National Clinical Effectiveness Committee (NCEC)

On 23rd September 2010, the Patient Safety First initiative was launched in response to recommendations of the *Report of the Commission on Patient Safety and Quality Assurance – Building a Culture of Patient Safety* (DoHC 2008). A key component of the Patient Safety First initiative is the National Framework for Clinical Effectiveness. Clinical effectiveness involves a number of processes, but primary among these are:

(i) the development or adaptation and use of clinical guidelines to support evidence-based practice

(ii) the use of clinical audit to improve service user care and outcomes.

The oversight of the National Framework for Clinical Effectiveness is provided by the National Clinical Effectiveness Committee (NCEC). The NCEC is a partnership between key stakeholders in service user safety. The NCEC mission is to provide a framework for national endorsement of clinical guidelines and audit to optimise service-user care. The NCEC terms of reference are to:

- Apply criteria for the prioritisation of clinical guidelines and audit for the Irish health system
- Apply criteria for quality assurance of clinical guidelines and audit for the Irish health system
- Disseminate a template on how a clinical guideline and audit should be structured, how audit will be linked to the clinical guideline and how and with what methodology it should be pursued
- Recommend clinical guidelines and national audits, which have been quality assured against these criteria, for Ministerial endorsement within the Irish health system
- Facilitate with other agencies the dissemination of endorsed clinical guidelines and audit outcomes to front-line staff and to the public in an appropriate format
- Report periodically on the implementation of endorsed clinical guidelines.

The NCEC draws on international guideline development methodology and the expertise of established clinical guideline groups where available. It is recognised that the NCEC and the health system as a whole is likely to be able to effectively implement and monitor only a small number of national clinical guidelines each year. However, this in no way should detract from the importance or value in developing clinical guidelines in response to the needs of individual organisations.

Guidelines should continue to be developed and implemented as required in line with best practice methodology. However, when a guideline has received Ministerial endorsement as a national clinical guideline it will supersede any other guidelines on that topic.
Table of Contents

National Clinical Effectiveness Committee (NCEC) 1
Abbreviations 3
About this Manual 4
Executive Summary 5
Clinical Guidelines 7
How to use this Manual? 9
Clinical Guideline Path 10
  Stage 1: Plan 11
  Stage 2: Develop 25
  Stage 3: Disseminate 51
  Stage 4: Implement 52
  Stage 5: Evaluate 55
  Stage 6: Revise 58
Document Control 59
References 60
Appendix I: National Quality Assurance Criteria 62
Appendix II: Example of Economic Impact 64
Appendix III: National Quality Assurance Criteria Scoring Sheet 73
Appendix IV: NCEC Clinical Guideline Template 76
Appendix V: Acknowledgements 80
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AGREE</td>
<td>Appraisal of Guidelines for Research and Evaluation</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
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<tr>
<td>HIQA</td>
<td>Health Information Quality Authority</td>
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<td>MDT</td>
<td>Multidisciplinary Team</td>
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<td>NCEC</td>
<td>National Clinical Effectiveness Committee</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Effectiveness</td>
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<tr>
<td>PICO</td>
<td>Population, Intervention, Comparison, and Outcomes of interest</td>
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<tr>
<td>PIPOH</td>
<td>Population, Intervention, Professional, Outcomes and Healthcare Setting</td>
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<tr>
<td>RCT</td>
<td>Randomised Control Trial</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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About this Manual

What is the aim this manual?
The primary aim of this manual is to support guideline development groups in preparing their clinical guidelines for submission to the NCEC in order to become endorsed as national clinical guidelines.

Who is this manual for?
This manual has been developed to assist guideline development groups planning to submit to NCEC. However, other Irish guideline development groups may find the information useful for developing clinical guidelines for their services locally or regionally.

What does it cover?
This manual describes the stages of clinical guideline development and implementation. It flags the prioritisation and quality assurance criteria that NCEC will use to appraise clinical guidelines submitted for consideration to become national clinical guidelines. This manual also describes the stages of the clinical guideline path, which are necessary for successful implementation and evaluation of a guideline.

What does it not cover?
The leading international guideline development and appraisal bodies (e.g. AGREE, GRADE, ADAPTE) have developed extensive resources for each stage of the guideline path process. This manual has been informed by these expert groups and aims to synthesise their guidance rather than repeat their full guidance. The links to these expert bodies are provided in the manual for groups who require more detail on any stage of the guideline development process.

This document does not describe how to submit clinical guidelines to the NCEC. Please see NCEC Framework for Endorsement of National Clinical Guidelines V3 (NCEC 2012).

Review and updating of this manual
This is an evolving document and will be updated as required to incorporate feedback from guideline development groups. NCEC will also endeavour to add useful guidance as it is developed. The formal process for updating this document will begin three years after publication. Suggestions and feedback on content and presentation of this document are always welcome and should be addressed to ncec@health.gov.ie

NCEC and other relevant resources are available on the NCEC website www.patientsafetyfirst.ie
Executive Summary

The *NCEC Guideline Developers Manual* aims to support guideline development groups in preparing their clinical guidelines for submission to the NCEC in order to become endorsed as national clinical guidelines. However, other Irish guideline development groups may find the information useful for developing guidelines for their services locally or regionally.

Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service user decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.

Clinical guideline development and implementation should be approached as a continuous cycle in which all of the activities in the cycle are interrelated and influence each other with an emphasis on a process of continuous improvement. The clinical guideline path has six stages.

Clinical Guideline Path

This executive summary lists each of the six guideline development stages and provides a checklist so that guideline development groups can confirm that they have examined the requirement for each of the associated steps. Not all steps will be relevant to each guideline development group; however consideration should be given to all the steps in the stages to ensure that the development process is robust and comprehensive.
**Clinical Guideline Path - Checklist**

<table>
<thead>
<tr>
<th>Stage 1 Plan</th>
<th>Steps</th>
<th>Checklist (✓)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Clarify context</td>
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<tr>
<td>Step 2</td>
<td>Select topic</td>
<td></td>
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<tr>
<td>Step 3</td>
<td>Determine objectives and scope</td>
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<tr>
<td>Step 4</td>
<td>Identify key stakeholders</td>
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<tr>
<td>Step 5</td>
<td>Establish guideline development group</td>
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<tr>
<td>Step 6</td>
<td>Outline communication and consultation process</td>
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<tr>
<td>Step 7</td>
<td>Determine resources</td>
<td></td>
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<tr>
<td>Step 8</td>
<td>Address and manage conflicts of interest</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Stage 2 Develop</th>
<th>Steps</th>
<th>Checklist (✓)</th>
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</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Define key questions</td>
<td></td>
</tr>
<tr>
<td>Step 2</td>
<td>Search for clinical guidelines and research studies</td>
<td></td>
</tr>
<tr>
<td>Step 3</td>
<td>Screen clinical guidelines</td>
<td></td>
</tr>
<tr>
<td>Step 4</td>
<td>Appraise clinical guidelines</td>
<td></td>
</tr>
<tr>
<td>Step 5</td>
<td>Appraise other research studies</td>
<td></td>
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</tbody>
</table>
| Step 6          | - Adopt a clinical guideline  
                  - Adapt a clinical guideline  
                  - Develop a new guideline | |
| Step 7          | Prepare a draft clinical guideline | |
| Step 8          | Communicate and consult | |
| Step 9          | External review | |
| Step 10         | Prepare final guideline | |
| Step 11         | Endorsement | |

| Stage 3 Disseminate | | Checklist (✓) |
|---------------------|----------------|
| A dissemination plan is developed using the most appropriate combination of options. | |

| Stage 4 Implement | | Checklist (✓) |
|-------------------|----------------|
| An implementation plan is developed using the most appropriate combination of options. | |

<table>
<thead>
<tr>
<th>Stage 5 Evaluate</th>
<th>Steps</th>
<th>Checklist (✓)</th>
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<tbody>
<tr>
<td>Step 1</td>
<td>Identify evaluation experts</td>
<td></td>
</tr>
<tr>
<td>Step 2</td>
<td>Decide what should be evaluated</td>
<td></td>
</tr>
<tr>
<td>Step 3</td>
<td>Identify data collection techniques</td>
<td></td>
</tr>
<tr>
<td>Step 4</td>
<td>Decide detail required</td>
<td></td>
</tr>
<tr>
<td>Step 5</td>
<td>Share learning</td>
<td></td>
</tr>
</tbody>
</table>

| Stage 6 Revise | | Checklist (✓) |
|----------------|----------------|
| A plan is developed for how the guideline will be reviewed and updated. | |
Clinical Guidelines

The term ‘clinical guideline’ has synonyms that may elsewhere be considered to be broadly interchangeable. These include ‘guideline’, ‘health guideline’, ‘clinical practice guideline’, ‘evidence-based guideline’, ‘evidence-based guidance’ and ‘guidance’. For the purpose of consistency, the NCEC utilises the term ‘clinical guideline’ in its work. The following identifies the specific meaning that should be inferred for this term.

Clinical guidelines are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service user decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.

Clinical guidelines can improve health outcomes, reduce variation in practice, improve quality of clinical decisions, influence health service policy and inform service users and the public about the service they should be receiving.

Safer Better Healthcare (HIQA 2012) highlights 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 circumstances. Healthcare that is supported by best available evidence helps assure providers that they are delivering safe high quality reliable care.

Preparing to develop a clinical guideline

Prior to developing a clinical guideline, guideline development groups should prioritise the most important clinical guideline for service delivery. The NCEC Clinical Guideline Screening and Prioritisation Criteria (NCEC 2012b) can be used by guideline development groups to help objectively assess what clinical guideline is most important. These criteria must be addressed if the guideline development group is planning to submit their clinical guideline to NCEC.

The guideline development group should then examine whether the clinical issue is best addressed through development of a new clinical guideline, adopting or adapting an existing clinical guideline or whether the clinical issue can be addressed in another way for example through the introduction of a care pathway or a quality assurance process.
It is recommended that the guideline development group give consideration to, and familiarise itself with, the following prior to development of a clinical guideline:

- This NCEC Guideline Developers Manual

Other resources that may be of interest include:

AGREE II Tutorial - http://www.agreetrust.org/
HIQA (2011a) National Quality Assurance Criteria for Clinical Guidelines
(HSE 2012) Principles for Clinical Governance
http://www.hse.ie/go/clinicalgovernance

Relevant resources to support guideline development groups are available on the NCEC website www.patientsafetyfirst.ie

Generally the development of a new clinical guideline can take up to two years to complete (depending on the scope and complexity of the guideline topic) and involves significant commitment by guideline development groups and those experts who take part in the consultation process. Consideration of required time commitment and resources for each of the six stages of the guideline development path and implementation is important at the outset.
How to use this Manual?

The clinical guideline path is described in six stages in this document. Each of the stages has a number of steps which are described in detail. This manual also provides links to useful resources should more detailed information be required.

Key information is highlighted in this manual as follows.

**KEY ELEMENTS** highlight the NCEC *Clinical Guideline Screening and Prioritisation Criteria V2 (2012)* and the HIQA *National Quality Assurance Criteria for Clinical Guidelines (2011a)*. This is to assist guideline development groups, who plan to submit their guidelines to NCEC to ensure that they have addressed all required criteria. Guideline development groups should note that the NCEC can use only the documentation submitted. Therefore guideline development groups must ensure that there is an explicit statement within the guideline, or supporting documentation, addressing each criterion, even if that statement is to outline why the criterion could not be addressed.

**TIPS** are practical suggestions to help guideline developers in developing their guidelines.

**EXAMPLES** are statements that illustrate the application of the clinical guideline path.
Clinical Guideline Path

Clinical guideline development and implementation should be approached as a continuous cycle in which all of the activities in the cycle are interrelated and influence each other. There should be a strong emphasis on encouraging a process of continuous improvement and review, which is based on the real experiences of guideline development groups and services during all stages from development to implementation and revision of the clinical guideline.

There should also be an emphasis on promoting open, transparent communication at all stages to build trust and confidence in the process between various stakeholders and service providers.

The clinical guideline path sets out the key stages of clinical guideline development and implementation.
Stage 1: Plan

<table>
<thead>
<tr>
<th>Step 1.</th>
<th>Clarify context</th>
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<tr>
<td>Step 2.</td>
<td>Select topic</td>
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<td>Determine objectives and scope</td>
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<td>Step 7.</td>
<td>Determine resources</td>
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<tr>
<td>Step 8.</td>
<td>Address and manage conflicts of interest</td>
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</table>

**Step 1: Clarify context**

Consideration needs to be given to national priorities within healthcare, including the national clinical care programmes, to ensure that the proposed clinical guideline is in line with these priorities and programmes. Guideline developers need to take into consideration previously developed guidelines on this topic. Guideline developers should make every effort to identify if work on a guideline on a similar topic is underway in Ireland. Guideline development groups are encouraged to notify their intent to develop a guideline on the NCEC website at [www.patientsafetyfirst.ie](http://www.patientsafetyfirst.ie)

**Key Element**

National health policy and programmes and relevant existing guidelines are specifically considered.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
**Step 2: Select topic**

There should be a clear description of how the need for the clinical guideline was identified. Guideline development groups planning to submit to the NCEC need to ensure that their proposed guideline has given consideration to the NCEC Clinical Guideline Screening and Prioritisation Criteria as outlined below:

**Key Elements**

- **Burden of clinical topic** – Does the disease/condition/circumstance cause substantial burden to the population and/or the health system?
- **Evidence analysis** – Are clinical guideline recommendations based on an analysis of the evidence?
- **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 if the guideline is implemented? Is there research on cost effectiveness in the literature?
- **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?
- **Clinical guideline implementation** – Is it feasible to implement the guideline?

*(National Clinical Effectiveness Committee Clinical Guideline Screening and Prioritisation Criteria, V2, 2012)*

**Other factors that can be drivers in developing a guideline:**

Legislation, European Union Directives, court decisions.

**Local factors can also be drivers in developing a guideline**

- A desire to keep practice up to date or evidence-based
- Incidents/near misses identified through quality, safety and risk management systems
- Variability in practice
- Local initiatives.
**Step 3: Determine objectives and scope**

The overall objective(s) of the clinical guideline should be described with the expected benefit or outcome of the guideline clearly outlined.

Determining the scope sets the boundaries of the group, and establishes exactly what the group is trying to achieve, including the issues that the guideline is going to cover.

Equally as important, this will help to determine what the group does not have to do. The scope of the clinical guideline should be described.

**Key Elements**

- The overall objective of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined.
- The health question covered by the guideline is specifically described.
- The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
- The intended users of the guideline are clearly defined.

_(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)_
Tips

- Look to existing guidelines to see what key questions are commonly included.
- The more key questions that are included, the more work it takes to develop a guideline.
- Decide on the amount of detail for each key question.
- Use internationally agreed nomenclature where possible, e.g. ICD (disease), ICHI (health interventions) ICF (functioning, disability and health) and DSM IV (psychiatric) to facilitate national and international use.
Step 4: Identify key stakeholders

Stakeholders are people who have a common interest in improving health services. This includes those responsible for delivering and those who receive services related to the guideline. It is important, therefore, that the whole system is mapped to ensure that all those that have a contribution to make are included in the guideline development and implementation process at appropriate stages. All of the relevant connections should be identified and an assessment of impact in different areas should be taken into account.

Key stakeholders are likely to include:

- service users, carers, the public and their representative groups
- healthcare professionals, ensuring primary, secondary and tertiary care, as well as local and national organisations are represented if relevant
- healthcare managers, 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
- professional organisations
- education providers
- government e.g. Department of Health
- regulators e.g. HIQA
- international organisations who may be in the process or have completed relevant clinical guidelines
- others as appropriate.

Stakeholder analysis

A stakeholder analysis is a technique that can be used to identify and assess the importance of key people, groups of people, or institutions that may significantly influence the success of clinical guideline development and implementation. Strategies for obtaining support and reducing barriers should be used throughout the clinical guideline development and implementation path. A stakeholder analysis matrix should be completed – see example below.
**Stakeholder Analysis Matrix**

<table>
<thead>
<tr>
<th>Clinical guideline stage</th>
<th>Stakeholder</th>
<th>Stakeholder interest</th>
<th>Assessment of impact</th>
<th>Potential strategies for obtaining support or reducing barriers</th>
</tr>
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<td>1</td>
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**How to use the Stakeholder Analysis Matrix:**

1. Identify all the people, groups, and institutions locally and nationally, that will affect or be affected by each stage of your clinical guideline and list them in the column under “Stakeholder.”

2. When you have a list of all potential stakeholders, review the list and identify the specific interests these stakeholders have in your guideline at each clinical guideline stage. Consider questions like:
   - The benefit(s) of the guideline to the stakeholder
   - The changes that the guideline might require the stakeholder to make
   - The guideline related activities that might cause conflicts for the stakeholder.

Record this interest as high, medium or low in the column “Stakeholder interest”.

3. Review each stakeholder listed. Ask the question: how important are the stakeholder’s interests to the success of the development and implementation of the proposed guideline? Consider:
   - The role the key stakeholder must play for the guideline to be successful, and the likelihood that the stakeholder will play this role
   - The likelihood and impact of a stakeholder’s positive or negative response to the guideline.

Assign A for extremely important, B for fairly important, and C for not very important. Record these letters in the column entitled “Assessment of impact.”

4. Plans for communications and engagement with stakeholders groups will be directly related to the level of interest and impact the change has for these individuals/groups. Consider how you might approach each of the stakeholders. What kind of information will they need? How important is it to involve the
stakeholder in the guideline development group, any working groups and/or the consultation process? Are there other groups or individuals that might influence the stakeholder to support your guideline? Are there specific factors that you need to be aware of? Record your strategies for obtaining support or reducing barriers to your guideline in the last column in the matrix. “Potential strategies for obtaining support or reducing barriers”. Use this to inform your communications plan (see step 6).

**Key Elements**

- The views and preferences of the population to whom the guideline will apply (patients, public etc) are sought and the guideline development group takes these into consideration.
- The intended users of the guideline are clearly defined.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*

**Step 5: Establish a guideline development group**

The development of a clinical guideline requires the formation of a multidisciplinary guideline development group for the adoption of pre-existing guidelines developed elsewhere, the adaptation of other guidelines for use in an Irish context or the development of a new set of guidelines. Guideline development is a complex process and it is essential that the required clinical, research, economic, management and administrative skills are available on the group in order to produce a robust evidence based guideline. It is also essential that that the group includes, or involves, all relevant stakeholders. This contributes to increased awareness of clinical guidelines and opportunities for group members to develop ownership of the guidance. The group should be large enough to include representatives with expertise and experience, but small enough to ensure effective group working. All members should play an active role in the development of the guideline.

*Who should be on the guideline development group?*

Guideline development group members will be people whose involvement is essential to completion or achievement of one or all stages of the clinical guideline path. This will include clinical, research, economic, management and administrative specialists. A
stakeholder analysis should be utilised to determine membership and extent of involvement at the various stages of the clinical guideline path (see step 4). Professional organisations who are significantly affected by the clinical guideline e.g. Royal College Physicians of Ireland, Irish College of General Practice, Irish Association of Directors of Nursing and Midwifery, can be asked to nominate relevant experts so that such expertise is involved from the outset.

Other stakeholders who are not represented on the guideline development group can have input to the guideline development process during the consultation phase. The guideline development group should ensure clarity of the roles and responsibilities of their group as well as reporting paths to any overseeing committee.

Guideline development group members may represent a region, a healthcare organisation, a professional group or a speciality. Each member who is acting as a representative has a role in consulting with their colleagues to ensure that a wide range of views are considered.

### Key Elements

The guideline development group includes individuals from all the relevant professional groups and intended users, for example healthcare professionals, hospital managers, methodological experts etc.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*

### Tips

- It may be effective to set up subgroups to undertake particular aspects of guideline development, such as searching for, and appraising clinical guidelines, and then bring back findings to the larger group.
- Invite professionals with expertise required in one specific area of the guideline to comment on specific sections of the guideline or attend particular meetings as required.
The Guideline Development Group is likely to include:

<table>
<thead>
<tr>
<th>Chair</th>
<th>Clinical experts</th>
<th>Management</th>
<th>Research, Information and Economic experts</th>
<th>Project Management and Administrative support</th>
<th>Service users</th>
</tr>
</thead>
<tbody>
<tr>
<td>This person should be neutral (if possible) and have expertise in chairing groups.</td>
<td>Representation from professional groups significantly affected by the clinical guideline (e.g. members of the MDT). Local and national experts should be represented for national guidelines.</td>
<td>Senior management representatives from the relevant services (e.g. HSE, Hospital Trust CEO). Local and national representation is important.</td>
<td>Experts may be chosen from disciplines such as clinical librarians, epidemiology, biostatistic, healthcare research, bioethics, health economics, health technology &amp; information sciences.</td>
<td>Project managers and administrators are essential to ensure the complex process of guideline development is adequately supported and resourced.</td>
<td>Service users to provide their perspectives on healthcare processes, priorities and outcomes.</td>
</tr>
</tbody>
</table>

**Skills and attitudes of guideline development group members:**

- Competence in the clinical topic or area
- Competence in the stages of the clinical guideline path – involvement of a librarian/information specialist, economic expert and researcher is invaluable
- Project management skills – ideally there should be a designated project manager to support the guideline development group in identifying and achieving its aims
- Interest and enthusiasm for improving healthcare services
- Time to commit to the work of the group (e.g. attending meetings, background reading, consultation, commenting on drafts)
- 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
- Skills and attitudes for service users representatives – see section on service user involvement.
The guideline development group chair’s responsibilities are to:

- Develop and agree terms of reference
- Ensure the guideline is developed using a robust methodology and that each of the stages of the clinical guideline path are addressed
- Set and agree timelines (using a standard project management approach, where possible)
- Set and circulate the agenda of each meeting to members
- Encourage broad participation from members in discussion
- Identify and assign tasks
- Agree a process for dealing with conflicts of interest
- Identify and oversee the progress of specific subgroups
- End each meeting with a summary of decisions and actions.

The role of guideline development group members are to:

- Review and agree membership of group
- Agree timelines for meetings and the clinical guideline development process
- Convene as required
- Give consideration to each of the stages of the clinical guideline path
- Review existing policies, guidelines, national and international evidence of best practice, relevant scientific and clinical expert opinion pertaining to the clinical guideline area
- Determine whether to adapt, adopt or develop a new clinical guideline
- Draft clinical guideline using a robust methodology
- Consult with relevant interested parties and the public
- Review and incorporate feedback from consultation process as appropriate
- Finalise and approve clinical guideline.

*Service user involvement*

Service users have different perspectives on healthcare processes, priorities, and outcomes from those of healthcare professionals. Service users can identify issues that may be overlooked by healthcare professionals, can highlight areas where the service user’s perspective differs from the views of healthcare professionals, and can ensure that the guideline addresses key issues of concern to service users.

Service users may not necessarily want to be engaged extensively over every healthcare issue. Instead they should be engaged appropriately; hence different types of involvement are appropriate at different times. There are many different ways of involving service users, e.g. participation on the guideline development group, surveys, in-depth interviews, focus groups, public meetings and forums and participation in workshops. Where it is decided to invite service users onto the guideline development group, ideally more than one service user representative should be invited as it may be intimidating to be the only ‘lay’ member of the group.

Each method of service user involvement will have its own strengths and weaknesses. It is important to understand the type of service user involvement that you require and select the right method for the particular purpose and context in question. Utilisation of a variety of methods to engage with service users is encouraged. To explore each method in greater detail is beyond the scope of this document however, for further information on service user involvement visit [www.peopleandparticipation.net](http://www.peopleandparticipation.net).

**Key Elements**

The views and preferences of the population to whom the guideline will apply (patients, public etc) are sought and the guideline development group takes these into consideration.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
**Additional roles for service users on clinical guideline groups:**

- To ensure that key questions are informed by issues that matter to service users
- To identify outcome measures they think are important for each key question
- To assist the guideline development group with the collection of service user views e.g. by helping to prepare questions for focus groups
- To help the guideline development group with consultation arrangements
- To identify areas where service users’ preferences and choices may need to be acknowledged in the clinical guideline
- To help write the information for the service users section of the clinical guideline including identifying sources of further information
- To help ensure that the clinical guideline is clearly and sensitively worded.

**Step 6: Outline communications and consultation process**

A communications plan involves the guideline development group giving consideration to the information and messages they need to convey and the information they need to hear from staff and service users during development and implementation of the clinical guideline. It outlines the key audiences for messages; and the best way to deliver them. Use your stakeholder analysis matrix to inform the development of your communications plan (see Step 4).

**Sample communications plan**

<table>
<thead>
<tr>
<th>Who</th>
<th>Why</th>
<th>When</th>
<th>What</th>
<th>How</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use your stakeholder analysis to list each stakeholder you need to communicate with.</td>
<td>Use your stakeholder analysis to identify why you need to communicate with them.</td>
<td>Plan the timing of your communication relative to the stage of your clinical guideline and also ensuring that your communication does not compete unnecessarily with other events.</td>
<td>Clearly articulate what information you need to communicate to each stakeholder bearing in mind: - What they know already - How the guideline may affect them - Where they can get more information - What you want them to do.</td>
<td>Identify the best channels available to you to communicate with each stakeholder e.g. in person inter/intranet, newsletters.</td>
</tr>
</tbody>
</table>
It is important that a communications plan is put in place from the early stages to help to outline the key stakeholders and the best way to engage with them. There should be clear lines of responsibility to ensure that regular communication is maintained and the plan should be reviewed on a regular basis. It is also important that the intention to develop a clinical guideline is reflected in the relevant service plans. This will help to secure management support, resources and will signal the intention to develop the clinical guideline.

**Step 7: Determine resources**

It is important that the resources required to complete the development of the clinical guideline are planned for, to ensure that the process is as efficient as possible. These resources include suitable qualified and multi-disciplinary staff expertise and their time, project management and administrative support, access to electronic resources, meeting rooms, printing and publication costs, research commissioning (consider seeking grants from Health Research Board and other organisations) etc.

Identifying the resources required, utilising available resources where possible and including others with expertise in the service planning or other relevant processes (e.g. grant applications) to get access to resources can increase likelihood of timely completion of guideline.

The source of funding must be listed in the guideline documentation, 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.

**Key Element**

The views of the funding body have not influenced the content of the guideline. The funding body or source of funding is clearly described or there is an explicit statement of no funding.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
**Step 8: Address and manage conflicts of interest**

Minimising conflicts of interest in guideline development are critical to ensuring public and healthcare practitioner 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 or other commercial companies. These relationships may have an influence on guideline development group members. Other potential conflicts of interest 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. Thus all members of the guideline development group should complete a written declaration of conflict of interest early in the development process. These declarations should be reviewed and regularly updated during the course of guideline development. The NCEC conflict of interest document can be used as a template and is available at [www.patientsafetyfirst.ie](http://www.patientsafetyfirst.ie)

**Key Element**

Competing interests of guideline development group members are recorded and addressed with a clear description of the measures taken to minimise the influence of these interests on guideline development.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
Stage 2: Develop

| Step 1. | Define key questions |
| Step 2. | Search for clinical guidelines and research studies |
| Step 3. | Screen clinical guidelines |
| Step 4. | Appraise clinical guidelines |
| Step 5 | Appraise other research studies |
| Step 5. | - Adopt a clinical guideline |
| Step 5. | - Adapt a clinical guideline |
| Step 5. | - Develop a new guideline |
| Step 6. | Prepare a draft guideline |
| Step 7. | Communicate and consult |
| Step 8. | External review |
| Step 9. | Prepare final guideline |
| Step 10. | Endorsement |

Guideline development groups develop new guidelines by adopting or adapting an existing clinical guideline or creating a new one (de novo), or through a combination of adopting or adapting certain aspects of a guideline and creating de novo recommendations where existing guidelines are lacking. What these terms mean are outlined below in order for the guideline development group to consider, from the outset, which method, or combination of methods they are likely to use.

**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 recommendations within a guideline may be applicable and adopted following appraisal.*

**Adaptation**
Adaptation is defined as “the systematic approach for considering the use and/or modifying guideline(s) produced in one cultural and organisational setting for application in a different context” (Harrison and van den Hoek 2010). This takes advantage of existing high-quality clinical guidelines which are then modified to meet the needs, priorities, legislation, policies and resources of a targeted setting.
Creating a new guideline (de novo)

Developing a complete new clinical guideline using primary research only should only be undertaken if an existing clinical guideline of good quality cannot be identified and if sufficient resources and expertise are available. However, certain recommendations within the clinical guideline may be developed de novo, where an existing guideline recommendation is out of date due to more recent or more robust evidence becoming available.

Creating a clinical guideline can take place at the national or local level; there are benefits and disadvantages to both approaches. A national approach will mean greater availability of expertise and resources to enable the creation of high-quality, valid clinical guidelines with a broad perspective. Local initiatives to develop new clinical guidelines increase ownership and commitment; however it may be difficult to source sufficient resources and expertise locally to develop new guidelines to a national standard.

Evidence on (a) effectiveness and (b) cost-effectiveness should be included in the development of all guidelines. Guidance for searching and appraising both effectiveness and cost-effectiveness is presented in Step 2. This is to support guideline development groups who are likely to lack general experience around searching for economic/cost-effectiveness evidence.

Tips

- Given the resources and time involved in creating clinical guidelines and the expertise required, the NCEC recommends adapting an existing clinical guideline when feasible.
- Unless the guideline/guidelines being adapted have been very recently developed, it is likely that some recommendations are out of date. Where this is the case, the guideline development group should search the literature for other research published in relation to that particular recommendation and develop a de novo recommendation based on that research if the evidence is robust.
- All aspects of the development stage must be explicitly described either within the guideline or within the supporting documentation. Guidelines can only be endorsed by the NCEC where all prioritisation and appraisal criteria are explicitly addressed, or the reasons why they could not be addressed articulated.
Step 1: Define key questions

The broad topic area which the guideline will address should already be identified in the planning phase.

In order to identify the evidence required to address the topic it is essential to define one or more key questions.

Ideally with the help of a librarian or information specialist, each key clinical question should be framed into a detailed question to enable a search strategy to be developed. Two widely-used approaches to framing these questions are known as:

- PICO, for Population, Intervention, Comparison, Outcome
  or
- PIPOH, for Population, Intervention, Professional, Outcomes of interest and Healthcare Setting.

- Population - the population concerned and characteristics of disease or condition
- Intervention - the intervention(s) or diagnostic test of interest
- Comparator - to which the intervention is compared
- Professional - the professionals to whom the guideline will be targeted
- Outcome - the expected outcomes, including service user outcomes, system outcomes and/or public health outcomes
- Healthcare setting - the healthcare setting and context in which the guideline is to be implemented

Ensuring that the clinical question addresses all four or five of these areas as outlined will help to ensure that the evidence will be relevant to the particular circumstance being addressed by the clinician.

The most difficult aspect of framing appropriate key clinical questions is determining the level of specificity of what goes into each of these categories. The clinical questions should be clear, unambiguous, focused and concise. The guideline development group should allow time to draft and refine key questions in order that they cover the core elements of the proposed clinical guideline.
**Step 2: Search for clinical guidelines and research studies**

**Search Strategy**
Based on the key question(s) defined above, a search strategy should be developed. The search strategy should be documented explicitly in order that it can be replicated.

**Search Terms**
Suggested search terms include: MeSH (Medical Subject Headings) and text words that can be used are clinical guideline(s), practice guidelines, clinical practice guideline(s), standard(s), consensus statement(s), and protocol(s) consensus.

Where required the search strategy should be replicated substituting the search terms used for guidelines for other research studies.

**Search Limits**
The search strategy may include limits such as language of publication (e.g., English only) or date of publication (e.g., within the past 5 years).
Inclusion and Exclusion Criteria

Additional inclusion and exclusion criteria can then be applied when potentially relevant guidelines have been retrieved. For example, a group may only be interested in guidelines based on high quality scientific literature and therefore exclude consensus documents; or they may include only guidelines developed by credible professional organisations and exclude those developed by one person. Regardless, the criteria should be determined before starting the search.

Where to Search?

To search for clinical guidelines, commence with a search of guideline clearinghouses such as the United States National Guideline Clearinghouse (www.guideline.gov) and the Guidelines International Network (www.g-i-n.net) or search websites of known guideline developers such as the Scottish Intercollegiate Guidelines Network (www.sign.ac.uk) and the National Institute for Health and Clinical Excellence (www.nice.org.uk).

Next search the Internet. Guideline developers may also post their guidelines directly on the web. One should not assume that guidelines found on the Internet are poor quality or that those indexed in Medline are necessarily high quality. All guidelines that meet the inclusion criteria should be retrieved.

Next undertake a search in major medical and allied health search engines such as Medline, Pubmed, Embase and/or PsycINFO initially for clinical guidelines but then also for other high quality evidence.

One good source of high quality research is the Cochrane Database of Systematic Reviews and this should be searched for Cochrane systematic reviews published on the topic. See (www.cochrane.org) for more information.

Finally, involve front-line staff. This can give insight as to how the topic of the clinical guideline has been addressed elsewhere e.g. in other organisations and services, in order to determine what has worked well. It may also produce local guidelines that have not been published.
In some cases, the published guideline will have minimal information about the development process because this information is presented elsewhere, perhaps in a technical report. Efforts should be made to obtain these supplemental documents.

**Tips**

- If undertaking searches, utilise a librarian or other information specialist who has experience in this area (service providers may already have access to these specialists on site, particularly in hospital libraries, or through their local/regional/national office).
- Contact previous clinical guideline developers for sharing of information or resources.
- The search strategy used for clinical guidelines could be used as the basis for the economic search by removing the search terms focusing on guidelines and adding an economic filter.

**Example**

Example of one search in Oral Health Assessment
(note in the absence of clinical guidelines the search was widened to all studies)

Timing of tooth emergence
1. Tooth Eruption [Mesh]
2. (tooth OR dental) AND (emergence or erupt*)
3. permanent dentition
4. Dentition/Permanent [Mesh]
5. “permanent tooth” OR “permanent teeth” OR “permanent molar”
6. age OR time OR timing OR chronology OR duration
7. OR 2
8. Tooth Eruption, Ectopic [Mesh]
9. 7 NOT 8
10. 3 OR 4 OR 5
11. 9 AND 10
12. 6 AND 11
Total Hits: 313 (April 2011)
Longitudinal studies: 9
Search for economic evidence

Any systematic literature 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, the NHS Economic Evaluation Database and the Health Technology Assessment Database (all available through www.crd.york.ac.uk/CRDWeb), the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews (www.thecochranelibrary.com). Along with searching these specialised databases, a search should be performed using the major health search engines such as MEDLINE and EMBASE. A number of economic search filters are available on www.york.ac.uk/inst/crd/interstasc/econ.htm covering CINAHL, EMBASE, MEDLINE and PsycINFO. An example of a systematic search of the economic literature is included in Appendix II.

Key Elements

- The criteria for selecting the evidence are clearly described with reasons for including and excluding evidence clearly stated.
- Systematic methods have been used to search for evidence on effectiveness and cost-effectiveness to ensure that the clinical guideline is based on best available evidence. The full search strategy should be clearly outlined.

(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)

- Evidence Analysis - Are clinical guideline recommendations based on an analysis of the evidence?

(National Clinical Effectiveness Committee Clinical Guideline Screening and Prioritisation Criteria, V2, 2012)
Step 3: Screen clinical guidelines

The objective of this step is to select guidelines for further appraisal. A preliminary assessment of the health questions covered by retrieved guidelines should be carried out to eliminate those clearly not relevant. Other criteria such as the guideline publication date should be decided upon in advance in order to screen out guidelines (a good search strategy will already have screened out of date clinical guidelines).

One strategy to reduce the number of clinical guidelines for more detailed appraisal is to use the domain ‘rigour of development’ outlined by HIQA (2011) in the National Quality Assurance Criteria to identify those guidelines which are of higher quality (see Appendix 1).

The guideline screening exercise should be noted in a matrix – see example below.

<table>
<thead>
<tr>
<th>Clinical Guideline Publication Date</th>
<th>Clinical Guideline 1</th>
<th>Clinical Guideline 2</th>
<th>Clinical Guideline 3</th>
<th>Clinical Guideline 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigour of Development Score</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Key Question 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Key Question 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Key Question 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Step 4: Appraise clinical guidelines**

Those guidelines screened in Step 3 as likely being of high quality must now be assessed and interpreted in order to ensure that any recommendations adopted or adapted from those guidelines are based on evidence, that the evidence supports the recommendations listed, that the recommendations are current, and acceptable and applicable to the Irish health system.

All the appropriate people must be involved in the appraisal phase. Each guideline should be appraised separately by at least two and preferably four appraisers. This helps minimise potential bias. The appraisers should include at least one clinical expert and one research/information expert. The conclusions from the appraisal exercise should be discussed and validated by the whole guideline development group.

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

**A. Appraise the overall quality of the guideline**

The National Quality Assurance Criteria (HIQA 2011) should be applied to all guidelines that have been screened for inclusion. Note, in Step 3: screen clinical guidelines, the appraisers may already have used the rigour of development domain of the criteria; in this case the appraisers can add to that work by examining all other domains. The National Quality Assurance Criteria Scoring Sheet can be used to record results of appraisal process (see Appendix III). This process provides an explicit method of rating the quality of a guideline. 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.

**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
To ensure the guideline is current or has plans to update it, a search on a major medical or allied health search engine for systematic reviews and other significant research published since the release of the guideline may also be useful (this should already have been undertaken in Step 2- Searching for guidelines and research studies).

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.

Guideline quality and currency should be noted in a matrix – see example below:

<table>
<thead>
<tr>
<th>Indicate with a ✓ if key question(s) is included in the Clinical Guideline. Note (a) Quality (b) Currency of the Clinical Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guideline 1</td>
</tr>
<tr>
<td>Quality</td>
</tr>
<tr>
<td>National Quality Assurance Criteria Scores (HIQA 2011)</td>
</tr>
<tr>
<td>Currency</td>
</tr>
<tr>
<td>Key Question 1</td>
</tr>
<tr>
<td>Key Question 2</td>
</tr>
<tr>
<td>Key Question 3</td>
</tr>
</tbody>
</table>

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 should be drawn up. Each guideline should be associated with overall National Quality Assurance Criteria scores 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 the National Quality Assurance Criteria, and each recommendation is associated with a description of the level of evidence on which it is based, it is likely not necessary 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.
The difficulty with levels of evidence is that there is no common classification system and therefore one may need to reclassify each level from the source guideline into a comparable system.

Generally it is agreed that a hierarchy of evidence exists where:

- Meta-analyses and systematic reviews (Cochrane or other)
  *Are a higher level of evidence than:*
- Randomized Controlled Trials
  *Are a higher level of evidence than:*
- Evidence-Based Guidelines and Summaries, Cohort Studies, Case-Control Studies
  *Are a higher level of evidence than:*
- Case Reports, Case Series, Practice Guidelines, Clinical Reference Textbooks,
  *Are a higher level of evidence than:*
- Expert opinion and anecdotal evidence.

NCEC recommends either

Reclassifying the level of evidence into a written description e.g. recommendation based on one systematic review of RCTs, or 3 case control studies or

If a system of classifying the level of evidence is used an explanatory table outlining the level of evidence rating associated with each study type is provided.

The level of evidence associated with each recommendation in each guideline should be included in a matrix – see sample below.

<table>
<thead>
<tr>
<th>Guideline - Evidence and Recommendations Matrix</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note level of evidence for each recommendation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Clinical Guideline 1</th>
<th>Clinical Guideline 2</th>
<th>Clinical Guideline 3</th>
<th>Clinical Guideline 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommendation 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommendation 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Step 5: Appraise other research studies

Following appraisal of clinical guidelines, it may be necessary to examine other research studies. The need to augment the clinical guidelines with other more current or more robust research evidence will have been identified in the previous steps.

Critically appraise the quality, validity and relevance of all evidence gathered as part of your search. As a first step, studies can be categorised according to the ‘hierarchy of evidence’ as described in Step 4. A librarian or other information professional should be able to assist you with this process.

Following this a methodological assessment of studies should be completed. The strengths and limitations of studies should be detailed as per example below.

There are critical appraisal tools available e.g. CASP (available at http://www.casp-uk.net/) that can be used to appraise the strengths and weaknesses of research studies.

If any research studies are found to be current and of high quality, the guideline development group need to consider whether any recommendations from previous guidelines need to be changed or whether any new recommendations should be included within the guideline.

The level of evidence associated with each recommendation in each research study should be included in a matrix – see example below.
Reviewing the economic evidence

Studies retrieved from the economic literature search must be reviewed to identify relevant data. A systematic and transparent review process involving the following three steps should be used: selecting relevant studies, appraisal of the evidence, synthesising and summarising the results.

1. 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. 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. Inclusion criteria should specify the following: the relevant populations, interventions, date range (older studies may include outdated practices), countries or settings (studies performed in different healthcare systems may not be applicable to Ireland).

2. 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 system similar to the Irish setting? Secondly, is the study of adequate quality? Are there major limitations in the study design or in the economic modelling? There are a number of tools that can be used to assist in considering the quality of economic studies: the CHEC-list\(^1\), the NICE guidelines Methodology checklist- economic evaluations\(^2\) and the health technology assessment checklist for decision-analytic models\(^3\).

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\(^1\)www.maastrichtuniversity.nl/web/Institutes/Theme/DepartmentsCAPHRI/HealthServicesResearch/ResearchHSR/CHECProject.htm
\(^3\)http://www.hta.ac.uk/project/1342.asp
3. 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 limitations 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.

**Key Element**

The strengths and limitations of the body of evidence are clearly described with the methods or tools for assessing the quality of the evidence documented.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
Step 6: Adopt, adapt or develop a new clinical guideline

Following the above appraisal of each of the guidelines, research studies and other relevant documents found, the guideline development group should collectively review the evidence and recommendations tables developed by the appraisers in order to decide on the best approach to develop their Irish clinical guideline.

The options are to:

a. Adopt (accept the entire guideline and recommendations)
b. Adapt the clinical guideline
c. Reject the entire guideline (and develop a new guideline).

The evidence and recommendations matrix can be the focus of the group’s discussion and the agreement of the level of evidence should involve all members of the guideline development group. The evidence and recommendations matrix facilitates identification of similar recommendations in different guidelines, as well as differences in recommendations between guidelines. The matrix also facilitates easy identification of recommendations supported by strong evidence.

Tip

If adopting or adapting a guideline it is important and helpful to contact the original guideline development group in order to obtain permission to use the guideline, to discuss any modifications to the actual recommendations (to make sure it still accurately reflects the evidence as applied to the local setting), and to gain helpful suggestion and lessons learned from professionals who have experience with the guideline development process.

Adopt

As per step 4, appraisal, the clinical guideline group has identified a guideline that is of the highest quality and fit exactly for the context in which it is required. It can be adopted following branding and consultation.

Adapt

As per step 4, appraisal, the clinical guideline group has identified one, or a number of, guidelines that are high quality clinical guidelines, and with modification could meet the
needs, priorities, legislation, policies and resources of the Irish setting that can be ‘adapted’ to produce an Irish guideline.

The guideline development group can decide to:

1. Accept the evidence summary of the guideline: Having reviewed the guidelines the guideline development group accept the description of the evidence, but reject the interpretation and recommendations. The guideline development group will develop their own recommendations based on the evidence description.

2. Modify specific recommendations.

3. Accept specific recommendations but not others. The guideline development group 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.

Additional Resources for Guideline Developers:

Guideline Adaptation: A Resource Toolkit for further information to guide the adaptation of guidelines [www.g-i-n.net](http://www.g-i-n.net) or visit [http://www.adapte.org/www/](http://www.adapte.org/www/)

**Develop a new guideline**

Creating a new guideline requires the identification and synthesis of research studies to develop evidence based recommendations. This manual does not provide detail on how to undertake this process and NCEC recommends that de novo development should only be undertaken if an existing clinical guidelines cannot be identified and sufficient resources and expertise are available.

**Additional resources for de novo guideline developers:**

- SIGN ([www.sign.ac.uk](http://www.sign.ac.uk))
- NICE ([www.nice.org.uk](http://www.nice.org.uk))
- hselibrary.ie
Step 7: Prepare a draft clinical guideline

Use the NCEC Clinical Guideline Template (Appendix IV) to structure the clinical guideline. This encourages uniformity but it can be modified to suit guideline content requirements.

- Make the clinical guideline as user friendly as possible. A summary section including scope, list of recommendations and list of criteria for audit and monitoring, ideally on the front and back of an A4 page can be invaluable to busy practitioners.
- Decide what content is essential to the guideline and what content can be part of a resource document, a link to another site or a link to a PDF document etc.
- Keep the audience in mind when writing guidelines. Guideline topics are rarely restricted to one discipline so they must be relevant to medical staff, nursing staff and health and social care professionals. Service users are also a key audience.
- The guideline needs to include content specific to the variety of settings in which the target service user group or clinical practice is present. For example, does the guideline include management in the acute care setting and/or the community?
- Use internationally agreed nomenclature where possible, e.g. ICD (disease), ICHI (health interventions), ICF (functioning, disability and health) and DSM IV (psychiatric) to facilitate national and international unity.
- Include performance indicators and audit criteria to encourage service providers to monitor their adherence to the guidelines.

Recommendations

- Each recommendation statement should be clear, concise and only address one topic, action or intervention.
- Avoid ambiguity
- ‘DO NOT DO’ recommendations should be included where there is evidence that a practice is ineffective or harmful and should be discontinued.
- Link the recommendations to the evidence (where possible note the type or level of evidence and the recommendations strength).
- Identify key recommendations, i.e. those that the guideline development group consider of key importance.
NOTE: The NCEC requires recommendations to be based on the highest level of evidence available. While generally meta-analyses of randomised controlled trials are considered the highest level of evidence, they are often not available, or even appropriate, to answer certain clinical questions. Other research studies, such as cohort or case control studies may be more suitable evidence to address the clinical question. For some clinical questions, only case histories, consensus or expert opinion are available. Therefore, a guideline development group need not reject their clinical guideline or recommendations if their clinical guideline or recommendations are not based on RCT evidence, where RCT evidence is not available. However, they must demonstrate that through their search strategy they have identified the highest level of evidence available. The guideline must explicitly state what that level of evidence each recommendation is based on i.e. whether it is a meta-analysis or expert opinion. Should a guideline development group want to use an international system, NCEC recommends the use of GRADE to provide explicit rating of the quality of evidence. However, NCEC will accept recommendations that have any explicit description of the quality of evidence on which they are based. Further information on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system of rating quality of evidence and grading strength of recommendations is available at

http://www.gradeworkinggroup.org/publications/JCE_series.htm

Consider the economic impact of guidelines

General principles

Budget impact analysis 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 budget impact analysis may be a more appropriate methodology to use when determining the economic impact of a guideline. Further detailed guidance on the conduct of both a budget impact analysis and economic evaluation can be found at http://www.hiqa.ie/healthcare/health-technology-assessment/guidelines.
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. 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 multidisciplinary approach.

Assessing the economic impact can be broken into three distinct steps: identifying the resource use that may change, estimating the size of these changes and determining the relevant costs for these changes. A worked example from the ‘Guiding Framework and Policy for the National Early Warning Score System to Recognise and Respond to Clinical Deterioration’ is included in Appendix II.

1. Identifying the resource use that may change

The incremental cost is the total cost of implementing the national guideline less what would have been spent on the current standard of care. When evaluating the economic impact, it is the incremental impact that should be considered. Thus, it is the additional resources which 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 are included. In the base case analysis, 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 intervention 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.

Indirect costs including both individual and societal costs can be considered in a scenario analysis. Such costs could include cost of, or savings from changes in absenteeism from work, disability, need for long-term care etc. It is particularly important to consider these costs in instances where significant budget implications for other publicly-funded services or transfer payments are anticipated. For example, interventions enabling patients to return to employment will have resource implications for incapacity benefits, consumption and employment-related taxes.

Introducing a new guideline may lead to reductions in resource use and costs. This may arise due to improved health outcomes (e.g. fewer bed days), a reduction in adverse events or stopping or changing current practice (different material costs). Although introduction of a new guideline may lead to a reduction in staff requirements, it may be difficult to realise any potential savings (e.g., redeployment of staff).

2. Estimating the size of these changes

Once the key resources and costs changes have been identified the next step is to consider the size of these changes. To do this, the relevant time horizon should be agreed- this should be reasonable and clear and include the initial set-up period. It is usually necessary to estimate the number of individuals with a given condition or disease who will be affected by guidelines within the defined time horizon. In some instances however, it will be necessary instead to consider the episodes of care. Whether to use patient-based or episode-based methodology will depend on how the costs are incurred.
3. Determining the relevant costs for these changes

Labour (pay) costs should be calculated using national consolidated salary scales and include pay-related costs (e.g. superannuation, PRSI). These should be estimated in accordance with agreed methods. Further details and a worked example can be found in *Guidelines for Budget Impact Analysis of Health Technologies in Ireland* (HIQA 2010).

As Ireland does not have a central medical costs database, the generation of valid Irish cost data is challenging and time consuming. Where Irish data is not available, it may be necessary to use data from other countries; if converting international cost data it is vital that the appropriate methods are used, namely, using the Purchasing Power Parity. In some circumstances it may be necessary to inflate retrospective cost data. This should be done using the consumer price index. Further details and worked examples on both these methods can be found in *Guidelines for Budget Impact Analysis of Health Technologies in Ireland* (HIQA 2010).

**Tips**

- If an economic evaluation is to be performed, a useful framework to use is that of a ‘miniHTA’ these are typically conducted in a shorter timeframe and with fewer resources than a full health technology assessment. For an example of a completed miniHTA see [http://www.hiqa.ie/publications/economic-evaluation-repeat-universal-antenatal-screening-hiv-third-trimester-pregnancy](http://www.hiqa.ie/publications/economic-evaluation-repeat-universal-antenatal-screening-hiv-third-trimester-pregnancy)
- A good way to avoid overlooking any resource changes is to clearly map out the clinical pathways being compared. At each point where the pathways differ consider the change in staff and material resources that will be required.
Key Elements

- The methods used for formulating the recommendations are clearly described.
- The health benefits, side effects, risks, cost effectiveness, resource implications and health service delivery issues have been considered in formulating the recommendations.
- The recommendations have been graded for quality of evidence and strength of recommendation with an explicit link between the recommendations and supporting evidence.
- The guideline has been externally reviewed prior to its publication. There is a clear description of the selection process for experienced and knowledgeable external reviewers and how the information gathered was used by the clinical guideline group.
- A procedure for updating the guideline is provided and includes an explicit time interval.
- The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined.
- The different options for management of the condition or health issue are clearly presented with a description of the population or clinical situation most appropriate to each option.
- Key recommendations are easily identifiable.

(HQA National Quality Assurance Criteria for Clinical Guidelines, 2011)

- What are the direct health costs? What are the indirect costs?
- Is there evidence to indicate that alternative interventions differ significantly in cost but produce similar health outcomes and have similar level of acceptability to consumers and clinicians?
- Is there potential for cost avoidance?
- Is a cost-benefit analysis presented?

(National Clinical Effectiveness Committee Guideline Screening and Prioritisation Criteria, V3 2012)

Refer to the following resources for more information:


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.

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.

Key Element

The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations.

(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)
Refer to the following resources for more information:

1. Guidance on developing key performance indicators and minimum data sets to monitor healthcare quality by HIQA. This is a generic document which may be useful. http://www.hiqa.ie/resource-centre/professionals/kpi-data-sets

2. National Clinical Audit Guidance Document (awaiting final publication - HSE)

3. Audit support tools
   - http://guidance.nice.org.uk/CG81/AuditSupport/doc/English
   - http://guidance.nice.org.uk/CG102/AuditSupport

**Step 8: Communicate and consult**

Refer the clinical guideline for consultation and feedback to a wider group of interested parties (refer to stakeholder analysis Stage 1 - Steps 4 and 6).

Consultation must take place at a stage when it can have a meaningful effect on the outcome. Thus is important to seek and document feedback from all those expected to use the guidelines (clinicians, administrators, professional bodies, service users etc.) and, if necessary, modify the guideline recommendations to address any concerns prior to final public release of a clinical guideline. Consultations should last for approximately six weeks. If a shortened consultation period is necessary, the guideline development group must be clear as to the reasons why. If a consultation covers a period when people are less likely to be able to respond, such as holiday periods, then the guideline development group should try, as far as possible to allow a longer consultation.

This process can improve the wording of recommendations, allow wide buy-in and improve compliance once finalised. Thus the resulting draft clinical guideline should be sent to local practitioners, service users, other stakeholders, and organisational policy

**Tip**

*National key performance indicators*

Considerable work has been undertaken within the clinical care programmes to outline and monitor indicators of performance based on good practice within key initial clinical areas. Guideline developers may wish to review these key performance indicators (KPIs) as a useful mechanism to identify criteria for audit and evaluation. Existing KPIs should be used where they are evidence based, relevant to and consistent with the aims of the guideline.
makers for review and comment. This step should be completed even if a single clinical guideline is adopted in its entirety. Seeking feedback on the proposed clinical guideline ensures that those intended to use the clinical guideline have an opportunity to review the document and identify potential difficulties for implementation before the guideline is finalised.

This step allows policy makers to consider the organisational effects of implementing the recommendations and to begin preparing for its future adoption. It also serves as the first wave of dissemination of the guideline and provides the group with an opportunity to address the issues raised by reviewers before finalising the guideline.

**Tips**
- Consult as widely as possible. This alerts people to the fact that the guideline is being developed and will soon be available.
- Consult with individuals who were not directly involved in the development process.

**Step 9: External review**

It is important to request feedback on a national clinical guideline from reviewers outside the guideline development group. This can identify any problems in presentation, process of development, robustness of the search, content, acceptance of the clinical guideline and its implementation. External review can also help to ensure that recommendations from existing guidelines have not been taken out of context or adapted inappropriately. Being explicit and transparent about the external review, including selection process for the reviewer and how the reviewer comments were responded to within the guideline, should increase the credibility of the process among potential guideline users.

**Key Element**

The guideline has been externally reviewed prior to its publication. There is a clear description of the selection process for experienced and knowledgeable external reviewers and how the information gathered was used by the guideline development group.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
Step 10: Prepare final guideline

The final draft will need to be prepared and signed off by the guideline development group to ensure that it meets organisational requirements and, if it is being submitted to NCEC, follows NCEC guidance for clinical guidelines.

Step 11: Endorsement

The final document should be submitted to relevant professional bodies and/or the NCEC for endorsement. As endorsement by the Minister for Health, on the recommendation of NCEC, will designate a guideline as the national clinical guideline on that topic it will supersede any other guideline on that topic and will be required to be implemented nationally.

Tip

- Contact relevant professional bodies, including NCEC, as early as possible in the development process. They may have requirements that should be considered during the development process.
- Publicly acknowledging endorsement may increase acceptance and uptake of guidelines.
Stage 3: Disseminate

Once complete, the guideline must be made as widely available as possible. Consider both hard copy and electronic formats. A dissemination strategy should be developed and launched as soon as the guideline is available for public release. The clinical guideline should be distributed widely:

- Create a master list of all relevant stakeholders
- Ensure all relevant stakeholders receive a copy of the clinical guideline
- Produce short summaries for use in a range of forums including intranet and websites
- Involve potential users in the development of clinical guidelines to promote ownership (thus the consultation process on the draft clinical guideline can form part of the dissemination strategy)
- Use the media, professional journals and magazines
- Use communication links developed by clinical colleges, healthcare worker organisations, service user groups and educational processes
- Ask leaders and champions to promote the clinical guideline
- Advertise the clinical guideline’s availability e.g. at events, induction sessions etc.

Note: strategies are generally more effective when used in combination
Stage 4: Implement

An implementation plan template should be developed simultaneously to developing the content of the guideline. Some guideline development groups will have an oversight role in relation to implementation (e.g. clinical care programmes), others will not. However, best practice indicates that the guideline development group should keep a log of potential implementation issues and develop solutions and implementation tools during development of the clinical guideline. Service providers can then use the implementation plan template and implementation tools to facilitate implementation within their own service.

Strategies to encourage guideline uptake, such as professional education, audit and feedback, and where possible, accreditation should be utilised. The challenge is to use a systems approach that links guidelines to quality data collection, effective multi-pronged implementation, and a mechanism for evaluation.

It is important that there is a clear statement regarding levels of accountability and responsibility for implementation. This will include being clear about who is responsible for the implementation and monitoring of the clinical guideline at national, regional and local levels. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations should be considered and described.

There are many channels for implementation. The guideline development group should consider the following options and utilise as many options as are appropriate for the implementation of the guideline.

Option 1: Use opinion leaders or champions

Opinion leaders can be enlisted to promote clinical guidelines at every opportunity, both formally and informally. These opinion leaders are often members of guideline development groups.

Option 2: Endorsement by professionals, local groups and/or NCEC

Described in Stage 2 development, this is key to improving uptake.

Option 3: Education of service users
Providing information and education to service users that there is a clinical guideline with regard to an element of care enables them to participate in their own care, to understand what they can expect from an effective service and to voice their expectations with regard to the clinical guideline. Educating service users raises their expectations, which then increases the demand on healthcare workers, which in turn may improve performance.

**Option 4: Educate and train workforce**

Developing capacity to implement a new clinical guideline may require additional skills and competencies. A planned, consultative approach to meeting these requirements will therefore be needed. Refocusing of existing teams may be required to ensure the appropriate skill mix to implement the clinical guideline.

**Option 5: Organise workshops and conferences**

Conferences requiring active participation through workshops, and with follow-up, have been shown to influence healthcare workers’ behaviour.

**Option 6: Incorporate reminder systems in daily work routines**

Reminder systems may influence healthcare workers’ behaviour. These reminders provide a prompt that can be acted on immediately.

**Option 7: Include in quality improvement activities**

If clinical guidelines are to be effective in promoting and improving service delivery at local level, they must form part of an integrated quality improvement strategy rather than being developed and implemented in isolation. For maximum effectiveness, clinical guidelines should be integrated with broader quality improvement activities such as self-assessment, peer review, continuing professional development, performance monitoring and accreditation to promote and improve the quality of care at local level.
Key Element

- The guideline describes facilitators and barriers to its application.
- The guideline provides advice and/or tools on how the recommendations can be put into practice.
- The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered.

*(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)*
Stage 5: Evaluate

| Step 1. | Identify evaluation experts |
| Step 2. | Decide what should be evaluated |
| Step 3. | Identify data collection techniques |
| Step 4. | Decide detail required |
| Step 5. | Share learning |

Evaluation of the clinical guideline in action is essential to test its success and to ensure that it is meeting its purpose and intended objectives. The purpose of the evaluation should be clearly defined and set out at the outset, i.e. clinical guideline developers should clearly define what they want to learn.

A mechanism should be put in place for staff responsible for delivering the clinical guideline, i.e. front-line staff in order that they can feedback directly to clinical guideline developers on the effectiveness of the clinical guideline at operational level.

The NCEC recommends that clinical guidelines are evaluated at least once every three years.

**Step 1: Identify evaluation experts**

Evaluation experts may be available within one’s organisation (e.g., quality improvement programmes), through collaborations (e.g. researchers at universities) or as external consultants. Evaluation experts should be consulted at all stages of the evaluation (e.g. planning, data collection, data analysis, report writing).

**Step 2: Decide what should be evaluated**

An evaluation plan should be generated when guidelines are being developed, and this plan should take into account what data the evaluation will require e.g. data on processes, practices and outcomes.

An evaluation plan of clinical guidelines should consider some or all of the following:
- Assessment of guideline dissemination
- Assessment of whether or not clinical practice is 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
- An economic evaluation of the guideline process

Evaluations may include conducting audits on healthcare records, customised surveys and other data collection initiatives. It may be appropriate to also collect data that can be usefully compared against national data.

**Step 3: Identify data collection techniques**

There are a variety of techniques for collecting data on clinical guidelines:
- healthcare record audit, chart review or electronic records
- healthcare professional survey/questionnaire/interview
- service user survey/questionnaire/interview
- database review (e.g. medical billing information)
- log books/department record/register
- other (e.g., results of blood tests, clinical examination, etc.).

When choosing a data collection technique, always consider whether the measures will provide the desired information, the importance of efficiency in data collection and uses for data collected.

**Step 4: Decide how much detail is required**

The guideline development group should decide not only what is feasible, but also how much detail is required. For example, an evaluation could be conducted to learn about a particular intervention in a specific setting or to inform scientific knowledge. The latter approach will require a more rigorous study design.
Step 5: Share learning

The feedback from the evaluation of clinical guideline effectiveness needs to be communicated to the relevant people and groups to promote learning and continuous improvement. This will facilitate the sharing of best practice and learning from experiences and knowledge of what works best in the organisation.
Stage 6: Revise

Key Element

A procedure for updating the guideline is provided and includes an explicit time interval.

(HIQA National Quality Assurance Criteria for Clinical Guidelines, 2011)

The guideline development group should develop a plan for how the guideline will be reviewed and updated.

Criteria for determining when a guideline needs updating include changes in evidence on existing benefits or harms associated with recommendations, important outcomes, available interventions, evidence that current practice is optimal, values placed on outcomes and resources available for healthcare. An analysis of the factors impacting upon clinical guideline implementation should also be carried out. Based on this analysis, it is important that appropriate action is taken to influence and shape refinement of the clinical guideline, address barriers to implementation and shape future clinical guideline development.

Depending on the extent of the changes to recommendations required by new evidence, the guideline development group may want to seek practitioner or policy-maker feedback on the changes or begin the entire guideline evaluation cycle over again. If a clinical guideline is no longer relevant or appropriate, it is important that corrective action is taken to address the situation.
**Document Control**

A robust document control process lies at the heart of good clinical guideline development.

Your document control procedure must define:
- How you approve documents prior to use e.g. signed-off paper versions or added to your computer network via a password protected system
- How you update and re-approve amended documents
- How you identify changes e.g. by date or issue number
- How you ensure that documents are available where they are needed
- How you control documents of external origin
- How you prevent the inadvertent use of obsolete documents.

To get the most out of your document control procedure it must communicate the steps necessary to ensure that staff and other users of the organisation’s documentation understand what they must do in order to manage that information effectively and efficiently.

**Good document control principles**
- All clinical guideline documents should be clearly identified as such by a clinical guideline number.
- Clinical guidelines should have a cover page showing clinical guideline number, version, title, approval date and revision date.
- Each clinical guideline should have a version status indicator.
- Every time a clinical guideline is changed the version status increments by one.
- Clinical guideline documents should not be changed without the approval of the guideline development group.
- Each page should show the clinical guideline number, version, title, and page number.
- For a clinical guideline in DRAFT state being circulated for comment, the status can be indicated for example by being marked (watermark) "DRAFT" in red.
- Where a clinical guideline is superseded by a new version the old version master can be marked (watermark) "OBSOLETE" (red) and archived. Copies of previous obsolete clinical guidelines should be destroyed when the new version is circulated.
References


Appendices

Appendix I: National Quality Assurance Criteria

Appendix II: Example of Economic Impact

Appendix III: National Quality Assurance Criteria Scoring Sheet

Appendix IV: Clinical Guideline Template

Appendix V: Acknowledgements
## Appendix I: National Quality Assurance Criteria (HIQA 2011a)

### Planning stage

#### Feasibility

1. National health policy and programmes and relevant existing guidelines are specifically considered

#### Scope and purpose

2. The overall objective of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined

3. The health question covered by the guideline is specifically described.

4. The population (service users, public, etc.) to whom the guideline is meant to apply is specifically described

#### Stakeholder involvement

5. The guideline development group includes individuals from all the relevant professional groups and intended users for example healthcare professionals, hospital managers, methodological experts etc.

6. The views and preferences of the population to whom the guideline will apply (service users, public etc) are sought and the guideline development group takes these into consideration

7. The intended users of the guideline are clearly defined

#### Editorial independence

8. The views of the funding body have not influenced the content of the guideline. The funding body or source of funding is clearly described or there is an explicit statement of no funding

9. Competing interests of guideline development group members are recorded and addressed with a clear description of the measures taken to minimise the influence of these interests on guideline development

### Development stage

#### Rigour of development

10. Systematic methods have been used to search for evidence on effectiveness and cost-effectiveness to ensure that the clinical guideline is based on best available evidence. The full search strategy should be clearly outlined

11. The criteria for selecting the evidence are clearly described with reasons for including and excluding evidence clearly stated

12. The strengths and limitations of the body of evidence are clearly described with the methods or tools for assessing the quality of the evidence documented

13. The methods used for formulating the recommendations are clearly described

14. The health benefits, side effects, risks, cost-effectiveness, resource implications and health service delivery issues have been considered in formulating the recommendations

15. The recommendations have been graded for quality of evidence and strength of recommendation with an explicit link between the recommendations and supporting evidence

16. The guideline has been externally reviewed prior to its publication. There is a clear description of the selection process for experienced and knowledgeable external reviewers and how the information gathered was used by the guideline development group
17. A procedure for updating the guideline is provided and includes an explicit time interval

<table>
<thead>
<tr>
<th>Clarity of Presentation</th>
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</thead>
<tbody>
<tr>
<td>18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined</td>
</tr>
<tr>
<td>19. The different options for management of the condition or health issue are clearly presented with a description of the population or clinical situation most appropriate to each option</td>
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<tr>
<td>20. Key recommendations are easily identifiable</td>
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</table>

**Preparing for implementation stage**

<table>
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<th>Applicability</th>
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<tr>
<td>21. The guideline describes facilitators and barriers to its application</td>
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<tr>
<td>22. The guideline provides advice and/or tools on how the recommendations can be put into practice</td>
</tr>
<tr>
<td>23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered</td>
</tr>
<tr>
<td>24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations</td>
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Appendix II - Example of Economic Impact (Clinical Guideline - Early Warning Score)

There is evidence of Economic Impact:

Economic literature review

A systematic review was conducted to identify existing literature on the economic evaluation of early warning score systems. The search was performed in October 2012 (see details in the next section). No economic evaluations, costing studies or studies which focused on the resource implications of introducing an early warning score system were found. Only two studies were found in which the cost or resources implications were considered. (1,2) Detailed descriptions of the literature search terms and inclusion and exclusion criteria are provided in the next section.

Patel et al(1) states that although the cost of the early warning score system itself is inexpensive, the coupled ICU outreach service is expensive but no details on the relative costs of the two aspects of the intervention were provided. Jones et al(2) found a significant reduction in both number of patients admitted to critical care and their length of stay (LOS) in the critical care unit when they moved from a paper based EWS system to an electronic EWS system with automated alerts. This was on top of initial 2 day reduction in LOS seen after the introduction of the paper based system.

There is conflicting evidence on the clinical improvements which may be attributed to the introduction of an EWS system. Mitchell et al.(3) observed a relative reduction of 72% in the number of unplanned admissions to ICU along with reductions in unexpected hospital deaths after the introduction of an early warning score system. However, Subbe et al (4) observed that the rates of cardio-pulmonary arrest, intensive care unit or high dependency unit admissions were similar both before and after introducing a modified early warning score system.

Detailed consideration of budget impact and resource implications

Initial phase

The COMPASS/NEWS Education Programme for the early detection and management of the deteriorating patient was chosen as the national training programme. This training
programme is currently being rolled out, with full implementation expected before the end of 2013.

**Savings**
The COMPASS/NEWS Education Programme is replacing the previously used ALERT system which along with training costs also included an annual licence fee of €600 for each organisation which was being paid by 10 hospitals. Thus moving to COMPASS will result in an annual saving of €6000.

**Costs - staff**
There are approximately 17,500 WTE nurses working in acute hospitals (excluding children’s and maternity hospitals). Although this underestimates the total number of nurses, not all will require training, for instance those working in administration roles or outside the areas that are using the NEWS. Also some will have received the training as part of their undergraduate training. Thus, it was considered a conservative estimate of the number of nurses who require training. A certain proportion of doctors and allied health professionals will also require training. Using the current numbers trained across staff groups based on the latest NEWS audit data, it was estimated that in total an estimated 20,500 staff will require training split amongst nurses (17,500), doctors (2,000) and allied health professionals (1,000).

The training takes approximately 8.5 hours which consists of reading the manual (2 hours), working through an interactive training CD (15 minutes), an on-line quiz (15 minutes) and a 6-hour face to face session. To cost the staff time for training an average salary\(^{(5)}\) for each of the three staff groups was assumed as follows: nurses were staff nurses, doctors were registrars and allied health professionals were physiotherapists. Using these estimates the approximate cost for staff time spent training is €7.3million.

A ‘train the trainer’ model was adopted for implementation of the COMPASS/NEWS Education Programme, that is, suitable staff, doctors, nurses and physiotherapists train as trainers and deliver the multi-disciplinary programme to staff. Approximately 300 staff have been trained to deliver the training consisting of 80% nurses, 10% doctor, 10% allied health professional (based on the NEWS database of trainers). Delivering a training session is estimated to take 8 hours (6 hours training and 2 hours preparation time). On average the training sessions will include 10 trainees (2 trainers) thus each trainer is
required to deliver 6 or 7 sessions. Assuming the same average salary costs as before, the staff time cost involved to deliver training is an estimated €172,000.

Although the staff resources consumed during the training phase are significant these are opportunity costs, that is diverting staff members from their usual activities to attend and provide training, rather than an actual cash cost to the HSE.

Costs - materials
To support the initial phase of training and education, training materials were provided by the Office of the Nursing and Midwifery Services Directorate/Nursing and Midwifery Planning and Development Units. These included 5,000 Manuals, 700 CD’s, 10,000 sample observation charts and 3,000 ISBAR Charts, costing a total of €17,982

On-going intervention costs

Costs - staff
Using the NEWS consists of taking a number of observations, charting these and calculating a score. Of these observations only the AVPU score to detect neurological deterioration is not routinely taken; this consists of assessing whether a patient is alert or if not if they are responsive to voice or pain stimulus. The additional staff time to take the AVPU observation would in most cases be negligible. The time taken to chart and calculate the score is expected to be minimal (approx 15 seconds) and as such no additional staff time is envisioned to be required for the tracking element of the intervention.

Additional staff time may be incurred as there is evidence that introducing an early warning score system can lead to additional work for emergency response systems.\(^3\) The model of emergency response system varies by institution thus the change to the workload will not be uniform across the system. There is evidence however that an increase in emergency response system call outs lead to a reduction in the rate of cardiac arrests and unexpected deaths decrease.\(^6\)

On-going training will consist of a short refresher course to be completed every 2 years. Assuming this refresher training takes approximately 1hr with no additional material costs, then on-going training would cost approximately €425,000 annually. This is based on the same number of staff estimated to need the initial training.
Costs - materials

The early warning score chart is likely to replace currently used charts. These vary across sites with some consisting of a single sheet, however the change to the NEWS chart will have a negligible cost implication.

Cost savings from improved outcomes

It is anticipated that introducing a NEWS will improve patient outcomes by reducing the number of unplanned admissions to ICU and reducing the number of cardiac-respiratory arrests. Patients who experience a cardiac respiratory arrest spend a number of days on ICU thus savings are expected to arise due to the reduction of ICU bed day use, along with potential savings on follow-up treatments for disability that the patient may suffer. For a patient admitted to ICU there is an additional cost of €1,316 per day compared with remaining on a general acute hospital ward (ICU per diem cost €2,225\(^7\), general ward per diem cost €909\(^8\)). On average patients with a cardiac-respiratory arrests spend 5 days in ICU \(^7\), thus that is a saving of €6,580 per patient not admitted to ICU. In 2011, approximately 3,750 inpatients were diagnosed with a cardiac or respiratory arrest, where this was not the main reason for their admittance to hospital.\(^9\) Although the evidence on reduction in cardio-respiratory arrest and ICU admissions is mixed ranging from no observed difference\(^4\) to over 70% reduction with an associated 95% CI of (26%-89%) \(^3\) we assumed a reduction of 26%, which is similar to the lower estimate observed by Mitchell et al\(^3\). If we assume those institutions without a EWS in place observe the full reduction in ICU utilisation for cardio-respiratory events and conservatively that the third of hospitals who already have a EWS see no reduction in ICU utilization, then there could be potential savings of an estimated €4.2million or 3,200 ICU bed days per year.

The savings to be made from a reduction in ICU bed day utilisation, will likely not be realised as a cash saving to the system but rather as an efficiency saving through freeing up of ICU resources to be available for use to other patients in the system.

Table 1 Summary of Incremental Economic Impact over 5 years

<table>
<thead>
<tr>
<th>Category</th>
<th>Item</th>
<th>Approximate Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Phase</td>
<td></td>
<td></td>
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<tr>
<td>Non staff</td>
<td>Materials (Manuals, CDs, Sample Observation Charts and ISBAR charts)</td>
<td>€18,000</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
<td>Cost/Year</td>
</tr>
<tr>
<td>-------------------</td>
<td>-------------------------------------------------------</td>
<td>-------------</td>
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<tr>
<td><strong>Staff</strong></td>
<td>Trainees</td>
<td>€7.3 million</td>
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<tr>
<td></td>
<td>Trainers</td>
<td>€172,000</td>
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<tr>
<td><strong>Ongoing intervention costs</strong></td>
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<td><strong>Non staff</strong></td>
<td>NEWS charts</td>
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<td><strong>Staff</strong></td>
<td>Additional measurements</td>
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<tr>
<td></td>
<td>Charting score</td>
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<tr>
<td></td>
<td>Additional resources to respond to triggers</td>
<td>Unknown but likely to increase</td>
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<tr>
<td></td>
<td>On-going training</td>
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</tr>
<tr>
<td><strong>Savings</strong></td>
<td>ALERT license fee</td>
<td>€6,000 per year</td>
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<td></td>
<td>Reduction ICU bed days, from cardiac respiratory arrests</td>
<td>€4.2 million per year</td>
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<tr>
<td></td>
<td>Follow-up disability treatment from reduction in cardiac respiratory arrests</td>
<td>Unknown</td>
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</table>
Reference List


(8) Parliamentary Question 48039/10: (2011) To ask the Minister for Health and Children the average annual cost of a public bed in an acute hospital.


Economic literature search

The search strategy is based on that used in the clinical literature review with the addition of an economic filter \(^{(10)}\) for the Medline and EMBASE search. The PICOs are provided below along with the search strategy and the detailed search terms used in OVID (Medline and EMBASE) and the Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Database, Health Technology Assessment Database, Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews.

**PICOs:**

*Population:* Adult acute patient, Adult patient, medical patient  
*Intervention:* Early warning score, Modified Early warning Score, VitalPAC\(^{TM}\) (ViEWS), Track and Trigger System  
*Comparison:* Early warning score, Modified Early warning Score, VitalPAC\(^{TM}\) (ViEWS), Track and Trigger System (comparison against each other or with no intervention)  
*Outcome:* Resources, costs

**Search strategy**

Detailed search terms for *Embase Classic + Emtree* 1947 to 2012 October 09 and *Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present*, run through OVID on the 10\(^{th}\) October 2012.

**CONCEPTS:**

A – Early warning score  
B – Methodology filter; economic  
C – A AND B Early warning score and economic filter  
D – Remove duplicates from C All results, no limits, no duplicates

<table>
<thead>
<tr>
<th>Concept A: Early warning score</th>
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<td><strong>ID</strong></td>
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Detailed search terms for the following databases: Database of Abstracts of Reviews of Effects, NHS Economic Evaluation Database, Health Technology Assessment Database, Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews. All searches were limited to Title, Abstract or Keyword. Search was run on 10th October 2012

Figure 1. Flow chart of Excluded studies
### Appendix III: National Quality Assurance Criteria Scoring Sheet

**Guideline Title:**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Criteria - <em>National Quality Assurance Criteria for Clinical Guidelines (HIQA 2011a)</em></th>
<th>Rating (1 to 7) (1 Strongly Disagree) (7 Strongly Agree)</th>
<th>Comments</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Feasibility</strong></td>
<td>1. National health policy and programmes and relevant existing guidelines are specifically considered</td>
<td></td>
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<tr>
<td><strong>Scope and Purpose</strong></td>
<td>2. The overall objective(s) of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined</td>
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<td>3. The health question(s) covered by the guideline is (are) specifically described.</td>
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<td>4. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described</td>
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<tr>
<td><strong>Stakeholder Involvement</strong></td>
<td>5. The guideline development group includes individuals from all the relevant professional groups and intended users (for example healthcare professionals, hospital managers, methodological experts etc)</td>
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<td>6. The views and preferences of the population to whom the guideline will apply (patients, public etc) are sought and the guideline development group takes these into consideration</td>
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<td>7. The intended users of the guideline are clearly defined</td>
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<tr>
<td><strong>Editorial Independence</strong></td>
<td>8. The views of the funding body have not influenced the content of the guideline. The funding body or source of funding is clearly described or there is an explicit statement of no funding</td>
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<td>9. Competing interests of guideline development group members are recorded and addressed with a clear description of the measures taken to minimise the influence of these interests on guideline development</td>
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<tr>
<td>Rigour of Development</td>
<td>10. Systematic methods have been used to search for evidence on effectiveness and cost-effectiveness to ensure that the clinical guideline is based on best available evidence. The full search strategy should be clearly outlined</td>
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<td>11. The criteria for selecting the evidence are clearly described with reasons for including and excluding evidence clearly stated</td>
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<td>12. The strengths and limitations of the body of evidence are clearly described with the methods/tools for assessing the quality of the evidence documented</td>
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<td>13. The methods used for formulating the recommendations are clearly described</td>
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<td>14. The health benefits, side effects, risks, cost effectiveness, resource implications and health service delivery issues have been considered in formulating the recommendations</td>
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<td>15. The recommendations have been graded for quality of evidence and strength of recommendation with an explicit link between the recommendations and supporting evidence</td>
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<td>16. The guideline has been externally reviewed prior to its publication. There is a clear description of the selection process for experienced and knowledgeable external reviewers and how the information gathered was used by the guideline development group</td>
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<td>17. A procedure for updating the guideline is provided and includes an explicit time interval</td>
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<td>Clarity of Presentation</td>
<td>18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined</td>
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<td>19. The different options for management of the condition or health issue are clearly presented with a description of the population or clinical situation most appropriate to each option</td>
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<td>20. Key recommendations are easily identifiable</td>
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<td>Applicability</td>
<td>21. The guideline describes facilitators and barriers to its application</td>
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<td>22. The guideline provides advice and/or tools on how the recommendations can be put into practice</td>
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<td>23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered</td>
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<tr>
<td>24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations</td>
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</table>

**Name:**

**Date:**
Appendix IV: NCEC Clinical Guideline Template

The full guideline contains all the recommendations, together with details of the methods used and the evidence underpinning the recommendations. Core elements of the guideline are outlined as follows:

**Summary**

- Aim of clinical guideline with expected outcome
- Scope of clinical guideline

The health questions covered by the clinical guideline:
- What the clinical guideline covers
- What the clinical guideline does not cover
- The service users to whom the guideline applies
- The health service areas where the guideline applies
- The intended users of the clinical guideline/who is the clinical guideline for?
- List of recommendations highlighting key recommendations
- List of criteria for audit or monitoring

**Stakeholders**

- Guideline Development Group names, organisational affiliation
- Stakeholders (including service users/target populations) names, organisational affiliation and mode of consultation with stakeholders described
- External reviewers names, organisational affiliation
- Conflict of interest statement
- Funding body and statement of influence

**Introduction**

- Rationale for clinical guideline (burden of clinical topic, evidence analysis, economic impact, variability in practice, potential for addressing health issues, guideline implementation)
- Context in which the guideline is being developed – consideration of legislation or regulations that impact upon the clinical guideline area being addressed. Consideration of national priorities within healthcare, including national clinical care programmes.

**Methodology (include appendices as appropriate)**

- Methodology utilised (de novo developments/use of evidence base of an existing clinical guideline/adaptation of a single or a number of clinical guidelines)
- Methods used to search for evidence
- Details of search strategy
- Process for reviewing and synthesising the evidence
- Criteria for selecting evidence listed
- Methods for assessing quality described
- Methods for developing recommendations
• Consensus techniques used
• External review process (comments received from peer reviewers and others should be tabulated, each point addressed and any changes to the clinical guideline as a result noted or if no change made, the reason for this recorded. This should include comments regarding the robustness of the search.)

Recommendations

• Recommendations should be articulated in a standardised format detailing precisely what the recommended action is, and under what circumstances it should be performed. Recommendations should be specific and unambiguous. If different options for management exist these are clearly described.

• Key recommendations are those considered by the clinical guideline group as having the greatest potential impact on service user care, not necessarily those with the highest level of evidence.

• Recommendations for further research should be detailed.

For each recommendation, the following should be provided:
An explanation of the reasoning underlying the recommendation, including:
  ▪ A clear description of potential benefits/ harms, cost-effectiveness, resource implications and service delivery issues.
  ▪ A summary of relevant available evidence (and evidentiary gaps).
  ▪ An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation. It should be noted whether a unanimous decision was reached and if not detail of the difference of opinion should be recorded.
Criteria for audit or monitoring, to include descriptions or operational definitions of 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
  - Recommended frequency and interval of measurement.

Implementation

• Additional resources which may be required to implement the recommendations (e.g. equipment, staff, training, costs). Identify potential facilitators and barriers in accessing resources.
• Identification of potential facilitators and barriers in applying the recommendations
• Supporting advice or tools for guideline implementation
• Options for dissemination of clinical guidelines
• A procedure for updating the clinical guideline

Appendices

This section should include additional information that will support and provide a rationale
for the guideline. This could include:

- Relevant diagrams
- Flow charts
- Models
- Service user information
- Assessment tools
- Staff training and learning packages
- Declarations of interest
- List of individuals/groups that provided feedback
- Each appendix should be incrementally numbered using roman numerical script (e.g. Appendix I, II, III, IV, etc.)

**References**

- List all references used in the guideline adhering to the Harvard method for referencing. In the Harvard system cited publications are referred to in the text by giving the authors surname and year of publication and are listed in a bibliography at the end of the document
Appendix V Acknowledgements

Guideline Development Groups
The National Clinical Effectiveness Committee wishes to acknowledge the following Guideline Development Groups who gave permission for reproduction of guideline elements.

- The Irish Oral Health Services Guideline Development Group
- The National Early Warning Score Guideline Development Group

The NCEC Writing Group
Dr. Jennifer Martin, Consultant in Public Health Medicine, Health Service Executive
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Dr. Máiríin Ryan, Director of Health Technology Assessment, HIQA

(Writing Group declared no conflicts of interest)

Peer Review
Dr Sara Twaddle, Director of SIGN