Guideline Adaptation: Methods and experiences of the National Disease Management Guidelines Programme (NDMG Programme)

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AGENDA

- Background NDMG Programme
- Methodology of guideline adaptation
- Experiences (e.g. costs, duration of the development process), barriers/ solutions
- Lessons learned
Background – German National Disease Management Guidelines Programme

- NDMGs are evidenced-based recommendations for highly prevalent chronic diseases with a special focus on coordination of care

Methodology of adaptation has always been the basis of the NDMG development, i.e. they are primarily adapted guidelines which use other high quality guidelines as the main source of evidence

- 2002 - Set up by the German Medical Association

- Since September 2003 a joint project of: German Medical Association, National Association of Statutory Health Insurance Physicians, Association of Scientific Medical Societies

- Organised by us: German Agency for Quality in Medicine, Berlin
Methodology – stepwise approach I

1. Selection of guideline topics
2. Composition of guideline development group and formulate key questions
3. Systematic search for guidelines
4. Appraise potential source guidelines in accordance to German Instrument for Methodological Guideline Appraisal (DELBI) (s. Algorithm)
5. Synopsis of the guidelines focusing on the key questions
6. For those guidelines which are not adequately addressed in the source guidelines, we do an additional systematic search for other sources of aggregated evidence (e.g. systematic reviews, meta-analyses and HTA reports) and primary studies
7. Critical appraisal of the additional evidence
Criteria for selection of guidelines

Selection of guidelines

Guidelines pool

Relevance?

yes -> Adequate methodological quality? (DELBI domain 3)

no -> Exclusion

Adequate methodological quality? (DELBI domain 3)

yes -> Transferability?

no -> Exclusion

yes -> Validity?

no -> Exclusion

yes -> Detailed justification of source guideline

no -> Exclusion

Override criteria? - unique position* - transferability* - publisher*

yes -> Exclusion

no -> Validity?

ja -> Detailed justification of source guideline

nein -> Exclusion

Transferability?

no -> Exclusion

yes -> Validity?

no -> Exclusion

yes -> Source guideline

In the case of inadequate methodology, guidelines may be used in full or in part if:
- different methodological production of the guidelines is probably not possible
- the guidelines are not interest-led
- the guidelines were issued in Germany by recognised institutions and they are of importance in the public discussion
- no international guidelines are available.
Methodology – stepwise approach I

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Methodology – stepwise approach II

- Critical appraisal of the additional evidence
- Development of the background text as evidence summaries
- Formulation and grading of recommendations using formal consensus methods
- Consultation and peer review (3 months)
Example: NDMG for Heart Failure

National and international guidelines were used as sources of evidence:

• 2 German guidelines (German Cardiac Society, German College of General Practitioners and Family Physicians)
• 2 International Guidelines (Scottish Intercollegiate Guidelines Network, Canadian Cardiovascular Society)

• Other guidelines were considered for specific questions

Additionally, we performed systematic literature searches for the topics:

• Rehabilitation
• Complementary therapies
• Disease management approaches (e.g. telemedicine)
## NDMG for Diabetic Neuropathy in Adults

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of development</td>
<td>244 weeks</td>
</tr>
<tr>
<td>Experts</td>
<td>19</td>
</tr>
<tr>
<td>Meeting days</td>
<td>15</td>
</tr>
<tr>
<td>Telephone conferences</td>
<td>5</td>
</tr>
<tr>
<td>Material and staff costs</td>
<td>approx. 195.365 € = 241.461 US $</td>
</tr>
</tbody>
</table>

### NDMG for Heart Failure

<table>
<thead>
<tr>
<th>Duration of development</th>
<th>157 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experts</td>
<td>15</td>
</tr>
<tr>
<td>Meeting days</td>
<td>11</td>
</tr>
<tr>
<td>Telephone conferences</td>
<td>10</td>
</tr>
<tr>
<td>Material and staff costs</td>
<td>approx. $138,535 € = $171,248 US $</td>
</tr>
</tbody>
</table>

13 National Disease Management Guidelines

= development period
\( \bar{\sigma} = \text{ca. } 3.5 \text{ years} \)

* = CHD pharmaco-therapy chapter

Hypertension
DM Therapy
DM Neurupathy
Low Back Pain
DM Nephropathy
Heart Failure
DM Education
Depression
DM Foot syndrome
DM Retinopathy
COPD
Coronary Heart Disease
CHD 1st update*
Asthma
Asthma 1st update

In 2008, a new Domain was added as an appendix to the existing German Instrument for Methodological Guideline Appraisal (DELBI) to describe distinct methodological quality criteria for the development of adapted guideline recommendations.

- Developed by a German multidisciplinary group of experts
- Based on sources of information as national and international manuals for guideline adaptation such as ADAPTE and other manuals
- Additionally, experts and various stakeholders in the field of German guideline development were surveyed
- The first draft version was validated in a piloting process
DELBI Domain 8 for Quality Assessment of Adapted Guidelines

- Item 1: Systematic methods were used to search for pre-existing guidelines.

- Item 2: The criteria for selecting appropriate guidelines (the so-called “source guidelines”) are clearly described.

- Item 3: The selected “source guidelines” were assessed for methodological quality.

- Item 4: The evidence base of “source guidelines” was complemented by update searches of primary evidence.

- Item 5: Modifications and deviations from “source guideline” recommendations are clearly marked and reasons for modifications are given.
Barriers / potential solution I

- Limited acceptance on the side of the experts for the guideline adaptation methodology

- Limited confidence in external guidelines or too much confidence in guidelines with lower quality

Potential solution:
More training on the issue of guideline adaptation methodology for the experts required
Barriers II

Transferability and applicability of the identified source guidelines not in all specific aspects

→ Effect: Performance of additional literature searches
Barriers / potential solution III

- Heterogeneity of the grading schemes of several source guidelines

Solutions which we tried out were:

- To adopt level of evidence unchanged and to explain the grading schemes

- Development of a reconciliation table for uniform presentation in the NDMG
Example for reconciliation table used in NDMG for Low Back pain

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Meaning</th>
<th>NDMG (CEBM)</th>
<th>EU-LL</th>
<th>DEGAM</th>
<th>AkdÄ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strong evidence</strong></td>
<td>1</td>
<td>1</td>
<td>A</td>
<td>I</td>
<td>↑↑/↓↓</td>
</tr>
<tr>
<td><strong>Moderate evidence</strong></td>
<td>2</td>
<td>2</td>
<td>B</td>
<td>II</td>
<td>↑</td>
</tr>
<tr>
<td><strong>Low evidence</strong></td>
<td>3</td>
<td>3</td>
<td>C</td>
<td>III</td>
<td>⇔</td>
</tr>
<tr>
<td><strong>Very low evidence</strong></td>
<td>4/5</td>
<td>4/5</td>
<td>D</td>
<td>IV</td>
<td></td>
</tr>
</tbody>
</table>

Method report on NDMG Low Back Pain, June 2011
Lessons learned

- Identification of suitable guidelines for adaptation is a very critical issue to meet demands of methodological quality and appropriateness
- More training on the issue of guideline adaptation methodology for the experts is required
- Due to the heterogeneity of the grading schemes of source guidelines, a reconciliation table developed for uniform presentation in the NDMG is very useful
Method report for NDMG guideline development in Englisch available at:

www. azq.de
Disclosure of conflicts of interest (last 3 years)

Carmen Khan

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:

employment at Agency for Quality in Medicine (AQuMed)
Thank you for your attention!

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