Clinical Practice Guidelines
Aims, Design and Implementation

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Joint Institution of the German Medical Association (GMA) and
the National Ass. of Statutory Health Insurance Physicians (NASHIP)
Clinical Practice Guidelines 2002

Satellite Symposium

www.cpg2002.de

Berlin, June 7-8, 2002
Content

- About AQuMed
- Rationales of Clinical Practice Guidelines
- Guideline Standards in Europe – Council of Europe CPG Recommendation 2001
- Guideline Implementation
Activities and Structure of AQuMed

AQuMed Steering Group
(Representatives of German Medical Association and National Assoc. of Statutory Health Insurance Physicians)

GGC Steering Group
- GMA
- NASHIP
- Statut. Sickn.F.
- Priv. Insuran.F.
- Publ.Pension Insur.Funds

German Guideline Clearinghouse
- Office for CPG Implementation
- Office for Quality Progr. Clearing

Patient Information Clearinghouse
- Center for Evidence Based Medicine
- Task Force Patient Safety – Error Prevention

PIC Steering Group
- GMA
- NASHIP
- Disabled People Ass.
- Health Care Consum. Ass.
- Self Help Gr.A.

AQuMed Executive

- Communication, Information
- Programme Management
- Research and Development
- Training, Education

Website
- www.aezq.de

Expert Committees & Panels

Journ. for CME, Qual.Ass. ZaeFQ
Increasing need, demand, costs for healthcare as a consequence of

- Changes in the volume and intensity of clinical practice resulting from
  - Population ageing
  - New technology and knowledge
  - Expectations of consumers and professionals

- Price inflation
Financing and Quality Problems in Health Care

Quality Incentives of German Health Care Legislation

- Promotion of gatekeeping in ambulatory care
- Removal of non evidence based technologies from sickness funds benefits catalogue
- Implementation of TQM in all hospitals
- Implementation of evidence based guidelines for priority health care problems

effective since January 2000
# German Quality Implementation Projects

**Evidence-based Medicine + Quality Management**

## Ongoing Projects

<table>
<thead>
<tr>
<th>Action</th>
<th>Ongoing Projects</th>
</tr>
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</table>
| Critical appraisal of interventions and technologies (CPGs + HTA) | **Guideline Clearinghouse**  
(Physicians / Hospital Ass. and Sickness Funds) |
| Need assessment, priority setting; decision making | **Prioritisation Agency** |
| Professional education; consumer empowerment, quality management / assurance | **Joint Definition of Benefits**  
(Physicians / Hospital Ass. and Sickness Funds) |
| | **Promoting effective practice**  
(Implement. of CPGs, TQM, EBM, POL, Pat. Information Systems)  
International Guideline Institutions
(Selected)

- Danmark
- Canada
- England / Wales
- Finland
- France
- Germany
- Italy
- Netherlands
- New Zealand
- Norway
- Poland
- Scotland
- Spain
- Sweden
- Switzerland
- USA

- www.dsam.dk, www.dihta.dk
- www.cancercare.on.ca/ccopgi
- www.nice.org.uk
- www.duodecim.fi
- www.awmf-leitlinien.de - www.leitlinien.de
- www.assr.it
- www.cbo.nl - www.artsen.net
- www.helsetilsynet.no/
- www.nzgg.org.nz
- quality.cmj.org.pl/standardy/standardy.htm
- www.sign.ac.uk
- www.msc.es
- www.sbu.se/
- www.fmh.ch
- www.guideline.gov
Problems of Guidelines Worldwide

1. Only few mention recommendations' evidences

2. Most of them without information on development process, sponsorship / accountability, implementation tools

3. Cost-benefit-questions often excluded as topics

4. Conflicting guidelines on relevant topics

5. Most of them academic recomm.(non-compliance in amb.care)
### Differing CPG Recommendations and Quality

#### Example: German Clearing Report on Hypertension 2001

#### Key Topics of a German Hypertension CPG

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<th>CHS (DT)</th>
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<th>JNC 97</th>
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<th>BHS 99</th>
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<td>Open Questions</td>
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<td>●</td>
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#### Formal Appraisal

<table>
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<tr>
<th>(Yes-answers of German CPG Appraisal Checklist)</th>
<th>EB</th>
<th>EB</th>
<th>EB</th>
<th>EB</th>
<th>EB</th>
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<td>EbM-CPG</td>
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<td>Factor 1.CPG-Develop.</td>
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<td>6</td>
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<td>6</td>
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<td>Factor 3.CPG-Applicability</td>
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<td>28</td>
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</table>

#### Appraised CPGs (● = Focus Group Recommend.)
Intern. Activities concerning CPG Quality / Use

Promotion of international networking between organisations, research institutions, clearinghouses and other agencies producing evidence-based medical information (CoE Recommend. (2001)13

- Research on CPG quality and use
- Policy Paper on develop., dissem., and use of CPGs
- CPG information, dissemination

- Agree Collaboration (Biomed 2, EU)
- Council of Europe CPG Recommendation
- US Guideline Clearinghouse
Recommendation on developing a methodology for drawing up guidelines on best medical practices

Rec (01) 13 / 10.10.2001
…recommends that the governments of member states:

i. develop a national policy framework that:

- ensures that the national methods for the production and appraisal of CPGs comply with internationally accepted, current state of the art practices;
- ensures that policy makers, health care professionals, citizens and patients use the best available evidence to provide information to support medical decisions;
- supports the production, use and timely updating of nationally and locally relevant, evidence-based guidelines…, targeting important issues in health care;
Council of Europe Rec (2001)13 (2)

Recommends that the governments of member states:

i. develop a national policy framework that:

- ensures that CPGs are implemented in an appropriate manner, and that their effects on the clinical process and its results, as well as on the legal consequences with regard to the patient and those who provide medical care, are monitored;

- facilitates the availability and use of CPGs, as well as the availability of information on their aim, legal status, legal implications, health care literature and databases to citizens, patients and professionals in language they can understand and formats they can use easily;
Recommends that the governments of member states:

ii. promote international networking between organisations, research institutions, clearinghouses and other agencies that are producing evidence-based medical information;

iii. support an active, targeted dissemination of these recommendations and the explanatory memorandum, paying special attention to individuals and organisations involved in decisions within health care.
CPG are systematically developed statements to assist important professional and patient decisions about appropriate health care for specific circumstances.

There has always been a body of opinions providing guidance to individual professionals. The novel aspect of evidence based guidelines is the systematic way in which they are developed, and their explicit nature.

CPGs must be developed using state of the art methodology and be critically appraised before implementation is considered.
Desirable Attributes of „Clinical Practice Guidelines“ (IOM 1990)

- Validity
- Strength of evidence
- Estimated outcomes
- Reliability/reproducibility
- Clinical applicability
- Clinical flexibility
- Clarity
- Multidisciplinary process
- Scheduled review
- Documentation

Council of Europe Rec. No. R (01) 13
## Quick Reference Guide

### CARDIAC ASSESSMENT

**immediately following MI**

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<tbody>
<tr>
<td><strong>B</strong></td>
<td>Exercise tolerance test</td>
</tr>
<tr>
<td></td>
<td>If positive, consider coronary angiography (See SIGN guideline on coronary revascularisation)</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>Echocardiography</td>
</tr>
<tr>
<td></td>
<td>(See SIGN guideline on heart failure due to LVSD)</td>
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### DRUG THERAPY

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<tbody>
<tr>
<td><strong>A</strong></td>
<td>Aspirin</td>
</tr>
<tr>
<td><strong>A</strong></td>
<td>β-blocker</td>
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<tr>
<td><strong>A</strong></td>
<td>ACE-inhibitor</td>
</tr>
<tr>
<td><strong>A</strong></td>
<td>Pravastatin and simvastatin are drugs of choice for lipid lowering in patients following MI</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Drug choice should be made on the balance of trial evidence, safety and cost-effectiveness considerations</td>
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### LIFESTYLE MODIFICATION

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<tr>
<td><strong>B</strong></td>
<td>Stop smoking</td>
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<tr>
<td><strong>A</strong></td>
<td>Increase fruit and vegetables</td>
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<tr>
<td><strong>B</strong></td>
<td>Restrict alcohol ≤3 units/day (men) or ≤2 units/day (women)</td>
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<tr>
<td><strong>B</strong></td>
<td>Regular exercise</td>
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### RISK FACTOR MANAGEMENT

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<tbody>
<tr>
<td><strong>B</strong></td>
<td>Measure serum cholesterol within 24 hours of acute MI</td>
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<tr>
<td></td>
<td>Repeat (ideally fasting) after 6-12 weeks</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>Reinforce dietary advice</td>
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</tbody>
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**Robust CPGs:**

www.sign.ac.uk
CPGs have several primary and secondary functions.

They can

- be used to support health care decisions,
- be referred to in legal proceedings,
- be used to provide information about cost effectiveness
- help to link research, education and practice.

Council of Europe Rec. No. R (01) 13
Guidelines support health care decisions (1)

- CPG can be used to plan health care for individuals or populations.

- They help to make decisions in health care more rational and transparent.

- The use of CPGs can improve the consistency of care (reduction of inexplicable variations) and help to achieve better health outcomes.

Council of Europe Rec. No. R (01) 13
Primary Goal of Clinical Practice Guidelines
Definition, Quality Management of Health Care

PLAN

Evidence based Guidelines

ACT

DO

CHECK
Guidelines support health care decisions

- CPGs can support patients in making informed choices.

- A properly developed patient version of a CPG, tailored to the educational and socio-economic status of the lay population in language that they can understand and use, enables patients to make appropriate choices concerning their health problems.

Council of Europe Rec. No. R (01) 13
Implementation Aid: *Patient Information Clearinghouse*  
Gateway to „Best Available“ Patient / Consumer Guidelines

www.patienten-information.de

Appraisal Instr.: www.discern.org.uk
Guideline Characteristics

- CPGs are intended to be flexible.
- CPG recommendations can and should be tailored to fit individual needs.
- Deviation from a CPG does not by itself imply malpractice.

(Council of Europe Rec. No. R (01) 13)
CPG topics should be selected for development to support and assist decision making on important issues in health care.

Prioritisation may be based on the epidemiology of health problems, health inequalities, variations in the provision and quality of care, emergence of new technologies, or other factors that create a need for high quality, updated information.

The existence of presently available evidence-based guidelines should be considered.
Guideline Topic Prioritisation
Procedures and Methods in Germany

- **Specific Search**
  - refering to health care delivery data, documented problems with health care delivery

- **Proposal Process**
  - open to scientific medical societies, professional associations of health care providers, health care providers, health care purchasers, patients, other interested parties

- **Structured Consensus Process**
Prioritisation of Guideline Topics

I. Weitgehende Übereinstimmung von intern. Leitlinienthemen und Gesundheits-Problemen in D

<table>
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<tr>
<th>Thema</th>
<th>Scot</th>
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II. Teilweise Übereinstimmung von Gesu-Problemen in D mit Leitlinienthemen oder
Topic Selection

- There are SIGN specialty subgroups for cancer, cardiovascular disease, general medicine, mental health, primary care, surgery, and women’s & children’s health.

- Work programmes of HTBS, CSBS and NICE taken into account.

- Individual or group expresses interest in developing a SIGN guideline on a topic of concern.

- Guideline Programme Advisory Group allocates topic to the appropriate specialty subgroup.

- Specialty subgroups develop a priority list of potential guideline topics in consultation with clinical networks (including submissions from individuals or groups).

- Feedback discussed with Guideline Programme Advisory Group & proposer. Guideline Programme Advisory Group selects topics to be worked up into full proposals.

- Detailed guideline proposal form completed by specialty subgroup and proposer and submitted to SIGN Council.

- Full discussion of proposal at Autumn meeting of SIGN Council.

- Decision by SIGN as to whether to accept proposed topic into the guideline development programme.

- FORMATION OF THE GUIDELINE DEVELOPMENT GROUP (see section 4)

- Agree funding with CRAG.
SIGN 50:
A guideline developers' handbook

SIGN Publication No. 50
Published February 2001

Contents

1. Introduction
   1.1 Clinical guidelines and SIGN
   1.2 Aim and structure of this report
   1.3 Guidelines in context
   1.4 Medico-legal implications of guidelines
   1.5 Review and updating
2. Organisation of guideline development
   2.1 The Scottish Intercollegiate Guidelines Network
   2.2 Funding for guideline development
   2.3 Timescale for guideline development
3. Selection of guideline topics
   3.1 The SIGN programme
CPG should be produced by multiprofessional groups in a systematic, independent and transparent fashion, using appropriate quality criteria.

End user involvement through a wide review and/or testing of the pilot version is necessary before adopting a CPG for implementation.

If CPGs are adapted from other countries or areas, they must be re-edited and reviewed or tested for applicability in the new environment.
The approach is to use several strategies for developing guidelines:

(i) Developing guidelines from first principles (i.e. starting with a literature review to identify relevant studies and research);
(ii) Starting with the results of meta-analyses of the literature, and updating where necessary;
(iii) Starting from a foreign guideline and modifying it in the light of subsequent research findings and according to Romanian conditions.

The most often used approach is the third one. Considerable savings in time and cost were achieved by starting from the foreign meta-analyses and even more by starting with the already developed guidelines.
Development Steps

3. **Selection of guideline topics**
   3.1 The SIGN programme
   3.2 Criteria for selection of topics
   3.3 Topic selection process
   3.4 Application procedure

4. **The guideline development group**
   4.1 Composition of the guideline development group
   4.2 Patient participation in guideline development
   4.3 Responsibilities of development group members
   4.4 Training for guideline development group members
   4.5 Declarations of interests

5. **Systematic literature review**
   5.1 Identifying and selecting the evidence
   5.2 Evaluating the evidence

6. **Forming guideline recommendations**
   6.1 Synthesising the evidence
   6.2 Considered judgement
   6.3 Levels of evidence and grades of recommendation
   6.4 Resource implications
   6.5 Current areas for development

7. **Consultation and peer review**
   7.1 National open meeting
   7.2 Peer review

8. **Presentation and dissemination**
   8.1 Content and presentation of the guideline
   8.2 Quick reference guides and key messages
   8.3 Electronic publishing
   8.4 Information for patients
   8.5 Distribution
Example: Guideline Development Group

1. Consultation with members of SIGN Council
2. Discuss remit, suggested group chairman and membership with Guideline Programme Advisory Group and proposer
3. Select, invite, brief and train chairman of guideline development group
4. Invite group members Select/invite ‘methodologist’ and secretary
5. Training for key group members in guideline development, SIGN methodology & critical appraisal
6. Critical appraisal training for guideline development group
7. SIGN approves group composition and remit
8. Guideline development group meeting: introduction to SIGN methodology, discussion of remit and key questions to be addressed
9. SYSTEMATIC LITERATURE REVIEW (see section 5)
Timescale for Guideline Development

AVERAGE TIMESCALE FOR SIGN GUIDELINE DEVELOPMENT

<table>
<thead>
<tr>
<th>Group composition</th>
<th>Systematic review and drafting recommendations</th>
<th>Consultation and peer review</th>
<th>Publication</th>
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<tr>
<td>6 months</td>
<td>12 months</td>
<td>9 months</td>
<td>3 months</td>
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</table>

Elapsed time (months): 0 12 21 24

Group c. Lit.search Meth. apprai Appropriat. appraisal Publication
Systematic Literature Review

AGREED GUIDELINE REMIT

1. Population - intervention - outcome - control
2. Defined search strategy to identify the evidence
3. Defined inclusion/exclusion criteria to select the evidence
4. Defined methodological criteria to evaluate the evidence
5. Evidence level = study type + quality assessment
6. Literature search for existing evidence-based guidelines, systematic reviews, meta-analyses
7. Abstracts reviewed to select papers of correct study type and meeting agreed clinical criteria
8. Methodological quality of the studies selected evaluated using appropriate checklist
9. Literature search extended to randomised controlled trials
10. Literature search extended to include observational studies

FORMATION OF GUIDELINE RECOMMENDATIONS (see section 6)
**Figure 5.2**

**EXAMPLE LITERATURE SEARCH SPECIFICATION:**
**SIGN GUIDELINE ON ANTIBIOTIC PROPHYLAXIS IN SURGERY**

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<thead>
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<td>controls, operating</td>
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<td>– New Zealand Guidelines Project</td>
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</table>
International Guideline Data-Bases searched during the German Clearing Project Tumor Pain (2000) available via [http://www.leitlinien.de](http://www.leitlinien.de)

<table>
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</table>
Formation of Guideline Recommendation

FORMATION OF GUIDELINE RECOMMENDATIONS

SYSTEMATIC LITERATURE REVIEW  (see section 5)

Evidence level = study type + quality assessment

Volume, consistency, generalisability, etc. of evidence

Evidence table for key question 1
Evidence table for key question 2
Evidence table for key question 3

Considered judgement of multidisciplinary guideline development group

Graded recommendation(s)

Draft guideline

CONSULTATION AND PEER REVIEW  (see section 7)
### Consistency

Comment here on the degree of consistency demonstrated by the available evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

| High degree of consistency - no conflicting results. |

### Clinical impact

Comment here on the potential clinical impact that the intervention in question might have – e.g. size of patient population; magnitude of effect; relative benefit over other management options; resource implications; balance of risk and benefit.

| Large potential impact - large numbers of patients with Type 2 diabetes are likely to be prescribed ACE inhibitor therapy. |

### Other factors

Indicate here any other factors that you took into account when assessing the evidence base.

| None |

### Evidence statement

Please summarise the development group’s synthesis of the evidence relating to this key question, taking all the above factors into account, and indicate the evidence level which applies.

| Evidence level |

In the absence of sound evidence, the group may produce statements about essential care decisions using a consensus approach.

There remains however the question if the practices recommended by the guideline have actually been shown to be effective in improving health outcomes.
## Levels of Evidence

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>1**</td>
<td>High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1*</td>
<td>Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2**</td>
<td>High quality systematic reviews of case-control or cohort or studies</td>
</tr>
<tr>
<td>2*</td>
<td>Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

### Grades of Recommendation

- **A**: At least one meta analysis, systematic review, or RCT rated as 1**, and directly relevant to the question of interest.
| A | At least one meta analysis, systematic review, or RCT rated as 1**, and directly applicable to the target population; or 
   | A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1*, directly applicable to the target population, and demonstrating overall consistency of results; or 
   | Extrapolated evidence from studies rated as 1** or 1* |
|---|---|
| B | A body of evidence including studies rated as 2**, directly applicable to the target population, and demonstrating overall consistency of results; or 
   | Extrapolated evidence from studies rated as 1** or 1* |
| C | A body of evidence including studies rated as 2*, directly applicable to the target population and demonstrating overall consistency of results; or 
   | Extrapolated evidence from studies rated as 2** |
| D | Evidence level 3 or 4; or 
   | Extrapolated evidence from studies rated as 2* |

Related documents:
- [Considered judgement form](#)
- [Example guideline extract](#)
4.3.4 Sustained DMARD therapy

While early initiation of therapy is of importance, a sustained input is vital if disease suppression is to be maintained. Remission is the goal but is seldom achieved. Equally 'cure' is not attained, thus withdrawal of treatment is seldom appropriate.

Two randomised placebo controlled studies have demonstrated relapse on withdrawal of disease modifying agents. In both these studies, disease modifying effect was unequivocal. These results confirm the efficacy of DMARDs in comparison with placebo, and demonstrate that sustained prescription of DMARDs is necessary to suppress disease activity. Serial use of DMARDs has been shown to be safe after 10-15 years. Evidence level 1+

**B** DMARD therapy should be sustained in inflammatory disease in order to maintain disease suppression.


Indications for surgical antibiotic prophylaxis

Cardiothoracic surgery

Antibiotic prophylaxis is recommended in:

- **A** Cardiac pacemaker insertion
- **B** Open heart surgery, including coronary artery bypass grafting and prosthetic valve surgery
- **A** Pulmonary resection

ENT surgery

Antibiotic prophylaxis is recommended in:

- **A** Head and neck surgery (clean-contaminated/contaminated)

Antibiotic prophylaxis is **not** recommended in:

- **A** Ear surgery (clean)
- **C** Head and neck surgery (clean)
- **C** Nose or sinus surgery
- **C** Tonsillectomy

Graded Recommendations
Neither is there always a direct link between the level of evidence and the strength of the recommendations.

When studies have been done on very selected patients, for example, the evidence for applying results in the general population may be considered weaker than otherwise.

Sometimes there is very little data to support an important decision in health care, and in these cases, experts in the guideline group may decide the grade of recommendation to be higher than the evidence in usual cases would allow.
Council of Europe Rec (2001)13
Levels of Evidence / Strength of Recomm.

Science
Level of evidence

Guidelines
Grade of recommendation

1   
2   
3   
4   
5   

Modulated by principles of need, applicability, or cost-effectiveness
Changes in interpreting the evidence may also take place at the implementation stage.

While guidelines should predominantly remain based on scientific and professional considerations, there may be a need to modulate and weigh the evidence locally according to value judgements, priorities and local conditions.

Translating guidelines into regional treatment programmes or local practice policies may thus mean changes in the content of recommendations.
Funding for CPG dissemination, implementation, evaluation, and updating must be carefully considered at the same time as the decision is made to develop the CPG. Funding support may vary. The source of support must be transparent.

CPGs should target multiple audiences (professionals, patients, and policy makers) and be available in suitable formats for these different groups.

CPG clearinghouses or CPG production programmes facilitate the accessibility of multiple CPG on similar problems and may increase CPG quality.
Tools for evaluating the quality of existing guidelines should be used to decide which guidelines should be implemented.

An internationally co-ordinated research network should study the methodology of guidelines evaluation and impact monitoring, including the impact of guidelines on learning process and medical knowledge of professionals.
# Annex 3

**Example:**

## Indicator Data Set

### Minimum Core Data Set

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<th>Data Item</th>
<th>Field Name</th>
<th>Coding Details</th>
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Evaluation of CPG Implementation:

Diabetes CPGs in Thuringia
German Guideline Clearinghouse: Aims and Scopes

- Setting up standards for CPG development
- National prioritisation of CPG topics
- Identification of „best available CPGs“
- Implementation of best available CPGs
- Evaluation of CPG programmes
- Monitoring of the CPG’s quality and „market“

Well-planned monitoring of guideline effects is essential, and especially the impact of guidelines on health outcomes needs further development and evaluation.

Guidelines can include a list of essential indicators that can be used for evaluating the results of guideline implementation.
German Clearinghouse for Patient Information
Joint Project of Federal Patient Ass. and AQuMed

Consent on standards for „best“ patient information

Setting joint priorities for PI topics

Identification of „best available PI“ (refering to evidence based literature: Cochrane Reviews, HTA-Reports, CPGs)

Joint Appraisal and certification of PI

PI implementation via consumer groups and physicians
Council of Europe Rec (2001)13
Guideline Implementation (1)

- For the most effective implementation of CPGs, a systematic approach to managing the quality of health care and determining those responsible is essential.

- Various guideline dissemination and implementation strategies should be used in combinations to ensure maximum effect.

- Professional, organisational, financial, and regulatory incentives and disincentives need to be considered together with other barriers and facilitators of guideline use at both national and local levels (tailored implementation).
Council of Europe Rec (2001)13
Guideline Implementation (2)

- In implementing guidelines, the best interest of the patient should be served and professional responsibility and patients’ rights should be respected.

- Guidelines must become an essential element in the undergraduate and clinical training of health care professionals as well as in the continuing professional development of health care teams.
9. **Implementation**
   9.1 Getting guidelines into practice
   9.2 Identifying barriers to implementation
   9.3 Implementation initiatives
   9.4 Practical steps
   9.5 Monitoring implementation

10. **Audit and review**
   10.1 Scheduled review
   10.2 Links with audit
   10.3 Recommendations for research
   10.4 Review proposals and procedures
   10.5 Monitoring interim updates

**Annexes**

A. **AGREE: the AGREE guideline appraisal instrument**
B. **Background: the SIGN guideline programme**
C. **Critical appraisal: notes and checklists**
D. **Documentation: considered judgement form, resource implications questionnaire, etc.**
E. **Examples: completed checklists, evidence tables, and other documentation**
F. **Further reading**
G. **Glossary**
H. **How to contact SIGN**
Barriers against CPGs in Germany
User Rate of Information Tools

- Journals
- Peers
- Books
- Non-comm.Infos
- GUIDELINES
- Peer Groups
- Internet
- PharmaInfo

(very) often
somet./never
Awareness of Hypertension CPGs by Ambulatory Care Physicians in Germany

HEP Study - Schneider et al. ZaeFQ 2001; 95: 339-344

Respondents with adequate guideline awareness (%)

- Less than 2 years
- 2 - 5 years
- 5 - 10 years
- 10 -15 years
- 15 - 20 years
- More than 20 years

p = 0.005
p < 0.0001
p = 0.136
# Implementation of Evidence-based Information

## How to Overcome Barriers?

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<th>Evidence-based Information</th>
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<table>
<thead>
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<th>In- and Out-Patient Care, Health Professionals, Patients, Health Administration, Politicians</th>
<th>Practice</th>
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**GAP**
### Figure 9.2: IMPLEMENTATION STRATEGIES

<table>
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<th>Method</th>
<th>Effectiveness</th>
<th>Local considerations</th>
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<tr>
<td>Written materials</td>
<td>Variable findings; at best, small effect</td>
<td>Whilst impact is small, could be used to raise awareness of the guideline through materials or through medical journals or local publications. Useful in combination with other strategies.</td>
</tr>
<tr>
<td>Audit and feedback</td>
<td>Sometime effective; small to moderate effect but potentially important</td>
<td>This could be a valuable starting point to provide baseline information from which to develop an implementation strategy.</td>
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<tr>
<td>Education (group)</td>
<td>Variable effects which improve when the influence of peers is included</td>
<td>Identify a local multiprofessional group who can be supported with education from experts or by attending workshops or conferences. Facilitation at practice/unit level is helpful.</td>
</tr>
<tr>
<td>Education (individual)</td>
<td>More effective than other educational initiatives</td>
<td>Targeting issues that centre around education and performance issues.</td>
</tr>
<tr>
<td>Opinion leaders</td>
<td>Mixed effects</td>
<td>Identify key opinion leaders and how they could influence others.</td>
</tr>
<tr>
<td>Product champions</td>
<td>No conclusive evidence</td>
<td>Identifying product champions might highlight innovative methods for implementation.</td>
</tr>
<tr>
<td>Academic detailing / educational outreach</td>
<td>Effects are small to moderate but of potential importance</td>
<td>Could be incorporated with individual education approach and written materials.</td>
</tr>
<tr>
<td>Mass media</td>
<td>May have a positive influence on how health services are used</td>
<td>Take advantage of mass media coverage and additionally local media sources.</td>
</tr>
<tr>
<td>Patient-mediated interventions</td>
<td>No conclusive research evidence</td>
<td>Consider local patients, consumer and pressure groups so that involvement is part of strategy at the outset.</td>
</tr>
<tr>
<td>Continuous quality</td>
<td>No conclusive research evidence</td>
<td>Include local audit/clinical governance/ effectiveness</td>
</tr>
</tbody>
</table>

Educational Tool for Authors, Editors, and Users of CPGs –

Joint Project of Ass. of Scient. Med. Soc. and AQuMed
Barriers against Use of CPGs:

**Mandatory Top-Down CPG Implementation**

- Mandatory, nationwide implementation of guideline-based quality measures for 10 top priority health care problems per year.

(Social Code Book V of Germany)
Risks of CPGs: Inadequate Standardisation of Health Care

- CPGs should …not simply be imposed on professionals by hospital management or third party payers.

- That would result in a standardisation of care that leaves insufficient room to do justice to the needs of each individual patient.

- Neither are guidelines a simple tool for allocating scarce resources at the population level.

Council of Europe - Rec. (01) 13 / 10.10.2001
(Rec. on developing a methodology for drawing up guidelines on best medical practices)
Medicolegal Status of Guidelines

- Since guidelines are not issued by legislative bodies, they are **not legal rules**.

- However, they may have or acquire **legal significance**, for instance when they are incorporated in binding rules or when they are applied by a court as auxiliary standards to decide a case of professional misconduct or malpractice.

(Council of Europe Rec. No. R (01) 13)
Use of Guidelines in Court

- Basically, guidelines will not provide definite answers even when they do not allow for much flexibility in application. A particular course of action must be judged in the light of the specific health problem and the specific circumstances of a given patient.

- Sometimes, there can be competing guidelines, for instance developed in different hospitals or regions.

- For all these reasons, the courts will not automatically equate compliance with guidelines with good medical practice.

(Council of Europe Rec. No. R (01) 13)
Barriers against Use of CPGs: Conflicting CPG Recommendations

![Barriers against Use of CPGs: Conflicting CPG Recommendations](image_url)
Clinical Practice Guidelines in Germany

Status Quo

- More than 1000 national guidelines of various quality (Editors: Scientific Medical Societies – n > 120)

- Legal obligation to implement 10 evidence based CPGs per year (since 2001)

- Less than 30% of primary care physicians are aware of key CPGs
Goals of German Guideline Clearinghouse:
To establish practicable evidence-based CPGs of good quality

- Multiprofessional author groups
- System. literature search/ review
- Use of available best evidence
- Structured / transparent consensus processes for selecting recommendations
- Explicit link between recommendations / underlying evidence
- Regularly updating of CPGs
Critical Appraisal of CPGs Quality: AGREE Instrument

<table>
<thead>
<tr>
<th>Rigour of formulation of the guideline</th>
<th>Y</th>
<th>N</th>
<th>UC</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there a description of the methods used to formulate the recommendations?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Is there a description of the methods to obtain consensus on the guideline's recommendations?</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>Is there an indication of how the views of interested parties not on the panel were taken into account?</td>
<td>0</td>
<td>0</td>
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</tr>
<tr>
<td>Is there an explicit link between the major recommendations and the level of supporting evidence?</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</table>

<table>
<thead>
<tr>
<th>External validation and pilot studies</th>
<th>Y</th>
<th>N</th>
<th>UC</th>
<th>NA</th>
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</thead>
<tbody>
<tr>
<td>Was the guideline independently reviewed prior to publication/release?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>If so, is explicit information given about the methods and how comments were addressed?</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Was the guideline piloted?</td>
<td>0</td>
<td>0</td>
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<tr>
<td>If so, is there explicit information given about the methods of pilots used and about the results adopted?</td>
<td>0</td>
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</tr>
<tr>
<td>Has the guideline been compared to other topical guidelines?</td>
<td>0</td>
<td>0</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Period of validity and update of the guideline</th>
<th>Y</th>
<th>N</th>
<th>UC</th>
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</tr>
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<tbody>
<tr>
<td>Is there a mention of a date for reviewing or updating the guideline?</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Is the body responsible for the reviewing and updating clearly identified?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Transparency of the guideline development</th>
<th>Y</th>
<th>N</th>
<th>UC</th>
<th>NA</th>
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<tbody>
<tr>
<td>Have the potential biases of guideline development been adequately dealt with?</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Is there a summary of the content and the recommendations of the guideline as well as the supporting evidence?</td>
<td>0</td>
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</tbody>
</table>
Implementation Aid: CPG Clearing
Disclosure of Best Available CPGs

- Hypertension
- Tumor Pain
- Low Back Pain
- Asthma bronchiale
- Diabetes mellitus Type 2

In preparation
- CHD
- Heart Failure
- Depression
SIGN 50: A guideline developers' handbook
Annex A

AGREE (Appraisal of Guidelines for Research & Evaluation)

SCOPE AND PURPOSE
1. The overall objective(s) of the guideline should be specifically described.
2. The clinical question(s) covered by the guideline should be specifically described.
3. The patients to whom the guideline is meant to apply should be specifically described.

STAKEHOLDER INVOLVEMENT
4. The guideline development group should include individuals from all the relevant professional groups.
5. The patients' views and preferences should be sought.

RIGOUR OF DEVELOPMENT
6. Systematic methods should be used to search for evidence.
7. The criteria for selecting the evidence should be clearly described.
Scope and Purpose; Question 3

The patients to whom the guideline is meant to apply are specifically described.

Context, flexibility; Question 2.3

Is there a satisfactory description of the patients (regarding sex, age, stage of the disease, concurrent diseases) to which the guideline is meant to apply?

Y = yes  N = no  uc = unclear  na = not applicable
The AGREE Collaboration

How can a practitioner decide if the guidelines they are using have been developed and adopted using good methods? A group of European guideline developers agreed that this was a question. They formed a collaboration called AGREE.

The AGREE collaboration developed a proforma or checklist, called the AGREE instrument, which can be used to help make an informed judgement about the methods that were used to develop a guideline, and an assessment about the overall quality of the guideline and the recommendations it contains.

The AGREE Instrument

The AGREE instrument considers 6 different aspects, or domains, of guideline development:

1. **Scope and purpose**
2. **Stakeholder involvement**
3. **Rigour of development**
4. **Clarity and presentation**
5. **Applicability**
6. **Editorial Independence**
Guideline Appraisal Instrument (Comments and Examples)

<table>
<thead>
<tr>
<th>AGREE CRITERIA</th>
<th>BACKGROUND</th>
<th>EXAMPLES</th>
</tr>
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<td>6. The target users of the guideline should be clearly defined.</td>
<td></td>
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Sind die an der Erstehung der Leitlinie Beteiligten hinsichtlich ihrer Funktion und Art ihrer Beteiligung klar genannt?

Die Antwort JA setzt voraus, daß zumindest für alle direkt an der Leitlinienerstellung beteiligten Personen (z.B. die Mitglieder des verantwortlichen Lenkungsausschusses, die Arbeitsgruppe, welche die Recherche und Bewertung der Evidenz durchführte, weiterhin berücksichtigte Kommentatoren oder Gutachter) klare Angaben über Namen, über die beruflichen Qualifikationen, über das Fachgebiet, über den
MEMBERSHIP OF THE SIGN EARLY RHEUMATOID ARTHRITIS GUIDELINE
DEVELOPMENT GROUP

Chairman:
Consultant Rheumatologist, Glasgow

Methodologist:
Consultant Physician/Rheumatologist, Glasgow

Group members:
Patient representative, Strathpeffer
Patient representative, Glasgow
Chief Pharmacist, Paisley
Senior Occupational Therapist, Dundee
Senior 1 Physiotherapist and Lecturer, Glasgow
Consultant in Public Health, Fife Health Board
General Practitioner, Dingwall
General Practitioner, Glasgow
General Practitioner, Glenrothes
Consultant Physician/Rheumatologist, Inverness
Consultant Rheumatologist, Edinburgh
Consultant Rheumatologist, Aberdeen
Consultant Rheumatologist, Glasgow
Specialist Registrar, Edinburgh
Nurse Specialist, Glasgow
Podiatrist, East Kilbride
Dietitian, Glasgow

Scottish Intercollegiate Guidelines Network
APPLICABILITY

16. The target users of the guideline should be clearly defined.

17. The potential organisational barriers in applying the recommendations should be discussed.

18. The potential cost implications of applying the recommendations should be considered.

19. The guideline should be supported with tools for application.

20. The guideline should presents key review criteria for monitoring and audit purposes.

21. The guideline should be piloted among end users.

EDITORIAL INDEPENDENCE

22. The guideline should be editorially independent from the funding body.

23. Conflicts of interest of guideline development members should be recorded.

For further information, see the AGREE website: http://www.agreecollaboration.org

SIGN guide to the AGREE guideline appraisal instrument.
RIGOUR OF DEVELOPMENT

6. Systematic methods should be used to search for evidence.

7. The criteria for selecting the evidence should be clearly described.

8. The methods used for formulating the recommendations should be clearly described.

9. The health benefits, side effects and risks should be considered in formulating the recommendations.

10. There should be an explicit link between the recommendations and the supporting evidence.

11. The guideline should be externally reviewed by experts prior to publication.

12. A procedure for updating the guideline should be provided.

CLARITY AND PRESENTATION

13. The recommendations should be specific and unambiguous.

14. The different options for diagnosis and/or treatment of the condition should be clearly presented.

15. Key recommendations should be easily identifiable.
Best Available Guidelines: Clearing Project „Hypertension 2000“ - Summary

- 11 out of 132 identified hypertension CPGs met the formal criteria of German Guideline Appraisal Instrument.

- 7 out of 11 might be useful as blueprints for German hypertension guideline.

- 16 key topics for a national hypertension CPG were consented.

- Benchmark CPGs: BHS, CanHSF, JNC VI / ICSI
RIGOUR OF DEVELOPMENT

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15. Key recommendations should be easily identifiable.
Consultation / Peer Review

- Draft guideline available on SIGN web site for limited period
- Draft guideline presented and discussed at national open meeting
- Feedback incorporated and draft guideline submitted to SIGN
- In-house editing and methodological checks
- Peer review reports obtained
- Draft circulated for information to various health service organisations
- Comments compiled and discussed with development group chairman, in consultation with group
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| APPLICABILITY |
Example:
Quick Reference Guide
Key Points for CPG’s Acceptance

Clinical practice guidelines should

- link recommendations with underlying evidences
- deal with every day health care problems
- help professionals in providing best medical practice at minimal expenses
- give detailed description of best medical practice processes
Disease Management in Germany
Goal: Effective Chronic Illness Care
(AQuMed Recommendation 02/02)

Self-management support: to help patients / families cope with the challenges of living with and managing chronic illness.

Patient support: goes beyond patient education and information; it equips patients with skills in managing their conditions

Decision support to practitioners: includes the effective implementation of evidence-based guidelines

Delivery system: includes well-prepared teams able to efficiently coordinate tasks and utilize key clinical data

Clinical information system: collects information about important elements of care and makes that information available to health care team members.

Disease Management in Germany
Program Accreditation Principles
(Federal Ministry of Health 05/02)

• Use of evidence-based guidelines, as available, as a basis for program design
• Population-based management through identification and stratification of patients who need support to manage their conditions
• Support for the physician-patient relationship
• Quality interaction between the program and the affected patients and practitioners
• Population-based measurement of process and/or outcomes
• A QI process that enables an organization to continually learn better ways to provide DM.

adapted from NCQA
Categories:

A. Program Content
B. Patient Service
C. Practitioner Service
D. Clinical Systems
E. Measurement and Quality Improvement
F. Program Operation
Disease Management in Germany
Program Accreditation Categories and Standards
(Federal Ministry of Health 05/02)

A. Program Content

• Using evidence-based guidelines or standards of care in developing program content for patients and practitioners

• Ensuring that all content is consistent with adopted guidelines

• Developing information for patients that assists in self-management

• Developing information for treating practitioners about current guidelines and how program recommendations relate to guidelines and cited evidence
Disease Management in Germany
Program Accreditation Categories and Standards
(Federal Ministry of Health 05/02)

B. Patient Service

• Enlisting and measuring the participation of eligible patients

• Supporting patient self-management with consumer-tested information, coaching, reminders, referrals and feedback on progress

• Providing feedback to patients about their progress toward treatment goals

• Encouraging patient communication with practitioners.
C. Practitioner Service

- Supporting practitioner decisions with evidence-based recommendations on care of chronic conditions and reminders, and feedback on the progress of individual patients

- Providing feedback to practitioners on the condition and progress of their patients
E. Measurement and Quality Improvement

• Measuring quality for each condition managed and across the organization

• Using evaluative data from patients and practitioners to assess their experience with the DM program for quality improvement

• Analyzing performance data and taking action for quality improvement.
Primary Goal of Clinical Practice Guidelines
Definition, Quality Management of Health Care

PLAN

ACT

Evidence based Guidelines

DO

CHECK
Results and Perspectives of GGC

1. Joint national strategy for CPG devel. and use
2. Clearing Report – a CME resource
3. CPG-based disease management programmes
4. Guideline implementation technologies
   - Annotated CPG retrieval system (www.leitlinien.de)
   - Decision support system (Prodigy-Program)
4. Linking CPGs with
   - Patient information (Patient Information Clearinghouse)
   - Clinical measures (Measures Clearinghouse)
   - National hospital certification program KTQ®
   - CME programs
Thank you for your Patience !!!

http://www.aezq.de