



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Statement of Outcomes

Report on the outcome of the public
consultation on the Draft National Quality
Assurance Criteria for Clinical Guidelines

October 2011

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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1.0 Introduction and Overview

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.

The Health Information and Quality Authority (the Authority) has developed *National Standards for Safer Better Healthcare* to describe what a high quality, safe service looks like. 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 (NCEC) was established in 2010 to promote clinical effectiveness within the Irish healthcare system. The role of the Committee is to prioritise and quality assure clinical guidelines and clinical audit to address key issues such as safety, quality and efficiency in the delivery of healthcare. 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.

In July 2011, the Authority published *Draft National Quality Assurance Criteria for Clinical Guidelines* (the Draft Criteria), which described National Quality Assurance Criteria and how they will be applied to clinical guidelines intended to become part of a suite of National Clinical Guidelines (NCGs). The Draft Criteria also provided a brief overview 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 Draft Criteria included a description of AGREE II, an internationally recognised tool for quality assuring clinical guidelines, as the proposed national quality assurance criteria closely reflect this tool but with a number of modifications to take into account the Irish healthcare setting. Detailed guidance for the development of clinical guidelines will be developed separately by the National Clinical Effectiveness Committee (NCEC).

1.1 The consultation process

The *Draft National Quality Assurance Criteria for Clinical Guidelines* were published on the Authority's website, www.hiqa.ie, and launched for consultation on the 15 July 2011 with a six-week consultation period which ran to 25 August 2011

A consultation feedback form (see Appendix 2) was developed to assist people make a written submission on the Draft Criteria. The form was made publicly available in downloadable format as a further channel for providing feedback. In addition, stakeholders could provide general feedback on the Draft Criteria by email (to a dedicated email address), by post or by telephone.

A targeted campaign was undertaken to promote and raise awareness about the consultation. Personalised emails were sent to over two hundred stakeholders including service-user representatives who had been identified as having an interest in the development of national clinical guidelines, inviting them to give feedback on the Draft Criteria. The members of the NCEC were also consulted.

2.0 Consultation summary

2.1 Overview of consultation submissions

A total of 35 written submissions were received as part of the consultation process. The majority of respondents submitted their response by e-mail with a small number choosing to send their comments by post (using the printed feedback forms or other formats).

Of the 35 submissions, 26 (equivalent to 74%) were submitted on behalf of organisations, 6 (equivalent to 17%) were in a personal capacity, while 3 (equivalent to 9%) did not specify. The individual submissions were made by healthcare professionals and a service user representative.

Table 1 gives an overview of the 35 submissions by respondent category. Appendix 1 provides a full list of all organisations that made a submission.

Respondent category	Number	Percentage
Acute care	8	23%
Primary care (including general practice)	2	6%
State body or policy makers	1	3%
HSE corporate management	6	17%
Union or representative bodies	2	6%
Regulatory bodies	1	3%
Professional body	10	28%
Postgraduate Training Bodies	4	11%
Service user representative	1	3%
Total	35	100%

Table 1- Overview of submissions by respondent category

The breakdown of those who took part in the consultation illustrates good engagement across healthcare professionals, representative bodies and relevant organisations. The varied makeup of consultees also ensured that a broad range of comments were received in response to the Draft Criteria.

2.2 Thematic analysis of submissions

A thematic analysis of all submissions was conducted. All submissions were read in their entirety by three reviewers. Each reviewer individually identified the main themes raised by the submissions. These individually identified themes were then compared across the three reviewers, and consensus reached as to the main themes raised by submissions.

3.0 General feedback

The majority of submissions welcomed the Draft Criteria and provided positive, supportive feedback. Examples of this feedback include the comments:

"Well done on putting together a fine document"

"The document is clear and comprehensive while remaining concise"

4.0 Specific feedback on consultation questions

The consultation form included six questions requesting feedback on aspects of the *Draft National Quality Assurance Criteria for Clinical Guidelines*. The following section sets out a summary of the responses received to these six questions, and outlines how the Authority will use this feedback in revising the Draft Criteria.

4.1 Language

Question 1: Is the language used clear and easy to understand?

In general, respondents thought that the language used in the document was clear and user-friendly. Some responses indicated that the language used in the document was particularly appropriate for a target audience of healthcare professionals who would be familiar with the area of clinical guideline development.

4.2 Layout and Design

Question 2: Is the layout and design of the document clear and easy to follow?

The majority of respondents said that the layout and design used in the Draft Criteria was clear, and easy to follow and understand. The use of diagrams was welcomed but some additional clarification was requested. Some respondents expressed the view that the document was rather long with some unnecessary repetition in places.

4.3 Criteria

Question 3: Are the criteria understandable and presented in a clear format?

The majority of respondents stated that the criteria were clear and well presented. The easy comparison with the AGREE II tool was welcomed. A number of suggestions for further details were made, and some clarification and expansion was requested (see below on specific feedback on the document).

4.4 Comprehensiveness of criteria

Question 4: Do these criteria cover the aspects needed to assure the quality of clinical guidelines?

The majority of respondents believed the Draft Criteria were comprehensive and covered the important issues in the development of guidelines.

Respondents stated that they welcomed the emphasis in the criteria on a multidisciplinary approach to, and service user involvement in, the development of clinical guidelines.

Respondents also welcomed the inclusion of the feasibility domain in the quality assurance criteria tool for clinical guidelines, and considered it an improvement on the AGREE II tool.

Some respondents indicated that they would like additional information in relation to aspects of the guideline development process (see below on specific feedback on the document).

4.5 Comprehensiveness of background

Question 5: Is the background information provided on clinical guidelines helpful to you in understanding the criteria?

The majority of submissions that responded to this question agreed that the background information was helpful in understanding the criteria. Respondents particularly welcomed the sections on guideline development, clinical guidelines and the Irish healthcare system as they thought that these sections allowed the reader to appreciate the context of the development of guidelines in the Irish health system.

4.6 Applicability

Question 6: Do you think that these criteria can be applied to all clinical guidelines including those intended to become part of a set of National Clinical Guidelines?

Most of those who responded considered the criteria applicable to all clinical guidelines. However, feedback suggested that some respondents were unsure if the quality assurance criteria are to be used for the development of clinical guidelines at a local or service level.

Some respondents also suggested that the criteria were unrealistic for the development of clinical guidelines at a local level as the resources (including staff) are not available this level to develop guidelines in the manner proposed.

Finally, respondents highlighted that the process as set out would be challenging and time-consuming for those involved in clinical guideline development at a local level.

The Authority's response

In revising the *Draft National Quality Assurance Criteria for Clinical Guidelines* the Authority is cognisant of the overall issues raised by submissions in response to these six consultation questions.

Each of the areas highlighted as potentially requiring clarification or expansion will be examined and the text and diagrams made more explicit in the revised *National Quality Assurance Criteria for Clinical Guidelines* where appropriate.

These are criteria for the assessment of clinical guidelines and are intended to be used in conjunction with other guidance and documents developed by the National Clinical Effectiveness Committee. Relevant feedback on clinical guidelines and clinical effectiveness will be passed on to this Committee, which will be in a position to deal with these suggestions more appropriately; for instance, the prioritisation of guideline development is a matter for the NCEC.

5.0 Specific Feedback on the Document

This section summarises the main issues that submissions raises and details the Authority's response under each heading.

5.1 Purpose of the document

A number of submissions suggested that there was a need for greater clarity regarding the purpose of the document and the purpose of the National Quality Assurance Criteria.

The responses suggested that it was not entirely clear if the approach being presented in the document was being recommended for clinical guideline development or assessment of the quality of the clinical guideline development process (to ascertain if a clinical guideline is suitable for inclusion in the National Suite of Clinical Guidelines) or, if the approach is being proposed for use in both situations.

Specific feedback on this point included:

"...One significant lack of clarity in the document is the applicability of the document/intended document purpose..."

"...the only possible confusion that may arise is to the issue of are they guidance for guideline development or guidance for guideline assessment. For me they are the same thing as we should guide people on guideline development using the same criteria we will judge them by."

The Authority's response

The Authority will include a section in the introduction chapter outlining the purpose of this document and the *National Quality Assurance Criteria for Clinical Guidelines*.

5.2 The National Clinical Effectiveness Committee

A number of submissions suggested that there was a need for further information and clarification on the role of the NCEC in developing guidelines. Respondents also suggested that it would be beneficial to see documents being produced by the NCEC as these documents would place the national quality assurance (QA) criteria guidelines in context with the other developments that are taking place in this area.

Several submissions requested further information in relation to the guideline development process and how this relates to the work of the NCEC (including how guideline topics will be prioritised for development, the timelines for guideline development and the processes for auditing of compliance with guidelines).

Finally on this point, respondents also sought information on whether or not there would be a process for determining if a clinical guideline needs to go to the NCEC for quality assurance. It was suggested that if the intention is to have such a process that it should be reflected in the document's Clinical Guideline Development Path (Figure 1) as a decision point prior to the point on submission of clinical guidelines to the NCEC.

In addition, respondents queried what the role of other bodies such as the Health Information and Quality Authority (the Authority), professional bodies and higher education institutions would be in developing national guidelines and how such organisations would work with the NCEC in this regard.

The Authority's response

The Authority will include additional information on the NCEC including its role, membership and terms of reference in the introduction chapter of the updated document, and will include references to documents developed by the NCEC.

5.3 Development of national and local clinical guidelines

The work of the NCEC in developing national guidelines was generally welcomed. However, it was also suggested that locally developed guidelines were more useful to end users.

The responses suggested that there was some confusion as to whether the quality assurance criteria are to be used for national or local or service level development of clinical guidelines. Some submissions suggested that the QA criteria and elements of them could present some challenges and difficulties in relation to the development of clinical guidelines at a local level.

Respondents also recommended that more information may be required to guide the implementation of the quality assurance criteria at a local level. Specifically, respondents queried how people working in the health service would know what guidelines are being developed by the NCEC in order to avoid duplication of effort.

The Authority's response

It is envisaged that the National Clinical Effectiveness Committee will adopt these National Quality Assurance Criteria and use them in quality assuring clinical guidelines intended to become part of the suite of National Clinical Guidelines. The brief overview of the steps involved in the development of clinical guidelines is provided to give appropriate context for the proposed criteria, rather than as a development tool.

However, groups developing clinical guidelines can also use the criteria set out here to inform their methodology in developing guidelines. The NCEC have issued *Interim Guidance for Clinical Guideline Development Groups*. Detailed guidance for the development of clinical guidelines will also be developed by the NCEC. It is anticipated that National Clinical Guidelines will be implemented at a local or service level and therefore, there will be less of a requirement for the development of local or service level clinical guidelines.

In the absence of National Clinical Guidelines, it is envisaged that local or service level clinical guidelines would be developed based on best available evidence. In this instance, guideline development groups can use the quality assurance criteria to inform their guideline development methodology.

The revised *National Quality Assurance Criteria for Clinical Guidelines* document will clarify the functions of the criteria document and refer to the guidance on development issued by the NCEC.

5.4 Existing guidelines and adoption

Some responses suggested that there was a need for clarity regarding the guideline development approach that is being proposed for Ireland. With several submissions highlighting the point that the development of *de novo* clinical guidelines is a time consuming process and that many clinical guidelines exist which could be adopted or adapted for use in the Irish health system.

Respondents highlighted that guidelines have not only been developed in other jurisdictions which could be adopted or adapted for use in Ireland, but that many clinical guidelines have been developed in Ireland (by organisations such as higher education institutions and professional bodies) that could be adopted or adapted for use at a national level.

Finally, several responses suggested that the adoption or adaptation of clinical guidelines from within and outside Ireland should be the preferred route of guideline development.

The Authority's response

Regardless of the approach taken, each guideline development group should clearly outline, document and justify the approach they have chosen for their guideline initiative. The criteria document includes some advantages and disadvantages of each approach. It is outside the scope of the *National Quality Assurance Criteria for Clinical Guidelines* document to specify a preference for one approach over any other. During the course of its work, the NCEC may give guidance or direction on this.

5.5 Planning stage: stakeholder involvement and the development group

Respondents considered that the role of the clinical guideline development group is crucial in ensuring the objectivity of clinical guideline development. Further detail was requested regarding membership and leadership of the guideline development group.

A range of views were expressed regarding wider stakeholder involvement, particularly service user involvement, with some consultees suggesting that the greater involvement of a range of stakeholders should be a criterion, and some suggesting it was not feasible to have the level of involvement specified in the Draft Criteria.

The Authority's response

The criteria set out the principles for membership of the guideline development group and the members for each group will depend on the nature and focus of the guideline being developed. The criteria do not provide details of the extent of stakeholder involvement or appointment of a chair. Further guidance on this may be provided by the NCEC.

In the finalised document, the criteria will specify that the views of service users should be sought and taken into consideration by the guideline development group. It is essential that this happen in order to provide person-centred care. As it may not always be possible, or appropriate, to have a service user as a member of the guideline development group, a variety of mechanisms to engage with and capture service users' views should be considered.

5.6 Development stage

The criteria in the section on the development stage were generally welcomed but respondents requested further information on how to search for evidence and the type of systematic methods that should be used for this, the criteria that they should use to select evidence and how they should grade the quality of the evidence. Respondents also requested additional information on the external review process and how this should be undertaken.

The Authority's Response

The description of the steps has been expanded to give more information on evaluation and rating of evidence but criteria 10, 11 and 12 have not been changed. As a number of submissions mentioned that 'expert' external advice was specified in the AGREE II tool but not in these Draft Criteria, the criteria have been revised to require 'experienced and knowledgeable' external reviewers.

5.7 Preparing for implementation phase

It was suggested that this section should provide more detailed criteria. Specific feedback suggested that the piloting of the clinical guideline should be part of the preparation for implementation phase. A further suggestion was that the QA criteria for clinical guidelines should be piloted to help establish how broad and applicable the QA criteria are.

The Authority's response

Some further clarification of the 'planning for implementation' stage will be given in the revised criteria document. This will highlight that the 'preparing for implementation phase' can involve developing a dissemination and implementation plan. 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 QA criteria for clinical guidelines described in this document are based on AGREE II, a tool which has been used internationally for clinical guideline development and has been validated and endorsed by the World Health Organization. Therefore, it is not necessary for the QA criteria for clinical guidelines to be piloted.

5.8 Monitoring and auditing criteria

This section was broadly welcomed, however some feedback suggested it needed further clarification. Respondents queried if the monitoring and / or auditing criteria could take account of information arising from implementation of the clinical guideline which may highlight aspects of the guideline which do not work in practice, or which may need to be amended to facilitate successful implementation of the guideline.

The Authority's response

Some further clarification of this stage will be made in the descriptions as a revision to section 12 of the draft document, while the criteria themselves will remain unchanged. A number of issues raised here will be referred to the NCEC, as they are more pertinent to the Committee's activity.

6.0 Conclusions and Next Steps

Once revised, the *National Quality Assurance Criteria for Clinical Guidelines* will go through internal review and will then be published. The Authority will work with the NCEC to develop a quality assurance process based on these criteria for quality assuring clinical guidelines intended to become part of the suite of National Clinical Guidelines.

The level of engagement and interest of all stakeholders including service providers, professional representative bodies, service user representatives and other regulators in the *Draft National Quality Assurance Criteria for Clinical Guidelines* was very encouraging. The Authority welcomed all contributions and would like to thank all who contributed to the public consultation on the *Draft National Quality Assurance Criteria for Clinical Guidelines*.

Appendix 1: List of organisations that made submissions

This list details the names of organisations that made submissions to the public consultation in an organisational capacity. Submissions were also made by individuals in a personal capacity and each of them has received an acknowledgement of their contribution.

The Adelaide and Meath Hospital, Dublin Incorporating the National Children's Hospital
An Bord Altranais
Connolly Hospital Blanchardstown
Department of Health and Children
Health Service Executive National Ambulance Service
Irish College of General Practitioners Quality in Practice Committee
Independent Hospital Associations of Ireland
Irish Association for Emergency Medicine
Irish Association of Speech and Language Therapists
Irish College of General Practitioners
Irish Faculty of Primary Dental Care
Irish Hospital Consultants Association
Irish Medical Organisation
Irish Pharmaceutical Healthcare Association
Irish Society for Quality and Safety in Healthcare
Irish Society of Chartered Physiotherapists
Mental Health Commission
National Poisons Information Centre
Office of Nursing and Midwifery Services
Office of the Regional Director of Operations Health Service Executive Dublin North
Our Lady of Lourdes Hospital Drogheda – Emergency Department
St Vincent's University Hospital

The Royal College of Physicians of Ireland National Quality Assurance Programmes in
Histopathology and Radiology
The Royal College of Physicians of Ireland Quality Assurance Programme GI Endoscopy
Voluntary Hospitals Risk Management Forum

Appendix 2: Consultation Feedback Form



**Health
Information
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An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Draft National Quality Assurance Criteria for Clinical Guidelines

Consultation Feedback Form

July 2011

Your views are very important to us. We would like to hear what you think about the Draft National Quality Assurance Criteria for Clinical Guidelines. Your comments will be considered and will inform the development of these criteria.

We are consulting on the national quality assurance criteria. This document describes clinical guidelines, their benefits, limitations, effectiveness as well as international quality assuring tools, which influenced the development of these national criteria. Your comments are welcome on all aspects of the document.

For more information, see <http://www.higa.ie/getting-involved/consultations>

The closing date for consultation is 5.00pm on 25 August 2011

You can complete this form electronically and either select the submit button at the end of the form, or print the form and post it to us.

About you

Name:	
Contact details:	
Date:	
Are you commenting on behalf of your organisation or in a personal capacity?	Organisation <input type="radio"/> Personal <input type="radio"/>
Organisation: * <small>(Please include if making this submission on behalf of your organisation)</small>	

Feedback questions

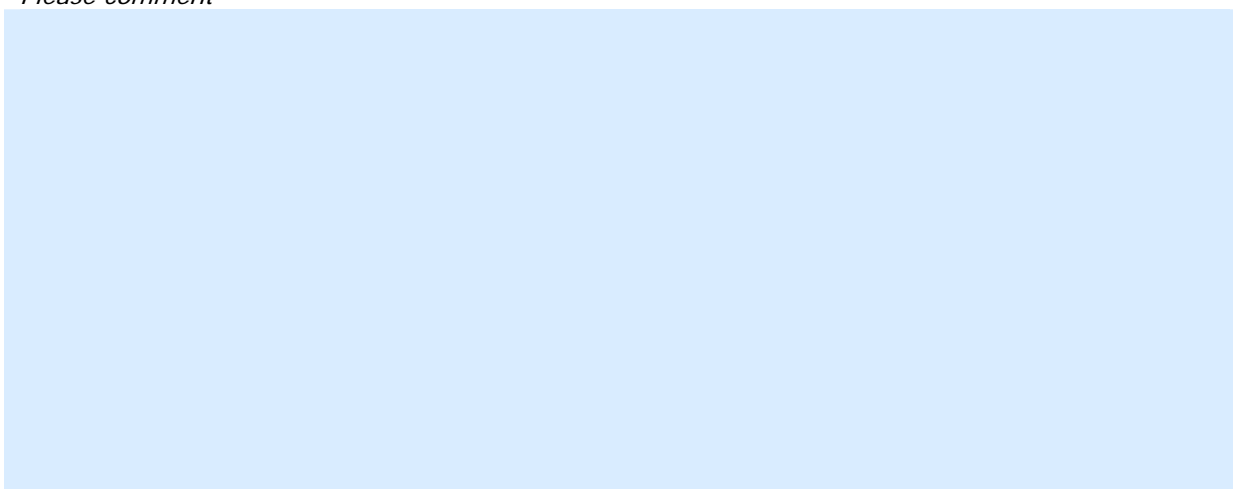
The consultation document outlines quality assurance criteria and how they will be applied to clinical guidelines intended to become part of a suite of National Clinical Guidelines.

We would like to know your views on the criteria and their role in supporting the National Clinical Effectiveness Committee in quality assuring clinical guidelines.

Layout and design

Question 1: Is the language used clear and easy to understand?

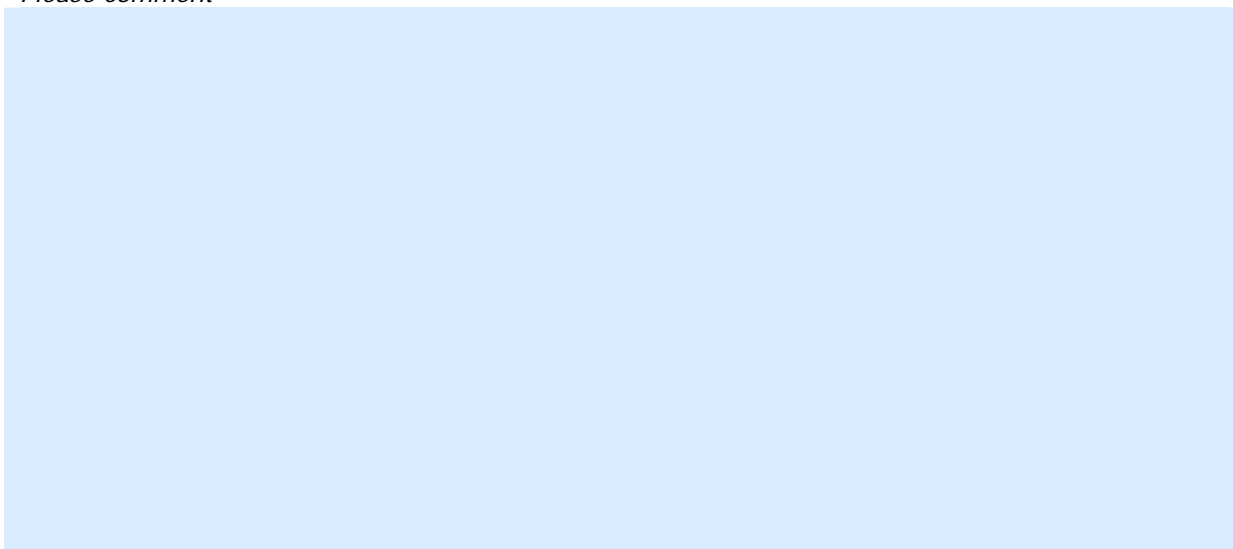
Please comment



(Please use page 5 for any additional comments that you may have)

Question 2: Is the layout and design of the document clear and easy to follow?

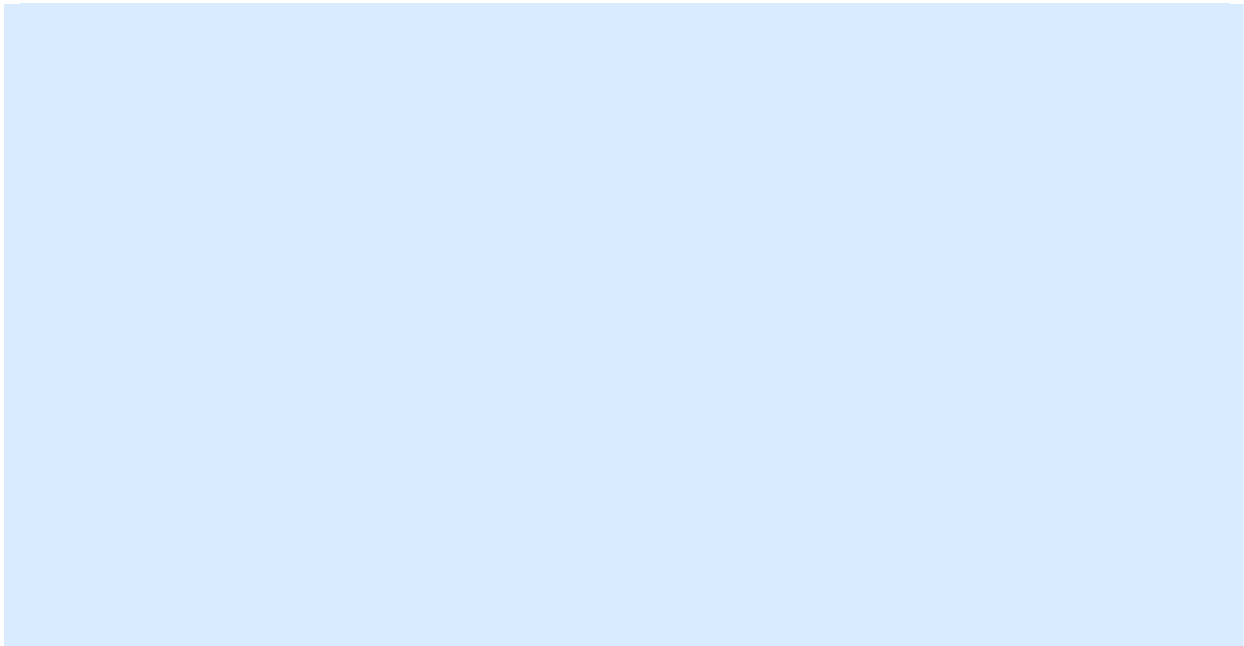
Please comment



(Please use page 5 for any additional comments that you may have)

Question 3: Are the criteria understandable and presented in a clear format?

Please comment

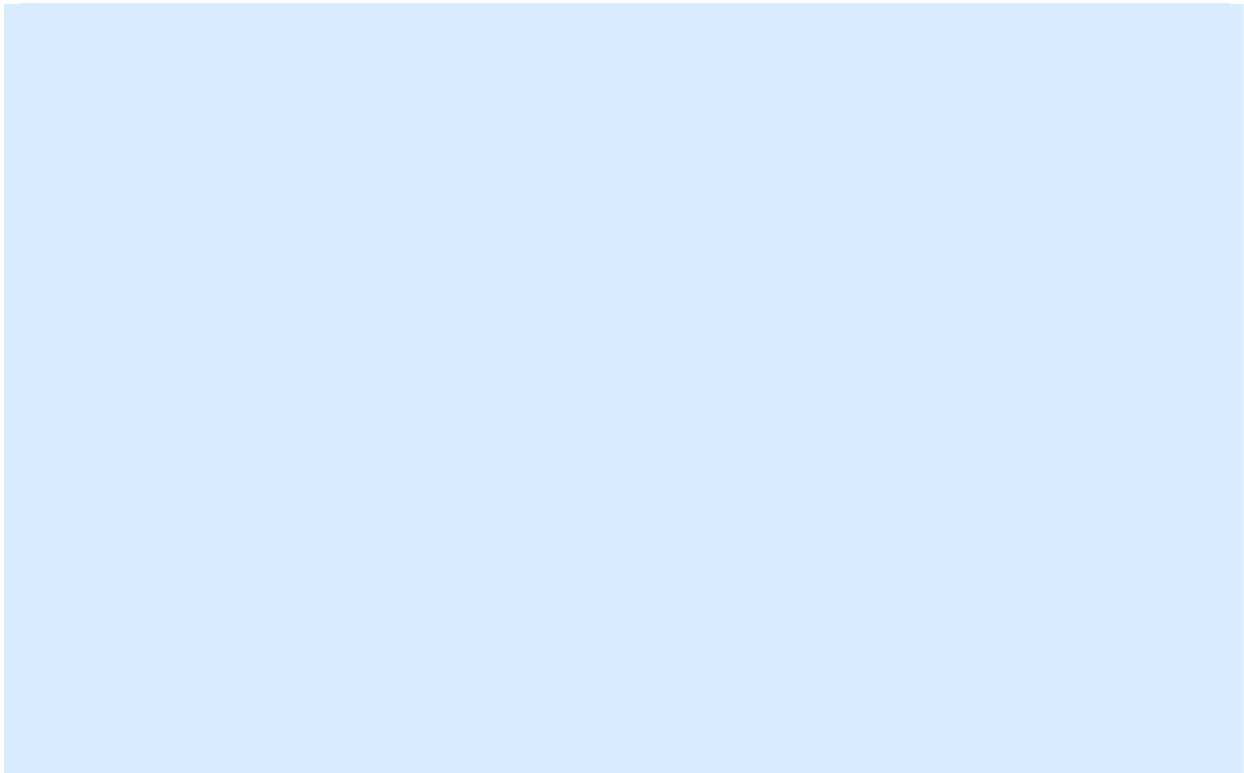


(Please use page 5 for any additional comments that you may have)

Comprehensiveness

Question 4: Do these criteria cover the aspects needed to assure the quality of clinical guidelines?

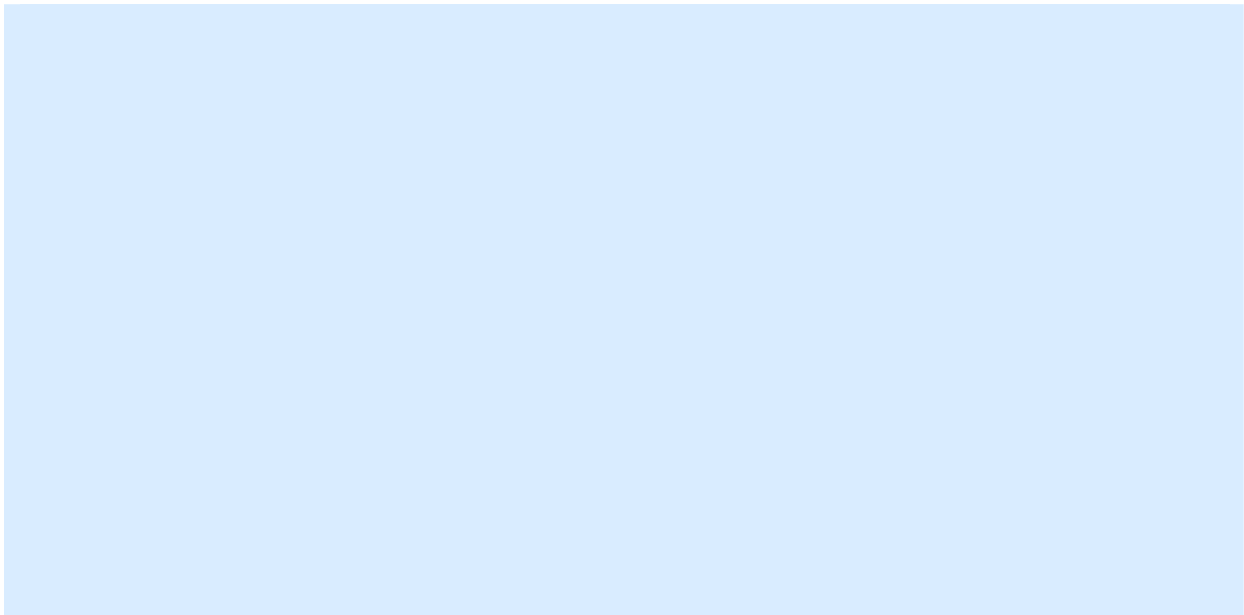
Please comment



(Please use page 5 for any additional comments that you may have)

Question 5: Is the background information provided on clinical guidelines helpful to you in understanding the criteria?

Please comment

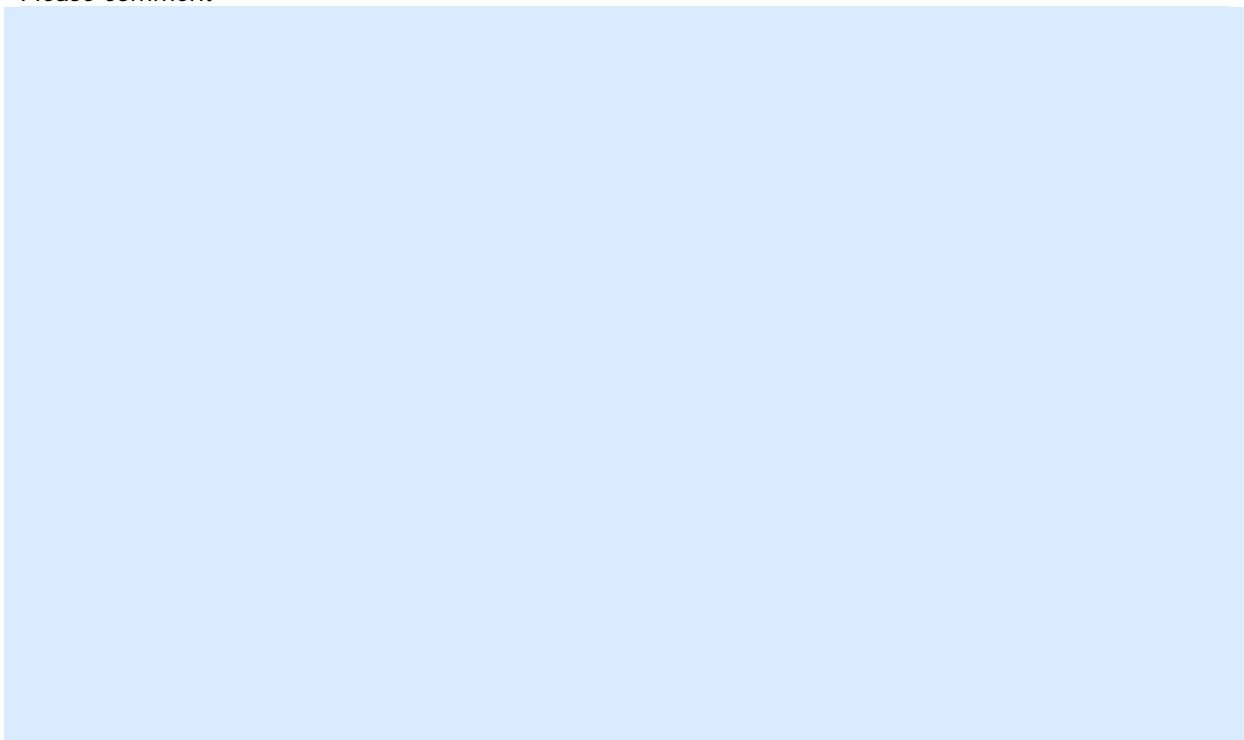


(Please use page 5 for any additional comments that you may have)

Applicability

Question 6: Do you think that these criteria can be applied to all clinical guidelines including those intended to become part of a set of National Clinical Guidelines?

Please comment



(Please use page 5 for any additional comments that you may have)

General Comments

Question 7: Do you have any further comments on this consultation document?

Please comment

A large, solid light blue rectangular area that occupies most of the page below the question. It is intended for users to provide their comments on the consultation document.

Thank you for taking the time to give us your views on the Draft National Quality Assurance Criteria for Clinical Guidelines.

Please return your feedback to us either by email or post:



Click here to send your feedback directly to us by email:



Click here to print your form:
Please send completed forms to:
Health Information and Quality Authority
National Standards for Safer Better Healthcare
George's Court
George's Lane
Smithfield, Dublin 7



If you have any questions on this document, you can contact the consultation team by calling (01) 814 7446.

Please Note:

Following the consultation we will include in the final National Quality Assurance Criteria for Clinical Guidelines document a description of the consultation that we undertook and the general findings from it.

Organisations and individuals providing submissions should keep in mind that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

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