9 Appendix I

APPRAISAL OF GUIDELINES FOR RESEARCH & EVALUATION



INSTRUMENT

The AGREE Collaboration

September 2001





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1. The overall objective(s) of the guideline is (are) specifically described.									
Strongly Agree	4	3	2	1	Strongly Disagree				

Comments: **4 – Strongly Agree.** The guideline clearly describes the clinical imperative for the guideline and the overall purpose of the guidance. Additionally, Section 4 addresses the aim of the guideline and provides the details about groups covered, health care setting and clinical questions.

2. The clinical question(s) covered by the guideline is(are) specifically described.								
Strongly Agree	4	3	2	1	Strongly Disagree			
Comments:	<i>Comments:</i> 4 – Strongly Agree. The questions addressed by the guideline							

are listed in section 4.5.

3. The patients to whom the guideline is meant to apply are specifically described.								
Strongly Agree	4	3	2	1	Strongly Disagree			
Comments:	4 – Strongly	Agree. The p	atients for wh	om the guidel	ine was			

written are identified in Sections 4.1, 4.2 and 4.3.



1.

This deals with the potential health impact of a guideline on society and populations of patients. The overall objective(s) of the guideline should be described in detail and the expected health benefits from the guideline should be specific to the clinical problem. For example specific statements would be:

Preventing (long term) complications of patients with diabetes mellitus;

Lowering the risk of subsequent vascular events in patients with previous myocardial infarction;

Rational prescribing of antidepressants in a cost-effective way.

2.

A detailed description of the clinical questions covered by the guideline should be provided, particularly for the key recommendations (see item 17). Following the examples provided in question 1:

- How many times a year should the HbA1c be measured in patients with diabetes mellitus?
- What should the daily aspirin dosage for patients with proven acute myocardial infarction be?
- Are selective serotonin reuptake inhibitors (SSRIs) more cost-effective than tricyclic

antidepressants (TCAs) in treatment of patients with depression?

3.

There should be a clear description of the target population to be covered by a guideline. The age range, sex, clinical description, comorbidity may be provided. For example:

A guideline on the management of diabetes mellitus only includes patients with non-insulin dependent diabetes mellitus and excludes patients with cardiovascular comorbidity.

A guideline on the management of depression only includes patients with major depression, according to the DSM-IV criteria, and excludes patients with psychotic symptoms and children.
 A guideline on screening of breast cancer only includes women, aged between 50 and 70 years, with no history of cancer and with no family history of breast cancer.

4. The guideline development group includes individuals from all the relevant professional groups.									
Strongly Agree	4	3	2	1	Strongly Disagree				

Comments: **4** - **Strongly agree.** The guideline development group was multidisciplinary and fully disclosed at the beginning of the guideline.

Comments

5. The patients' views and preferences have been sought.

Strongly Agree	4	3	2	1	Strongly Disagree
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Comments: **4 – Strongly Agree.** The guideline development group included a patient representative.

6. The target users of the guideline are clearly defined.								
Strongly Agree	4	3	2	1	Strongly Disagree			

Comments: **4 – Strongly Agree.** The target users are described in Section 4.1.

7. The guideline has been piloted among target users.									
Strongly Agree	4	3	2	1	Strongly Disagree				
Comments:	1 – Strongly	7 Disagree.	This guideline	was not pilote	AGREE				

4.

This item refers to the professionals who were involved at some stage of the development process. This may include members of the steering group, the research team involved in selecting and reviewing/rating the evidence and individuals involved in formulating the final recommendations. This item excludes individuals who have externally reviewed the guideline (see Item 13). Information about the composition, discipline and relevant expertise of the guideline development group should be provided.

Information about patients' experiences and expectations of health care should inform the development of clinical guidelines. There are various methods for ensuring that patients' perspectives inform guideline development. For example, the development group could involve patients' representatives, information could be obtained from patient interviews, literature reviews of patients' experiences could be considered by the group. There should be evidence that this process has taken place.

6.

The target users should be clearly defined in the guideline, so they can immediately determine if the guideline is relevant to them. For example, the target users for a guideline on low back pain may include general practitioners, neurologists, orthopaedic surgeons, rheumatologists and physiotherapists.

7.

A guideline should have been pre-tested for further validation amongst its intended end users prior to publication. For example, a guideline may have been piloted in one or several primary care practices or hospitals. This process should be documented.

8. Systematic methods were used to search for evidence.									
Strongly Agree	4	3	2	1	Strongly Disagree				

Comments: **4 – Strongly Agree**. The methodology was systematic and is clearly described in Section 5.

Comments					
9. The criteria	for selecting the	e evidence are c	learly described.		
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: **4 – Strongly Agree.** Selection criteria are well described in Section 5 – Inclusion and exclusion criteria are clearly presented

5. Inclusion and exclusion criteria are clearly presented.

10. The methods used for formulating the recommendations are clearly described.									
Strongly Agree	4	3	2	1	Strongly Disagree				

Comments: **4 – Strongly Agree.** Methods for formulating recommendations are well described in Section 5.5.

11. The health benefits, side effects and risks have been considered in formulating the recommendations.									
Strongly Agree	4	3	2	1	Strongly Disagree				

Comments: **3 - Agree.** Benefit and risk was considered by the GDG in making all recommendations (see Section 5.5). Methods for resolving differences within the GDG group are not described.



8.

Details of the strategy used to search for evidence should be provided including search terms used, sources consulted and dates of the literature covered. Sources may include electronic databases (e.g. MEDLINE, EMBASE, CINAHL), databases of systematic reviews (e.g. the Cochrane Library, DARE), handsearching journals, reviewing conference proceedings and other guidelines (e.g. the US National Guideline Clearinghouse, the German Guidelines Clearinghouse).

Criteria for including/excluding evidence identified by the search should be provided. These criteria should be explicitly described and reasons for including and excluding evidence should be clearly stated. For example, guideline authors may decide to only include evidence from randomised clinical trials and to exclude articles not written in English.

10.

There should be a description of the methods used to formulate the recommendations and how final decisions were arrived at. Methods include for example, a voting system, formal consensus techniques (e.g. Delphi, Glaser techniques). Areas of disagreement and methods of resolving them should be specified.

11.

The guideline should consider health benefits, side effects, and risks of the recommendations. For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes. These may include: survival, quality of life, adverse effects, and symptom management or a discussion comparing one treatment option to another. There should be evidence that these issues have been addressed.

12. There is an explicit link between the recommendations and the supporting evidence.

Strongly Agree	4	3	2	1	Strongly Disagree
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Comments: **4** – **Strongly Agree.** Complete evidence summaries are presented in conjunction with the recommendations.

13. The guideline has been externally reviewed by experts prior to its publication.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: **4 – Strongly Agree.** A peer review process was undertaken and completed before publication.

14. A procedu	ocedure for updating the guideline is provided.					
Strongly Agree	4	3	2	1	Strongly Disagree	

Comments: 4 – Strongly Agree. The guideline update is scheduled for 2009.



12.

There should be an explicit link between the recommendations and the evidence on which they are based. Each recommendation should be linked with a list of references on which it is based.

A guideline should be reviewed externally before it is published. Reviewers should not have been involved in the development group and should include some experts in the clinical area and some methodological experts. Patients' representatives may also be included. A description of the methodology used to conduct the external review should be presented, which may include a list of the reviewers and their affiliation.

14.

Guidelines need to reflect current research. There should be a clear statement about the procedure for updating the guideline. For example, a timescale has been given, or a standing panel receives regularly updated literature searches and makes changes as required.

15. The recommendations are specific and unambiguous.

Strongly Agree	4	3	2	1	Strongly Disagree
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Comments: **4 – Strongly Agree.** The recommendations are clear and are action oriented.

16. The different options for management of the condition are clearly presented.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: 4 – Strongly Agree. Options are given if appropriate.

17. Key recommendations are easily identifiable.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: 4 – Strongly Agree. The recommendations are presented in

Section 2 as well as within the results section for each patient group.

18. The guideline is supported with tools for application.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: **4 – Strongly Agree.** The following tools for implementation were developed: an algorithm, short version of guideline, quick reference guide for clinicians, information for patients leaflet and Web based material.



15.

A recommendation should provide a concrete and precise description of which management is appropriate in which situation and in what patient group, as permitted by the body of evidence.

- An example of a specific recommendation is: Antibiotics have to be prescribed in children of two
 years or older with acute otitis media if the complaint last longer than three days or if the complaint
 increase after the consultation despite adequate treatment with painkillers; in these cases amoxycillin
 should be given for 7 days (supplied with a dosage scheme).
- An example of a vague recommendation is: Antibiotics are indicated for cases with an abnormal or complicated course.

However, evidence is not always clear cut and there may be uncertainty about the best management. In this case the uncertainty should be stated in the guideline.

16.

A guideline should consider the different possible options for screening, prevention, diagnosis or treatment of the condition it covers. These possible options should be clearly presented in the guideline. For example, a recommendation on the management of depression may contain the following alternatives:

- a. Treatment with TCA
- b. Treatment with SSRI
- c. Psychotherapy
- d. Combination of pharmacological and psychological therapy



Users should be able to find the most relevant recommendations easily. These recommendations answer the main clinical questions that have been covered by the guideline. They can be identified in different ways. For example, they can be summarised in a box, typed in bold, underlined or presented as flow charts or algorithms.

18.

For a guideline to be effective it needs to be disseminated and implemented with additional materials. These may include for example, a summary document, or a quick reference guide, educational tools, patients' leaflets, computer support, and should be provided with the guideline.

19. The potential organisational barriers in applying the recommendations have been discussed.

Strongly Agree	4	3	2	1	Strongly Disagree
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Comments: **4 – Strongly Agree.** These discussions are described in Section 11, Dissemination of the guideline.

20. The potential cost implications of applying the recommendations have been considered.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: **1 – Strongly Disagree.** There is no economic analysis in this guideline.

21. The guideline presents key review criteria for monitoring and/or audit purposes.					poses.
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: **4 – Strongly Agree.** Audit criteria are discussed in Section10 of this guideline.



Applying the recommendations may require changes in the current organisation of care within a service or a clinic which may be a barrier to using them in daily practice. Organisational changes that may be needed in order to apply the recommendations should be discussed. For example:

- i. A guideline on stroke may recommend that care should be co-ordinated through stroke units and stroke services.
- ii. A guideline on diabetes in primary care may require that patients are seen and followed up in diabetic clinics.

20.

The recommendations may require additional resources in order to be applied. For example, there may be a need for more specialised staff, new equipment, expensive drug treatment. These may have cost implications for health care budgets. There should be a discussion of the potential impact on resources in the guideline.

21.

Measuring the adherence to a guideline can enhance its use. This requires clearly defined review criteria that are derived from the key recommendations in the guideline. These should be presented. Examples of review criteria are:

- The HbA1c should be < 8.0%.
- The level of diastolic blood pressure should be < 95 mmHg.
- If complaints of acute otitis media lasts longer than three days amoxicillin should be prescribed.

22. The guideline is editorially independent from the funding body.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: **3 – Agree.** The funding source for this guideline is not explicitly

stated. However, the GDG is a diverse interdisciplinary group which includes a patient representative and is therefore likely to be independent, at least in part, from the funding body.

23. Conflicts of interest of guideline development members have been recorded.					
Strongly Agree	4	3	2	1	Strongly Disagree

Comments: 2 – Disagree. This has not been explicitly stated.



22.

Some guidelines are developed with external funding (e.g. Government funding, charity organisations, pharmaceutical companies). Support may be in the form of financial contribution for the whole development, or for parts of it, e.g. printing of the guidelines. There should be an explicit statement that the views or interests of the funding body have not influenced the final recommendations. Please note: If it is stated that a guideline was developed without external funding, then you should answer 'Strongly Agree'.

23.

There are circumstances when members of the development group may have conflicts of interest. For example, this would apply to a member of the development group whose research on the topic covered by the guideline is also funded by a pharmaceutical company. There should be an explicit statement that all group members have declared whether they have any conflict of interest.

FURTHER COMMENTS

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice?

Strongly recommend

Recommend

(with provisos or alterations): This guideline is recommended with following provisos:

- a. Update searches for the period from 2005 2009 are carried out.
- b. Description of consensus methodology used for any Grade D recommendations is described.
- c. Conflict of interest records for GDG should be summarised.

Would not recommend
Unsure

NOTES



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