Evidence-based guideline development

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Dutch Institute for Healthcare Improvement CBO

- Founded in 1979 by the Order of medical specialists & Association of hospitals
- Mission: Continious improvement of patient care
- target groups: medical specialists, nurses, allied health professionals
- 100 employees
- 3 Programmes
  - Guideline development and auditing
  - Breakthrough (implementation)
  - Reachout Improvement projects

Definitions

- Guideline (decision-aid)

  'Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances'. (Field and Lohr, IOM 1990)

- Protocol (directive)

  'Local tools that set out specifically what should happen, when and by whom in the care process. They can be seen as the local definition of a particular care process derived from a more discretionary guideline. They are in essence tools that assist in quality improvement and reducing inequalities'.

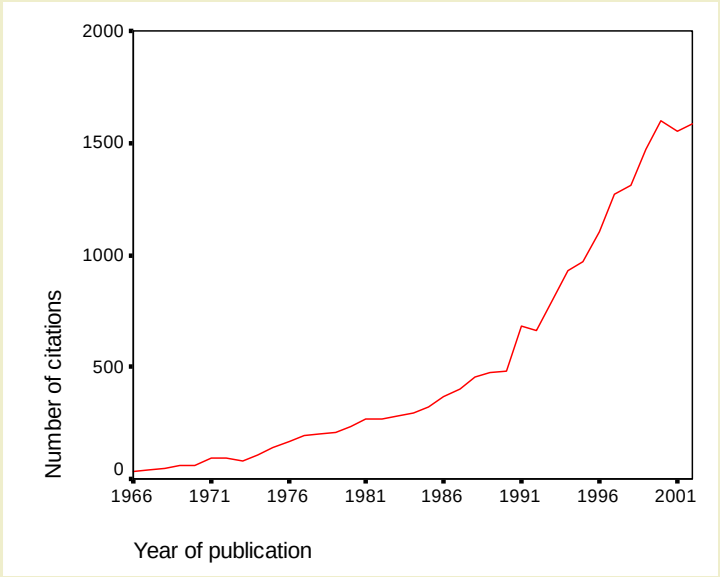
  Protocols reflect local circumstances, and variation will occurdue to the differing types of local provision.

Why do we make guidelines?

- Overload of information
- Reduce interdoctor (regional) variation
- Clinical practice based on evidence and experience (transparancy)

The ultimate goal: Improve quality of patient health care!

Citations of ‘guideline(s)’ in PubMed



Aims of guidelines

- To summarise and synthesise knowledge and innovations in medicine
- To reduce variation in practice
- To promote evidence-based clinical practice
- To improve quality of care
- To satisfy the need for transparancy and accountability

History

- National Institute of Health (US) – consensus development program (1977)
- Canadian Task Force on the Periodic Health Examination (now CTFPHC) – grades of evidence (1979)
- CBO start consensus guideline development (1st guideline published in 1982 ‘Bloodtransfusion’)
- Agency for Health Care Policy and Research (AHCPR, now AHRQ) – evidence-based guideline programme (1989-1996)
- National evidence-based guideline programmes in most Western countries (1990s)

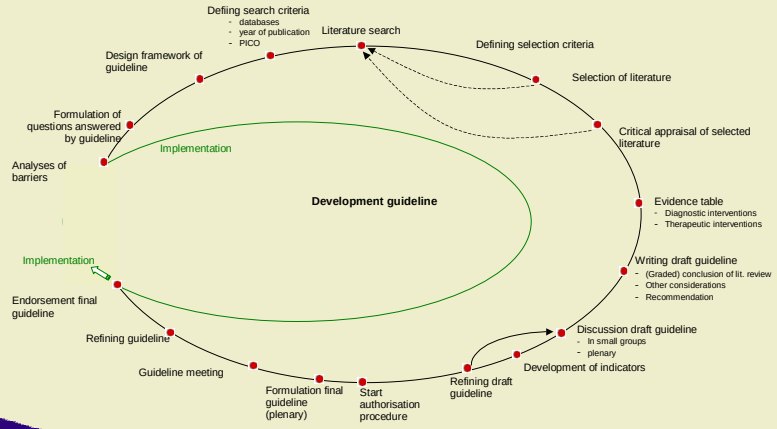
Trends

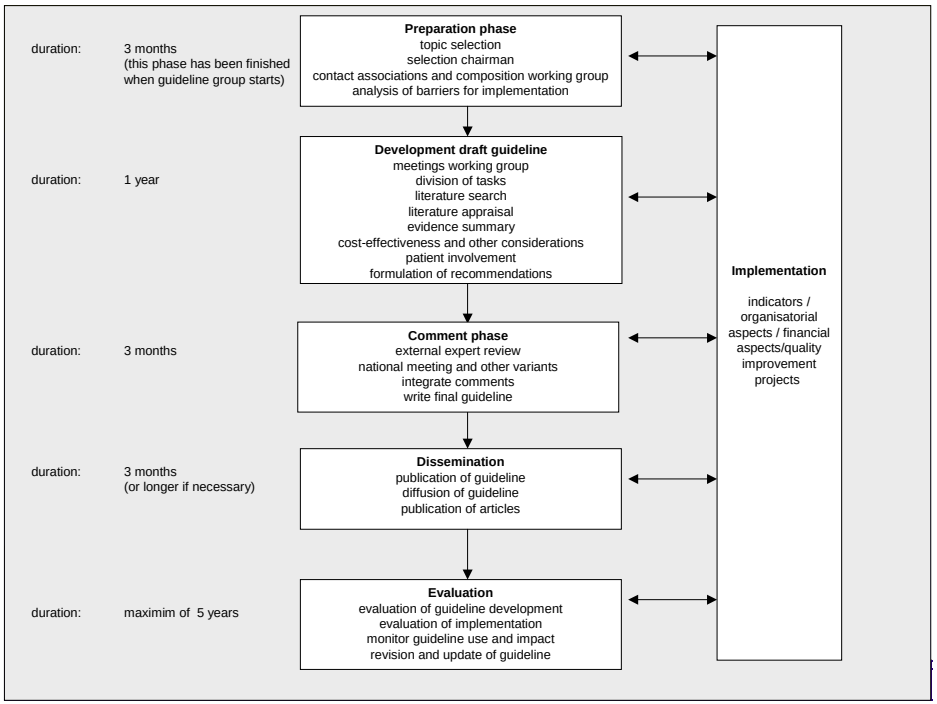
From	To
regional guidelines from professional groups	national guideline programmes
informal consensus	evidence-based
monodisciplinary	multidisciplinary
focus on development	focus on implementation
limited life-expectancy	‘living guidelines’
paper versions	Internet
guidelines for clinicians	patient versions and patient involvement

Steps in guideline development

1. Preparation
2. Design
3. Review
4. Endorsement
5. Dissemination
6. Implementation
7. Evaluation

Guideline development cycle





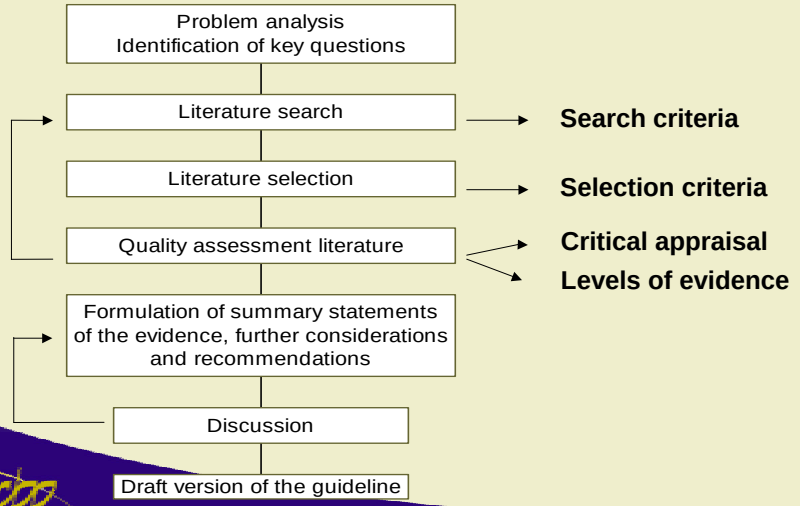
1. Preparation

- Topic selection
- Problem analysis in practice
- Identification of key clinical questions
- Composition working group
- Contact relevant societies/ organisations and potential working group members (incl. chair)

2. Design draft guideline

- Meetings working group
- Division of tasks and responsibilities
- Clinical knowledge and experience
- Literature study
- Cost-effectiveness analysis (not obligatory)
- Patient involvement/perspectives
- Drafting concept guideline

Design



Grading the evidence

Prevention and Treatment

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

Evidence table

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

Summary statement of the best evidence (format)

1	Meloxicam is as effective as piroxicam in treating patients with osteoarthritis. A_2 Linden 2002, Marshall 2002, Hovell 2001

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.[1] 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[2,3]. No difference in effect was found between both drugs.

Conclusion

Level 1	Drug A and drug B are both effective in reducing severity and duration of headache episodes in male patients. *A1* *Thijssen et al*[1] *A2* *Vianden et al*[2], *Swartz et al*[3]

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.[4]
All mentioned medical literature was based on male patients. However de 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

3/4. Review and endorsement

- External peer review
- National open meeting (not obligatory)
- Contact all relevant stakeholders
- Pilot testing among target users
- Formulation final guideline
- Endorsement/authorization

5. Dissemination

- Diffusion of guideline to:
- - target group
- - all relevant organisations
- Publication in (peer-reviewed) journal
- Website

6. Implementation=Catherine's talk

- Computer support!

7. Evaluation

- Quality of guideline and guideline program (using AGREE criteria)
- Monitoring use of guidelines
- Measuring effect on patient care (using indicators)
- Update procedure

Recent developments

- Integrating guideline use in patient consultation (“shared decision making”)
- Guidelines in your pocket (palmtop)

- Continuous updating (“living guidelines”)
- International collaboration (www.g-i-n.net)

Living guidelines

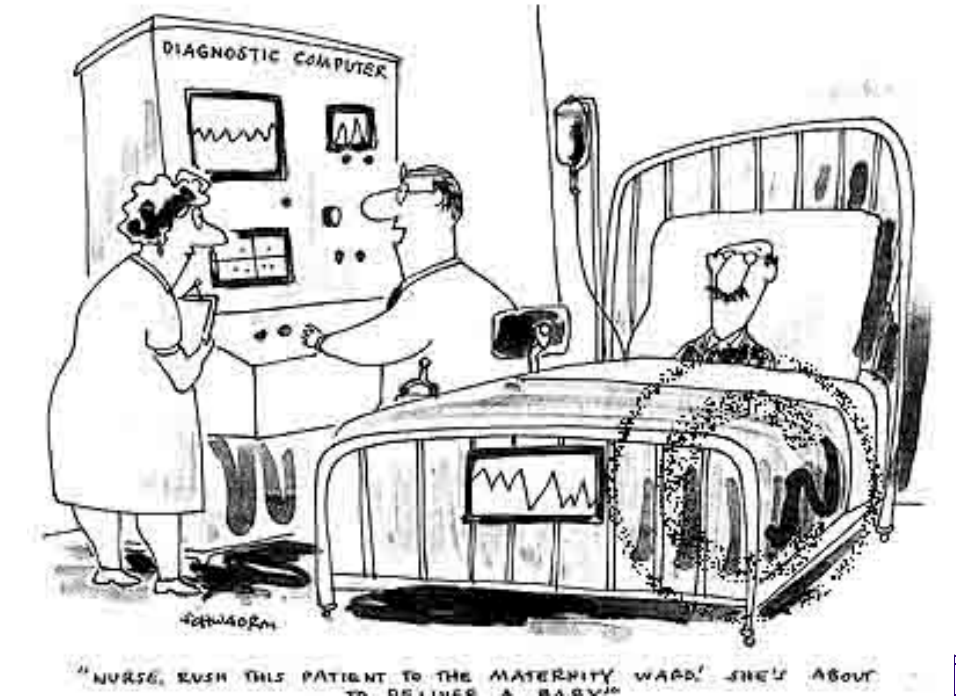
- Maintenance on a more continuous basis
  - Now: 2 yr of development, revision after 5 yr -> recommendations in guidelines can be outdated or ineffective in practice
  - Future: 2 times a year judgement of actuality of guideline
  - For example maintenance based on:
    - New evidence or practice data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

Living guidelines

- 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?

Tools

- Easy access to guidelines: clearinghouse
- Integrating the guidelines in the care processes: integrating in decision support systems, EPR
- Important issue is to have easy computer interpretable representation of guidelines
- Facilitating use of the guidelines with IT-tools



Lots of work to do!!

APPRAISING CLINICAL PRACTICE GUIDELINES

AGREE

http://www.agreecollaboration.org

WHAT IS A 'GOOD' GUIDELINE?

A 'good' guideline is one that leads to improved outcomes for patients

Needs to be based on evidence

Needs to be used (implementation)

Needs to be assessed

WHY APPRAISE GUIDELINES?

- ✓ A guideline is a form of intervention
- ✓ It can potentially affect a lot of patients
- ✓ Guideline users need to have confidence in recommendations
- ✓ Professional and governmental agencies have to ensure guidelines are 'good' before recommending them

PURPOSE OF THE AGREE INSTRUMENT

- ✓ To provide a systematic framework for appraising the quality of clinical guidelines
- ✓ To help *guideline developers* follow a structured and rigorous methodology
- ✓ To help *policymakers* decide which guideline to recommend for use in practice
- ✓ To help *health care providers* assess guidelines before adopting recommendations in practice

DEFINITION

'Quality of clinical guidelines' is the confidence that:

- ✓ the potential biases of guideline development have been addressed adequately
- ✓ the recommendations are both internally and externally valid, and are feasible for practice

STRUCTURE

23 items
4-point Likert Scale

Overall assessment

User guide

Six domains

1. Scope & purpose (3)
2. Stakeholder involvement (4)
3. Rigour of development (7)
4. Clarity & presentation (4)
5. Applicability (3)
6. Editorial independence (2)

DOMAIN 3.
RIGOUR OF DEVELOPMENT (1)

8. Systematic methods were used to search for evidence.
9. The criteria for selecting the evidence are clearly described.
10. The methods used for formulating the recommendations are clearly described.
11. The health benefits, side effects and risks have been considered in formulating the recommendations.

DOMAIN 3.
RIGOUR OF DEVELOPMENT (2)

12. There is an explicit link between the recommendations and the supporting evidence.
13. The guideline has been externally reviewed by an expert panel prior to publication.
14. A procedure for updating the guideline is provided.

RESPONSE SCALE

Strongly Agree	4	3	2	1	Strongly Disagree

EXAMPLE DOMAIN SCORE (1)

	Item 1	Item 2	Item 3	Totaal
Appraiser 1	2	3	3	8
Appraiser 2	3	3	4	10
Appraiser 3	2	4	3	9
Appraiser 4	2	3	4	9
Total	**9**	**13**	**14**	**36**

Max. possible score = 4 (strongly agree) x 3 (items) x 4 (appraisers) = 48

Min. possible score = 1 (strongly disagree) x 3 (items) x 4 (appraisers) = 12

EXAMPLE DOMAIN SCORE (2)

The ***standardised domain score*** will be:

$$\frac{\text{obtained score - min. possible score}}{\text{max. possible score - min. possible score}} =$$

$$\frac{36-12}{48-12} = \frac{24}{36} = 0.67 \times 100 = 67\%$$

CONCLUSIONS

- ✓ AGREE is the first appraisal instrument for clinical guidelines to be developed and tested internationally
- ✓ It can be used consistently by a wide range of professionals from different cultural backgrounds
- ✓ Need several appraisers to assess one guideline
- ✓ Domain scores should not be aggregated