Health Information and Quality Authority

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.hiqa.ie/getting- involved/consultations

The closing date for consultation is 2 August 2011

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

About you

Name:	Irish Medical Organisation
Contact details:	10 Fitzwilliam Place, Dublin 2 01 676 72 73 vhetherington@imo.ie
Date:	
Are you commenting on behalf of your organisation or in a personal capacity?	**Organisation** ⊙ **Personal** ○
Organisation:* **(Please include if making this submission on behalf of your organisation)**	Irish Medical Organisation

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

Please comment

1) The criteria describe clearly how to develop national level guidelines, however the recommended standard has not been nominated. Each of the 24 proposed quality criteria is to be scored 1 – 7, however, it is not stated what score is the quality level desired by the assurance guidelines. Quality scores for criteria are not aggregated either by development stage or overall and it is unclear if a low score on a single criterion can fail a guideline.

2) The assessment process which rates criteria on a scale of 1-7 (Strongly disagree =1, strongly agree 7) is subjective.

3) It might be useful to provide or point to a worked example of a quality assured clinical guideline.

(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

1) Scope and Purpose
Topics for Clinical Guidelines are to be selected because they are important to large numbers of people with substantial morbidity or mortality and where evidence of variation in care exists. Classical Quality Assurance (QA) seeks to control to a quality standard removing variation both below and above the standard chosen. Clinical guidelines must not require reducing quality of care where this is above standard. Recent national policy is for standardising care in a single tier system. Clinicians providing excellent care should not be required to dumb down quality.

2) Stakeholder Involvement
The guideline development stage involves experts who provide evidence of efficacy. The frontline clinicians who have knowledge of effectiveness should be explicitly represented.

Service users involved in guideline development should be appropriate to the topic and bring practical experience to the table. QA comment on how patient representatives get their mandate is appropriate. Some patient organisations are not membership organisations.

3) Rigour of Development
As mentioned in our response to question 2 the guideline development path suggests that the External Review Process takes place following consideration of resources. External Assessors should not be expected to endorse financial decisions which may negatively impact on the clinical value of the guidelines.

(continued on separate page)

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

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

(continued from page 3 question 4)

4) Applicability
While Clinical Guidelines are designed to be applied to groups (population care), clinical practitioners are required to respond to the expectation of patients for personalised care. Modern scientific developments are increasingly identifying individual factors that underlie disease and strengthen the evidence for the need to personalise care.

The matter of individual care needs to be dealt with in the applicability stage of guideline development. Clinicians are expected to be wise in their application of data, information and knowledge. Clinicians judge the effectiveness and appropriateness of care by monitoring individual patient response and need to be able to react to this clinical feedback on the effects of any guidance they may be following. Guidelines are to be adhered to only if they result in an optimal clinical outcome. It seems that the role for guidelines is for an initial introduction of care for some conditions. Having options within each guideline is important.

The Medical Council's Guide to Professional Conduct and Ethics states that Medical Practitioners have a paramount responsibility to act in the best interest of their patients. Following a guideline or failure to follow a guideline (while acting in the best interest of a patient) should not create the basis for a complaint to the Medical Council.

Clinical Protocols as defined in Table 2 may in certain circumstances be incompatible with Medical Council Requirements of Medical Practitioners in so far as doctors have a duty to help patients make an informed decision about their own care. Precise sequence of activities with little scope for variation may conflict with this depending on how the patient presents.

5) Resources
At many points along the guideline development path it is mentioned that the standard of care to which the guideline is aimed to attain is to be constrained by consideration of resources. Medical Practitioners have a paramount responsibility to act in the best interest of a patient and to advise patients on the different options of care available to them including the most effective care. It is not appropriate for a clinical guideline that is constrained by resources to propose conflict with this requirement.

Clinical guidelines in a country which is unable/unwilling to fund essential health care to normal international standards will impose further impossible targets on health care professionals. It is essential that HIQA clearly direct such guidelines at entities which fund health care provision and not solely at health care professionals who have no control over funding of service provisions.

For GPs, it is likely that most guidelines produced will be ex-contractual as the GP GMS contract makes provision for the management of acute presentations only.

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

Please comment

It is a misjudgement to presume based upon a 1999 BMJ article (ref 2) that guidelines will not be used as a routine tool in litigation against health care professionals in Ireland. Ireland has a reputation as the most litigious state in Europe, second only to the US. It is inevitable that HIQA produced guidelines will be used in litigation against health care professionals and health care institutions in Ireland. It behoves HIQA along with all stakeholders including the public to address the negative impact of the current adversarial litigation system as a tool for redress for those injured from adverse events arising from health care.

Other articles referenced in the document date back to the 1990s and the early 2000s. Quality Assurance research must be up to date.

(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

It is important that National Quality Assurance Criteria for Clinical Guidelines should be applied as a guiding tool to the development of clinical guidelines and not as a strict protocol which must be adhered to.

- As mentioned in our response to question 4 above Quality Assurance standards remove variation below and above the standard chosen. It is important that Guideline Development Groups that produce excellent Clinical Guidelines are equally not required to dumb down. This is particularly important given the resource constraints that are imposed by these criteria at all stages in the development path.

- Medical practice is a dynamic process and guidelines are quickly dated. Practitioners will be up to date in their field of practice through CPD/CME. Given the time lag involved in gathering the evidence for systemic reviews and the additional time for its incorporation into formally quality assured clinical guidelines, many guidelines will not be as up to date as the practitioners who may be requested to apply them. Provision should be made for clinicians to modify guidelines accordingly. Also the Medical Council in its competence assurance process could be frustrated by a mismatch between clinical guidelines and maintaining up to date practice.

(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

No Quality Assurance programme will succeed unless clinicians really engage with it. Clinicians must be given ownership of the QA agenda. The IMO benchmark survey (April 2011) found morale among consultants at an all-time low. Consultants do feel suitably involved in the running of their own clinical and speciality services. However, more broadly consultants do not feel their views carry enough weight in the overall hospital decision making process or indeed that they are consulted about changes taking place in the hospital. HIQA have a duty not to contribute further to the alienation and demoralisation of clinicians by adopting a top-down approach to quality improvement.

Finally, the broader aspects of practice by guideline must be taken into consideration. If all practice were to be undertaken on the basis of guidelines medicine advancement would cease, innovation would be stifled and personalised care would cease. Guidelines are useful where what they are seeking to guide is a uniform simple linear process. However individual patients are not linear and change is constant. Realistic QA must be flexible and embrace the complexity of clinical care.

The IMO is committed to a better quality service for patients and welcomes the Draft National Quality Assurance Criteria for Clinical Guidelines. With further development and application it has the potential to be a really useful tool.

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: Submit by Email

Click here to print your form: Print 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.