Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

National Quality Assurance Criteria for Clinical Guidelines

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Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority is the independent Authority established to drive continuous improvement in Ireland's health and social care services.

The Authority's mandate extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting directly to the Minister for Health, the Health Information and Quality Authority has statutory responsibility for:

Setting Standards for Health and Social Services — Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland (except mental health services)

Social Services Inspectorate — Registration and inspection of residential homes for children, older people and people with disabilities. Inspecting children detention schools and foster care services.

Monitoring Healthcare Quality — Monitoring standards of quality and safety in our health services and investigating as necessary serious concerns about the health and welfare of service users

Health Technology Assessment — Ensuring the best outcome for the service user by evaluating the clinical and economic effectiveness of drugs, equipment, diagnostic techniques and health promotion activities

Health Information — Advising on the collection and sharing of information across the services, evaluating information and publishing information about the delivery and performance of Ireland's health and social care services

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Executive Summary

Clinical guidelines are an important contributor to safe, high quality healthcare. Good quality guidelines that are based on the best available evidence of clinical and cost-effectiveness will support a sustainable healthcare system in Ireland that achieves optimal outcomes for service users, using the finite resources that are available.

Within the Irish healthcare system there are many examples of clinical guidelines developed for use at national and local level. There has however, been no specific national group to oversee and quality assure the development of clinical guidelines or to recommend them at a national level. The National Clinical Effectiveness Committee (NCEC) was established in 2010 as a Patient Safety First initiative to promote clinical effectiveness within the Irish healthcare system. One of the roles of the NCEC is to prioritise and quality assure clinical guidelines leading to the development of a suite of National Clinical Guidelines to support the delivery of high quality safe care.

These *National Quality Assurance Criteria for Clinical Guidelines* are intended to aid the development of guidelines, such as those developed by the National Clinical Effectiveness Committee and they can be used by the NCEC in quality assuring and recommending clinical guidelines to become part of the suite of National Clinical Guidelines. This assessment will provide legitimacy to those guidelines that have gone through a standardised development process and have been recommended by the NCEC for endorsement by the Minister for Health as National Clinical Guidelines.

The proposed National Quality Assurance Criteria closely reflect AGREE II - an internationally recognised instrument that has been validated and endorsed by the World Health Organization and is considered by many as the standard in quality assessing clinical guidelines. These criteria, while incorporating the essential elements of the AGREE II instrument, have included a number of modifications to take into account the context of the Irish Healthcare system.

The purpose of this document is to describe the proposed National Quality Assurance Criteria and how they will be applied to clinical guidelines intended to become part of a suite of National Clinical Guidelines.

An overview of the benefits, limitations and effectiveness of clinical guidelines and the steps involved in developing them are also presented to outline the context for the proposed Criteria.

National Quality Assurance Criteria

The proposed National Quality Assurance Criteria for quality assuring clinical guidelines are presented in Table 1. The Criteria are placed under their respective domains and stages of development. For ease of use, the corresponding sections that provide a more detailed explanation are outlined in column two.

Table 1. National Quality Assurance Criteria

Planning stage:

Domain	Section
Feasibility	
1. National health policy and programmes and relevant existing guidelines are specifically considered.	**9.1**
Scope and purpose	
2. The overall objective of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined.	**9.3**
3. The health question covered by the guideline is specifically described.	
4. The population (patients, 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.	**9.4**
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.	
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.	**9.5**
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:

Domain	Section
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.	**9.6**
11. The criteria for selecting the evidence are clearly described with reasons for including and excluding evidence clearly stated	**9.6, 9.7, 9.8**
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.	**9.6, 9.7, 9.8**
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.	
Clarity of Presentation	
18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined.	**9.7**
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.	
20. Key recommendations are easily identifiable.	

Preparing for implementation stage:

Domain	Section
Applicability	
21. The guideline describes facilitators and barriers to its application.	**9.9**
22. The guideline provides advice and/or tools on how the recommendations can be put into practice.	
23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered.	
24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations.	

Applying the criteria

Overall Guideline Assessment	
1.	Rate the overall quality of this guideline (See Appendix 4 for rating template).
2.	I would recommend this guideline for use.

Introduction

1 Purpose of this document

The purpose of this document is to clearly set out, for the Irish context, criteria for quality assuring clinical guidelines and describe their application to become part of a suite of National Clinical Guidelines. It is envisaged that the National Clinical Effectiveness Committee will adopt these criteria and use them in quality assuring clinical guidelines. Groups developing clinical guidelines can also use the criteria set out here to inform their methodology in developing guidelines.

This document provides a description of AGREE II [(1)] - an internationally recognised instrument for quality assuring clinical guidelines - as the proposed national quality assurance criteria closely reflect this instrument but with some modifications to take into account the Irish healthcare setting.

A brief overview is presented in this document of the benefits, limitations and effectiveness of clinical guidelines and the steps involved in their development in order to provide appropriate context for the proposed criteria. The National Clinical Effectiveness Committee (NCEC) have issued Guidance for Clinical Guideline Development Groups [(2)]. NCEC documentation and resources are available at http://www.patientsafetyfirst.ie

It is envisaged that, as national clinical guidelines are endorsed, these will be implemented in local contexts. When national guidelines are not available, the principles set out in this document may also be used to inform the development of clinical guidelines.

2 Setting the scene

Clinical guidelines are an important contributor to safe high quality healthcare. Good clinical guidelines help change the process of healthcare, reduce variation, improve outcomes for service users and ensure the efficient use of healthcare resources [(3)].

There has been a proliferation of clinical guidelines, both nationally and internationally, in the last two decades. This has been driven by a number of factors including rising healthcare costs, variations in the quality of healthcare being provided and a desire among healthcare professionals to provide (and among service users to receive) the best care possible [(4)].

The Health Information and Quality Authority (the Authority) has developed the *National Standards for Safer Better Healthcare* to describe what a high quality, safe service looks like [(5)]. These Standards are an important driver for the implementation of National Clinical Guidelines as they set out the need for clinical decisions to be based on best available evidence and information.

The National Clinical Effectiveness Committee was established in 2010 to promote clinical effectiveness within the Irish healthcare system. Its 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 audit, 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.[6]

Membership of the Committee includes representatives from the Clinical Indemnity Scheme, Department of Health, Health Information and Quality Authority, Health Service Executive, Mental Health Commission, independent hospital sector, postgraduate training bodies, professional regulatory bodies, private medical insurers and patient advocates. The National Quality Assurance Criteria developed by the Authority will support the National Clinical Effectiveness Committee in quality assuring clinical guidelines.

3 Clinical guidelines and the Irish healthcare system

Clinical guidelines and quality assurance are not new concepts within the Irish health system. There are many examples of clinical guidelines that have been developed for use at local and national level by various organisations and professional groups including the Irish College of General Practitioners, Royal College of Physicians Ireland and Royal College of Surgeons Ireland [7-10].

Similarly, a number of national quality assurance programmes have been initiated by the Faculty of Histopathology, Royal College of Physicians of Ireland and the Faculty of Radiology, Royal College of Surgeons in Ireland in collaboration with the Health Service Executive to promote patient safety and the enhancement of patient care. With the establishment of clinical care programmes, under the Directorate of Clinical Strategy and Programmes in the HSE, initial work has been undertaken to develop clinical guidelines.

There has, however, been no specific national group to oversee and quality assure the development of clinical guidelines or to recommend them at a national level.

The Commission on Patient Safety and Quality Assurance (the Commission) in 2008, chaired by Dr Deirdre Madden, highlighted clinical guidelines as a key intervention to support evidence-based practice within a healthcare system [(11)]. The Commission acknowledged the work on guideline development that has been carried out within Ireland and highlighted that:

> 'value can be added to these initiatives through a strategic, systematic approach, properly resourced and supported, where responsibilities are clearly assigned and where guideline development is quality assured and linked to service delivery'.

Following on from the report of the Commission, the then Minister for Health and Children established the National Clinical Effectiveness Committee.

In March 2011, the Government introduced its Programme for Government [(12)]. This programme set out the Government's intention to reform the model of healthcare delivery and how healthcare is paid for by introducing a universal health insurance system. In such a system, where insurers commission services from different providers, agreed National Clinical Guidelines can help commissioners in evaluating healthcare delivery and the effectiveness and cost-effectiveness of different treatments.

Overview of clinical guidelines

4 Defining clinical guidelines

There is an increasing awareness of the importance and benefits of taking an evidence-based approach to clinical decision making. One way of supporting this approach is through the implementation of high quality clinical guidelines.

The National Clinical Effectiveness Committee has defined clinical guidelines as:

> "systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum [(2)]."

Similarly, the American Institute of Medicine (IOM) defines them as:

> "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [(13)].

The Canadian Partnership Against Cancer has undertaken a significant amount of work in the field of clinical guidelines and its Guidelines Action Group defines a guideline as:

> "a set of recommendations about the most appropriate practice for a particular health condition, together with a summary of the evidence that supports the recommendation and a transparent description of the process used to develop recommendations, including how the evidence was interpreted and summarized" [(14)].

The Scottish Intercollegiate Guideline Network (SIGN) describe guidelines as being

> "neither cookbook nor textbook but where there is evidence of variation in practice which affects patient outcomes and a strong research base providing evidence of effective practice, guidelines can assist healthcare professionals in making decisions about appropriate and effective care for their patients" [(15)].

Clinical guidelines are intended as an aid to clinical judgment - they do not replace it. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual service user's condition, circumstances and wishes, and the clinical judgment of the healthcare team.

While it is important to define clearly what a clinical guideline is, there is an equal (if not greater) need to define what it is not. Table 2 defines a number of terms which are often used interchangeably with the term clinical guideline. The definitions within Table 2 are those that will be used for the purpose of this document.

Table 2: Definition of commonly used terms for the purposes of this document

Clinical guideline: systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances, across the entire clinical spectrum.
National Clinical Guidelines: a suite of guidelines that meet specific quality assurance criteria and that have been recommended by the National Clinical Effectiveness Committee.
Clinical policy: a written operational statement of intent which helps staff to make appropriate decisions and take actions, consistent with the aims of the service provider and in the best interests of service users.
Clinical protocol: an agreed statement about a specific clinical issue, with a precise sequence of activities to be adhered to, with little scope for variation. Clinical protocols are usually based on guidelines and/or organisational consensus.
Integrated care pathway (clinical care pathway): a multidisciplinary care plan that outlines the main clinical interventions that are carried out by different healthcare practitioners for patients with a specific condition or set of symptoms. They are usually locally agreed, evidenced-based plans that can incorporate local and national guidelines into everyday practice.
Standard: A definable measure against which existing structures, processes or outcomes can be compared.

5 Potential benefits of clinical guidelines

There are wide ranging benefits to the development and implementation of clinical guidelines but these benefits are dependent on guidelines being developed, reported and implemented within a robust, methodologically sound framework. There are many potential benefits of clinical guidelines in relation to service users, healthcare professionals and healthcare systems [(4)].

For service users, clinical guidelines:

- improve health outcomes in terms of morbidity, mortality, quality of life
- reduce variation in practice, making care more consistent
- inform service users and the public about the care they should be receiving
- empower service users to make more informed healthcare choices
- influence public policy – services not previously offered may be made available as a response to newly released guidelines.

For healthcare professionals, clinical guidelines:

- help improve the quality of clinical decisions
- reassure practitioners about the appropriateness of their treatment policies
- support quality improvement activities for example, act as a reference point for auditing of healthcare professionals' or hospitals' practices
- identify gaps in evidence thereby highlighting areas where further research is required.

For the healthcare system, clinical guidelines:

- optimise service users outcomes and improve the efficient use of healthcare resources
- highlight the commitment of a healthcare system to excellence and quality.

6 Potential limitations of clinical guidelines

The use of clinical guidelines can also have a number of limitations. Difficulties tend to arise in the absence of a rigorous approach to the development and implementation processes. Potential limitations include:

- Poor quality or out-of-date guidelines can encourage the delivery of ineffective, wasteful interventions that may do more harm than good [(16)]
- the evidence base that allows development of recommendations may be incomplete, misleading or misinterpreted
- guidelines can be viewed as being restrictive for healthcare professionals making it difficult to tailor care to service users' specific conditions and circumstances
- recommendations may be influenced by the opinions, clinical experience and composition of the guideline development group
- recommendations for costly interventions may displace limited resources that are needed for other services of greater value to service users
- the value judgment made by a guideline development group may be inappropriate for individual service users

- there may be concerns that guidelines could be used as citable evidence for malpractice litigation against healthcare professionals, although there has not been significant use of guidelines for this purpose [4].

7 Effectiveness of clinical guidelines

Evidence regarding the effectiveness of clinical guidelines has been varied [17-20]. This has been largely due to the lack of randomised controlled methods being used for evaluations as well as the majority of research focusing on changes in the process of delivery of care rather than outcomes [21].

However, with increasing methodological rigour around the guideline development process, the evidence base has been improving with the general consensus that clinical guidelines can be of benefit in the provision of clinical care. However, clinical guidelines need to be developed within a methodologically sound framework with a detailed implementation plan prepared alongside the development process [16;22].

One systematic review of the evidence regarding the effect of clinical guidelines on clinical practice found that 55 out of 59 published evaluations of clinical guidelines detected significant improvements in the process of care after the introduction of guidelines. However, the size of improvement varied considerably [17]. Within the same review, 9 out of 11 studies that assessed outcome of care found some significant improvements [17].

The effectiveness of clinical guidelines in improving patient outcomes specifically in primary care has also been assessed [23]. Of the 91 studies identified, only 13 met the inclusion criteria. 4 of the studies followed nationally developed guidelines and 9 used locally developed guidelines. Statistical significance was found in only 5 of the 13 studies (equivalent to 38%). The authors concluded that there was very little evidence that the use of clinical guidelines improved patient outcomes in primary medical care. However, they cautioned that most studies published to date had used older guidelines and methods and the sample sizes may have been too small to detect small changes in outcomes.

In another study that explored the determinants of uptake of new medicines in secondary care in the United Kingdom (UK), researchers noted that the impact of clinical guidelines has been variable [24]. Some guidelines had significantly increased the uptake of new medicines, while others had little discernable impact despite extensive dissemination.

Results from a Cochrane review[¥] that sought to identify and assess the effects of the introduction of clinical practice guidelines in nursing, midwifery and therapy

[¥] Cochrane reviews are systematic reviews of primary research in human healthcare and health policy. They help ensure that treatment decisions are based on the most up-to-date and reliable evidence.

professions, found some evidence that guideline driven care could be effective in changing the process and outcome of care provided by professions allied to medicine. However, caution is needed in generalising these findings as nurses and physiotherapists were the only two professional groups identified within the 18 studies selected in the review [20].

8 Approaches to developing clinical guidelines

There are a number of approaches to developing clinical guidelines. Agreement on the best approach for the development of specific guidelines will be influenced by the availability of resources, the availability of existing high quality guidelines and identified potential barriers to guideline implementation.

Approaches to developing clinical guidelines include:

- *de novo* development
- using the evidence base of an existing guideline from another jurisdiction
- adapting a single or a number of existing clinical guidelines
- adopting an existing clinical guideline.

The advantages and disadvantages of each of the above approaches are outlined in Appendix 1. Regardless of the approach taken, each guideline development group should clearly outline, document and justify the approach they have chosen for their guideline development initiative and ensure the resultant guideline meets the National Quality Assurance Criteria for Clinical Guidelines.

8.1 Developing guidelines by producing de-novo guidelines

De novo development is the creation of a completely new clinical guideline from scratch. This can require significant resources including support from people with the necessary skills and experience in searching for and critically appraising the evidence to support the development process. Different guideline development organisations and programmes such as SIGN, the National Institute for Health and Clinical Effectiveness (NICE) and the Australian National Health and Medical Research Council (NHMRC) have developed handbooks to provide guidance on developing *de novo* guidelines by outlining their respective development methodologies.

Similarly AGREE II - a guideline development and appraisal instrument (see section 10) - can also be used to support the development process which can take anything from 18 months to over two years to complete [14-15; 25].

8.2 Developing guidelines using the evidence base of an existing guideline from another jurisdiction

A guideline development group may choose to use the evidence base of any existing well-conducted clinical guideline as a starting point for its own critical analysis and formulation of recommendations [15]. These guidelines may require some updating

with new evidence or newly undertaken meta-analyses. Therefore, in this approach, the benefits of a systematic literature review and critical appraisal undertaken elsewhere are combined with the benefits of input from a multidisciplinary group made up of intended users of the guidelines. Recommendations will be developed having taken into account professional and cultural values and considerations of the cost of applying the evidence.

8.3 Developing guidelines by adapting existing clinical guidelines

Guideline adaptation has been proposed as an alternative approach to *de novo* guideline development which can be viewed as a resource-intensive method of producing quality recommendations for care [14]. Adaptation has become increasingly popular with a number of guideline development programmes over the last number of years that are looking to reduce their costs and wanting to avoid unnecessary duplication of work [15;26].

Guideline adaptation is the "systematic approach to considering the use and/or modification of a guideline(s) produced in one cultural and organisational setting for application in a different context" [27].

It essentially involves taking the best or most appropriate recommendations from a single, or a number of, different existing guidelines and repackaging them into a new national guideline which takes account of the local healthcare setting [16].

All modifications to an existing guideline must be accompanied by an explicit statement of the rationale for the changes, and be included in the final guideline document [28]. The ADAPTE framework and the CAN-IMPLEMENT Resource are international tools developed to support the adaptation of clinical guidelines [14; 27].

8.4 Developing guidelines by adopting existing clinical guidelines

Adopting a clinical guideline is the acceptance of a guideline as a whole after the assessment of its quality, currency and content [27]. It involves choosing the best guideline and accepting all recommendations as written [28].

This approach may be considered when high quality guidelines developed locally, or nationally outside of Ireland, are directly relevant to issues to be addressed by a newly proposed guideline for Ireland.

Guideline adoption does not take account of the national context into which the guideline is being adopted. Therefore, some recommendations within an adopted guideline may refer to services and interventions which are unavailable or inappropriate in the Irish national setting or which are not consistent with available resources.

9 Key steps in developing clinical guidelines

Good quality guidelines that are based on the best available evidence of clinical- and cost-effectiveness will support a sustainable healthcare system in Ireland that achieves optimal outcomes for service users, using the finite resources available.

Having a standard guideline development process in place for all clinical guideline initiatives is essential to ensure firstly, the production of methodologically sound, valid and reliable guidelines, which healthcare professionals and service users can use with confidence; and secondly, that guidelines arising from this process will have the necessary legitimacy for those funding, delivering or receiving healthcare services.

Different countries have their own guideline development processes but there are consistent key steps within these processes which help to ensure the development of high quality guidelines. What follows is a brief overview of the steps involved in guideline development in order to provide appropriate context for the proposed criteria.

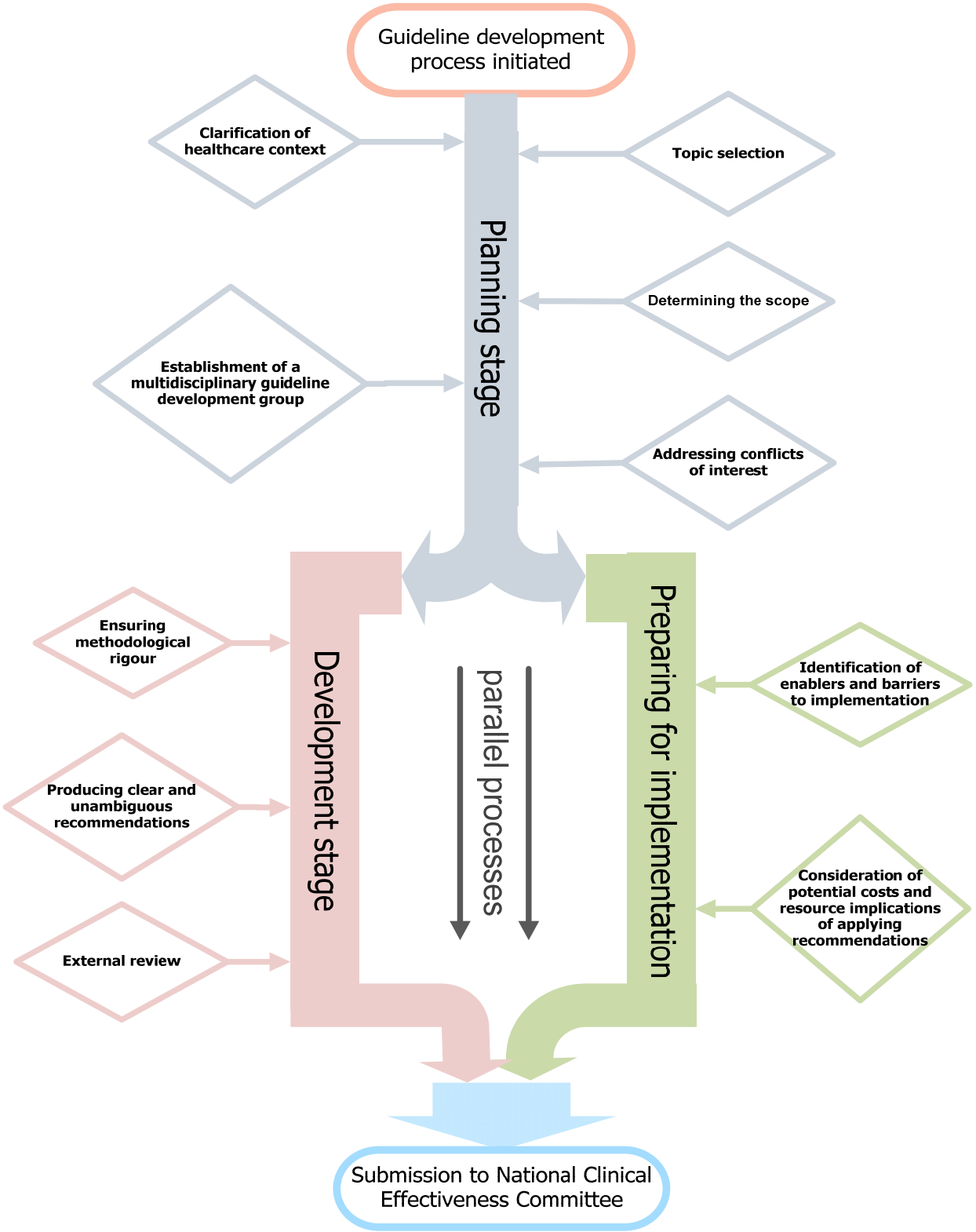
Figure 2 provides an overview of a clinical guideline development path and highlights key components that feed into different stages along this path which can aid developers in producing quality clinical guidelines.

Key steps in the development of clinical guidelines include:

1. Topic selection
2. Clarification of the healthcare context
3. Determining the scope
4. Establishing a multidisciplinary guideline development group
5. Addressing and managing conflicts of interest
6. Ensuring methodological rigour
7. Producing recommendations
8. External review
9. Identification of enablers and barriers to implementation.

The National Quality Assurance Criteria reflect many of these key steps in guideline development. A brief description of these steps is provided so that readers of this document will have a clearer understanding of the criteria.

Figure 1: Clinical guideline development path



9.1 Clarification of the healthcare context

An important factor to be considered before undertaking any guideline initiative is the context within which the guideline will be implemented. Consideration needs to be given to national priorities within healthcare, including national clinical care programmes, to ensure that the proposed guideline is in line with these priorities and programmes. Guideline developers need to ensure that guidelines similar to their proposed initiative have not previously been developed. Developers must also be aware of how their initiative might relate to existing clinical guidelines and how best to address this.

9.2 Topic selection

Clinical guideline developers need to ensure that their proposed guideline initiative is in line with nationally prioritised criteria as set out by the NCEC.

The following are a selection of the criteria used by international guideline development organisations when selecting or prioritising topics for guideline development [15;22;26-27;29]:

- clinically important - affecting large numbers of people with substantial morbidity or mortality (the burden of disease is large)
- evidence of variation between actual and appropriate care
- adequate amount of existing evidence available to support recommendations on effective practice
- consistent with the current governmental health priority issues
- a need to conserve resources in providing care
- implementation of the guideline is feasible, within available resources and barriers to clinical change are not so high that they cannot be overcome
- potential for improving quality of care and/or service users' outcomes is evident.

9.3 Determining the scope

Once a topic has been selected, it is important to set out clearly the intended scope of the guideline. The scope sets the boundaries and provides criteria within which the guideline development work will be undertaken. It provides an overview of what the clinical guideline will include and what will not be covered.

The scope also includes an agreed and documented decision regarding the methodology that will be used to produce the guideline, for example, *de novo* development, adaptation, as well as the reasons for choosing a particular methodology. The scope can also provide an insight into the potential timeline and costs that may be associated with the development process.

9.4 Establishing a multidisciplinary guideline development group

A multidisciplinary guideline development group that has a broad membership including service users, healthcare professionals and experts in methodology is important, as it ensures that the views of all relevant groups are taken into account, facilitates the objective development of clinical guidelines and contributes to the robustness of the guideline development process.

The involvement of professional bodies can be an effective way of engaging with healthcare professionals with wide representation having additional benefits in terms of the validity and generalisability of the recommendations produced by the group and with the successful implementation and adoption of the final guideline [15].

The involvement of service users in the guideline development process is also important as they provide a different perspective to that of healthcare professionals in such areas as service design, healthcare priorities and outcomes. They can provide advice on the use of language within the guideline so that it is sensitively worded, appropriate and understandable to service users [3;15].

Including at least two service-user representatives in guideline development groups is recommended by many of the guideline development handbooks [3;15;26]. Where it is not feasible to involve service users directly, the groups obtain their views in other ways and take them into consideration in the development of the guideline.

The multidisciplinary group should ensure clarity of the governance structure of their group, in particular the different roles and responsibilities of individuals within the group, including chairing, as well as reporting paths to any overseeing committee. The group should decide on a timeframe for the guideline's development.

9.5 Addressing and managing conflicts of interest

All members of the guideline development group should complete a written declaration of conflict of interest early in the development process. A conflict of interest may arise when members of the guideline development group have financial interests, in or a close working relationship with, pharmaceutical companies or other commercial institutions [30]. These relationships may have an influence, or a perceived influence, on the interpretation of evidence by an individual within a guideline development team. Failure to acknowledge conflicts of interests threatens the credibility and successful implementation of a guideline [14].

Generally, those involved in producing clinical guidelines are asked to declare and document any financial or other interests related to their work on the guideline. These declarations are evaluated, managed and regularly updated during the course of guideline development.

Depending on the guideline development programme, these declarations may be appended to the relevant guidelines, or made easily accessible by any interested parties [3;15;31].

9.6 Ensuring methodological rigour

Many of the past criticisms of clinical guidelines related to the use of a development process solely based on group consensus which reflected only the clinical experience of those within the working group. Such a basis in consensus made guidelines and their recommendations more open to bias.

Clinical guidelines should be based on the best available evidence of clinical and cost-effectiveness that has been derived from a systematic review of all high quality, relevant evidence. Developing a specific number of clear and focused questions that address the key issues in the area to be covered by a clinical guideline, helps provide a starting point and focus for the systematic literature search.

A clear description of the systematic process used to obtain relevant information should be provided. This includes the methodology (for example, *de novo* development, adaptation etc.) being used to develop the guideline. The process should include a description of the search strategy, inclusion and exclusion criteria applied, and restrictions used in searching for studies. Studies selected for inclusion should be critically assessed for their validity and relevance to the study question.

Guideline developers should take note of any guidance that pertains to the undertaking of systematic reviews for example, Cochrane guidance for conduct of systematic reviews. Guidance on the methods for evaluating cost-effectiveness and resource implications may be obtained from national guidelines on the economic evaluation and budget impact analysis of health technologies [32-34].

9.7 Producing recommendations

Producing clinical guideline recommendations involves grading the quality of evidence and grading the strength of recommendations. The quality of evidence relates to the extent to which a guideline user can be confident that an estimate of effect is correct, while the strength of a recommendation indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm [35].

Factors that need to be considered, when grading the quality of evidence, include study design, study methods, implementation of these methods, consistency of results across studies, generalisability of studies and the extent to which the population, interventions and outcome measures are similar to those of interest.

There are a number of evidence-based tools or strategies such as GRADE which assist in making judgements about evidence [36]. When grading the strength of recommendations, consideration must be given to not only the quality of evidence but to other factors such as:

1. Does the intervention do more harm than good?
2. What is the extent of impact on the target population?
3. What is the cost of incremental health benefits?

Once these two grading exercises have been undertaken, graded guideline recommendations can be made which will allow users of clinical guidelines to decide on the confidence that they can place in recommendations within different guidelines.

9.8 External review

Seeking and receiving feedback on clinical guidelines from reviewers outside of the guideline development group is an integral part of the quality assurance process for all guideline development. It is a valuable opportunity to identify any problems in formatting, acceptance of recommendations and in guideline implementation [37].

Sharing draft guidelines with experienced and knowledgeable reviewers from varying backgrounds (for example international reviewers, people with experience of guideline development, service users, healthcare professionals within community, primary, secondary or tertiary care or those with a healthcare policy focus) ensures input from a number of different perspectives.

9.9 Identification of enablers and barriers to implementation

The importance of good guideline implementation strategies has been highlighted by the failure to realise expected changes in practice following the publication of clinical guidelines in specific areas [37]. Guideline development involves the identification of any specific enablers and barriers to implementation of that guideline.

Effective guideline implementation strategies are central to guidelines being adopted and embedded into clinical practice at a local level. Guidelines' clarity, practicality and production by end users all contribute to their effective implementation. Education and communication strategies such as workshops, practical sessions and the provision of promotional materials are also key enablers of the implementation of clinical guidelines [38].

Barriers to implementation include lack of organisational support, financial constraints and lack of support from healthcare professionals [22;39-40]. Planning an implementation strategy is best undertaken alongside the guideline development process with individuals within the development group leading implementation. Guideline development groups should consider the budget impact and the additional resources (for example capital, equipment, staff, training) required when implementing the recommendations in their clinical guidelines.

National Quality Assurance Criteria

10 Assuring the quality of clinical guidelines in Ireland

The proposed National Quality Assurance Criteria will support the NCEC's assessments and decision-making, regarding the recommendation of clinical guidelines. This assessment will provide legitimacy to those guidelines that have gone through a standard development process and have been recommended by the NCEC as National Clinical Guidelines.

An extensive search of the literature was undertaken to identify the methodologies and tools used internationally to quality assure clinical guidelines. From this search, we chose those tools most relevant and applicable to the Irish setting. The National Quality Assurance Criteria presented in Table 1 closely reflects the AGREE II [(1)] instrument but includes a number of modifications.

The purpose of these modifications is to take into account the context of the Irish healthcare system and to provide additional information about elements within each of the different criteria.

11 AGREE II Instrument

The AGREE II instrument provides criteria for the assessment of the quality of clinical guidelines as well as providing a strategy for guideline development and informing how information and what information ought to be reported in guidelines [(1)].

The AGREE II instrument is based on the Institute of Medicine's founding principles of guideline development (validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review and documentation) as well as international consensus on methods for developing evidence-based clinical guidelines [(41)]. It has been validated and endorsed by the World Health Organization and is considered by many as the standard in quality assessing clinical guidelines [(42)].

The AGREE Enterprise is an international organisation aimed at improving the quality of practice guidelines. Its predecessor, the AGREE Collaboration, developed the initial AGREE instrument in 2003, to address the issue of variability in guideline quality. It defined guideline quality as "the confidence that potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice" [(1)].
Following research to improve the AGREE instrument, the original instrument was refined and replaced by AGREE II instrument which includes a users manual and is now the preferred tool.

The purpose of the new AGREE II instrument is to provide a framework to:

- Assess the quality of guidelines
- Provide a methodological strategy for the development of guidelines and
- Inform what information and how information ought to be reported in guidelines [(1)].

AGREE II consists of 23 key items organised within 6 domains and 2 global rating criteria (see appendix 2). Each of the 23 items is rated on a 7 point response scale.

The six domains of the AGREE II instrument are:
- scope and purpose
- stakeholder involvement
- rigour of development
- clarity of presentation
- applicability
- editorial independence.

The two global ratings items are:
- rate the overall quality of this guideline
- I would recommend this guideline for use.

12 Structure of the National Quality Assurance Criteria

The National Quality Assurance Criteria consists of 7 domains and 24 criteria. These domains are grouped under 3 stages which relate to the process of guideline development: planning, development and preparing for implementation.

Each of the criteria, as with the AGREE II instrument, are rated on a 7-point scale (from 1-strongly disagree to 7- strongly agree). Similar to the AGREE II instrument there are also two overall guideline assessment criteria accompanying the criteria.

All of the elements of the Agree II instrument are included in the National Quality Assurance Criteria with the following modifications:
- domains are grouped under three stages – planning, development and preparing for implementation
- a new feasibility domain has been added with one new criteria
- the editorial independence domain has been reordered
- the text of a number of criteria has been changed to reflect the Irish context.

Appendix 3 provides a comparison of the National Quality Assurance Criteria and the AGREE II instrument.

The AGREE II instrument provides additional information in the user's manual on each criterion for users of the instrument, including:
- where to look in the guideline for information relevant to the criterion
- specific elements and details to look for when assessing the guideline against that criterion
- additional considerations in guideline development that indicate compliance with the guideline.

These features of the AGREE II instrument may be used to guide application of the corresponding criteria in the National Quality Assurance Criteria. Appendix 4 provides a list of amendments to the AGREE II instrument, so that it can be coherently used as an aid in applying the National Quality Assurance Criteria.

12.1 National Quality Assurance Criteria Stage 1: Planning

The planning stage includes all preparatory work that may need to be undertaken prior to the commencement of any guideline initiative. It focuses on the context within which the guideline will be implemented and how it relates to current national healthcare policy. It looks at the overall aim of the guideline, the specific questions which the guideline aims to address and answer ('health questions') as well as expected health benefits or outcomes from implementing the guideline. Both, the intended users of the guideline and the population group to whom the guideline will apply, are described.

This stage is also concerned with ensuring that the appropriate stakeholders such as healthcare professionals, healthcare managers and methodological experts are part of the guideline development group, while recognising that some may be involved during different stages of the process for example, methodological experts may be involved in the identification, reviewing and selection of the evidence.

Involvement of those service users and the public to whom the guideline will apply is also included in this stage so that their experiences and expectations of healthcare can inform the development process. Finally, the issues of competing interests of guideline developers and the external funding of guidelines are addressed, guideline development groups and their members have to provide clear statement on both matters.

The four quality assurance domains in this stage are:

- feasibility
- scope and purpose
- stakeholder involvement
- editorial independence.

12.2 National Quality Assurance Criteria Stage 2: Development

Quality assurance of the development stage focuses on the strategy used to gather and synthesise the evidence to support guideline development. Evidence sources may include electronic databases (for example Medline) [43], systematic review databases (for example Cochrane library) [44] and clinical guidelines repositories (for example G-I-N and the US National Guideline Clearinghouse) [45-46].

Clear descriptions of the criteria used to include and exclude different evidence should be provided - for instance, the study designs included in the evidence base, or the populations excluded in the evidence. Quality assurance of this stage also includes how evidence was evaluated for rigour and bias.

If a formal system such as the GRADE methodology has been used, this is noted. Confidence in the guidelines among service users and healthcare practitioners, and therefore use of the guidelines, can be increased by clear description of the quality of evidence upon which the guideline is based.

This stage also describes the methods used to formulate the recommendations for example, informal consensus or a voting system, the clarity with which recommendations are presented and how explicitly they are linked to their supporting evidence.

Quality assurance of the development stage also examines how external review/advice was sought for the guideline in question. The development stage also involves setting out the procedure for updating the guideline to take account of emerging issues and new technologies.

The two quality assurance domains in this stage are:
- rigour of development
- clarity of presentation.

12.3 National Quality Assurance Criteria Stage 3: Preparing for Implementation

Quality assurance of the preparation for implementation looks at whether the guideline is accompanied by a dissemination and implementation plan. This plan should outline how identified enablers and barriers to implementation are to be addressed.

The development of the dissemination and implementation plan may be informed by discussions with key stakeholders or a testing of the clinical guideline to help identify the enablers and barriers to implementation of the guideline. The inclusion of criteria to assess adherence to guideline recommendations as well as the impact of implementing the recommendations are evaluated in this stage. Such criteria may focus on structure, process, behavioural outcomes or health outcomes.
Assessing adherence to guideline recommendations also involves identifying reasons for non-adherence and mechanisms for amending the guideline, where necessary, in the light of experience. Consideration of the potential budget impact and resource implications (for example, requirements for equipment or facilities, staff or training) for providers of implementing the guidelines will also be assessed during this stage. The ability of the provider to realise savings arising from a reduction in resource use and costs elsewhere in the system should be included where appropriate.

The single quality assurance domain in this stage is:
- applicability.

13 Overall Guideline Assessment

The overall guideline assessment requires the assessors of the clinical guideline to make a judgment as to the overall quality of the guideline, taking into account the criteria that have already been considered during the assessment process. The first statement is rated on a seven-point response scale, (where 1 = Strongly Disagree and 7 = Strongly Agree - see Appendix 4 for rating template) while the second requires the assessor to choose:

- to recommend the guideline for use
- to recommend it for use but with modifications
- not to recommend it.

Table 3: National Quality Assurance Criteria

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 (patients, 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 (patients, 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.
Clarity of Presentation
18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined.
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.
20. Key recommendations are easily identifiable.

Preparing for implementation stage

Applicability
21. The guideline describes facilitators and barriers to its application.
22. The guideline provides advice and/or tools on how the recommendations can be put into practice.
23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered.
24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations.

Overall Guideline Assessment	
1.	Rate the overall quality of this guideline.
2.	I would recommend this guideline for use.

Conclusions

Clinical guidelines can be effective in bringing about change and improving health outcomes for service users but must be developed within a rigorous methodological framework. Good clinical guidelines also support a sustainable healthcare system that maximises the efficient use of resources. For maximum effectiveness, clinical guidelines should be integrated with other quality and safety improvement programmes to support a system-wide approach to the promotion and improvement of healthcare delivered at all levels throughout the system.

This document presents National Quality Assurance Criteria to support the assessment of the quality of clinical guidelines developed in Ireland. These Criteria are based on international clinical guideline quality assuring tools but with greater emphasis on issues that have higher relevance and importance within the Irish healthcare system.

These Criteria will support the National Clinical Effectiveness Committee in recommending clinical guidelines to the Minister of Health for inclusion in a suite of National Clinical Guidelines for use in the Irish healthcare system. They will also support the drive for continuous improvement in the quality and safety of healthcare in Ireland.

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Appendix 1

Advantages and disadvantages of the potential approaches to clinical guideline development within Ireland

Clinical guidelines can be developed by a number of different methods. The following section describes four approaches to guideline development and outlines the advantages and disadvantages of each approach.

1. Developing guidelines by producing *de novo* guidelines

In this scenario, a completely new clinical guideline is developed; usually within an established guideline development program. A guideline development and appraisal tool, such as the AGREE II instrument, can be used to support the guideline development process. The entire process for each guideline can take from 18 months to over two years [14-15;25].

Advantages:

- guidelines being developed are appropriate for the Irish culture and clinical setting
- confidence that the entire development process has conformed to agreed quality assurance criteria as set by a national overseeing body
- recommendations will better reflect available resources
- greater feeling of ownership with more buy-in when disseminated locally.

Disadvantages:

- an entire development programme would need to be established
- an expensive process - not only in terms of the financial cost of producing the guidelines but also the need to have appropriately skilled and experienced people to systematically search and critically analyse the literature
- time-consuming process
- demand for national clinical guidelines will outstrip potential to produce them.

2. Develop guidelines using the evidence base of an existing guideline from another jurisdiction

In this approach, the benefits of a systematic literature review and critical appraisal undertaken elsewhere are combined with the benefits of input from a multidisciplinary group, made up of intended users of the guidelines. Recommendations will be developed having taken into account professional and cultural values and considerations of the cost of applying the evidence.

Advantages:

- more efficient use of resources – avoids unnecessary duplication of effort
- less expensive process - removes the need for the time and skill dependent steps of literature search and critical appraisal [47]
- will maintain feeling of ownership
- recommendations will reflect cultural setting and available resources
- will better meet the demand for national guideline development.

Disadvantages:

- dependent on the validity of a literature search undertaken elsewhere
- evidence base may require significant updating.

3. Developing guidelines by adapting existing clinical guidelines

Guideline adaptation essentially involves taking the best or most appropriate recommendations from a single or a number of different existing guidelines and repackaging them into a new guideline [48]. All modifications to an existing guideline must be accompanied by an explicit statement of the rationale for the changes and be included in the final guideline document [28].

Advantages:

- potentially greater number of clinical guidelines developed
- avoids unnecessary duplication of effort
- removes the need for the time and skill dependent steps of literature search and critical appraisal.

Disadvantages:

- implementation of guideline may be difficult because of lack of feeling of local ownership
- there is a significant learning curve with the adaptation method [14]
- the adaptation process can be complex and time-consuming, as services within other countries can be very different and are subjected to different legislative frameworks [49]
- high quality source guidelines may not exist for some topics [50].

4. Developing guidelines by adopting existing clinical guidelines

This approach may be considered when good quality, directly relevant guidelines developed outside of Ireland, or locally in Ireland may be relevant to the issues that are to be addressed by a newly proposed national guideline within Ireland. These existing guidelines would require evaluation for their methodological quality and applicability.

Advantages:

- more efficient use of resources – avoids unnecessary duplication of effort [(50)]
- removes the need for the time and skill-dependent steps of literature search and critical appraisal
- removes the need for the establishment of a group to develop evidence-based recommendations.

Disadvantages:

- recommendations may refer to services and interventions which are unavailable or inappropriate in the Irish setting or only available and appropriate in a local Irish setting
- recommendations may not adequately take into account available resources within the adopting setting
- implementation of guideline may be difficult because of lack of feeling of national ownership.

Appendix 2

The AGREE II instrument [(1)]

Domain 1. Scope and purpose	
1.	The overall objective (s) of the guideline are specifically described.
2.	The health question(s) covered by the guideline is (are) specifically described.
3.	The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
Stakeholder involvement	
4.	The guideline development group includes individuals from all the relevant professional groups.
5.	The views and preferences of the target population (patients, public, etc,) have been sought.
6.	The target users of the guideline are clearly defined.
Rigour of development	
7.	Systematic methods were used to search for evidence.
8.	The criteria for selecting the evidence are clearly described.
9.	The strengths and limitations of the body of evidence are clearly described.
10.	The methods used for formulating the recommendations are clearly described.
11.	The health benefits, side effects and risks are considered in formulating the recommendations.
12.	There is an explicit link between the recommendations and the supporting evidence.
13.	The guideline has been externally reviewed by experts prior to publication.
14.	A procedure for updating the guideline is provided.

Clarity of presentation	
15.	The recommendations are specific and unambiguous.
16.	The different options for management of the condition or health issue are clearly presented.
17.	Key recommendations are easily identifiable.
Applicability	
18.	The guideline describes facilitators and barriers to its application.
19.	The guideline provides advice and/or tools on how the recommendations can be put into practice.
20.	The potential resource implications of applying the recommendations have been considered.
21.	The guideline presents monitoring and/or auditing criteria.
Editorial independence	
22.	The views of the funding body have not influenced the content of the guideline.
23.	Competing interests of guideline development group members have been recorded and addressed.

Overall Guideline Assessment	
1.	Rate the overall quality of this guideline.
2.	I would recommend this guideline for use.

Appendix 3

Comparison of National Quality Assurance Criteria with AGREE II Instrument

National Quality Assurance Criteria	Agree II Instrument (Numbered as per Agree II Instrument)
Domain: Feasibility	
1. National health policy, programmes and relevant existing guidelines are specifically considered.	New domain that is not part of AGREE II Instrument
Domain: Scope and Purpose	
2. The overall objective of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined.	1. The overall objective (s) of the guideline are specifically described.
3. The health question covered by the guideline is specifically described.	2. No change.
4. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	3. No change.
Domain: 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).	4. The guideline development group includes individuals from all the relevant professional groups.
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.	5. The views and preferences of the target population (patients, public, etc,) have been sought.
7. The intended users of the guideline are clearly defined.	6. The target users of the guideline are clearly defined.
Domain: 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.	22. The views of the funding body have not influenced the content of the guideline.
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.	23. Competing interests of guideline development group members have been recorded and addressed.

Domain: 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.	7. Systematic methods should be used to search for evidence.
11. The criteria for selecting the evidence are clearly described with reasons for including and excluding evidence clearly stated.	8. The criteria for selecting the evidence should be clearly described.
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.	9. The strengths and limitations of the body of evidence are clearly described.
13. The methods used for formulating the recommendations are clearly described	10. No change.
14. The health benefits, side effects, risks, cost-effectiveness, resource implications and health service delivery issues have been considered in formulating the recommendations.	11. The health benefits, side effects and risks 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 the supporting evidence.	12. There is an explicit link between the recommendations and the 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.	13. The guideline has been externally reviewed by experts prior to publication.
17. A procedure for updating the guideline is provided and includes an explicit time interval.	14. A procedure for updating the guideline is provided.

Domain: Clarity of Presentation	
18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined.	15. The recommendations are specific and unambiguous.
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.	16. The different options for management of the condition or health issue are clearly presented.
20. Key recommendations are easily identifiable.	17. No change.
Domain: Applicability	
21. The guideline describes facilitators and barriers to its application.	18. No change.
22. The guideline provides advice and/or tools on how the recommendations can be put into practice.	19. No change.
23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered.	20. The potential resource implications of applying the recommendations have been considered.
24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations.	21. The guideline presents monitoring and/or auditing criteria.

Appendix 4

National Quality Assurance Criteria rating template

(Strongly Disagree = 1, Strongly Agree =7)

Domain	Criteria	Rating						
		1	2	3	4	5	6	7
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 (patients, 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 (patients, public etc) are sought and he 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.							
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.							
Clarity of Presentation	18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined.							
	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.							
	20. Key recommendations are easily identifiable.							
Applicability	21. The guideline describes facilitators and barriers to its application.							
	22. The guideline provides advice and/or tools on how the recommendations can be put into practice.							
	23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered.							
	24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations.							

Overall Guideline Assessment	1. Rate the overall quality of this guideline (Lowest possible quality=1, highest possible quality=7)	**1**	**2**	**3**	**4**	**5**	**6**	**7**
	2. I would recommend this guideline for use	**Y**	**Yes, with modifications**					**N**

Appendix 5

Amendments to AGREE II Instrument for use with National Quality Assurance Criteria

National Quality Assurance Criteria	Use Agree II Instrument parallel
Domain: Feasibility	
1. National health policy, programmes and relevant existing guidelines are specifically considered.	New domain that is not part of AGREE II Instrument. No specific Agree II guidance in handbook
Domain: Scope and Purpose	
2. The overall objective of the guideline is specifically described with the expected benefit or outcome of the guideline clearly outlined.	use guidance on criterion 1.
3. The health question covered by the guideline is specifically described.	use guidance on criterion 2
4. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	use guidance on criterion 3
Domain: 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).	Use guidance on criterion 4 **except**: In the 'How to rate' section, add 'intended users' as an example of the 'discipline/content expertise'.
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.	use guidance on criterion 5
7. The intended users of the guideline are clearly defined.	use guidance on criterion 6
Domain: 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.	use guidance on criterion 22.
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.	use guidance on criterion 23 **except:** in the "How to rate" section, add "description of the measures taken to minimise the influence of competing interests on the guideline development."

Domain: 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.	use guidance on criterion 7
11. The criteria for selecting the evidence are clearly described with reasons for including and excluding evidence clearly stated.	use guidance on criterion 8
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.	use guidance on criterion 9
13. The methods used for formulating the recommendations are clearly described	use guidance on criterion 10
14. The health benefits, side effects, risks, cost-effectiveness, resource implications and health service delivery issues have been considered in formulating the recommendations.	Use guidance on criterion 11 **except** in the 'How to Rate' section, add "supporting data and reports on cost-effectiveness and resource implications" and "supporting data and reports on health service delivery issues"
15. The recommendations have been graded for quality of evidence and strength of recommendation with an explicit link between the recommendations and the supporting evidence.	use guidance on criterion 12.
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.	use guidance on criterion 13.
17. A procedure for updating the guideline is provided and includes an explicit time interval.	use guidance on criterion 14

Domain: Clarity of Presentation	
18. The recommendations are specific, clear and easily identifiable with the intent or purpose of the recommended action clearly outlined.	use guidance on criterion 15
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.	use guidance on criterion 16
20. Key recommendations are easily identifiable.	use guidance on criterion 17
Domain: Applicability	
21. The guideline describes facilitators and barriers to its application.	use guidance on criterion 18
22. The guideline provides advice and/or tools on how the recommendations can be put into practice.	use guidance on criterion 19.
23. The potential budget impact and resource implications (equipment, staff, training etc.) of applying the recommendations have been considered.	use guidance on criterion 20, and also relevant documentation issued by the Authority.[32;33]
24. The guideline presents monitoring and/or auditing criteria to assess adherence to recommendations and the impact of implementing the recommendations.	use guidance on criterion 21

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