Clinical guidelines are:
‘systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances’.

Institute of Medicine (1990).

Clinical guidelines are not new
Rise of guidelines are linked to several factors:
  • Unexplained variation in practice
  • Escalating health care costs
  • Under-use of research findings
  • Evidence-based medicine
  • Explosion of computer technology

DEFINITION

HISTORICAL CONTEXT

Citations of ‘guideline(s)’ in PubMed

Year of publication

Number of citations

2000
1500
1000
500
0


Guideline appraisal - an international viewpoint

Mission Québec – France
9-12 February 2004

Jako Burgers, Béatrice Fervers, Margareth Haugh
PROBLEMS WITH GUIDELINES

✓ Pluralism: lacking co-ordination
✓ Variation in guidelines and conflicting recommendations
✓ Lack of quality and lack of internationally accepted criteria
✓ Insufficient evidence for improved patient care

WHY APPRAISE GUIDELINES?

✓ A guideline is a form of intervention
✓ It can potentially affect a lot of patients
✓ Guideline users need to have confidence in recommendations
✓ Professional and governmental agencies have to ensure guidelines are ‘good’ before recommending them

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 used (implementation)
- Needs to be assessed

WHY AN INTERNATIONAL COLLABORATION?

✓ Clinical guidelines play an increasingly important role in healthcare practice in most countries
✓ Shared concerns about quality
✓ There is a need for international guidance on guideline development
✓ ‘The whole is greater than the sum of its parts’
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)

INTEGRATED RESEARCH PROGRAMME

1. Create an international instrument to appraise the quality of clinical guidelines.
2. Formulate guidance for guideline developers.
3. Describe and compare guideline development programmes.
4. Undertake content analysis of appraised guidelines.

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

www.agreecollaboration.org
**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**

- Subgroup reviews literature
- First draft circulated for comments
- First workshop, instrument modified
- First validation study
- Second workshop, instrument revised
- Final validation study

**VALIDATION PROCESS (1)**

**Phase 1**

- The instrument was applied to 100 guidelines from 11 countries
- All countries followed the same protocol
- Each guideline was independently assessed by 4 appraisers (194 altogether)
- Instrument was used in English

**VALIDATION PROCESS (2)**

**Phase 2**

- Refined instrument tested on 33 guidelines randomly selected from 1st study
- Same countries participated
- New set of appraisers recruited (70)
- Each country assessed 3 guidelines
RESULTS OF VALIDATION

- Reliability was satisfactory for each domain
  - Cronbach’s Alpha 0.64 - 0.88
  - ICC 0.57 - 0.91
- There was suggestion of criterion validity
- Over 90% of appraisers found the instrument and the userguide useful
- The median time for appraising a guideline was 1.5 hours

AGREE INSTRUMENT

- 23 items
- 4-point Likert Scale

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)

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.

DOMAIN 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.

DOMAIN 5. APPLICABILITY

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.
DOMAIN 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>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>
</tr>
<tr>
<td>Appraiser 2</td>
<td>3</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Appraiser 3</td>
<td>2</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Appraiser 4</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>9</td>
<td>13</td>
<td>14</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:

\[
\frac{\text{obtained score} - \text{min. possible score}}{\text{max. possible score} - \text{min. possible score}} = \frac{36 - 12}{48 - 12} = \frac{24}{36} = 0.67 \times 100 = 67\%
\]

**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

**Mean domain scores cancer guidelines versus other guidelines**

<table>
<thead>
<tr>
<th></th>
<th>Cancer guidelines (n = 32)</th>
<th>Other guidelines (n= 68)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope and purpose</td>
<td>63.2</td>
<td>65.5</td>
<td>0.70</td>
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<tr>
<td>Stakeholder involvement</td>
<td>34.3</td>
<td>29.5</td>
<td>0.20</td>
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<tr>
<td>Rigour of Development</td>
<td>42.2</td>
<td>29.4</td>
<td>0.02</td>
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<tr>
<td>Clarity and Presentation</td>
<td>57.2</td>
<td>52.3</td>
<td>0.26</td>
</tr>
<tr>
<td>Applicability</td>
<td>25.8</td>
<td>29.6</td>
<td>0.36</td>
</tr>
<tr>
<td>Editorial Independence</td>
<td>47.3</td>
<td>40.9</td>
<td>0.32</td>
</tr>
</tbody>
</table>
## Mean domain scores SOR guidelines versus cancer guidelines

<table>
<thead>
<tr>
<th>Domain</th>
<th>SOR guidelines (n = 3)</th>
<th>Cancer guidelines (n = 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope and purpose</td>
<td>75.9</td>
<td>63.2</td>
</tr>
<tr>
<td>Stakeholder Involvement</td>
<td>41.7</td>
<td>34.3</td>
</tr>
<tr>
<td>Rigour of Development</td>
<td>70.8</td>
<td>42.2</td>
</tr>
<tr>
<td>Clarity and Presentation</td>
<td>73.8</td>
<td>57.2</td>
</tr>
<tr>
<td>Applicability</td>
<td>29.6</td>
<td>25.8</td>
</tr>
<tr>
<td>Editorial Independence</td>
<td>91.7</td>
<td>47.3</td>
</tr>
</tbody>
</table>

## OVERALL ASSESSMENT

- Ensure having adequate background documentation
- Do not aggregate the six domain scores into a single quality score!
- Take each appraisal criteria into account
- At least two appraisers required
- Use clinical judgment and 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
AGREE Continued

✓ Further EU funding received to disseminate AGREE Instrument in 22 European countries

✓ AGREE Instrument training manual (www.agreecollaboration.org)

✓ Electronic library with tools for guideline developers (www.sign.ac.uk)

✓ Guidelines International Network established in February 2003 (www.g-i-n.net)

✓ AGREE Oncology Network (in preparation)

Planned research projects

- Quality assessment of updated guidelines in oncology versus older versions (AGREE Oncology initiative)
- CPGs: what can be shared and what cannot be shared internationally? (AGREE Oncology initiative)
- Development of tool for local adaptation (France (SOR)-Quebec collaboration)
- Further validation and refinement of AGREE Instrument (McMaster University initiative)
- Standardisation of reporting of CPG’s (AHRQ initiative)