Guideline appraisal - an international viewpoint

Mission Québec - France
9-12 February 2004
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WHAT IS A ‘GOOD’ GUIDELINE?

A ‘good’ guideline is one that leads to improved outcomes for patients

- Needs to be based on evidence
- Needs to be assessed
- Needs to be used (implementation)

BACKGROUND

UK work
- Appraisal instrument developed and validated in the UK (funded by national R&D Programme)
- Used in the UK, Europe & Canada

EU funding
- Funding obtained from the 4th Framework of EU Programme for 3 years (1998-2001)

The AGREE Collaboration

The AGREE Collaboration includes:
- USA
- Canada
- New Zealand
**PURPOSE OF THE AGREE INSTRUMENT**

- To provide a systematic framework for appraising the quality of clinical guidelines
- To help policymakers decide which guideline to recommend for use in practice
- To help guideline developers follow a structured and rigorous methodology
- To help health care providers assess guidelines before adopting recommendations in practice

**DEFINITION**

'Quality of clinical guidelines' is the confidence that:

- the potential biases of guideline development have been addressed adequately
- the recommendations are both internally and externally valid, and are feasible for practice

**DEVELOPMENT PROCESS**

1. Subgroup reviews literature
2. First draft circulated for comments
3. First workshop, instrument modified
4. First validation study
5. Second workshop, instrument revised
6. Final validation study

**AGREE INSTRUMENT**

- **Six domains**
  1. Scope & purpose (3)
  2. Stakeholder involvement (4)
  3. Rigour of development (7)
  4. Clarity & presentation (4)
  5. Applicability (3)
  6. Editorial independence (2)

- **23 items**
- **4-point Likert Scale**

- **Overall assessment**
- **User guide**
**DOMAIN 1. SCOPE AND PURPOSE**

1. The overall objective(s) of the guideline is(are) specifically described.
2. The clinical question(s) covered by the guideline is(are) specifically described.
3. The patients to whom the guideline is meant to apply are specifically described.

**DOMAIN 2. STAKEHOLDER INVOLVEMENT**

4. The guideline development group includes individuals from all the relevant professional groups.
5. The patients’ views and preferences have been sought.
6. The target users of the guideline are clearly defined.
7. The guideline has been piloted among target users.

**DOMAIN 3. RIGOUR OF DEVELOPMENT (1)**

8. Systematic methods were used to search for evidence.
9. The criteria for selecting the evidence are clearly described.
10. The methods used for formulating the recommendations are clearly described.
11. The health benefits, side effects and risks have been considered in formulating the recommendations.

**DOMAIN 3. RIGOUR OF DEVELOPMENT (2)**

12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by an expert panel prior to publication.
14. A procedure for updating the guideline is provided.
DOMA I N 4. CLARITY AND PRESENTATION

15. The recommendations are specific and unambiguous.
16. The different options for management of the condition are clearly presented.
17. Key recommendations are easily identifiable.
18. The guideline is supported with tools for application.

DOMAI N 5. APPLI CABI LITY

19. The potential organisational barriers in applying the guideline have been discussed.
20. The potential costs implications of applying the recommendations have been considered.
21. The guideline presents key review criteria for monitoring and/or audit purposes.

DOMAI N 6. EDITORIAL INDEPENDENCE

22. The guideline is editorially independent from the funding body.
23. Conflicts of interest of guideline development members have been recorded.

RESPONSE SCALE

Strongly Agree 4 3 2 1 Strongly Disagree
CALCULATING DOMAIN SCORES

Standardised guideline domain scores are calculated by:

- summing up all the scores of individual items in a domain

and

- by standardising the total as a percentage of the maximum possible score for that domain

EXAMPLE DOMAIN SCORE (1)

<table>
<thead>
<tr>
<th>Appraiser</th>
<th>Item 1</th>
<th>Item 2</th>
<th>Item 3</th>
<th>Totaal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appraiser 1</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Appraiser 2</td>
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<tr>
<td>Appraiser 4</td>
<td>2</td>
<td>3</td>
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<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>13</td>
<td>14</td>
<td>36</td>
</tr>
</tbody>
</table>

Max. possible score = 4 (strongly agree) x 3 (items) x 4 (appraisers) = 48
Min. possible score = 1 (strongly disagree) x 3 (items) x 4 (appraisers) = 12

EXAMPLE DOMAIN SCORE (2)

The *standardised domain score* will be:

\[
\text{standardised domain score} = \frac{\text{obtained score} - \text{min. possible score}}{\text{max. possible score} - \text{min. possible score}}
\]

\[
\frac{36 - 12}{48 - 12} = \frac{24}{36} = 0.67 \times 100 = 67\%
\]

OVERALL ASSESSMENT (1)

*Would you recommend these guideline for use in practice?*

- Strongly recommend
- Recommend (with provisos or alterations)
- Would not recommend
- Unsure
OVERALL ASSESSMENT (2)

✓ Do not aggregate the six domain scores into a single quality score!
✓ Take each appraisal criteria into account
✓ Use common sense as well

CONCLUSIONS AGREE PROJECT

✓ AGREE is the first appraisal instrument for clinical guidelines to be developed and tested internationally
✓ It can be used consistently by a wide range of professionals from different cultural backgrounds
✓ It can be used to compare quality of guidelines across countries and disease areas.
✓ It provides standards for reporting of clinical guidelines published in medical journals.

OUTCOMES

✓ The AGREE Instrument has been translated into 10 European languages, Russian, Chinese and Japanese
✓ All EU-funded projects requested to assess guidelines with the AGREE Instrument
✓ The Council of Europe has formally recommended its use
✓ WHO has endorsed the AGREE Instrument