Clinical Practice Guidelines: International Consensus on Methodological Standards

Ina Kopp

Association of the Scientific Medical Societies in Germany
Institute for Medical Knowledge Management
Philipps-University Marburg

Guidelines International Network
Clinical Practice Guidelines: consensus on methodological principles

agreetrust.org

iom.edu

http://cebgrade.mcmaster.ca/guidecheck.html

G-I-N – McMaster Guideline Development Checklist
IOM standard 1.1:

The process by which a clinical practice guideline (CPG) is developed and funded should be detailed explicitly and publicly accessible.

A transparent development process makes clear how authors weighed evidence, pathophysiologic reasoning, expert experience, values of patients and the society and allows users to judge reasonableness of recommendations.

[Link to further information: www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx]
Principles of Guideline Development: 2. Stakeholder Involvement

The Guideline Development Group should be multidisciplinary and balanced including representatives of

**professional groups**
- medical speciality societies
- professional associations
- methodological experts

**target population and patients**
- those, who are addressed/affected by the recommendations

**NOT:** industry (however: may be consulted)

Example: http://www.awmf.org/leitlinien/detail/ll/032-045OL.html
Establish cooperation of clinicians and methodologists

Document strategy used to search and select evidence in a way it can be reproduced by others

Identify risks of bias—critically appraise the evidence

Document results: evidence tables / profiles


- formal, evidence based techniques to avoid bias (preferrably Nominal Group and Delphi)
- guided by an independent, experienced moderator
- ensuring effective group interaction
- avoiding bias, such as:
  - selection of participants
  - majority / minority influence
  - social loafing
  - groupthink
  - brainstorming
- documentation of processes and results
- allowing for scientifically justified dissent
Principles of Guideline Development: 5. Management of Conflicts of Interest

1. Guideline developers should make all possible efforts to not include members with direct financial or relevant indirect COIs.
2. The definition of COI and its management applies to all members of a Guideline Development Group…and this should be determined before a panel is constituted.
3. A GDG should use standardized forms for disclosure of interests.
4. A GDG should disclose interests publicly, including all direct financial and indirect COI.
5. All members of a GDG should declare and update any changes in interests at each meeting of the group and at regular intervals.
6. Chairs of GDGs should have no direct financial or relevant indirect COI. When COIs of a chair are avoidable, a co-chair with no COIs should be appointed.
7. Experts with relevant COI and specific knowledge or expertise may be permitted to participate in discussion of individual topics, but there should be an appropriate balance of opinion.
8. No member of the GDG deciding about the direction or strength of a recommendation should have a direct financial COI.
9. An oversight committee should be responsible for developing and implementing rules related to COI.

Reporting Standards for Guideline-based Performance Measures

1. Quality of the Guideline according to G-I-N Standards and AGREE II and of additional [evidence] sources, if used

2. Quality of evidence and/or the strength of recommendation qualifying the guideline recommendations to be used for PM development

3. Consensus methods used to select the PM from guideline recommendations

4. Consideration of core PM attributes:
   - Relevance (as a minimum: potential for improvement/clinical relevance)
   - Scientific Soundness (as a minimum: the evidence supporting the measure)
   - Feasibility (as a minimum: clarity of definition and measurability)

5. Unambiguous Specification of Numerator and Denominator

6. Intended use of the PM (e.g. quality improvement, quality assurance with or without accountability purposes as p4p, public reporting) and level in the health system (local, regional, national)

7. Practice test of PM prior to their broader implementation and routine use

8. Review and reevaluation: criteria for deciding to change or stop using PM

9. Composition of the panel deciding on PM
Clinical Practice Guidelines: Definitions

Systematically developed statements to assist physicians and, if necessary, other healthcare professionals and patients with decisions about appropriate health care in specific clinical circumstances.

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.
Standards: ISO Definitions

A normative document,
developed according to consensus procedures,
which has been approved by the ISO membership and P-
members of the responsible committee

in accordance with Part 1 of the ISO/IEC Directives as a draft
International Standard and/or as a final draft International
Standard and which has been published by the ISO Central
Secretariat.

…a document that provides requirements, specifications,
guidelines or characteristics

that can be used consistently to ensure that materials,
products, processes and services are fit for their purpose.

International Organization for Standardization:
http://www.iso.org/iso/home/standards.htm
## Definition and Methodological Principles: Differences between Standards and Guidelines

<table>
<thead>
<tr>
<th></th>
<th>Standards</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>trigger for development</strong></td>
<td>market requirement, need for standardisation</td>
<td>improvement potential, public health need, need for information about new technologies</td>
</tr>
<tr>
<td><strong>stakeholder involvement</strong></td>
<td>interested parties, including experts from the industrial, technical and business sectors “entrance fee”</td>
<td>healthcare professionals, patient representatives, methodologists industry not allowed, applicants with conflicts of interests restricted</td>
</tr>
<tr>
<td><strong>methodology of development</strong></td>
<td>informal consensus, informed by evidence, dissent not reported</td>
<td>systematic review of the evidence, structured consensus (formal techniques)</td>
</tr>
<tr>
<td><strong>key aspects covered</strong></td>
<td>technical specifications, systems, persons</td>
<td>clinical health care services, interventions</td>
</tr>
<tr>
<td><strong>goal for assessment of implementation</strong></td>
<td>conformity (normative requirements)</td>
<td>appropriateness (reference ranges)</td>
</tr>
<tr>
<td><strong>availability</strong></td>
<td>for a fee</td>
<td>for free</td>
</tr>
<tr>
<td><strong>responsiveness to new evidence</strong></td>
<td>relatively low</td>
<td>relatively high</td>
</tr>
</tbody>
</table>
Standards: need for a discussion about indications and contraindications

ISO 216 paper sizes


DIN EN ISO/IEC 17021:2011 certification bodies for management systems
DIN EN ISO 9001:2008 quality management
DIN EN ISO/IEC 17024:2012 certification bodies for persons

shared decisions

X

patients
Patient's right to appropriate health care on an individualised basis

**Physician**
- objective experience
- competence
- intuition, ethos
- consciousness of individual and societal perspective

**Patient**
- subjective experience
- expectations
- values, preferences
- coping, self-efficacy
- cultural aspects

**External Knowledge:**
- decision support
- Clinical Practice Guidelines
- Systematic Reviews
- Knowledge Banks

**Legal, ethical, social, economic framework of the system**
Outlook: Clinical Practice Guidelines at the Core of the PDCA Cycle

Quality Improvement
ensure guidelines are up-to-date and continuously implemented

Implementation
use tailored interventions (e.g. peer review, accreditation, motivation)

Quality Assessment
identify knowledge gaps, monitor guideline-based performance measures

Guideline Development
set priorities and develop goal-oriented, evidence-based, multidisciplinary guidelines

Force Field Analysis
identify forces driving and restraining the adoption of guidelines

Do

Act

Plan

Check
Outlook: Guidelines may be the way forward to improve quality at the European level.
Conclusions

- The development process of a guideline and accompanying performance measures must be outlined in detail in a method-report.

- The method report should be outlined at the beginning of a guideline project – agenda for all, who are involved.

- Clinical Practice Guidelines are the instruments to optimise health care delivery by assisting professionals and patients to make informed decisions, taking into account the needs of individuals.

- We need to differentiate between Standards and guideline-based performance measures.