Part 1

Content - Overview

Motivation - Introduction
Diagnostic-Therapeutic Cycle
Medical Therapy Planning
Guideline Repositories
Guideline Development (CBO)
Instruments for Quality of Guidelines
Agree Instrument (e)GLIA
Planning / Plan Management

Concepts → Motivation
Discourse Model vs. Process Model
Diagnosis vs. Treatment
Both are Indispensable
Guideline vs. Protocols
Cite-specific
Communication & Quality Assessment
Diagnostic-Therapeutic Cycle

Human
Observation
Reasoning
Action

Health Care
Observation
Diagnosis
Therapy

Van Bemmel & Musen 1997

Diagnostic-Therapeutic Cycle

Data

Information

Patient
Decision

Therapy
Plan
Diagnosis

Monitoring & Therapy Planning Tasks

Support physicians & nurses
"passive" patients

One cycle of data interpretation

Signal

Data selection

Data validation

Data abstraction

Interpretation of patient's status

Therapy recommendation

Assessment of therapeutic actions

Prediction of effects of therapeutic actions

Monitoring

Intelligent alarming

Monitoring & Therapy Planning

van Bemmel & Musen 1997
Problem Areas: User Perspective

- Information Overload
  - Due to Measurement Technology
- Transfer of Knowledge
  - Better Communication
- Reuse
  - Standardization
  - Reduction of Variation
- Quality Assessment
  - Quality of Care

Problem Areas: Computer Sciences

- Information Visualization
- Data and Process Modeling
- Temporal Representations & Reasoning
- Database Design
- Ontologies
- Plan Management (Continual Planning)
- Reuse
Definitions: **Guidelines & Protocols**

Definitions are widely discussed as well as context- and country-specific.

**Clinical Guidelines (C.. practice G..) - Decision-Aid**

A set of general rules and policies for management of patients who have a particular clinical condition

“... are systematically developed statements to assist the practitioners and patient decisions about appropriate healthcare for specific circumstances” [Field & Lohr, 1990].

“... are validated **policy statements** representing best clinical practice. Used to support standardized patient care.”

**Definitions: Guidelines & Protocols**

**Clinical Protocols - Directive**

"... are a standard set of tasks that define precisely how classes of patients should be managed or treated"

"standard procedure laid down to be followed step by step"

[IHCD paramedic manual 1993]

More Detailed
Cite-specific Adaptation - Hospital, etc.
Enables Statistical Analysis

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**Clinical Protocols**

"Protocols are 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 due to the differing types of local provision."

[CBO]

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**Clinical Pathways** (Integrated Care Pathways)

"... are structured, multi-disciplinary plans of care designed to support the implementation of clinical guidelines and protocols"

"Behandlungspfad, Patientenpfad, Indikationspfad"

(http://www.medinfoweb.de/clinpath.htm)

**Care Plans**

"... provide a "road map" of sorts, to guide all who are involved with a patient/resident's care"

clinical guidelines and protocols for nurses
but NOT the sole domain of nurses

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**Standards**

practice parameters in USA
Guideline <-> Standard <-> Protocol
Guidelines & Tasks

5 Principle Tasks That Computerised Guidelines Should Be Capable of Supporting

- Making Decisions
- Sequencing Actions
- Setting Goals (e.g. specific patient states) to be achieved
- Interpreting Data
- Refining Actions (i.e. breaking up into sub-components)


Approaches: Guideline Modeling

Rule-Based Specification

HELP, Arden/MLM

Augmented Decision Analysis

Logic and Decision Table Techniques

Multi-steps Guidelines

Modeled as Hierarchical Set of Nesting Guideline Tasks (Task-Based Paradigm)

Combine Procedural & Declarative Representation

Asbru, DILEMMA, EON, GLIF, Prodigy, PROforma

History: Guideline Modeling

Adapted from Elkin, Peleg, Lacson, Bernstein, Samson, Boxwala, Greenes, Shortliffe: Toward Standardization of Electronic Guideline Representation, MD Computing, 17(6), 2000, pp.39-44.
State of the Art of Guidelines

Guidelines:
- Guidelines describe best-practice care for patients
- Extensive documents: Designed for practitioners by practitioners
- Evidence based

Guideline: Quality

Evidence-Based Medicine (EBM)

Evidence-Based Medicine
- The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

Evidence-Based Guidelines
- Guidelines, based on the best available evidence, which are updated regularly.

Consensus-Based Guidelines
- Committee agrees about the content of a Guideline (consensus of 'expert opinion')
**Strongest Level of Evidence**

Meta-analyses  
Systematic Reviews  
Randomized Controlled Trials (RCT)  
Controlled Clinical Trials (CCT)  
Clinical Trials (CT)  
Cohort studies / Patient control studies  
Other

**Levels of 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

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**Summary of recommendations**

**DIAGNOSIS AND ASSESSMENT**

1. A full assessment of cardiovascular risk should be carried out for all hypertensive patients.
2. Blood pressure measurement is critical in the management of hypertension. Validated equipment should be used and the recommendations of the fifth hypertension society on blood pressure measurement should be adhered to.
3. The normal range for the home blood pressure measurement in antihypertensive patients is narrower than “normal” normative values.

**THRESHOLDS AND TARGETS FOR TREATING HYPERTENSION IN OLDER PEOPLE**

- Both systolic and diastolic hypertension require treatment.
- Thresholds for antihypertensive therapy should take into account both the level of blood pressure and other risk factors.
- The decision to start treatment should be based on an individual assessment of cardiovascular risk.
- For risk assessment in primary prevention of cardiovascular disease, use the Joint British Societies’ guidelines. The threshold for treatment of hypertension in patients aged >75 years is equal to >160/90 mmHg.
- For risk assessment in patients aged >75 years, the threshold for treatment of hypertension is >140/90 mmHg.
- A target blood pressure of <140/90 mmHg is recommended for older hypertensive patients.
- For small reductions in blood pressure in patients with moderate to severe disease, greater attention to treatment target is necessary.
- Hypertensive patients with diabetes or with renal disease should be considered for specialist evaluation. Some patients may require later intensive treatment and lower target blood pressure may be recommended. 

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**KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS**

- The definitions of the types of evidence and the grading of recommendations used in this guideline are from the U.S. Agency for Healthcare Policy and Research and are set out in the following table:

  **STATEMENTS OF EVIDENCE**
  1. Evidence obtained from meta-analyses of randomised controlled trials.
  2. Evidence obtained from at least one randomised controlled trial.
  3. Evidence obtained from at least one well-designed controlled study without randomisation.
  4. Evidence obtained from at least one other type of well-designed quasi-experimental study.
  5. Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies.
  6. Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

  **GRADES OF RECOMMENDATIONS**
  A. Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency: addressing the specific recommendation.
  B. Requires the availability of well-conducted clinical studies but no randomised clinical trials: addressing the specific recommendation.
  C. Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities: addressing the specific recommendation.

**GOOD PRACTICE POINTS**

- Recommended best practice based on the clinical experience of the guideline development group.
4 Thresholds and targets for treating hypertension in older people

4.1 WHAT SHOULD WE TREAT: THE SYSTOLIC, THE DIASTOLIC OR BOTH?

There has been much debate on the relative importance of systolic and diastolic hypertension and its relationship to increased cardiovascular risk in older patients. It is important to note that the risk of cardiovascular events is not the same for all older patients. Therefore, the thresholds for antihypertensive therapy and targets for treatment should be set.

**Thresholds for antihypertensive therapy and targets for treatment should be set.**

- Both systolic and diastolic hypertension require treatment.
- Threshold for antihypertensive therapy and targets for treatment should be set.

4.2 WHEN SHOULD WE START TREATMENT?

4.2.1 MULTIFACTORAL RISK ASSESSMENT

The relationship between blood pressure and adverse cardiovascular outcome is direct; higher blood pressure levels are associated with a higher risk of cardiovascular events. Therefore, treatment should be started any time blood pressure is above the threshold.

Decisions on starting treatment should be individualized and should take into account not just the level of blood pressure, but also the presence of other clinical features, including risk factors, evidence of target organ damage and associated clinical conditions.

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**

Drug A and drug B are both effective in reducing severity and duration of headache episodes in male patients.

| A1 | Thijssen et al
| A2 | Vianden et al, Swartz et al |

**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**

Kitty Rosenbrand

Summary Statement of the Best Evidence

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


Trends

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>regional guidelines from professional groups</td>
<td>national guideline programmes</td>
</tr>
<tr>
<td>informal consensus</td>
<td>evidence-based</td>
</tr>
<tr>
<td>monodisciplinary</td>
<td>multidisciplinary</td>
</tr>
<tr>
<td>focus on development</td>
<td>focus on implementation</td>
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<tr>
<td>limited life-expectancy</td>
<td>‘living guidelines’</td>
</tr>
<tr>
<td>paper versions</td>
<td>Internet</td>
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<tr>
<td>guidelines for clinicians</td>
<td>patient versions and patient involvement</td>
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</table>
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Guideline Repositories
National Guideline Clearinghouse
http://www.guideline.gov
Scottish Intercollegiate Network (SIGN)
http://www.sign.ac.uk
Tripdatabase
http://www.tripdatabase.com
e-guidelines
http://www.eguidelines.co.uk/
Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF)
http://www.awmf.de

National Guideline Clearinghouse
http://www.guideline.gov

Content
Comprehensive Database of Evidence-Based Clinical Practice Guidelines

Partners
Agency for Healthcare Research and Quality (AHRQ)
American Medical Association (AMA)
American Association of Health Plans (AAHP)
Scottish Intercollegiate Network (SIGN)

http://www.sign.ac.uk

Formed in 1993

Aim

Development and Dissemination of National Clinical Guidelines Containing Recommendations for Effective Practice Based on Current Evidence
**Overview of the SIGN Guideline Development Process**

- Organization of Guideline Development (section 2)
- Selection of Guideline Topics (section 3)
- Composition of the Guideline Development Group (section 4)
- Systematic Literature Review (section 5)
- Formulation of Recommendations (section 6)
- Consultation and Peer Review (section 7)
- Presentation and Dissemination (section 8)
- Local Implementation (section 9)
- Audit and Review (section 10)

**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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**G-I-N**

http://www.g-i-n.net/

**Mission Statement**

G-I-N seeks to improve the quality of health care by promoting systematic development of clinical practice guidelines and their application into practice, through supporting international collaboration.
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