis.

5.2.7 Assessing the quality of systematic reviews

Once the reviews are retrieved, they should be checked for:

- Potential commercial sources of funding. All potential conflicts of interest, including those beyond the commercial sector, should be declared e.g. involvement in a professional group that wishes to lead or take over the provision of a particular service.
- Relevance to the questions to be addressed in the recommendations. If the review is clearly not relevant, it should be excluded.
- Timeliness, as assessed by the date of the last search for studies for inclusion in the review. If the review is of high quality but more than three years old, consider updating the review to include more recent evidence.
- Quality, which may be assessed by using the [AMSTAR 2 instrument](#) (Shea et al 2017). It's recommend that two people assess each review and the individual ratings be compared.



Links to useful resources

Search and retrieve evidence

Lefebvre C, Manheimer E, Glanville J. Chapter 6: Searching for studies. In: Higgins JPT, Green S (editors). [Cochrane Handbook for Systematic Reviews of Interventions](#) Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011 [Open access]

Centre for Reviews and Dissemination (CRD) (2009) [Systematic reviews](#) - Guidance for undertaking reviews in health care. University of York [Reproduction of this book by photocopying or electronic means for non-commercial purposes is permitted]

Chapter 5: Identifying the evidence: literature searching and evidence submission. In National Institute for Health and Care Excellence (NICE) [Developing NICE guidelines: the manual](#). Published date: October 2014, Last updated: April 2017

Grade Working Group: [Database of Evidence Profiles](#)

Turning research into practice [Trip medical database](#)

[Epistemonikos database](#) -Epistemonikos is a collaborative, multilingual database of health evidence

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Links to useful resources

Documenting the search

Kable AK, Pich J, Maslin-Prothero SE. [A structured approach to documenting a search strategy for publication: a 12 step guideline for authors](#). Nurse Educ Today. 2012;32(8):878-886

[Appendix 3: Documenting the search process](#). In Centre for reviews, dissemination (CRD). Systematic reviews: CRD's guidance for undertaking reviews in health care. Centre for Reviews and Dissemination; 2009

Lefebvre C, Manheimer E, Glanville J. [Chapter 6.6.1 Documenting and reporting the search process](#). In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration

Higgins JPT, Green S (editors) (2011) [Cochrane Handbook for Systematic Reviews of Interventions](#) Version 5.1.0 [updated March 2011]. The Cochrane Collaboration



Links to useful resources

Search filters are used to identify higher quality evidence from the immense amounts of literature indexed in major medical data bases

InterTASC Information Specialists' Sub-Group. The InterTASC Information Specialists' [Sub-Group Search Filter Resource](#) [internet]

Glanville J, Fleetwood K, Yellowlees A, Kaunelis D, Mensinkai S. [Development and testing of search filters to identify economic evaluations in MEDLINE and EMBASE](#). Ottawa: Canadian Agency for Drugs and Technologies in Health, 2009

[Scottish Intercollegiate Guidelines Network, Healthcare Improvement Scotland. Search Filters](#) [internet]

NIH U.S. National Library of Medicine: [PubMed Subject Filters](#) [internet]



Links to useful resources

Assessing the quality of evidence

[Critical Appraisal tools](#) for individual studies are available from the Centre for Evidence-Based Medicine (CEBM), Oxford

CEBM: Centre for Evidence-based Medicine, Oxford [Levels of Evidence](#) (March 2009)

Schünemann, H., Brożek, J., Guyatt, G. and Oxman, A., 2014. [GRADE handbook for grading quality of evidence and strength of recommendations](#). Updated October 2013. The GRADE Working Group, 2013. [internet]

[Critical Appraisal Skills Programme \(CASP\) UK](#) [internet]

Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium (2010). [AGREE II: Advancing guideline development, reporting and evaluation in healthcare](#). Can Med Assoc J. Dec 2010

SIGN, Scotland Critical appraisal: [Notes and Checklists](#) [Internet] including a Considered Judgement proforma 2014

Shea Beverley J, Reeves Barnaby C, Wells George, Thuku Micere, Hamel Candyce, Moran Julian et al (2017) [AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both](#) BMJ, 358 :j4008 [Open access]

5.3 Economic evidence

In addition to searching for clinical evidence, studies retrieved from the economic literature search must be reviewed to identify relevant data. A systematic and transparent review process, should be conducted according to the HIQA Guidelines for the retrieval and interpretation of economic evaluations, and will involve the following three steps: selecting relevant studies, appraisal of the evidence, synthesising and summarising the results.

Identifying and selecting relevant studies. The review should aim to identify studies that are relevant to current practice, focusing on studies of economic evaluations that compare the costs and health outcomes of the interventions being considered. These will include cost-utility, cost-effectiveness, cost-benefit, cost-minimisation and cost-consequence studies. Any systematic search to identify cost-effectiveness evidence should be reproducible, thorough and transparent. A search should be performed in the Database of Abstracts of Reviews of Effects (DARE), the NHS Economic Evaluation Database, the Health Technology Assessment Database, the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews (all of which are available through www.thecochranelibrary.com). Along with searching these specialised databases, a search should be performed using the major health search engines such as MEDLINE and/or EMBASE. A number of economic search filters are available on www.york.ac.uk/inst/crd/intertasc/econ.htm covering CINAHL, EMBASE, MEDLINE and PsycINFO.

A search of economic grey literature for Ireland should also be conducted. At a minimum, this should include Health Technology Assessments (HTAs) and reviews from the Health Information and Quality Authority (HIQA) and the National Centre for Pharmacoeconomics (NCPE), Budget Impact Analyses (BIAs) from related NCGs and any relevant reviews and reports published on costing and economic impact in Ireland on the topic. This may also include European and/or Organisation for Economic Co-operation and Development (OECD) reports where Irish figures are available. Inclusion criteria should specify the following: the relevant populations, interventions, date range (older studies may include out-dated practices), countries or settings (studies performed in different healthcare systems may not be applicable to Ireland).

If no full economic evaluation studies are found, the search criteria may need to be widened to include any relevant costing or resource identification studies.

Appraisal of the evidence. All selected studies need to be appraised; this should consist of detailed consideration of two key questions. Firstly, how applicable is the study to the Irish context? Specifically, are the populations, interventions and healthcare systems similar to the Irish setting? Secondly, is the study of adequate quality? Finally, are there major limitations in the study design or in the economic modelling?

Synthesising and summarising the results. When synthesising the included studies, the key data should be extracted systematically from each study. This will typically include the key outcomes, the included costs and the results (incremental costs, effects and incremental cost-effectiveness ratio [ICER]). It is also important to extract details on the interventions compared, the study setting and the perspective (societal or payer) used.

The summary of the evidence should include an assessment of the limitation and applicability of the included studies. While recognising the limitations in transferability of results of economic evaluations from one setting to another (e.g. due to differences in care delivery pathways, costs, epidemiology etc.), a discussion should be included of the possible inferences that may be drawn for the likely cost-effectiveness of the intervention in the Irish setting. The results from the included studies should be presented as the best estimate or range available for the incremental effect, the incremental cost and when appropriate, the incremental cost-effectiveness ratio, highlighting the degree of uncertainty in these estimates. Where inconsistencies exist in the results, explanations on why these may have occurred should be presented (e.g. different settings, prevalence rates, input costs). The implications of unexplained differences between studies results should be considered when assessing the evidence. Where relevant economic evidence was not found this should be explicitly stated.



Links to useful resources

Search and retrieve economic evidence

HIQA Health technology assessment [webpage](#)

National Centre for Pharmacoeconomics - Evaluations [webpage](#)

HIQA Guidelines for Interpretation of Economic Evaluations [webpage](#)

EUnetHTA. [Process of Information Retrieval for Systematic Reviews and Health Technology Assessments on Clinical Effectiveness](#) Version 1.2 (updated Dec 2017). European Network for Health Technology Assessment

Institute of Health Economics. [Health Technology Assessment on the Net](#): 2016. A guide to internet sources of information. Edmonton (AB): Institute of Health Economics; 2016

HTAi Interest Group on Information Retrieval - [The HTAi vortal](#) - (IRG) [internet]

NCEC National Clinical Guidelines [webpage](#) – look for published BIAs

Assessing the quality of economic studies

Developing NICE guidelines: The Manual - [Incorporating economic evaluation](#)

5.4 Presentation of recommendations and results

Summary tables that include 1) the recommendations from included guidelines and 2) results relevant to each question and outcome from guidelines and systematic reviews should be prepared for presentation to the GDG. For summary tables of results from systematic reviews for each question and its outcomes, GRADE evidence profiles should be used (see section 5.6). Evidence tables may need to be supplemented with short narratives that describe the nature of the evidence.

5.5 Assess the certainty in evidence

The phrases quality of evidence, strength of evidence, certainty in evidence or confidence in estimates are used interchangeably. The term certainty in evidence is preferred; this is defined as the certainty 'that the true effect lies on one side of a particular threshold, or in a particular range' (Hultcrantz et al 2017).

After the evidence is retrieved, screened and appraised the next step is to assess its quality. Internationally, there is a growing use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of a body of evidence, and to develop and report recommendations. The GRADE working group began its work in 2000 with the goal of developing a common, sensible and transparent approach to grading the quality of evidence in support of recommendations in healthcare and assessing the strength of the recommendations. Currently, many national and international GDGs, including the WHO, use the GRADE approach. The GRADE working group continues to develop new methods, update and evolve existing methods, and monitor and evaluate the quality and utility of its approaches. As such, the methods continue to evolve as the evidence underpinning the approaches grows and experience with the methods expands.

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The strength of the GRADE approach rests on the use of a structured framework for the assessment of the quality of the evidence and on the requirements that processes be explicit and judgements transparent (WHO 2014, p. 121).

GRADE evidence profiles contain the assessment of the quality of the evidence and a summary of findings across studies for each important or critical outcome and each key question (in PICO format). The GDG uses these summaries as the basis for its discussions and to formulate recommendations.

GRADE categorises the certainty in evidence as high, moderate, low or very low (table 2). These ratings apply to the body of evidence for each outcome assessed for each question and not to individual studies. A judgement on the risk of bias of each individual study included in the body of evidence is needed to assess the quality domain of study limitations.

Table 2: Quality of evidence in GRADE

Quality level	Definition
High ⊕ ⊕ ⊕ ⊕	The GDG is very confident that the true effect lies close to that of the estimate of the effect.
Moderate ⊕ ⊕ ⊕ ○	The GDG is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low ⊕ ⊕ ○ ○	The GDG confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very Low ⊕ ○ ○ ○	The GDG has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

For questions that address interventions, the starting point or baseline for rating the quality of the evidence is always the study design, broadly classified into two types:

- randomised controlled trials (RCTs)
- non-randomised trials and observational studies, including interrupted time-series analyses, cohort and case-control studies, cross-sectional studies and other types of studies, such as case series and case reports.

As a starting point, a body of evidence based on RCTs is rated high quality and non-randomised trials and observational studies are rated low quality because of unknown confounding factors. Then this initial rating can be adjusted based on judgement of five factors i.e., limitations in study design and execution (risk of bias); indirectness; imprecision; inconsistency; and publication bias.

Observational studies are considered low quality evidence from the outset by virtue of their design. If, and only if, there are no further limitations, such as additional risk of bias (if, in other words, there is no reason to downgrade their quality), then the assessor can consider upgrading the quality of the evidence according to three criteria: dose–response gradient; direction of plausible bias; and the magnitude of the effect.

The reasons for adjustments to the quality of the evidence should be provided in explanatory footnotes in the GRADE evidence profile. The assessment of certainty in evidence is carried out automatically in the GRADEpro software. The criteria for the rating process are summarised in table 3.

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GDGs must determine the overall quality of the evidence across all the critical outcomes for each recommendation. Because quality of evidence is rated separately for each outcome, the quality can differ across outcomes.

Table 3: The GRADE approach to rating quality of evidence for each outcome (reproduced with permission from WHO 2014)

1. Establish initial level of quality or confidence		2. Consider lowering or raising level of quality or raising confidence		3. Final level of quality (confidence rating)
Study design	Initial confidence in an estimated effect	Reasons for considering lowering or raising confidence		Confidence in an estimate of effect across all considerations
		↓ Lower if	↑ Higher if ²	
Randomized controlled trials →	High confidence	Risk of bias Inconsistency Indirectness Imprecision Publication bias	Large effect Dose response All plausible confounding and bias • would reduce a demonstrated effect or • would suggest a spurious effect if no effect was observed	High ⊕ ⊕ ⊕ ⊕
Observational studies →	Low confidence			Moderate ⊕ ⊕ ⊕ ○
				Low ⊕ ⊕ ○ ○
				Very Low ⊕ ○ ○ ○

5.6 Presenting the evidence

Draft evidence summaries, and tables, including GRADE evidence profiles, and a draft assessment of costs, values and preferences, and feasibility, should be sent to the GDG for review in advance of a subsequent meeting. Summaries should highlight any current ongoing studies that may have an impact on any of the recommendations with expectations of when these studies are due for completion. This will help to inform and prioritise the timeline for updating. Members should be asked to identify any relevant evidence that is missing from the summaries. The final summaries are then used as the basis for its discussions and to formulate/draft recommendations.

GRADE evidence profiles contain the assessment of the certainty of the evidence and a summary of findings across studies for each important or critical outcome and each question (in PICO format). Outcomes are listed in rows and the judgements made about the factors that determine the quality of the body of evidence are described briefly for each outcome, along with a summary of the effect estimates for each. Additional details are provided in explanatory footnotes.

The evidence profiles and summary of findings tables are constructed using **GRADEpro GDT**, which is an easy to use all-in-one web solution for summarising and presenting information for healthcare decision making.

²Criteria for upgrading the quality are only applicable to observational studies without any reason for downgrading.

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It supports creating concise summary tables for systematic reviews and health technology assessments as well as facilitating development of clinical practice guidelines and other documents making recommendations for public health or health policy decisions (<https://gradepro.org/grade-pro-gdt-overview#overview-about>).

5.7 Budget impact analysis

A budget impact analysis (BIA) refers to an analysis of the added financial impact of implementing a new clinical guideline for a finite period and addresses the affordability of the recommendations. An economic evaluation on the other hand is more than just estimating the impact on resources; it refers to an analysis that evaluates the costs and health consequences of alternative courses of action. A comprehensive economic evaluation tends to be both time and labour intensive; in most instances, a BIA may be a more appropriate methodology to use when determining the economic impact of the recommendations in a clinical guideline. The BIA is closely linked to the implementation plan; both elements of the clinical guideline should be consistent with each other.

When evaluating the budget impact, it is the incremental impact that should be considered. Thus, it is the additional resources that need to be identified. The comparator used should be “routine care”, that is, the current or most widely used clinical practice in Ireland; in some cases, this may be a mix of a number of different practices. It is vital that all relevant costs and resources are included. All direct costs and resource requirements relevant to the public health and social care system should be identified. The costs directly associated with the condition for which the guideline is designed should be included. Other care costs directly resulting from the recommendation in question should be included. For a pharmaceutical, this may include the cost of the drug and any other drug-related costs (concomitant therapies, cost of adverse events, infusion-related costs such as consumables, and staffing). Costs incurred in the initial set-up period, any necessary capital investments, tools or additional training that may be required should also be identified.

The processes used for identifying resource and cost data should be transparent, with clarity on the quality and justification for their inclusion. Data can come from a wide range of sources. The data should be derived from the relevant Irish setting, when possible. Data on health outcomes could be sourced from published literature. Information on health service use or epidemiology may however be better sourced from national databases or statistics rather than from published studies. In cases where data is either of inadequate quality or unavailable, then it may be necessary to use expert opinion or to estimate or extrapolate data from international or other published data. As Ireland does not have a central medical costs database, the generation of valid Irish cost data is challenging and time consuming. When using international data, consider whether it could be suitably adjusted to account for differences in demography, epidemiology and clinical practice. Identifying, gathering and verifying these many varied data inputs (resource use and cost, clinical pathway, prevalence/incidence estimates) will typically require a multi-disciplinary approach.

Although the BIA cannot be completed until the recommendations are drafted, one of the seven criteria for NCEC prioritisation is Criteria 4 Economic Impact. Thus, the potential BIA of a guideline must be considered as early as preparing a guideline proposal for submission (see chapter 4 for more information). While there is often limited Irish data available on the economic impact of healthcare interventions, it is an important step to consider international evidence and make an effort to include some estimation or approximation of the cost-effectiveness, and any possible budget increases or savings, if the guideline is implemented. It is advised that when considering the economic impact of a proposed guideline that the following questions are considered:

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- a) Would implementing this guideline have a substantial budget impact on the healthcare system?**
- Have the resource implications of implementing the guideline been considered?
 - Have the resources required for any initial set up or roll out phase been considered?
 - Has the cost of these resources to the publicly-funded system been estimated?
- b) Are there potential cost savings to be realised if the guideline is implemented?**
- Are there any potential cost savings due to changes in the use of resources?
 - Have the benefits from improved outcomes been quantified and the associated costs or savings been estimated?
- c) Is there national or international cost-effectiveness evidence to support implementing the guideline?**
- Is a summary of the cost-effectiveness evidence presented? Is this generalisable or relevant to the Irish healthcare setting?
 - Has this evidence been gathered using systematic searching methods and are these methods documented?

A full BIA must be conducted, and the economic impact of the guideline recommendations must be fully considered and incorporated into the final recommendation prior to submitting the draft guideline for quality assurance to the NCEC (see Chapter 9 for more information). There are a number of resources available which may provide assistance to guideline developers in creating a budget impact analysis, these are outlined below.

Links to useful resources



HIQA [Guidelines](#) for the Economic Evaluation of Health Technologies in Ireland (2018)

HIQA [Guidelines](#) for the Budget Impact Analysis of Health Technologies in Ireland (2018)

NCEC [Resources & learning](#) web page

An E-learning module: *Budget impact analysis for guidelines and audit* is available from the [NPSO Learning Zone](#). At the end of the module you will be able to: demonstrate the steps in creating a BIA; identify and select appropriate resources of information and the available tools; and prepare the BIA for inclusion in the submission to the NCEC.

[Hultcrantz et al](#) (2017) The GRADE Working Group clarifies the construct of certainty of evidence. *Journal of Epidemiology*. Vol 87, p. 4-13 [Open access]

5.8 Develop recommendations

The next critical step is to develop recommendations based on the evidence. GRADE makes available a framework to carry out this step while allowing explicit consideration of factors that may affect the direction and strength of each recommendation. It is useful to agree on the collective perspective of the GDG or at a minimum acknowledge the different members' perspectives. Health systems, service users and individual patient perspective may at times be at odds, for example, when considering the impact of an intervention on resources. Considered judgment forms can also be used by GDG to document the decision making process.

<https://www.sign.ac.uk/checklists-and-notes.html>

5.8.1 GRADE evidence to decision (EtD) frameworks

GRADE EtD frameworks help GDGs use evidence in a structured and transparent way to inform decisions and arising recommendations. The EtD frameworks include three main sections i.e., formulating the question, assessing the evidence and additional considerations for each criterion (Alonso-Coello et al 2016).

EtD frameworks for clinical recommendations from a population perspective include 12 criteria. These factors must be considered by the GDG in turn to judge its importance and effect on the recommendation. Some criteria differ in how they are applied for recommendations from an individual patient perspective (table 4). The EtD framework represent how the factors that determine the direction and strength of a recommendation have informed the process of developing a recommendation. The frameworks enhance transparency of the guideline as they record the judgements made by the GDG about each criterion and how these judgements inform each recommendation.

The EtD framework should be completed with the support of individuals or teams with strong expertise in guideline methodology and in particular in using GRADE EtDs and other GRADE approaches e.g. summary of findings tables.

Table 4: Criteria for clinical recommendations from a population and an individual patient perspective (adapted from Alonso-Coello et al 2016).

Population perspective	Individual patient perspective
Is the problem a priority (from a population perspective)?	Is the problem a priority (from the perspective of individual patients)?
How substantial are the desirable anticipated effects?	
How substantial are the undesirable anticipated effects?	
What is the overall certainty of the evidence of effects?	
Is there important uncertainty about or variability in how much people value the main outcomes?	
Does the balance between desirable and undesirable effects favour the intervention or the comparison?	
How large are the resource requirements (costs)?	Does the cost effectiveness of the intervention (the out-of-pocket cost relative to the net desirable effect) favour the intervention or the comparison?
What is the certainty of the evidence of resource requirements (costs)?	
Does the cost effectiveness of the intervention favour the intervention or the comparison?	
What would be the impact on health equity?	
Is the intervention acceptable to key stakeholders?	Is the intervention acceptable to patients, their care givers, and healthcare providers?
Is the intervention feasible to implement?	Is the intervention feasible for patients, their care givers, and healthcare providers?

An example of a [completed EtD framework](#) is available from the BMJ (Oxman et al 2015).

5.8.2 Reach agreement on recommendations

Recommendations will be informed by the GRADE EtD frameworks. Discussions will be led by the Chair or in some circumstances led by, or at least supported by the guideline methodologist/GRADE expert. To make a recommendation, a GDG must consider the implication and importance of each of the above criteria and their judgements on same.

Based on their overall assessment across criteria, panels must reach a conclusion about the direction of their recommendation (for or against the intervention) and the strength of their recommendation.

Agreement is reached by the GDG by drafting and agreeing on the evidence-to-recommendation/decision tables considering the factors that determine the direction and strength of a recommendation (table 5). If the GDG is unable to reach consensus on a recommendation, the WHO (2014) recommends that a conditional recommendation is determined. Recommendations need to be clear and actionable, reflect the PICO format and contain an indication of their strength and of the quality of the evidence on which they are based.

The language of each recommendation is critically important. Wherever possible, it should be consistent across all recommendations in a guideline, which should be written in the active voice. For example, all strong recommendations ought to be phrased with “should”.

5.8.3 Strength of recommendations

The strength of a recommendation expresses the degree to which the GDG is confident in the balance between the desirable and undesirable consequences of implementing the recommendation. When a GDG is very certain about this balance (i.e. the desirable consequences clearly outweigh the undesirable consequences), it issues a strong recommendation in favour of an intervention. When it is uncertain about this balance, however, it issues a conditional (or “weak”) recommendation. See table 5 below that provides a guide to interpreting the strength of a recommendation.

Table 5: Guide to making strong and conditional recommendations for an intervention (Reproduced with permission from WHO, 2014)

Audience	Strong recommendation	Conditional recommendation
Patients	<p>Most individuals in this situation would want the recommended course of action; only a small proportion would not.</p> <p>Formal decision aides are not likely to be needed to help individuals make decisions consistent with their values and preferences.</p>	<p>Most individuals in this situation would want the suggested course of action, but many would not.</p>
Clinicians	<p>Most individuals should receive the intervention. Adherence to the recommendation could be used as a quality criterion or performance indicator.</p>	<p>Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences. Decision aides may be useful in helping individuals make decisions consistent with their values and preferences.</p>
Policymakers	<p>The recommendation can be adopted as policy in most situations.</p>	<p>Policy-making will require substantial debate and involvement of various stakeholders.</p>

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Strong recommendations. These recommendations confirm that the guideline is based on the confidence that the desirable effects of adherence outweigh the undesired consequences. The GDG must exercise caution when considering making strong recommendations when the quality of evidence is low or very low.

Conditional/weak recommendations. Conditional/weak recommendations are made when the GDG is less certain about the balance between the benefits and harms or disadvantages of implementing the recommendation. When used, an accompanying description is given to make clear the conditions under which the end user should or should not implement the recommendations.

GRADE recommends using terms or phrases such as “should” or “strongly recommend” for strong recommendations, and “suggest” or “might” for conditional ones.

A recommendation should include a justification as to why it is strong or conditional and why it is for or against a given intervention. It should also contain a set of remarks explaining the conditions and context in which the recommendation applies and the points to bear in mind regarding implementation. The quality of the underlying body of evidence (high, moderate, low or very low) should be specified. In the guideline, each recommendation must be linked to a summary of the evidence, the GRADE evidence profiles and the evidence-to-decision tables.

In rare situations, a GDG may decide that the evidence is not sufficient to be able to formulate a recommendation. For instance, it may not be appropriate to make a recommendation when no evidence about the effects of an intervention is found, in which case the following statement could be included:

“No recommendation can be made because evidence on the effectiveness (or harms) of intervention X was not identified.” (WHO 2014, p. 131).



Links to useful resources

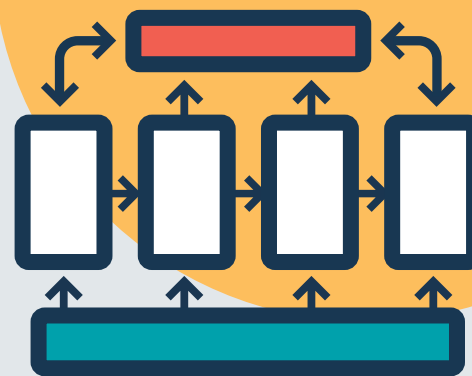
The [GRADEPro Guideline Development Tool](#) (GRADEPro GDT) - all-in-one web solution to summarise and present information for healthcare decision making

Free, web-based software tools for preparing and using interactive EtD frameworks

- Interactive EtD frameworks - <http://ietd.epistemonikos.org/>
- Interactive Summary of Findings iSoF - <http://isof.epistemonikos.org/>

Implementation

Research shows that there is a need to improve the implementability and implementation of guidelines (Gagliardi and Alhabib 2015; Gagliardi et al, 2015). Interventions should be based on the identified enablers and barriers of guideline implementation and aligned with the context and setting.



An Implementation Guide and Toolkit for National Clinical Guidelines was published by the NCEC in 2018 (see useful resources overleaf)

Planning for guideline implementation

- Implementation must be considered at the beginning, and throughout the guideline development process.
- Establish contact with key responsible persons in the HSE's service planning process (or analogous) and work with them during the financial estimates process to ensure funding for the guideline is secured.
- Form an implementation team from the start that includes stakeholders and a nominated lead for implementation.
- Assess current practice as a baseline assessment.
- Assess facilitators of guideline implementation and use.
- Consider implementation on a recommendation-by-recommendation basis, rather than for the entire guideline.
- Determine the implementation strategies that are effective and best suited to address identified needs and barriers (e.g. training, restructuring of service etc.).
- Develop an implementation plan describing dissemination and implementation strategies and tools, roles and responsibilities, timeframes and implementation actions.
- Clear measurable outcomes from the outset will assist with implementation planning and implementation success.
- Ensure guideline recommendations are implementable.
- Implementation may need to be phased over the three years between publication and update.

The implementation plan should be based on the most appropriate approach for addressing actionable factors to change current practice or correct the problem. Consider suitability to the Irish healthcare service, availability of resources (refer to the HSE financial estimates and service planning process and analogous business planning process as relevant) setting and stakeholders and whether the approach needs to be tailored to these elements.

Chapter 6: Implementation

Factors to consider when developing an implementation plan

- **Change in practice:** Identify the target behaviour or change in current practice required. Determine the implementation strategies that are effective and best suited to address identified needs and barriers. Consider equity, acceptability, feasibility and balance of consequences.
- **Appropriateness:** Consider the appropriateness of the intervention: Affordability, practicability, effectiveness, acceptability, side effects/safety and equity (Michie et al, 2014).
- **Feasibility:** Ensure guideline recommendations are implementable in the Irish health system.
- **Resources:** Specify any resources required to implement the guideline and incorporate into the budget impact analysis, cost effectiveness assessment and service planning process.
- **Timeframe:** Specify milestones and timeframes for implementation. Specify when each guideline recommendation is due to be fully implemented and embedded into practice.
- **Roles & responsibilities:** Specify who or what group/profession/discipline is mainly responsible for implementing each guideline recommendation.
- **Communication:** Effective ongoing communication is essential for implementation. All relevant stakeholders must be informed of the guideline development from the outset. Effective, ongoing communication is critical in motivating staff, overcoming resistance to change and giving and receiving feedback. Dissemination and awareness raising of the published guideline is also important for widespread adoption.
- **Implementation supports:** Implementation tools may be useful to assist implementation of the guideline e.g. toolkits, materials on websites, checklists, pathways, algorithms, presentations, podcasts, patient leaflets, local champions, teaching aids and training modules for health professionals linked to CPD points. Publish implementation tools at the same time as the guideline and ensure these tools are accessible in terms of format (paper, electronic, app) and location (website).
- **Implementation outcome variables:** Indicators of success of implementation include acceptability, adoption, appropriateness, feasibility, implementation cost, fidelity, coverage and sustainability (Proctor et al, 2010).
- **Implementation levers:** Levers for implementation may include endorsement from government (Ministerial mandate) or senior management, alignment with clinical indemnity schemes, regulators, insurers, activity-based funding, organisational culture, service planning and accountability frameworks (NCEC 2016).

Links to useful resources



[NCEC Resources & learning webpage](#)

[NCEC Implementation Guide and Toolkit for National Clinical Guidelines \(2018\)](#)

[NCEC Implementation planning tool](#) - for inclusion in the NCG

[Implementation Checklist](#) (Gagliardi et al, 2015) 'Developing a checklist for guideline implementation planning: review and synthesis of guideline development and implementation advice'

SIGN Implementation [resources](#)

European Implementation Collaboration (EIC) [Implementation resources](#)

King's College London – Centre for Implementation Science - [website](#)

Centre for Effective Services (CES) [website](#)



NCEC procedure and tips

- 1 An implementation plan must be prepared and included in the clinical guideline for submission to the NCEC for quality assurance. Inclusion of a logic model may also be useful.
- 2 Establish contact with key responsible persons in the HSE's service planning process (or analogous) and work with them during the financial estimates process to ensure funding for the guideline is secured. The BIA is an essential component to secure funding.
- 3 Using the implementation plan template will aid this process. For each recommendation you are required to:
 - Specify the actions planned/required to implement each recommendation
 - Specify timeframe for implementation
 - Identify who is responsible for implementation
 - Specify outcomes which this recommendation aims to achieve and verification/measurement of outcome
 - Identify tools to be published with the guideline to aid implementation e.g. algorithms, checklists, decision aids, teaching aids.
- 4 It's useful to include a list of the implementation tools as an appendix of the clinical guideline.
- 5 It is strongly recommended that the NCEC Prioritisation and QA Criteria on implementation (Applicability) are reviewed and are adhered to as appropriate (appendix 1 and 2).

Monitoring and audit

There are a number of ways in which the effectiveness of clinical guidelines can be measured. Clarity from the outset on the intended impact of the guideline will greatly assist the monitoring, evaluation and audit of the guideline.



Evaluation of the guideline will measure its success and ensure that it is meeting its aims and objectives at a point in time. Evaluation is defined as a formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved (HIQA, 2012). Consider evaluating at multiple levels i.e. patient or health professional level, team, organisational, system or population. Consider multiple measures e.g. reaction, learning, behaviour and outcomes.

Monitoring of the NCEC National Clinical Guideline takes a longer-term view and seeks to continuously measure compliance usually on a year to year basis. Monitoring can be defined as a systematic process of gathering information and tracking over time. Monitoring provides a verification of progress towards achievement of objectives and goals (HIQA, 2012).

Key performance indicators. Performance indicators are specific and measurable elements of practice that can be used to assess quality of care. Indicators are quantitative measures of structures, processes or outcomes that may be correlated with the quality of care delivered by the healthcare system (HIQA 2013).

An example of monitoring in the HSE is the monthly Performance Assurance Reports (PARs). This provides an overall analysis of key performance data from across many Divisions. The activity data reported is based on Performance Activity and Key Performance Indicators (KPIs) outlined in the current HSE National Service Plan. To date there are a number of KPIs relating to patient safety and clinical effectiveness, including elements of NCEC National Clinical Guidelines.

Audit is another means of measuring if compliance with the NCEC National Clinical Guideline has occurred. It can occur at any level, local, regional or national and is measured using agreed audit criteria.

Audit criteria. Audit criteria are derived from the key recommendations. Audit criteria should include descriptions or operational definitions on how criteria should be measured, to allow:

- assessment of guideline implementation
- meaningful comparison of performance across different settings
- measurement across process or outcome measures of care.

The characteristics of the audit criteria should be:

- explicit rather than implicit
- relevant to important features of care
- measurable
- evidence based including the use of consensus methods where necessary
- include recommended frequency and interval of measurement.

Chapter 7: Monitoring and audit

Audit criteria should be associated with a standard or threshold of expected compliance to be achieved. These may be core or developmental standards. Core standards set out the minimum level of service/care expected by service users, professional bodies and other relevant organisations. These are obligatory and will need to be met from the start. Developmental standards set out the goal to be achieved through improvements in service.

A monitoring and audit plan must be generated while the guideline is being developed. The plan is used to set out the process for monitoring, evaluation and audit of the implementation and effectiveness of the NCEC National Clinical guideline. It should be aligned closely to the implementation plan (see chapter 6). A plan should consider some or all the following:

- Identification of audit criteria from key recommendations
- Identification of key performance indicators from key recommendations
- Identification of short, medium and long-term outcomes for evaluation
- Assessment of guideline dissemination
- Assessment of whether or not current clinical practice is compliant or moving towards the guidelines' recommendations
- Assessment of whether or not health outcomes have changed
- Assessment of the guidelines' impact on service user' knowledge and understanding
- Who will carry out the monitoring/evaluation/audit?

The NCEC and National Clinical Audit. To become NCEC National Clinical Audit endorsed by the Minister for Health, clinical audit must go through prioritisation and quality assurance by the NCEC. Not all clinical audit will be submitted for national endorsement. Clinical Audit endorsed by the Minister will be titled 'NCEC National Clinical Audit' (NCEC, 2016). Examples include National Office for Clinical Audit's Major Trauma Audit; this is available from the NCEC website (see useful resources). All NCEC National Clinical Audits must align with NCEC National Clinical Guidelines as appropriate. The NCEC defines clinical audit as:

a cyclical process that aims to improve patient care and outcomes by systematic, structured review and evaluation of clinical care against explicit clinical standards.

(NCEC Prioritisation and Quality Assurance for National Clinical Audit, 2015, p.3).

Links to useful resources



[NCEC Clinical Audit Processes](#) – website

[NCEC Prioritisation and Quality Assurance for National Clinical Audit \(2015\)](#)

HSE Quality Improvement Division: About Clinical Audit

HSE Quality and Verification Division: Healthcare Audit

NCEC [Annual Reports](#) – look for - Health Service KPIs

Department of Health (2016) [Major Trauma Audit](#) (NCEC National Clinical Audit No. 1)

[HIQA Guidance on Developing Key Performance Indicators and Minimum Data Sets to Monitor Healthcare Quality \(2013\)](#)



NCEC procedure and tips

- 1 A monitoring and audit plan must be prepared and included in the submission to the NCEC for quality assurance.
- 2 The plan must include audit criteria and key performance indicators (KPIs) to enable assessment of compliance of the guideline with reference to the frequency and interval of measurement. KPIs can be measured locally, regionally or nationally as appropriate.
- 3 A list of audit tools as relevant can be included as an appendix of the clinical guideline.
- 4 It is strongly recommended that the NCEC Prioritisation and QA Criteria on monitoring and audit are reviewed and are adhered to as appropriate (appendix 1 and 2).

Consultation & expert review



Consultation

It is important to seek and document feedback from all those expected to use the guidelines (clinicians, administrators, professional bodies, service users etc.). If necessary, the recommendations can be modified to address any concerns prior to final public release of a clinical guideline. The evidence to support a requested change must be submitted with the consultation feedback and decisions documented transparently.

This process can improve the wording of recommendations, allow wide buy-in and improve compliance once finalised. The near completed draft clinical guideline should be sent to practitioners, patient/public (service users), other stakeholders including hospital group CEO/CHO lead as relevant and organisational policy makers for review and comment. Seeking feedback on the draft clinical guideline ensures that those intended to use it have an opportunity to review the document and identify potential difficulties for implementation before it is finalised. In addition, early consultation allows policy makers to consider the organisational effects of implementing the recommendations and to begin preparing for future adoption. Any changes proposed must be supported by evidence and documented. Consultations should last for approximately six weeks.

International expert review

It is important to obtain international expert review of the near complete clinical guideline from stakeholders outside the GDG. This can identify any problems in presentation, process of development, robustness of the evidence searches, content, acceptance of the clinical guideline and its implementation. Expert review can also help to ensure that recommendations from existing clinical guidelines have not been taken out of context or adapted inappropriately. Being explicit and transparent about the external review, including selection process for the reviewers and how the reviewer comments were responded to within the clinical guideline, should increase the transparency and credibility of the process among potential users.

Sample expert review questions include:

1. Has the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline?
2. Are there specific links between decisions and the available scientific evidence?
3. Have the risks and potential harms of recommendations been fully considered in the context of clinical practice?
4. Is the guideline clearly written, user friendly and allow for individual clinician decisions?
5. Is the guideline suitable for routine use as intended (in so far as you are able to comment on the Irish situation)?
6. Are there relevant international or well referenced guidelines (recommendations) on the same topic that these guidelines conflict with, and if yes are the reasons for this justified in the guidelines? (NCEC Framework for Endorsement of National Clinical Guidelines, 2015).



NCEC procedure and tips

- 1 A national consultation exercise with targeted stakeholders and/or broader must be conducted. The draft clinical guideline must be signed off by the GDG before it's shared with national stakeholders. The 'consultation version' should use the NCEC guideline template, with all sections completed, i.e. the implementation plan, the monitoring plan and the BIA. The feedback received must be integrated into the guideline by the GDG as appropriate, mindful of potential or perceived conflicts of interest.
- 2 Review by two International expert reviewers must occur. Their review must be integrated into the guideline by the GDG as appropriate, mindful of potential or perceived conflicts of interest.
- 3 A summary of how the consultation and the international review was carried out must be included in the clinical guideline. It should include an outline of:
 - the methods (postal, online, or other);
 - the period involved;
 - the organisations/individuals targeted and the names of organisations and individuals who responded
 - how feedback from national consultation and international peer review was considered by the GDG and how it was incorporated into the draft clinical guideline.A report of the actual feedback/review received should be saved by the GDG, but this is not required in the guideline submission to the NCEC for quality assurance.
- 4 It is strongly recommended that the NCEC Prioritisation and QA Criteria on consultation and external reviewers are reviewed and are adhered to as appropriate (appendix 1 and 2).

Submitting a guideline for NCEC quality assurance



Step 3 of the NCEC Framework for Endorsement is quality assurance (figure 6). In 2015, the NCEC and HIQA jointly approved and published the National Quality Assurance Criteria V2. The purpose of this document is to clearly set out, for the Irish context, clinical guideline quality assurance criteria that must be met for clinical guidelines to become part of a suite of NCEC National Clinical Guidelines. The NCEC uses national pre-requisite quality assurance criteria in addition to the Appraisal of Guidelines for Research & Evaluation (AGREE) II tool in quality assuring clinical guidelines (see appendix 2).

Assuring the quality of guidelines serves to provide evidence:

- for the NCEC's decision-making process to recommend the clinical guideline to the Chief Medical Officer (CMO) for endorsement by the Minister for Health
- that a standardised high-quality methodology has been adhered to which offers legitimacy to NCEC National Clinical Guidelines.



Figure 6: Step 3 on the Framework for Endorsement of NCEC NCGs

The National Quality Assurance Criteria comprises two parts.

Part A: Pre-requisite quality assurance criteria for the Irish context. There are ten pre-requisite quality assurance criteria for the Irish context. These criteria provide for a consistent approach to guideline development in Ireland considering the Irish context; i.e. national policies, organisational structure and fiscal considerations of the Irish health system. These criteria have been established by HIQA and NCEC to provide assurance that the expected benefit or outcome of the guideline is clearly established for the Irish healthcare system. The criteria promote implementation through consideration of the costs of recommendations through a structured budget impact analysis. Clear identification of responsibility for implementation of recommendations and the development of monitoring criteria provides for a culture of accountability for guideline implementation.

Part B: AGREE II is an internationally recognised instrument that has been validated and endorsed by the World Health Organization and is widely considered as the standard in quality assessing clinical guidelines.

The AGREE II instrument provides criteria for the assessment of the quality of clinical guidelines as well as providing a strategy for guideline development and informing how information and what information ought to be reported in guidelines (Brouwers et al 2010). This instrument has been adopted for use as an inherent part of NCEC quality assurance process.

AGREE II consists of 23 criteria under 6 domains and 2 overall global rating criteria. Each of the 23 criteria is rated on a 7-point response scale by the appraisal team. The domains are:

- Scope and purpose
- Stakeholder involvement
- Rigour of development
- Clarity of presentation
- Applicability
- Editorial independence.



Links to useful resources

NCEC and HIQA National Quality Assurance Criteria for Clinical Guidelines V2, 2015 [Weblink](#)

NCEC clinical guideline [full version template](#)

NCEC clinical guideline [summary version](#) template

AGREE [Reporting Checklist](#) - to assist GDGs to improve the completeness and transparency of reporting in guidelines

[AGREE II instrument](#) (Brouwers et al 2010) - a tool that assesses the methodological rigour and transparency in which a guideline is developed, and it is used internationally



NCEC procedure and tips

- 1 In accordance with the NCEC quality assurance (QA) process, the near completed clinical guideline must be prepared for submission based on the NCEC template 'full version'. The content must address every NCEC criterion for quality assurance, Part A and Part B (see appendix 2).
- 2 The NCEC guideline template allows the guideline authors (guideline development group) be credited and acknowledged for their work.
- 3 It is strongly recommended that the NCEC prioritisation report is reviewed in full to ensure that all items recommended and or raised by the NCEC are incorporated into the near completed guideline.
- 4 Adherence to the AGREE Reporting Checklist will improve the completeness and transparency of reporting in the guideline. The checklist maintains the AGREE II structure of six quality domains and its 23 key items, providing a systematic and logical process for reporting essential information.

- 5 The submission to the CEU (on behalf of the NCEC) for quality assurance must include:
 - the full version guideline as per current NCEC template (including the BIA, monitoring and audit plan, the implementation plan, the logic model and the consultation report)
 - All supporting reports/documents associated with the guideline must also be prepared for submission. This may include clinical and cost effectiveness reviews, the BIA and GRADE tables as relevant.
 - the completed signed submission checklist form, including written evidence of sign-off from HSE Corporate as relevant
 - copies of permissions (form/s) where applicable
 - copies of the completed conflict of interest declaration forms co-signed by the Chair
 - other supporting information (such as patient leaflets, implementation and audit tools).
- 6 The clinical guideline will be assessed by a team of appraisers appointed by the CEU. Each member of the appraisal team will complete an individual assessment that is collated into a composite QA report. A meeting will be organised to discuss individual assessments and to agree the final QA report.
- 7 The NCEC will consider the quality assurance report at their next meeting.
- 8 The clinical guideline must achieve sufficiently high scores across all criteria to be quality assured (or approved) by the committee. The possible outcomes are:
 - (a) Recommend the clinical guideline for endorsement
 - (b) Recommend the clinical guideline for endorsement following minor amendments approved by Clinical Effectiveness Unit, Department of Health
 - (c) Recommend the clinical guideline for endorsement following significant, but not fundamental, amendments approved by appraisal team
 - (d) Recommend resubmission for appraisal step following major amendments.
- 9 After the appraisal and committee decision the NCEC Chair will write to the GDG Chair, and will refer to areas for review and amendment as relevant. A copy of the QA report will also be sent. This information, in particular items listed as “amendments required”, must be used to assist with the further development and completion of the clinical guideline.
- 10 After completion of any amendments required, the clinical guideline must be resubmitted to the CEU (on behalf of the NCEC) for final assessment in accordance with the outcome letter and QA report. This final approval is required prior to proceeding with preparations for publication and Ministerial endorsement.

Clinical guideline endorsement and publication



Step 4 of the NCEC Framework for Endorsement is endorsement (figure 7). When the clinical guideline is formally approved by the NCEC, the Committee recommends it to the Chief Medical Officer, Department of Health who recommends it to the Minister for endorsement. Endorsement means that the NCEC National Clinical Guideline supersedes any existing guidance on the topic in Ireland.



Figure 7: Step 4 on the Framework for Endorsement of NCEC NCGs

Preparation for publication. Following endorsement, the clinical guideline is given the title of an “NCEC National Clinical Guideline (NCG)” and awarded a sequential number by the CEU. The Department of Health/ NCEC guideline template is used to provide uniformity and standardisation of the presentation in line with the existing suite of National Clinical Guidelines.

During this final step, typesetting and proof reading is co-ordinated by the CEU. Revisions on proofs are made for content accuracy, style and layout before the guideline is finally signed off by the GDG and the CEU. A summary version of the guideline may also be required and typeset.

Publication. All NCEC National Clinical Guidelines are published on the NCEC webpage of the Department of Health website. Supporting documents including systematic and economic reviews and budget impact analysis are published similarly. All supporting documents are made accessible using embedded hyperlinks in the electronic copy of the guideline. A limited number of hardcopies are printed and made available from the Department of Health. These are shared with the GDG for use at the launch and afterwards.

Chapter 10: Clinical guideline endorsement and publication

Launch of the guideline. As soon as practicable, an official publication launch will be arranged. This may often coincide with another planned event e.g. the NPSO Conference. The Minister for Health or Minister for State may speak at the launch but that is dependent on his/her availability and is subject to change at short notice. Nonetheless, the launch event will include an invited audience with opportunity for photographs and publicity. Following the publication launch, the Minister will write to several key persons in the Health Services and the Regulators to inform them about the new NCEC National Clinical Guideline and will request implementation across the Health Services.

Dissemination. The Department of Health makes the NCEC National Clinical Guidelines and supporting documents available as electronic copies in Adobe, portable document format (PDF). They can be viewed and downloaded from the NCEC webpages, this is the best source to find the current version. GDGs and health services are encouraged to create weblinks directly from this source. Additional supporting documents and information may also be linked from the NCEC webpages.



The CEU also uses social media such as: [@NCECIreland](#) and [@npsolRL](#) to notify the healthcare community.

Links to useful resources



NCEC [webpages](#) - view and download all published NCEC National Clinical Guidelines and supporting documents

NCEC procedure and tips



- 1 The full guideline and all associated documents/reports must be submitted by the GDG Chair or nominee in preparation for publication. High quality organisational logos (JPEGs or equivalent) if required, must also be provided during preparation for typesetting.
- 2 The CEU assigns the NCG number (and a version number for updates).
- 3 The CEU organises typesetting and undertakes initial proof reading.
- 4 Final sign-off on both the full version and/or summary editions (typeset copy) is required by the CEU and the GDG Chair or their nominee.
- 5 Ministerial approval will be sought. This is coordinated by the CEU.
- 6 The publication launch event will be arranged. This is co-ordinated by the CEU in conjunction with the GDG Chair or nominee.
- 7 Coinciding with the launch, the new NCEC National Clinical Guidelines are uploaded to the NCEC webpages.
- 8 The CEU is also responsible for the preparation of Ministerial letters which are issued shortly after the launch event.

Updating NCEC NCGs

This chapter is based on a preliminary process agreed by the NCEC in 2014. It was revised in 2018 to include learning from the experience of guideline updates underway during 2017/18. The NCEC is committed to further review and update of this chapter as appropriate.



NCEC National Clinical Guidelines need to be kept up to date to ensure the recommendations remain reliable and useful for the public, health professionals and policy makers. Updating guidelines is an iterative process with a systematic and explicit methodology that involves identifying and reviewing new evidence that had not been included in the current version (Moher and Tsertsvadze 2006). If new relevant evidence is identified and it is considered to have an impact on the recommendations, the NCEC National Clinical Guidelines should be modified. If the identification of relevant new evidence and assessment of the impact on the clinical guideline are continuous, this is considered a surveillance process (Martínez García et al 2018).

The NCEC recognises three update processes

Full update is when a guideline is updated completely, i.e. major content review and revision to its questions and recommendations, usually after a defined time period (currently 3 years). The NCEC Framework for Endorsement of National Clinical Guidelines (2013) identifies that it is essential that NCEC National Clinical Guidelines are reviewed and revised to take account of new evidence. NCEC and HIQA National Quality Assurance Criteria for Clinical Guidelines (2015) state the requirement for the provision of a procedure for updating a clinical guideline and that this should include an explicit time interval (i.e., no more than 3 years).

Rapid update. Periodically, new relevant evidence can emerge to challenge the validity of one or more of the clinical guideline recommendations. New relevant evidence may be new studies, clinical experts input or medicine alerts. In this case, an update occurs for one or more of the recommendations. The term rapid update is used to identify a partial clinical guideline update, that is carried out before the full update is due (within the designated 3-year period).

Partial update is an alternative to a full update and is used when the review process includes only certain sections, healthcare questions or recommendations. It is not possible to define a limit to the number of recommendations in terms of partial or full update.

3-yearly review procedure

Three years after the publication, a review is undertaken by 'the group'³. The review may include the following actions:

- Review how the guideline was implemented (including KPI or audit findings) and consider any implications for the content or scope of the guideline.
- Review the guideline (healthcare) questions and the scope – some questions may be dropped (there may be universal sustainable adoption of the recommendations), some may be modified/updated and there may be a need for some new questions based on new technology/treatments or implementation experience.

³ While recognising that the majority of NCEC NCGs are sponsored by HSE Clinical Programmes, the term 'the group' is used here to mean the relevant Clinical Programme/or equivalent to allow for governance structure changes in the future.

Chapter 11: Updating NCEC NCGs

- c) Conduct a systematic literature search from the date of the previous literature search if the scope of the guideline and questions remain the same. The previous search strategy should be utilised both for the clinical and economic systematic review. The aim of the search is to identify any new evidence in relation to the clinical guideline topic that has emerged which changes or has implications for the clinical guideline recommendations. Additional healthcare questions may need to be added if the scope is broadened.
- d) Consider other published NCEC National Clinical Guidelines, where relevant.
- e) Consider amending to utilise the GRADE system as appropriate, make editorial changes, or improve readability as necessary during the updating process.

Criteria for guiding the type of update required will likely include changes in evidence regarding existing benefits or harms associated with recommendations, interventions and outcomes. Consideration of the 4 points below will assist to determine the validity of the existing guideline.

1. Have interventions (whether diagnostic or treatment) been superseded or replaced by other interventions?
2. Has new evidence altered the relation between benefits and harms?
3. Have outcomes not considered at the time of the original guideline become important or have outcomes considered important now become unimportant?
4. Is there evidence that current performance is optimal, and the guideline is no longer needed? (Shekelle et al 2001).

Following the 3-yearly review, the group must next examine the results and in consultation with the CEU on behalf of the NCEC decide which of the options apply (figure 8):

- I. The NCEC NCG is completely revised and updated
- II. The NCEC NCG is partially updated with changes to specific recommendations
- III. The NCEC NCG stands with no change
- IV. The NCEC NCG is withdrawn/decommissioned.

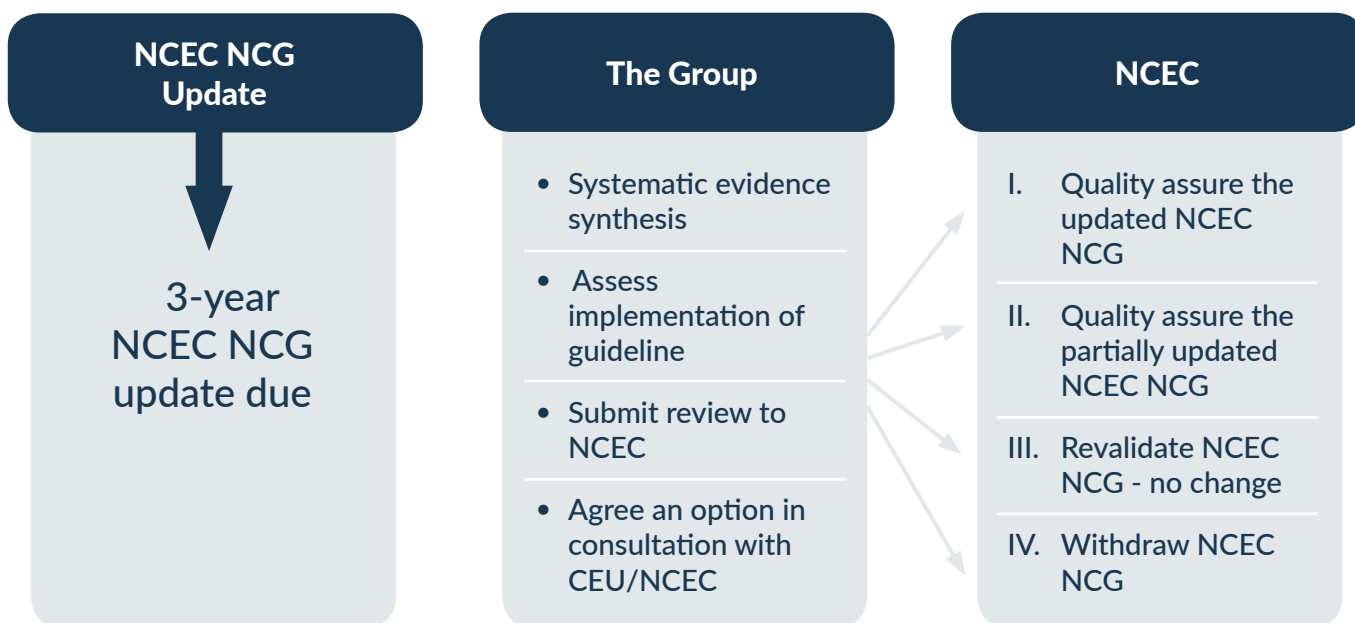


Figure 8: Updating NCEC NCGs

Chapter 11: Updating NCEC NCGs

- I. **The NCEC NCG is completely revised and updated.** The updated clinical guideline must be submitted for quality assurance by NCEC. The requirements in this case are the same as if a new guideline was being submitted for the first time.

The CEU will convene an appraisal team to assess the updated guideline by conducting a full guideline appraisal. The NCEC will review the QA report at a committee meeting and may decide to approve the fully updated guideline. In this case, the NCEC National Clinical Guideline will be republished with a subsequent version number e.g. V2 and date with supporting content to outline the full update process and summary of changes made. Alternatively, the NCEC may seek further information and this will be notified to the group.

- II. **The NCEC NCG is partially updated with changes to specific recommendations.** The group must submit the specific updates proposed with documentary evidence of the systematic search, strengths and limitations of the literature and conclusions of the evidence synthesis to provide a rationale for partial change(s) in the guideline recommendations. In addition, implementation of the guideline must be considered and how this may impact on the BIA and implementation plan. There is a requirement to provide a written rationale considering possible changes in implementation, auditing etc. Consultation and international peer review must be conducted. The clinical guideline and the evidence is submitted for approval by the NCEC.

The CEU will convene an appraisal team to review the submission. A report and recommendation will be made to the NCEC as appropriate. The NCEC will review the documentation at a committee meeting and may decide to approve the partially updated guideline. Alternatively, the NCEC may seek further information. When finalised, the NCEC National Clinical Guideline will be republished with a subsequent version number e.g. V2 and date with supporting content to outline the update process and the changes made.

- III. **The NCEC NCG stands with no change.** The group must submit documentary evidence of the systematic literature search, strengths and limitations of the literature and conclusions of the evidence synthesis to provide a rationale for no change in the guideline. In addition, implementation of the guideline must be considered. If for example new technology or new training methods were made available, this may impact on the BIA and implementation plan. There is a requirement to provide a written rationale considering possible changes in implementation, auditing etc. The clinical guideline and the evidence synthesis is submitted for approval by the NCEC.

The CEU will convene an appraisal team to review the submission. A report and recommendation will be made to the NCEC as appropriate. The NCEC will review the documentation at a committee meeting and will make a decision. Alternatively, the NCEC may seek further information. When finalised, the NCEC National Clinical Guideline will be republished with a subsequent version number e.g. V2 and date with supporting content to outline the process and conclusions made.

- IV. **The NCEC NCG is withdrawn.** The group will make a submission with supporting evidence of the rationale for withdrawal of the guideline. The NCEC will review documentation at a committee meeting and may decide to approve the withdrawal of the National Clinical Guideline from the suite and the Department of Health website. Alternatively, the NCEC may seek further information.

Chapter 11: Updating NCEC NCGs



Links to useful resources

[Garritty et al \(2016\)](#) Cochrane Rapid Reviews Methods Group to play a leading role in guiding the production of informed high-quality, timely research evidence [Open access]

[Abou-Setta et al \(2016\)](#) Methods for developing evidence reviews in short periods of time: a scoping review) [Open access]

[Wagner et al \(2017\)](#) Trading Certainty for Speed - How Much Uncertainty Are Decision makers and Guideline Developers Willing to Accept When Using Rapid Reviews: An International Survey [Open access]



NCEC procedure and tips

- 1 Three years after the publication date of the NCEC National Clinical Guideline, the CEU on behalf of the NCEC will write to the group. While recognising that the majority of NCEC National Clinical Guidelines are sponsored by a HSE Clinical Programme, the term 'the group' is used to mean the relevant Clinical Programme/or equivalent to allow for governance structure changes in the future.
- 2 The NCEC guideline template used by GDGs to submit for quality assurance, includes a section called "Plan to update the clinical guideline". 'The group' responsible for undertaking the update must be named in this section.
- 3 The NCEC National Clinical Guideline should never be updated merely to amend wording or introduce editorial changes. All updates, however minor, are version controlled and should not be taken lightly to avoid confusion to the end users. In addition, the administrative burden in redesign/ typesetting publication and dissemination needs to be considered.
- 4 It is strongly recommended that the NCEC Prioritisation and QA Criteria are reviewed (appendix 1 and 2).

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Appendices



Appendix 1: Prioritisation Criteria for Clinical Guidelines

Seven criteria and questions to guide development of the guideline proposal

Criteria 1: Patient Safety Issue

- What is the patient safety issue?
- Who is affected?
- How are they affected?
- Does the issue have national implications?
- What are the risks associated with this issue if not addressed?
- How can it be addressed?
- Is there potential for quality improvement in the area?

Criteria 2: Burden of Clinical Topic

- What is the incidence/prevalence of clinical topic (disease/condition/circumstance)? The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described?
- What is the associated mortality and morbidity?
- What are the rates of relapse, re-admission and complications?
- Is there reduced quality of life?
- Is there patient dissatisfaction?

Criteria 3: Evidence Analysis

- Are clinical guideline recommendations based on an analysis of the evidence? This should preferably be a systematic review of high-quality randomised controlled clinical trials or well-designed controlled studies that measure relevant outcomes demonstrating strong, clinically important beneficial public health effects?
- Is there detail of the search methods and evidence rating?
- Are recommendations graded based on the quality of evidence with an explicit link between the recommendations and supporting evidence?
- Has the clinical guideline been externally reviewed prior to its submission to the NCEC? Ideally the external review should provide commentary on the search strategy for the evidence review?

Criteria 4: Economic Impact

While there is often limited Irish data available on the economic impact of healthcare interventions, guideline developers should consider international evidence and make an effort to include some estimation or approximation of the cost-effectiveness, and any possible budget increases or savings, if the guideline is implemented.

Would implementing this guideline have a substantial budget impact on the healthcare system?

- Have the resource implications of implementing the guideline been considered?
- Have the resources required for any initial set up or roll out phase been considered?
- Have the cost of these resources to the publicly-funded system been estimated?

Are there potential cost savings to be realised if the guideline is implemented?

- Are there any potential cost savings due to changes in the use of resources?
- Have the benefits from improved outcomes been quantified and the associated costs or savings been estimated?

Appendix 1: Prioritisation Criteria for Clinical Guidelines

Is there national or international cost-effectiveness evidence to support implementing the guideline?

- Is a summary of the cost-effectiveness evidence presented? Is this generalisable or relevant to the Irish healthcare setting?
- Has this evidence been gathered using systematic searching methods and are these methods documented?

Criteria 5: Variability in Practice

- Are there gaps between current clinical practice and evidence-based practice?
- Are significant variations in practice evident?
- What is the associated risk of the variance from best practice?
- Would reducing variation incur beneficial effects for patients?
- Would reducing variation reduce avoidable morbidity and/or mortality?
- To what extent is there a high-risk impact for the health system?
- Are there high frequency risk factors (avoidable and inherent)?

Criteria 6: Potential for Addressing Health Issues

- The overall objective of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined
- Is there potential for improved health outcomes?
- What is the extent of potential improved quality of life?
- What is the extent of potential improved quality of care?
- Is there potential for health promotion at population health level?
- Is there potential for disease prevention at population health level?
- Will the clinical guideline reduce the extent of avoidable injury?
- Will the clinical guideline reduce inequalities in health?
- What are the potential short and long-term health outcomes taking into account the strength of evidence associated with each?
- Is there a maximum likelihood of benefit and minimum harm?
- Will the clinical guideline reduce symptoms, avoid or delay need for other therapies or reduce disease progression?
- Will the clinical guideline support the implementation of national health policy?
- Will the clinical guideline improve patient safety?

Criteria 7: Clinical Guideline Implementation

- What is the feasibility of implementation of the clinical guideline?
- What are the facilitators to the guideline application?
- Are there any significant barriers to implementation of the clinical guideline?
- What is the resource impact for implementation of the clinical guideline?
- How acceptable will the clinical guideline be to relevant stakeholders (consumers and clinicians)?
- Did the clinical guideline development group include individuals from all the relevant professional groups, methodological experts and intended users for example healthcare professionals, hospital managers etc.?
- Is there a degree of urgency for implementation of the clinical guideline?
- What is likelihood of the clinical guideline implementation strategy being successful?
- How accessible will the clinical guideline be?

Part A: Pre-requisite quality assurance criteria for the Irish context

1. National health policy and programmes and relevant existing guidelines should be specifically considered. Guidelines should be specifically cross-referenced with key recommendations of all National Clinical Guidelines endorsed by NCEC.
2. The Guideline Development Group should include the intended users or their representatives of the guideline in the Irish setting for example, healthcare professionals, hospital managers, CEO hospital groups, two patients/service users and methodological experts etc.
3. Conflicts of interest if declared should include a statement on the level of influence that the conflict of interest had on the decision making with regard to the recommendations and a description of the measures taken to minimise influence on guideline development. A copy of the Guideline Development Group's conflict of interest forms should be provided to NCEC for retention.
4. The evidence review should include both clinical and cost-effectiveness to ensure that the clinical guideline is based on best available evidence. The full clinical and economic search strategy should be clearly outlined.
5. The methods or tools for assessing the quality of the evidence should be documented. The level of evidence should be explicit and strength of recommendations graded.
6. Consideration of cost-effectiveness, resource implications and health service delivery issues should be included in the development of the recommendations. Resource implications from an Irish health service perspective should be explicit and include equipment, staff, training etc.
7. A description of the selection process for experienced and knowledgeable external reviewers and how the information gathered was used by the Guideline Development Group should be provided. Two international reviews should be included.
8. An explicit time interval (no more than 3 years) should be used for review and updating of the guideline. Responsibility for update of the guideline should be detailed.
9. Guideline recommendations should:
 - a) clearly identify responsibility for implementation of the recommendations in the Irish health system i.e. corporate, organisational and healthcare staff responsibilities. Practical guidance can be included under recommendations to support the delivery of the recommendations.
 - b) include a description of the population (e.g. hospital, community, older person, surgical etc.) or clinical situation most appropriate to each recommendation/option.
10. The monitoring or audit criteria should assess implementation of guideline and the impact of implementing the recommendations. Consideration should be given to key performance indicators (KPIs) at local, regional and national level including KPIs for inclusion in HSE service plans as appropriate. KPIs should be developed in line with guidance from HIQA on Developing Key Performance Indicators and Minimum Datasets to Monitor Data Quality (February 2013).

Part B: AGREE II Appraisal		
Domains (1-6) and Criteria (1-23):		
Domain 1 Scope and Purpose	1	The overall objective(s) of the guideline is (are) specifically described.
	2	The health question(s) covered by the guideline is (are) specifically described.
	3	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Domain 2 Stakeholder Involvement	4	The guideline development group includes individuals from all the relevant professional groups.
	5	The views and preferences of the target population (patients, public etc.) have been sought.
	6	The target users of the guideline are clearly defined.
Domain 3 Rigour of Development	7	Systematic methods were used to search for evidence.
	8	The criteria for selecting the evidence are clearly described.
	9	The strengths and limitations of the body of evidence are clearly described.
	10	The methods for formulating the recommendations are clearly described.
	11	The health benefits, side effects, and risks, have been considered in formulating the recommendations.
	12	There is an explicit link between the recommendations and the supporting evidence.
	13	The guideline has been externally reviewed by experts prior to its publication.
Domain 4 Clarity of Presentation	14	A procedure for updating the guideline is provided.
	15	The recommendations are specific and unambiguous.
	16	The different options for management of the condition or health issue are clearly presented.
	17	Key recommendations are easily identifiable.

Domain 5 Applicability	18	The guideline describes facilitators and barriers to its application.
	19	The guideline provides advice and/or tools on how the recommendations can be put into practice.
	20	The potential resource implications of applying the recommendations have been considered.
	21	The guideline presents monitoring and/or auditing criteria.
Domain 6 Editorial Independence	22	The views of the funding body have not influenced the content of the guideline.
	23	Competing interests of guideline development group members have been recorded and addressed.

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