RARE-Bestpractices Conference
24 November 2016, Istituto Superiore di Sanità, Rome, Italy
Stronger Together

guidelines on rare diseases
as a basis for a joint European quality initiative

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Clinical Practice Guidelines and the PDCA Cycle of Quality Improvement

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

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

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

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

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

Do

Check

Act

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http://cebgrade.mcmaster.ca/guidecheck.html
Principles of Guideline Development: Stakeholder Involvement

The Guideline Development Group should be multidisciplinary and balanced including representatives of professional groups - scientific medical societies - professional associations - methodological experts

target population / patients → those, who are addressed/affected by the recommendations

NOT: industry (however: may be consulted)

Example: http://www.awmf.org/leitlinien/detail/ll/026-022.html
Stakeholder Involvement in RD Guidelines: additional considerations

- study groups generating evidence and can close gaps
- groups synthesizing evidence to adress the right questions
- Reference Centres/Reference Networks as implementers
- Registries documenting course of the disease, interventions and outcomes
- Developers of Performance Measures for certification processes

German Guideline Hodgkin’s Lymphoma:
Cochrane Haematological Malignancies Group
German Hodgkin Study Group (GHSG)
Competence Network Malignant Lymphoma

- Players in the field!
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## Preparing for Implementation: 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</td>
<td>Benefit for individual professionals unclear, no reimbursement for documentation of performance measures</td>
</tr>
<tr>
<td>Incentives</td>
<td></td>
</tr>
<tr>
<td><strong>3. Social Theory</strong></td>
<td></td>
</tr>
<tr>
<td>Communication, Quality Circles</td>
<td>Lack of communication between professionals – especially transsectoral (primary/specialised care; ambulatory/in-hospital care)</td>
</tr>
<tr>
<td>Opinion Leaders</td>
<td></td>
</tr>
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</table>
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Addressing Clinicians, Patients/Caregivers: Tailored Information

Examples:
http://www.patienten-information.de/kurzinformationen
http://www.awmf.org/leitlinien/detail/ll/026-022.html
Implementation: evidence-based strategies (e.g. audit and feedback, professional peer review)
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Enhancing Quality: Documentation of Guideline-based Performance Measures

Example: http://www.awmf.org/leitlinien/detail/ll/025-012.html

<table>
<thead>
<tr>
<th>Qualitätsindikator</th>
<th>Referenz Empfehlung</th>
<th>Evidenzgrundlage/weitere Informationen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QI 1: Diagnostik und Stadieneinteilung: Die histologische Diagnostik</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Z: Anzahl Patienten mit Biopsie mittels Feinnadel-aspiration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N: Alle Patienten mit histologischer Erstdiagnose eines Hodgkin Lymphoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.2a Die histologische Diagnose soll an der Biopsie eines ganzen Lymphknotens oder eines anderen primär befallenen Organs gestellt werden.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expertenkonsens</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QI 3: Diagnostik und Stadieneinteilung: Stadieneinteilung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z: Anzahl der Studienteilnehmer (RCT, CCT)</td>
</tr>
<tr>
<td>N: Alle Patienten mit der Erstdiagnose Hodgkin Lymphom</td>
</tr>
<tr>
<td>9.4a Um eine Qualitätskontrolle der initialen Stadieneinteilung durch ein Referenzpanel zu gewährleisten, sollen Patienten in klinische Studien eingeschlossen werden.</td>
</tr>
<tr>
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</tr>
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</table>
Cave: Guidelines are decision aids - we need to be clear where and where not Standards are useful.

ISO 216 paper sizes

DIN EN ISO 15189:2014 medical laboratories

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

patients
Rationale: 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
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Outlook: Guidelines may be the way forward to improve quality at the European level.
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?**
Moving forward towards networking with guidelines: conceptual suggestion

- national development of evidence profiles and guidelines
- European guidelines: distillation of key recommendations
- monitoring of implementation and outcomes: EU-Reference Centers and Registries
Conclusion

“To help people with rare diseases, we need more than technological advances – we need global cooperation.”

Paul Lasko,
Scientific Director, Institute of Genetics, Canadian Institute of Health Research and former chair of the International Rare Diseases Research Consortium