A New Clinical Appropriateness Tool for Practice Guidelines: Item Generation and Refinement.

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on behalf of the AGREE A3 Team
Research Team

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Sharon Garden, Administrative Support
Funding and Conflict of Interest

Funding received from the Canadian Institutes of Health Research

Activities of daily living:
Brouwers, Cluzeau and Burgers are trustees of the AGREE Research Trust a non-profit entity that promotes the AGREE enterprise and research in this area.

With the exception of Levinson, Gagliardi and Schünemann, all members of the team were co-investigators in the AGREE II project.

professional, publication, press, prestige, personal interests
Background

- AGREE II (Brouwers et al., CMAJ 2010)
  - new 7-point response scale
  - $\frac{1}{2}$ items modified, added, or deleted
  - completely restructured User’s Manual
  - construct validity established

- AGREE A3 Stream Two
  - address a gap
Background

- AGREE II: quality of the execution of the guideline process
  - what was done
  - how it was done
  - what was considered
  - who was involved
Methodological rigour is necessary but not sufficient for clinically appropriate recommendations

Out of scope for the AGREE II
Background

- Nuckels 2007
  - PG methodologically rigorous but recommendations not acceptable to providers
- Since the publications of AGREE II
  - two letters discussing issues clinical appropriateness/validity
Background

- Presentations at GIN 2010 (examples)
  - Compatibility of AGREE and clinical experts review in guideline appraisal (Kuo et al.)
  - How to develop new methods for systematic evaluation of internal validity of CPG recommendations (Eikermann et al.)
  - Experience with the application of a tool to structure the process from conclusions to recommendations in a transparent way (Kersten, et al.)
Project Objectives

- To develop a tool to facilitate the development, reporting and evaluation of “clinically appropriate” recommendations in practice guidelines
- Complement to the AGREE II
- Received CIHR funding in 2009 to tackle this issue (launch fall 2010)
Methods

Traditional methods of health measurement design:

- scoping of concept
- domain and item generation
- scaling
- beta version to test
- refine
- beta two version and retest
- release
Methods

- Scoping of concept
- Domain and item generation

- Mixed methods
  - scoping reviews and systematic reviews
  - key informant interviews and focus groups
Today: Brainstorming

- where we are at...preparing for our launch
  - concept articulation
  - existing definitions
  - draft domains based on scoping review
- for each domain
  - existing tools that can inform these domains, some preliminary concepts
  - feedback, brainstorm, and debate
- are there other domains
- full circle to the label and the definition
Today Brainstorming

DOMAINS
- is this a reasonable domain?
- are these reasonable elements?
- what other inspiration? what other elements?

RECONVENE
- how should we refer to this concept?
- should it be a tool (i.e. AGREE II) OR a tool kit OR a mix?
- on what should we focus our attention? how?
Concept

- just what is the concept we are after?
- **recommendations** (vs. guideline document)
  - appropriate
  - acceptable
  - valid
  - implementable
  - ethical
- ultimately a good label is required
Concept

- development, reporting and evaluation
- quality of reporting and/or quality of execution
Definitions

PG are considered valid if when followed, they lead to the health gains and costs predicted for them. Hence, when valid guidelines, when appropriately disseminated and implemented can lead to changes in clinical practice and improvements in patients outcomes

Grimshaw et al. ‘95
**Definitions**

**Acceptability** describes whether the recommendation should put into practice and **applicability** describes whether an organization or group is able to put the recommendation into practice. Assessing whether a recommendation is acceptable and/or applicable or not is done by discussing each recommendation in light of the cultural and organizational context.

ADAPTE Working Group (from tool 14)
Definitions

To be useful, recommendations should give practical, unambiguous advice about a specific health problem; to be clinically important, a PG should convince you that the benefits of following the recommendations are worth the expected harms and costs. You should consider both the relative and absolute changes in outcomes; the "strength", "grade", "confidence", or "force" of a recommendation should be informed by multiple considerations: the quality of the investigations that prove the evidence for the recommendations, the magnitude and consistency of positive outcomes relative to negative outcomes (adverse effects, burdens to the patient and the health care system, costs), and the relative value placed on different outcomes.

Wilson ‘95
Draft Domains

- Methodological Rigour
- Evidence
- Clinical relevance
- Acceptability
  - Clinician
  - Patient
- Context
- Implementable
Additional Considerations

- values (patient, provider, societal)
- ethics
- legal
- culture

- are they independent domains or built into domains
how was the evidence underpinning the recommendations put together how were the recommendations ultimately determined
inspiration: AGREE rigour domain

- Systematic methods were used to search for evidence.
- The criteria for selecting the evidence are appropriate.
- The methods for formulating the recommendations are appropriate.
- The strengths and limitations of the evidence are clearly described.
- Recommendations are actionable.
- Conflicts of interest managed appropriately.
quality and appropriateness of the evidence, link between evidence and recommendations, story line
inspiration: GRADE and appraisal tools, AGREE II
- fidelity between evidence and recommendations
  - action
  - strength or definitiveness of statement
- appropriateness of study design
- appropriateness of outcomes
- generalizability: to patients, Domain
  Evidence context
recommendations for action
 - is it worth it from a clinical perspective

recommendations for no action
 - is it too risky not to offer
 - precautionary principle
inspiration: GRADE and other systems, CAPGO

- magnitude of effects
- precision of estimate of effects
- clinical risks associated options
- comparative value
will the recommendations be acceptable to those affected

- patients
- providers
- society (?)
- policy/decision makers (?)
inspiration: CAPGO

- agreement with reccs as stated
- recommendations will be supported by the clinical community
- recommendations will be supported by patients for whom they are intended
- recommendations are too rigid to apply to individual patients.
- recommendations are too technically challenging

Acceptability
are the recommendations applicable to the context in which they will be implemented
inspiration: CAPGO

- the recommendations are too expensive to apply
- the recommendations will require reorganization of services/care
- the recommendations require additional human resources
inspired by work on Gagliardi, Eccles, Bhattacharyya, Graham, and others
Table 3. Final framework of guideline implementability

<table>
<thead>
<tr>
<th>Domain</th>
<th>Element</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Useability</td>
<td>Navigation</td>
<td>Table of contents</td>
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<td>Evidence format</td>
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