NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

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

National Quality Assurance Criteria for Clinical Guidelines Version 2

To provide quality assurance of National Clinical Guidelines in Ireland

Tús Áite do Shábháilteacht Othar
Patient Safety First

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About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) 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

About the National Clinical Effectiveness Committee

The National Clinical Effectiveness Committee (NCEC) was established as part of the Patient Safety First Initiative. Clinical effectiveness is a key component of patient safety and quality which provides processes for the integration of national and international best available evidence in service provision. 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. National Clinical Guidelines, which have been quality assured and recommended by NCEC for implementation, provide robust evidence-based approaches to underpin or define models of care as appropriate.

About this document

This document has joint approval. It was approved by NCEC on 25th March 2015 and by HIQA on 16th April 2015.

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1.0 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. HIQA and the National Clinical Effectiveness Committee (NCEC) have jointly developed this second version of the *National Quality Assurance Criteria for Clinical Guidelines.* This updated document takes into consideration the experience of NCEC over the last few years in applying quality assurance criteria to guidelines. An overview of the benefits, limitations and effectiveness of clinical guidelines are provided.

Within the Irish healthcare system there are many examples of clinical guidelines developed for use at national and local level. The NCEC was established in 2010 as a Patient Safety First initiative to promote clinical effectiveness within the Irish healthcare system. The NCEC prioritises and quality assures guidelines in order for them to become National Clinical Guidelines. National Clinical Guidelines are endorsed by the Minister for Health and mandated for implementation in the health system.

A suite of National Clinical Guidelines will be established over time and implementation will be monitored through the HSE Performance Assurance Reports, compliance with HIQAs *National Standards for Safer Better Healthcare* and increased alignment with the clinical indemnity scheme. National Clinical Guidelines may also be subjected to National Clinical Audit.

NCEC recognises that not all clinical guidelines will or should become National Clinical Guidelines so NCEC recommends that organisations continue to develop guidelines at local level if there is a service need. Such guidelines should be developed using a robust methodology and it is recommended that Guideline Development Groups utilise NCEC resources to support this work. NCEC *Standards for Clinical Practice Guidance* are currently in development. However, a National Clinical Guideline which is endorsed by NCEC and the Minister will supersede any other guidelines on that topic.

Guidelines submitted to NCEC are firstly screened to confirm their status as a clinical guideline and then subject to successful prioritisation are appraised in line with the *National Quality Assurance Criteria for Clinical Guidelines V.2* (HIQA and NCEC 2014). This assessment provides legitimacy to those guidelines demonstrating that guidelines have undergone a standardised development process. Figure 1 outlines NCEC processes as detailed in the current *Framework for Endorsement of National Clinical Guidelines* (NCEC).

If guidelines score well on the quality assurance criteria, NCEC recommends these guidelines to the Minister for endorsement through the Chief Medical Officer in order for them to become part of the suite of National Clinical Guidelines.

2.0 Introduction

1 Purpose of this document

The purpose of this document is to clearly set out, for the Irish context, clinical guideline quality assurance criteria that must be met in order for guidelines to become part of a suite of National Clinical Guidelines. The National Clinical Effectiveness Committee (NCEC) uses national pre-requisite quality assurance criteria in addition to the AGREE II in quality assuring clinical guidelines.

A brief overview is presented in this document of the benefits, limitations and effectiveness of clinical guidelines in order to provide appropriate context for the quality assurance process. NCEC has issued a number of documents to support Guideline Development Groups. These include:

- *Framework for Endorsement of National Clinical Guidelines*
- *Guideline Developers Manual*
- *Prioritisation of National Clinical Guidelines.*

NCEC documentation and resources are available at www.health.gov.ie/patient-safety/ncec

It is however, envisaged that, as National Clinical Guidelines are endorsed, these will be implemented in full in national, local and regional services as appropriate.

It is recognised that in clinical practice, there are different types of guidance that vary in complexity and scope. For example, guidance can be a comprehensive overarching National Clinical Guideline or a more specific clinical protocol; not all guidance requires the same pathway of development as a National Clinical Guideline. However, regardless of the variation in scope and focus, it is important that the development of all clinical guidance be underpinned by an appropriate evidence-based approach and quality assurance measures to assist clinician and patient decisions about appropriate healthcare for specific clinical circumstances. Any other clinical guidance in the Irish health system which is not a National Clinical Guideline can be considered under the term 'clinical practice guidance'.

Clinical practice guidance is defined as systematically developed statements or processes to assist clinician[1] and patient decisions about appropriate health care for specific clinical circumstances with the choice of clinical practice guidance model determined by evidence-based criteria and clinical requirements. Such models may include but this is not an exhaustive list – local guidelines, protocols, policies, procedures, checklists, standard operating procedures, care pathways etc. The NCEC will publish *Standards for Clinical Practice Guidance* in 2015.

[1] A clinician is a health professional involved in clinical practice.

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.

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 [1].

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 [2]. 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.

NCEC was established as part of the Patient Safety First initiative to promote clinical effectiveness within the Irish healthcare system.

NCEC terms of reference are:

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

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 V.2 jointly developed by the Authority and the National Clinical Effectiveness Committee will support the National Clinical Effectiveness Committee in quality assuring clinical guidelines. This

updated document takes into consideration the experience of NCEC over the last few years in applying quality assurance criteria to 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 [4] [5] [6] [7].

In addition the National Clinical Programmes and the National Cancer Control Programme have developed a number of clinical guidelines to support practice.

The Commission on Patient Safety and Quality Assurance (the Commission) in 2008, highlighted clinical guidelines as a key intervention to support evidence-based practice within a healthcare system [8]. 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'.

In March 2011, the Government introduced its Programme for Government [9]. 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. The extension and implementation of the suite of National Clinical Effectiveness Guidelines is identified as a Ministerial priority for 2015.

3.0 Overview of clinical guidelines

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" [3].

Similarly, the American Institute of Medicine (IOM) defines clinical guidelines as: "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options" [10].

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" [11].

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" [12].

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 1 defines a number of terms which are often used interchangeably with the term clinical guideline. The definitions within table 1 are those that will be used for the purpose of this document.

Table 1: Definitions 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 prioritisation and quality assurance criteria and that have been recommended by the National Clinical Effectiveness Committee. Clinical guidelines endorsed by the Minister will be titled 'National Clinical Guidelines'.
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.

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 [1].

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.

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 [13]
- 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 [1].

4.0 Effectiveness of clinical guidelines

Implementation of evidence based healthcare has had varied success and Michie advises that 'improving implementation depends on changing the behaviour of health professionals, managers, commissioners and others working within and with the health care system' [14]. Clinical guidelines are utilised widely as processes to promote implementation of evidence based healthcare.

Evidence regarding the effectiveness of clinical guidelines has been varied [15] [16] [17] [18]. 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 [19].

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 [15]. Within the same review, 9 out of 11 studies that assessed outcome of care found some significant improvements.

The effectiveness of clinical guidelines in improving patient outcomes specifically in primary care has also been assessed [20]. 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. A recent systematic review of referral guidelines from primary to secondary care in 2010, Clarke and colleagues found that guidelines can improve appropriateness of care by improving diagnostics and treatment prior to referral [21].

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. To maximise potential benefit, clinical guidelines need to be developed within a methodologically sound framework with a detailed implementation plan prepared alongside the development process [13] [22].

The provision of information alone is not an effective way to change behaviour [23]. The National Institute for Health and Care Excellence (NICE) in the UK has published guidance on behaviour change for individuals and for broader population interventions [24] [25].

5.0 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 using the ADAPTE process. Further information is available at: http://www.g-i-n.net/document-store/working-groups-documents/adaptation/adapte-resource-toolkit-guideline-adaptation-2-0.pdf
- adopting an existing clinical guideline.

Further information on guideline development is available in the NCEC Guideline Developers Manual available at www.health.gov.ie/patient-safety/ncec

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 V.2.*

Important - 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 strategy 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.

6.0 Assuring the quality of clinical guidelines in Ireland

This *National Quality Assurance Criteria for Clinical Guidelines V.2* 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.

The *National Quality Assurance Criteria for Clinical Guidelines V.2* comprises two parts:

Part A
Pre-requisite quality assurance criteria for the Irish context (Table 2).

Part B
Appraisal of Guidelines for Research & Evaluation II (AGREE II) criteria.

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

There are ten pre-requisite quality assurance criteria for the Irish context as outlined in Table 2. These criteria provide for a consistent approach to guideline development in Ireland taking into account the Irish context; i.e. national policies, organisational structure and fiscal considerations of the Irish health system.

The initial mandatory step in the appraisal should indicate a yes/no on the pre-requisite quality assurance criteria. These criteria have been established by HIQA and NCEC in order to provide assurance that the expected benefit or outcome of the guideline is clearly established for the Irish healthcare system. The criteria promote implementation through consideration of the costs of recommendations through a structured budget impact analysis. Clear identification of responsibility for implementation of recommendations and the development of monitoring criteria provides for a culture of accountability for guideline implementation.

Table 2 - Pre-requisite quality assurance criteria for the Irish context

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

Table 3 - Sample set of international external reviewers questions

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

Part B Appraisal of Guidelines for Research & Evaluation II (AGREE II)

The **A**ppraisal of **G**uidelines for **R**esearch & **E**valuation II (AGREE II) is an internationally recognised instrument that has been validated and endorsed by the World Health Organisation and is widely considered as the standard in quality assessing clinical guidelines. The AGREE II criteria are subject to on-going review and revision. Further information on AGREE II criteria, additional AGREE II resources and the scoring process for AGREE II are available at: http://www.agreetrust.org/

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 [26].

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 [27]. It has been validated and endorsed by the World Health Organization and is considered by many as the standard in quality assessing clinical guidelines [28].

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" [26].
Following research to improve the AGREE instrument, the original instrument was refined and replaced by AGREE II instrument which includes a user's 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 [26].

AGREE II consists of 23 key items organised within 6 domains and 2 global rating criteria. 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.

Guideline developers should utilise the AGREE II Instrument to self-assess the guideline in order to provide assurance that the criteria have been met.

The NCEC Endorsement Process

The NCEC manages the endorsement process for National Clinical Guidelines in line with the following four steps – Figure 1.

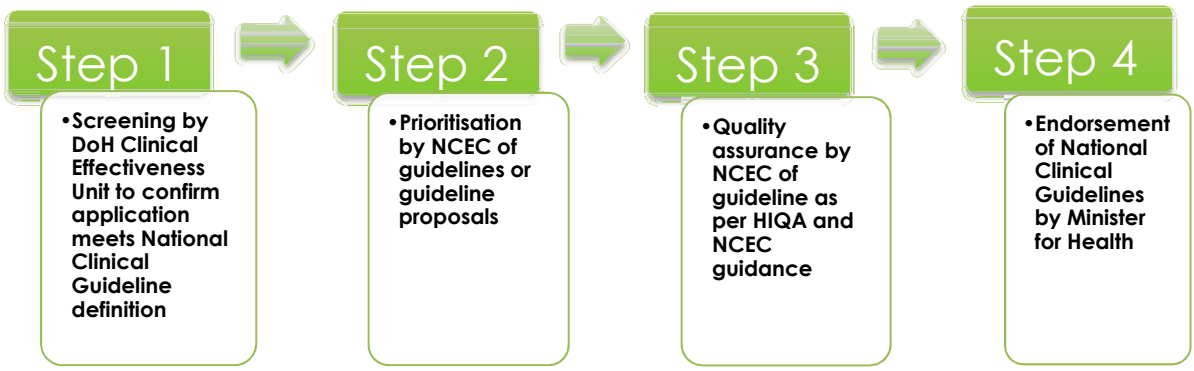

Figure 1 - NCEC National Clinical Guideline Endorsement Process

7.0 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 *National Quality Assurance Criteria for Clinical Guidelines V.2* presents pre-requisite criteria for quality assurance of guidelines for the Irish context before assessment of the guideline using AGREE II. These criteria are based on international clinical guideline quality assuring tools. The pre-requisite criteria place an emphasis on issues that have high 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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