Enhancing Medical Professionalism, Interdisciplinarity and Quality of Health Care through Clinical Practice Guideline development

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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.

Institute of Medicine 1990, 2011: http://www.iom.edu
Background to Guideline Development: Shared Interests with ERN Network Initiative

- concern about variation, quality, efficiency, and evidence for effectiveness of interventions in health care
- professional interest to define current optimal practice in an era of cost containment
- interest of purchasers (governments, insurers) and patients
- rapid expansion of medical knowledge (more than 1 Million new entries in Medline/PubMed per year)
- understanding of a need for decision aids (not standards) for health care professionals and patients in the individual encounter
Background to Guideline Development in the German Health Care System

• ownership and responsibility lie with the profession: guidelines are developed by scientific medical societies

• support, coordination and quality assurance are provided by a national umbrella organisation, AWMF (Association of the Scientific Medical Societies in Germany – currently representing 168 member societies)

• AWMF strives for networking with national quality initiatives to promote implementation and evaluation of guidelines

• AWMF is the primary contact to the Guidelines International Network (G-I-N)
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**
- Use tailored interventions (e.g. peer review, accreditation, motivation)

**Check**
- Identify knowledge gaps, monitor guideline-based performance measures

**Act**
- Ensure guidelines are up-to-date and continuously implemented

**Plan**
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IOM standard 1.1:
The process by which a clinical practice guideline (CPG) is developed and funded should be detailed explicitly and publicly accessible.
Open access to methodological support: The Guideline Development Checklist

http://cebgrade.mcmaster.ca/guidecheck.html
Stakeholder Involvement: Composition of the Guideline Development Group

The GDG 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

Example: German Breast Cancer Guideline. www.awmf.org
Rigor of Development: Systematic Review of the Evidence

- Document strategy used to search and select evidence in a way it can be reproduced by others
- Identify risks of bias-critically appraise evidence
- Document results: evidence tables / profiles

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### HEADINGS | DESCRIPTION
--- | ---
**Title** | Document strategy used to search and select evidence in a way it can be reproduced by others
**Sources of funding and competing interests** | The source of funding cited in the data, organization or corporation, etc.
**Method** | Identify the study design and critically appraise evidence
**Study results** | Summarize the primary outcome in each study and between studies, risk of bias in each study, and risks of other sources of bias
**Critical appraisal of the study quality** | Provide evidence of study quality

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### HEADINGS | DESCRIPTION
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**Study** | Number of studies included in the systematic review
**RESULTS** | Results
**DISCUSSION** | Discussion

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**GIRM profile 1: Colonoscopic surveillance compared with no surveillance for IBD**

<table>
<thead>
<tr>
<th>No. of studies</th>
<th>Design</th>
<th>Colonoscopic surveillance</th>
<th>No. colonoscopic surveillance</th>
<th>OR (95% CI) [around 100%]</th>
<th>Comments</th>
<th>Low</th>
<th><strong>Quality</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome 1: detected carcinoma at early stage</td>
<td>Enrolled stage C or D; AJCC stage II or I</td>
<td>10/19 (52.6°)</td>
<td>15/19 (78.9°)</td>
<td>0.66 (0.25 - 1.73)</td>
<td>N</td>
<td>N</td>
<td>Low</td>
</tr>
<tr>
<td>Outcome 2: detected carcinoma at advanced stage</td>
<td>Enrolled stage C or D; AJCC stage II or I</td>
<td>10/19 (52.6°)</td>
<td>15/19 (78.9°)</td>
<td>0.66 (0.25 - 1.73)</td>
<td>N</td>
<td>N</td>
<td>Low</td>
</tr>
</tbody>
</table>

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**http://www.g-i-n.net - GIN Evidence Tables Working Group: Template for summarising studies addressing Intervention questions**

NICE Clinical Guideline 118, March 2011: Evidence profile Colonoscopic surveillance for prevention of CRC in patients with ulcerative colitis, Crohn's disease or adenomas
Rigor of Development: from Evidence to Recommendations

Quality of evidence

- 1 – high
- 2 - moderate
- 3 - low
- 4 - very low

Strength of recommendation

- do / don’t do
  - „we recommend“
- probably do/don’t do
  - „we suggest“
- uncertain
  - „can be considered“
  - „we do not know“

Considered judgment

A criteria-guided group decision using formal consensus methods (e.g. Nominal Group Technique)

DM-CPG programme – method report (www.versorgungsleitlinien.de/english/methods)
European Council, Recommendation (2001) 13
GRADE 2004 (www.gradeworkinggroup.org)
Editorial Independence
Management of Conflicts of Interest

• **Source(s) of funding**
  - declare sources of funding
  - make sure funders have no role in CPG development
    and can not influence the content of the guideline

• **Competing interests of guideline development group**
  - declare all interests and activities potentially resulting in COI
    (commercial, academical and institutional)
  - document measures taken to minimize the influence of competing
    interests on guideline development or formulation of the
    recommendations
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**Plan**
- Do
  - Check
  - Act

**Act**
## Force Field Analysis

<table>
<thead>
<tr>
<th>Driving Forces</th>
<th>Restraining Forces (Barriers)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Learning Theory</strong></td>
<td></td>
</tr>
<tr>
<td>Knowledge transfer to target group improves motivation</td>
<td>Information is not evidence-based, not communicating absolute numbers (NNT, NNH), not useful in the individual encounter</td>
</tr>
<tr>
<td><strong>2. Behavioral Theory</strong></td>
<td></td>
</tr>
<tr>
<td>External audit / objective review based on performance measures Incentives</td>
<td>Benefit for individual professionals unclear, no reimbursement for documentation of performance measures</td>
</tr>
<tr>
<td><strong>3. Social Theory</strong></td>
<td></td>
</tr>
<tr>
<td>Communication, Quality Circles Opinion Leaders</td>
<td>Lack of communication between professionals – especially transsectoral (primary/specialised care; ambulatory/in-hospital care)</td>
</tr>
</tbody>
</table>
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Implementation: evidence-based strategies (e.g. audit and feedback, professional peer review)
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Criteria for the extraction of guideline recommendations

- impact on patient outcome
- level of evidence, grade of recommendation
- potential for improvement
- measurability
- relevance
- ….
Implementation and Monitoring / Evaluation: Networking with existing quality initiatives

• National Network of Certified Centers /Reference Centers support implementation, transfer of guidelines into practice

• National Network of Registers assess and report processes and outcomes, provide feedback

• External quality assurance (Germany: implemented in the Social Code book, carried out by a central institution) assess and report processes and provide feedback

• Outlook: Networking with international initiatives?

OECD Health Indicator Project
Enhancing Medical Professionalism and Interdisciplinarity: is the German bottom-up approach successful?

Enhancing Professionalism-improvement in systematic development: Quality Improvement of Guidelines in the AWMF-Register over time

- S1 - expert recommendations
- S2 - guidelines based on a systematic review of the evidence or on structured consensus of a multidisciplinary group
- S3 – evidence and consensus
Enhancing Quality: Documentation of Guideline-based Performance Measures

Patients receiving TME

Documentation according to Mercury (n= 173)

Performance Measure: Total Mesorectal Excision in Patients with Rectal Cancer (LoE 2a)
Source: M. F. Hofstädter, M. Klinkhammer-Schalke 2008
Data base: German Cancer Registries
Moving forward towards networking with guidelines: conceptual suggestion

- National development of evidence profiles and guidelines
- European guidelines: distillation of key recommendations
- Networking: EU-network of Scientific Medical Societies? EU-Network of Reference Centers and Registries?
Conclusions: how to move forward with networking to improve healthcare

- "For the future, systematic clinical practice guidelines of the highest quality is the way to go, to assure implementation of the right research results in clinical practice – so that EbM is used in each and every patient treatment, everywhere"

(Implementation of Medical Research in Clinical Practice, www.esf.org)

- concept:
  national guidelines / evidence profiles as basis for european consensus on key points

- outlook:
  EU- Network of Scientific Medical Societies?
  EU- Network of Reference Centres, Registries?