Guideline Development (CBO)

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Guideline development programme
- Start guideline development (1982 bloodtransfusion)
- Consensus-based to Evidence-based
- Multidisciplinary guideline development teams

Guideline development process
- Selection of guideline topics
- Installation of the guideline development group
- Design phase
- Comment phase
- Dissemination phase
- Evaluation phase

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Selection of guideline topics

- Major sources of morbidity and mortality
- Burden of disease
- High health care costs
- "Gap" between research and practice
- New development in medical research
- Dilemma's in treatment or diagnosis

Guideline development process

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- Evaluation phase

Installation of the guideline development group

- The guideline group chairman
  - Authority in the field
  - Conflict solving capacities
  - Excellent independent team-leader

- The guideline group
  - Representatives of all key disciplines
  - Patient participation should be considered
  - Open minded
Installation of the guideline development group

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Guideline development process

1. Selection of guideline topics
2. Installation of the guideline development group
3. Design phase
4. Comment phase
5. Dissemination phase
6. Evaluation phase
7. Implementation phase
Problem analysis and identification of the key questions

- Problem analysis by expert panel or survey
  - Focus on major issues in daily practice
  - No cookbook!

- Identification of the key questions

Design phase

- Problem analysis
  - Identification of key questions

- Literature search
- Literature selection
- Quality assessment literature

- Formulation of summary statements of the evidence, further considerations and recommendations
- Critical appraisal
- Levels of evidence

Discussion

Draft version of the guideline
Literature search

- Identify all existing evidence (Medline, Embase, Cochrane databases, Psychinfo etc)
- Define inclusion and exclusion criteria
- Select the evidence

Design phase

1. Problem analysis
   - Identification of key questions
2. Literature search
3. Literature selection
4. Quality assessment literature
5. Formulation of summary statements of the evidence, further considerations and recommendations
6. Discussion

Grading the evidence

A1 Meta-analysis of randomised trials of A2-level, with consistency between the independent studies
A2 Double-blind randomised controlled clinical trial of good quality
B Other comparative studies (cohort, case-control-studies)
C Non-comparative study
D Expert opinion

Critical appraisal

- Quality assessment of the study design
- Applicability in the Dutch Health Care System
### Evidence table

<table>
<thead>
<tr>
<th>Study</th>
<th>Study design</th>
<th>Duration</th>
<th>Population (includes, delays, patients, ages, predispensions, exclusions)</th>
<th>Region/group (sexual predispensions)</th>
<th>Data collection (sexual predispensions)</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RCT, crossover design</td>
<td>3 weeks</td>
<td>H.s. with OA, chronic H.A. and L.P. (40–60 yrs, 1:1 ratio)</td>
<td>Placebo</td>
<td>80%</td>
<td>Placebo</td>
<td>Significant evidence for differences</td>
</tr>
<tr>
<td></td>
<td>RCT, crossover design</td>
<td>6 weeks</td>
<td>H.s. with OA, chronic H.A. and L.P. (40–60 yrs, 1:1 ratio)</td>
<td>Placebo</td>
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### Summary statement of the best evidence (format)

1. Meloxicam is as effective as piroxicam in treating patients with osteoarthritis.

### Design phase

- **Problem analysis**
  - Identification of key questions
  - Literature search
  - Literature selection
  - Quality assessment literature
  - Critical appraisal
  - Formulation of summary statements of the evidence, further considerations and recommendations
  - Discussion
  - Draft version of the guideline

### Strength of summary statement of best evidence

1. At least 1 study of A1 or 2 studies of level A2
2. At least 2 independent studies of level B
3. Other studies than mentioned in level A or B
4. Opinion of the expert panel
**Recommendations based on:**

- The best available scientific evidence
- Further considerations
  - Organisational aspects
  - Compliance
  - Patient perspectives
  - Costs
  - Etc.

**Therapeutic interventions in headache patients**

**Scientific justification**

A meta-analysis of 22 randomised controlled trials showed a reduction in headache episodes in male headache patients using drug A. The headache episodes in the treatment group were less severe and the duration of the episodes was shorter than in the control group. Two randomised controlled trials compared the effectiveness of drug A and drug B with a placebo. Both drugs reduced severity and duration of the headache episodes. No difference in effect was found between both drugs.

**Conclusion**

<table>
<thead>
<tr>
<th>Level 1</th>
<th>Drug A and drug B are both effective in reducing severity and duration of headache episodes in male patients.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>Thijssen et al</td>
</tr>
<tr>
<td>A2</td>
<td>Van den et al, Swartz et al</td>
</tr>
</tbody>
</table>

**Other considerations**

Drug A has to be taken 3 times a day, drug B one time a day. For both drugs nausea is mentioned as adverse effect. This should be discussed with the patient.

A cost-effectiveness analysis showed that drug B is more cost-effective than drug A.

All mentioned medical literature was based on male patients. However, the guideline development group thinks that the results can be extrapolated to female patients.

**Recommendation**

As therapy for male and female headache patients drug B is recommended. Although the side effects should be taken into account and clearly discussed with the patient.

**Literature**

A1 Thijssen et al
A2 Van den et al, Swartz et al

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**Format**

**Antacida en mucosaprotectiva**

Een onderzoek is verricht met algepraat/magnesiumentraat. Deze medicatie had een onverwacht aanzienlijk effect. Algepraat en sucralfaat worden gebruikt bij de behandeling van maagulceren. In een preventieve dosering van 2 gram per dag minder effectief dan misoprostol.

**Conclusie**

Er zijn geen aanwijzingen dat algepraat en sucralfaat werkzaam zijn bij de preventie van maagulceratie door NSAID's.

**Aanbeveling**

Mucoaprotective en antacida dienen niet te worden voorgeschreven ter preventie van maagulceratie door NSAID's.
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Comment Phase

- Feedback of the medical scientific associations
- Draft guideline presented and discussed at national open meeting

Authorisation phase

- Scientific societies formally approve the guideline
- Guideline is to be used by all physicians involved with patient care of the topic of the approved guideline

Guideline development process
Dissemination phase

- Distribution of final guideline
- Publication in Nederlands Tijdschrift voor Geneeskunde (Dutch Journal of Medicine) and other journals
- www.cbo.nl
- Implementation tools

Flowchart Guideline development

Work in progress (1)

- Grading system
- Audit
- Pilots during the development process
- Combination with Breakthrough
- Implementation tools

Work in progress (2)

- More ICT applications
- Patient involvement in the guideline development process
- Gaps in evidence reported to research funding organisations
- Efficiency of guideline development process
- Living guideline
Living guidelines

- Maintenance on a more continuous basis
  - Now: 2 yr of development, revision after 5 yr -> recommendations in guidelines can be outdated or ineffective in practice
  - Future: 2 times a year judgement of actuality of guideline
- For example maintenance based on:
  - New evidence or practice data
  - Feedback from users
  - Medical audit data
  - Expansion or limiting the scope of the guideline

Pilot with two guidelines
- Aids
- Breast cancer (mamma carcinoma)

Testing:
- How frequently is updating necessary?
- How can be judged if updating is necessary?
- How can you organise this in a structured way?
- How to design the authorisation procedure?
- Which IT-support is necessary?