Guideline developers’ self-perception of adherence to and intentions to adhere to the IOM Standards for Trustworthy Guidelines

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Disclosure of Interests (last 3 years)

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I certify that, to the best of my knowledge, no aspect of my current personal or professional situation might reasonably be expected to affect significantly my views on the subject on which I am presenting, other than the following:

Employed by ECRI Institute as:

- Senior Medical Advisor to AHRQ’s National Guideline Clearinghouse and National Quality Measures Clearinghouse
- Senior Research Analyst for the AHRQ-funded ECRI Evidence-based Practice Center
Background

IOM Report 2011

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.
IOM’s 8 Standards for Trustworthy Clinical Practice Guidelines

1. Transparency
2. Conflict of Interest
3. Guideline development group
4. Systematic review
5. Evidence foundation for and rating strength of recommendation
6. Articulation of recommendation
7. External review
8. Updating

Systematic Review
Interests
Transparency
Articulation
Rating evidence and recommendations
GDG composition
Updating
External review
AHRQ-funded Pilot Study:

**Objectives**
(1) Assess developers’ self-perceptions of adherence to the IOM standards
(2) Assess developers’ intentions to adhere to the IOM standards

**Goals:**
To gain understanding of developers plans in order to plan NGC’s implementation of the new IOM definition and document adherence to the standards.
Methods - subset of standards:

1.1 CPG development and funding should be detailed explicitly and publicly accessible

4.1 Developers should use a Systematic Review

5 Evidence foundation for and rating strength of recommendations

For each recommendation, the following should be provided:
5.1 (a) An explanation of the reasoning underlying the recommendation, including:

- 5.1(a)i A clear description of benefits and harms
- 5.1(a)ii A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
- 5.1(b) A rating of the level of confidence in (certainty regarding) the evidence
- 5.1(c) A rating of the strength of the recommendation
Methods – Interview and survey:

- Interviews - Semi-structured telephone, conducted from 1/23/12 - 2/28/12
- Surveys: to query developers about impressions of and intentions to implement the IOM standards in their CPGs.
- Focus discussion on a guideline from developer
Methods: Guideline evaluation

• Self-evaluation of guideline against selected IOM standards
  - “On a scale from 1 to 5 (1 being not meeting standard at all, and 5 meeting standard completely), how would you rate this particular guideline with respect to meeting each of the following IOM standards?”
  - “On a scale from 1 to 5 (1 - will not meet standard at all, and 5- will meet standard completely), to what degree do you anticipate your organization will meet each of the following standards?”

• Internal evaluation of guidelines done by ECRI
Methods-Sample selection:

- Non-random sampling - purposive and convenience, based on:
  - Responsiveness to NGC communications.
  - Diversity among developers, size of organization, clinical specialty, and number of guidelines developed, rigor and transparency of guidelines.
  - Recent guideline summary posted in NGC within the last 2 years.

- Stratified 30 developers into three categories (high, medium, and low) on general rigor and transparency of guidelines, with roughly 10 developers in each strata.
Methods - Analysis

- Thematic analysis of interviews
- Survey results - descriptive
Results

- Participants:
  - 26 developers solicited; 22 responded
  - 14 interviewed (13 with guidelines)

Timeline of adaption of IOM standards

<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Number of Developers</th>
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<tr>
<td>Within a year</td>
<td>6 (42.9%)</td>
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<tr>
<td>Between 1-3 years</td>
<td>4 (28.6%)</td>
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<tr>
<td>“Ongoing”</td>
<td>2 (14.3%)</td>
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<tr>
<td>Could not give timeframe</td>
<td>2 (14.3%)</td>
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For their CPG, was SR used?
- 6 (42.9%) felt they used a SR
- 8 (57.1%) did not use a SR

Partnerships, consulting or off-shelf SR
- 5 (35.7%) used/considering AHRQ evidence reports (EPCs)
- 2 (14.3%) used/identified Cochrane SR
- 1 (7.1%) used outside group to do SR
Results: Systematic Review

Going forward will meet SR standard
- 8 (57.1%) YES
- 2 (14.3%) NO
- 4 (28.6%) partially

Going forward will provide NGC access to SR
- 11 (78.6%) YES
- 1 (7.1%) NO
- 2 (14.2%) no response
Results: Clear Description of Benefits and Harms

Benefits
• Vast majority felt they clearly described

Harms
• 10 (71.4%) felt they clearly described harms
• 4 (28.6%) felt they did NOT clearly describe harms
Results: Rating of Level of Confidence in the Evidence

Current rating of level of confidence in evidence:

3 (21.4%) NO
11 (78.6%) YES:
   2 (18.2%) GRADE/modified GRADE
   3 (27.3%) USPSTF/modified USPSTF
   3 (27.3%) AAP
   3 (27.3%) Other (unique systems)

Going forward, will use:

5 (35.7%) GRADE/modified GRADE
2 (14.3%) USPSTF/modified USPSTF
3 (21.4%) AAP
4 (28.4%) Other (1) or to be determined (3)
Results:
Rating of Strength of Recommendation

Current rating of strength of recommendations:

5 (35.7%) NO
9 (64.3%) YES: 2 GRADE/modified GRADE
2 USPSTF/modified USPSTF
2 AAP
3 Other

“Saying something is a ‘weak recommendation’ can be confusing and misleading” CPG developer comment
Results: Transparency

Extent to which the CPG meets IOM standard on Transparency (1=not at all; 5=completely)

- Rated 1
- Rated 2
- Rated 3
- Rated 4
- Rated 5

Explicit and public processes
- 11 (78.6%) manual/protocol
- 3 (21.4%) no document - “institutional memory”

Funding
- All stated that CPG development was not funded commercially
- 6/13 (46.2%) guidelines did not state the funding behind the guideline
Major Themes
Challenges for Developers

- Overall applauding of standards, but practicality in question, “aspirational in nature”
- Limited resources
- Time constraints
- Documentation
- Communication and translation of methodologic language for clinicians
- Evidence and outcomes
Limitations

- Small number of interviewees - limits representativeness, generalizability
- Limited depth
- Objective measures of standards
Next steps:

• **Public posting of revised NGC inclusion criteria, June 2013**
• NGC’s implementation of the revised inclusion criteria June 2014
• Possible incorporation of documenting adherence to the IOM standards into NGC
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Questions...

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  ▫ Lisa Haskell        lhaskell@ecri.org
  ▫ Vivian Coates      vcoates@ecri.org
The End
Extra slides
Rating of CPGs in pilot

ECRI’s Assessment of Adherence to the IOM Standards

| Developer: | | |
| Guideline: | | |

On a scale from 1 to 5 (1 being not meeting standard at all, and 5 meeting standard completely), how would you rate THIS PARTICULAR guideline with respect to meeting each of the following IOM standards:

1. The clinical practice guideline (CPG) is informed by a systematic review of evidence

   ECRI’s Rating: 1

   ECRI’s Rationale: While the guideline states that the Work Group meets monthly to discuss newly published studies, no information is provided as to how the studies are selected for consideration or the process for review. No systematic approach is described.

2. The CPG presents a clear description of the benefits and harms of care recommended

   ECRI’s Rating: 3

   ECRI’s Rationale: Benefits and harms are discussed in the context of outcomes of included studies. A separate section on adverse events associated with antiviral medications is presented. There is no comprehensive examination on the balance of benefits and harms
Results: Conflicts of Interest

Extent to which GDGs felt they would meet IOM standard on Management of COI: Disclosure
(1=not at all; 5= completely)

Extent to which GDG felt they would meet the IOM standard on Management of COI: Divestment (1=not at all; 5= completely)
Results: GDG Composition and External Review

Extent to which GDGs felt they would meet IOM standard on **Guideline Development Group Composition** (1-not at all; 5-completely)

- Rated 1
- Rated 2
- Rated 3
- Rated 4
- Rated 5

Extent to which GDGs felt they would meet IOM standard on **External Review** (1-not at all; 5-completely)

- Rated 1
- Rated 2
- Rated 3
- Rated 4
- Rated 5

Number of ratings

GIN Submission 163.00 - August 2013
Results:
Articulation of Recommendations and Updating

Extent to which GDG would meet IOM standard on **Articulation of Recommendations**
(1=not at all; 5= completely)

Extent to which GDG would meet IOM standard on **Updating**
(1=not at all; 5= completely)

GIN Submission 163.00 - August 2013