

# 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

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# Concepts → Motivation

## Discourse Model vs. Process Model



## Diagnosis vs. Treatment

- Both are Indispensable

## Guideline vs. Protocols

- Cite-specific
- Communication & Quality Assessment

# Diagnostic-Therapeutic Cycle

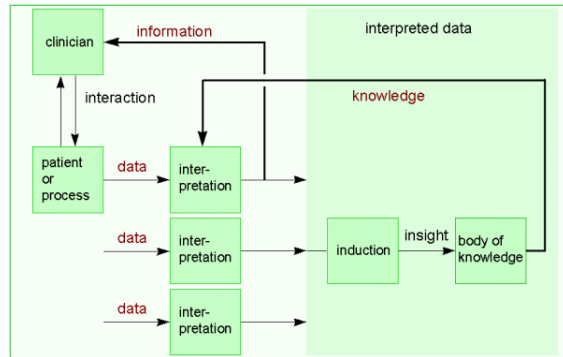
[Van Bommel & Musen 1997]

## Human

Observation  
Reasoning  
Action

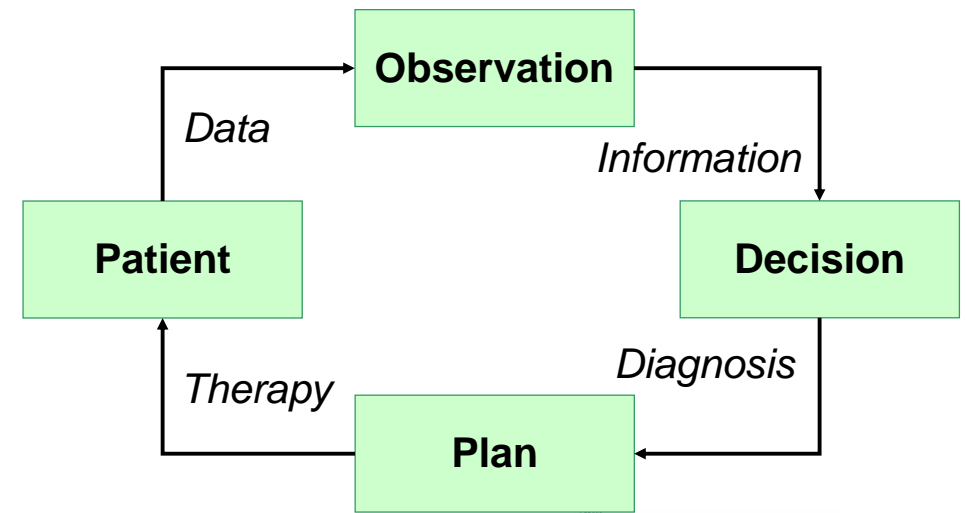
## Health Care

Observation  
Diagnosis  
Therapy

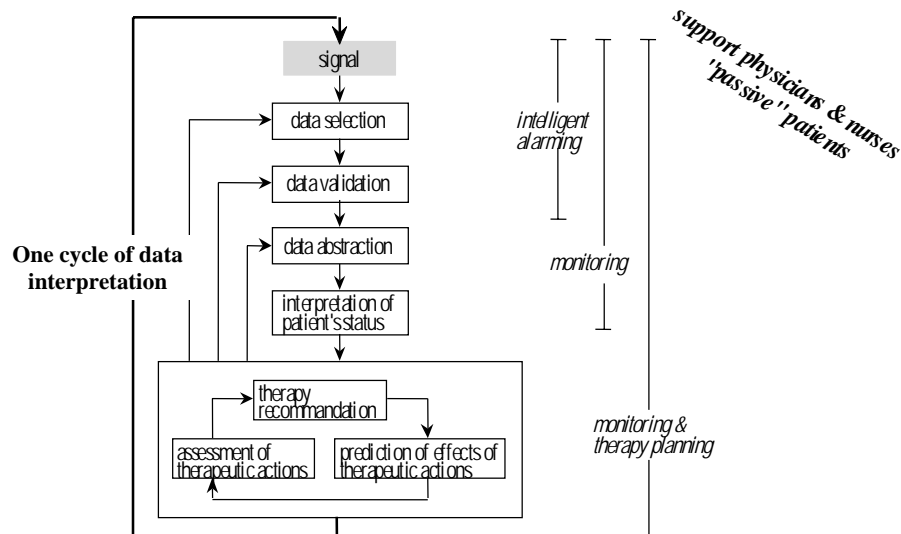


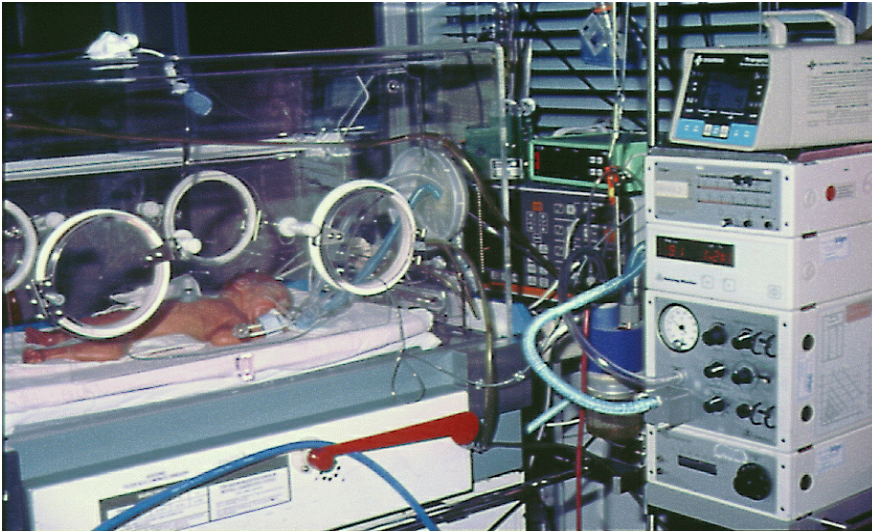
# Diagnostic-Therapeutic Cycle

[Van Bommel & Musen 1997]



# Monitoring & Therapy Planning Tasks





## 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

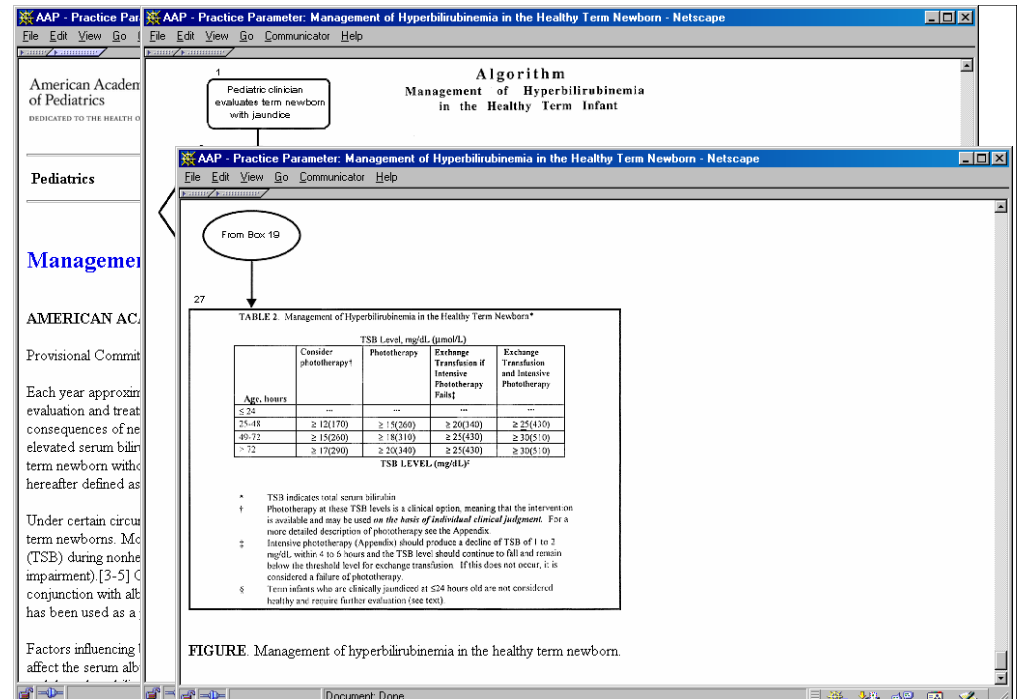
### Plan Management (Continual Planning)

### Reuse

# Medical Therapy Planning

## Clinical Protocols & Guidelines Current Representations of Protocols

Free Text  
Flow-Charts  
Tables



# Medical Therapy Planning

## Clinical Protocols & Guidelines Current Representations of Protocols

Free Text  
Flow-Charts  
Tables

### Used for

Communication  
Quality Assessment

# 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."

Field, MJ & Lohr KN (eds.) Guidelines for clinical practice: from development to use. Institute of Medicine, Washington, D.C. National Academy Press, 1990.

## 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

## Definitions: Guidelines & Protocols

### 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]

## Definitions: Guidelines & Protocols

### 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

## Definitions: Guidelines & Protocols

### Standards

practice parameters in USA

Guideline <-> Standard <-> Protocol

# Guidelines & Tasks

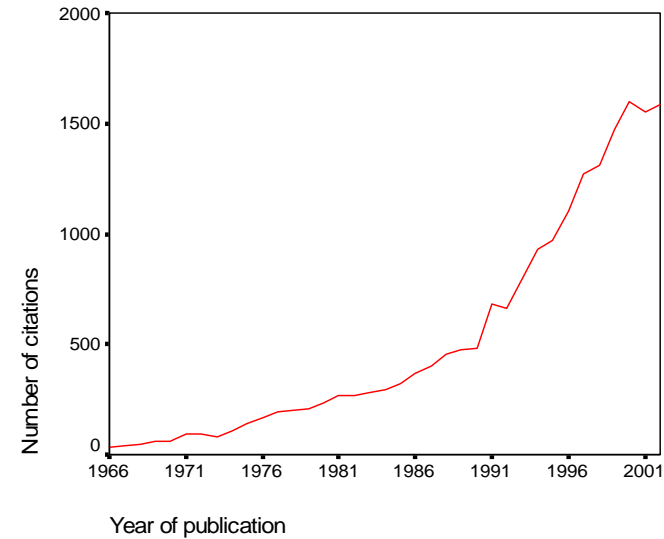
[Tu and Musen, 2000]

## 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)

S. W. Tu & M. A. Musen. *Representation Formalisms and Computational Methods for Modeling Guideline-Based Patient Care. First European Workshop on Computer-based Support for Clinical Guidelines and Protocols, Leipzig, Germany, 125-142. 2000.*

# Citations of 'Guideline(s)' in PubMed



# Approaches: Guideline Modeling

[Elkin, et al. 2000]

## Rule-Based Specification

HELP, Arden/MLM

## Augmented Decision Analysis

Logic and Decision Table Techniques

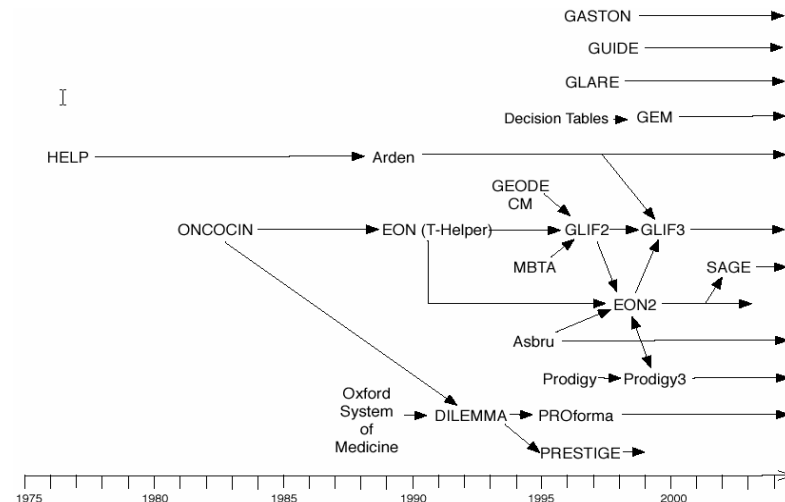
## Multi-steps Guidelines

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, Bernstam, Samson, Boxwala, Greenes, Shortliffe: *Toward Standardization of Electronic Guideline Representation*, MD Computing, 17(6), 2000, pp.39-44. |

# Between ...



Kitty Rosenbrand

## MEDICAL GUIDELINE- & COMPUTER SCIENCE world



"Nurse, get on the internet, go to SURGERY.COM, scroll down and click on the 'Are you totally lost?' icon."



SILVIA MIKSCH



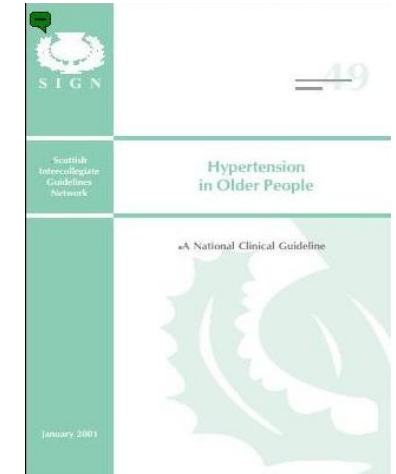
# State of the Art of Guidelines

## Guidelines:

Guidelines describe **best-practice** care for patients

**Extensive** documents:  
Designed for practitioners  
by practitioners

**Evidence based**



SILVIA MIKSCH



# Guideline: *Quality*



CONSENSUS

RESEARCH

EVIDENCE

# 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'*)

SILVIA MIKSCH



SILVIA MIKSCH



# 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

➤ Guidelines

# 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

## KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

The definitions of the types of evidence and the grading of recommendations used in this guideline originate from the US Agency for Health Care Policy and Research\* and are set out in the following tables.

### STATEMENTS OF EVIDENCE

- Ia** Evidence obtained from meta-analysis of randomised controlled trials.
- Ib** Evidence obtained from at least one randomised controlled trial.
- IIa** Evidence obtained from at least one well-designed controlled study without randomisation.
- IIb** Evidence obtained from at least one other type of well-designed quasi-experimental study.
- III** Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies.
- IV** 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.  
(Evidence levels Ia, Ib)
- B** Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.  
(Evidence levels IIa, IIb, III)
- C** Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality.  
(Evidence level IV)

### GOOD PRACTICE POINTS

- Recommended best practice based on the clinical experience of the guideline development group.

## Summary of recommendations

### DIAGNOSIS AND ASSESSMENT

- C** A full assessment of cardiovascular risk should be carried out for all hypertensive patients.
- C** Blood pressure measurement is critical to the management of hypertension. Validated equipment should be used and the recommendations of the British Hypertension Society on blood pressure measurement should be followed.
- C** The normal range for home blood pressure measurements and ambulatory blood pressure monitoring is lower than "normal" surgery or clinic values.
- C** Accelerated phase (malignant) hypertension requires urgent hospital admission for investigation and treatment.

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

- C** Both systolic and diastolic hypertension require treatment.
- C** Thresholds for antihypertensive therapy and targets for treatment should be set.
- C** Thresholds for antihypertensive therapy should take into account both the level of blood pressure and other risk factors.
- C** The decision to start treatment should be based on a structured assessment of cardiovascular risk.
- For risk assessment in primary prevention of cardiovascular disease, use the Joint British chart. Note that the charts are only valid for patients aged 32-74 and with no pre-existing atherosclerotic disease.
- For risk assessment in patients aged  $\geq 75$  or with pre-existing vascular disease, use the WHO tables. Although these patients will almost certainly require blood pressure therapy, other aspects of cardiovascular risk should be assessed and modified where possible.
- A** A target blood pressure of  $< 140/90$  mm Hg is recommended for older hypertensive patients.
- A** Even a small reduction in blood pressure is worthwhile if absolute targets prove difficult to achieve.
- C** Hypertensive patients with diabetes or with renal disease should be considered for specialist referral. Some patients may require further investigation and lower target blood pressures may be desirable.



## 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 in epidemiological studies both systolic and diastolic blood pressures are important risk factors for cardiovascular disease.<sup>20</sup> Treatment of systolic blood pressure<sup>21</sup> and diastolic blood pressure<sup>22</sup> have shown similar reductions in cardiovascular end points. There is evidence to suggest that it is the pulse pressure (difference between systolic and diastolic pressures) that may be the most important risk indicator in older hypertensive patients.<sup>23</sup>

Evidence levels  
Ia and Ib

**C** Both systolic and diastolic hypertension require treatment.

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

Extrapolated from  
evidence levels Ia and Ib

\* A threshold of 140/90 mm Hg means either  $\geq 140$  systolic  $\text{or} \geq 90$  diastolic. A target of  $< 140/90$  mm Hg means  $< 140$  systolic  $\text{and} < 90$  diastolic.

### 4.2 WHEN SHOULD WE START TREATMENT?

#### 4.2.1 MULTIFACTORIAL RISK ASSESSMENT

The relationship between blood pressure and adverse cardiovascular outcome is direct, log-linear and tends to be steeper for systolic than for diastolic blood pressure. There is no obvious "cut off" level of blood pressure at which treatment should be started and any such threshold is somewhat arbitrary. Decisions on starting treatment 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.<sup>1</sup> 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<sup>2,3</sup>. 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 <sup>1</sup>
A2	Vianden et al <sup>2</sup> , Swartz et al <sup>3</sup>

### 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.<sup>4</sup>

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

## Summary Statement of the Best Evidence

1	Meloxicam is as effective as piroxicam in treating patients with osteoarthritis.
A <sub>2</sub>	Linden 2002, Marshall 2002, Hovell 2001

## Trends

Kitty Rosenbrand

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

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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)

The screenshot shows the National Guideline Clearinghouse website. The header includes the logo and the URL [www.guideline.gov](http://www.guideline.gov). A navigation menu on the left lists: Search, Browse, Compare, and Resources. The main content area is divided into two sections: 'Browse' and 'Compare'. The 'Browse' section has links for Disease / Condition, Treatment / Intervention, Measures / Tools, Organization, Guideline Index, Guidelines In Progress, and Guideline Archive. The 'Compare' section has links for View My Collection and Guideline Syntheses. On the right, there is a 'Detailed Search' section with a search bar, a 'Clear Search' button, and a 'Keyword:' field. Below that, there are 'Sort results by:' options for Relevance and Publication Date. There are also input fields for 'Disease/Condition:', 'Treatment/Intervention:', 'Organization:', and 'Organization Type:'. The 'Guideline Category:' dropdown menu is open, showing options: (Not stated), Assessment of Therapeutic Effectiveness, Counseling, Diagnosis, Education, and Evaluation. The 'Organization Type:' dropdown menu is also open, showing options: (Not Stated), Academic Institution, Disease Specific Society, Federal Government Agency [U.S.], Hospital/Medical Center, and Independent Expert Panel.

Intended Users:

- (Not stated)
- Advanced Practice Nurses
- Allied Health Personnel
- Chiropractors
- Clinical Laboratory Personnel
- Dentists

Clinical Specialty:

- (Not stated)
- Allergy and Immunology
- Anesthesiology
- Cardiology
- Chiropractic
- Colon and Rectal Surgery

Methods Used to Assess the Quality and Strength of the Evidence:

- (Not stated)
- Expert Consensus
- Expert Consensus (Committee)
- Expert Consensus (Delphi Method)
- Subjective Review
- Weighting According to a Rating Scheme (Scheme Given)

Methods Used to Analyze the Evidence:

- (Not stated)
- Decision Analysis
- Meta-Analysis
- Meta-Analysis of Individual Patient Data
- Meta-Analysis of Observational Trials
- Meta-Analysis of Randomized Controlled Trials

Methods Used to Formulate the Recommendations:

- (Not stated)
- Balance Sheets
- Expert Consensus
- Expert Consensus (Consensus Development Conference)
- Expert Consensus (Delphi)
- Expert Consensus (Nominal Group Technique)

IOM Care Needs:

- (Unspecified)
- End of Life Care
- Getting Better
- Living with Illness
- Staying Healthy

IOM Domain:

- (Unspecified)
- Effectiveness
- Efficiency
- Patient-centeredness
- Safety
- Timeliness

Implementation Tools:

- (Not Stated)
- Audit Criteria/Indicators
- Chart Documentation/Checklists/Forms
- Clinical Algorithm
- Foreign Language Translations
- Patient Resources

Only include guidelines that have:

- Patient Resources

Only include guidelines that incorporate:

- A Formal Cost Analysis
- An Implementation Plan
- A Clinical Algorithm

Age of Target Population:

- (Not stated)
- Adolescent (13 to 18 years)
- Adult (19 to 44 years)
- Aged (65 to 79 years)
- Aged, 80 and over
- Child (2 to 12 years)

Sex of Target Population:

- (Not stated)

Publication Date:

- All Years
- 2007
- 2006
- 2005
- 2004
- 2003

Results per page:

- 20 Results

NGC Search Results

[Search Help](#) | [Guideline Comparison Help](#) | [Guideline Views](#) | [Quick Search Tips](#)

Your search criteria:

**Guideline Categories:** Treatment  
**Intended Users:** Physicians  
**Clinical Specialty:** Critical Care  
**Sort Order:** Relevance

Your search found 48 related guidelines, which are listed below by relevance. Use the "Limit Search" button to sort by publication date.

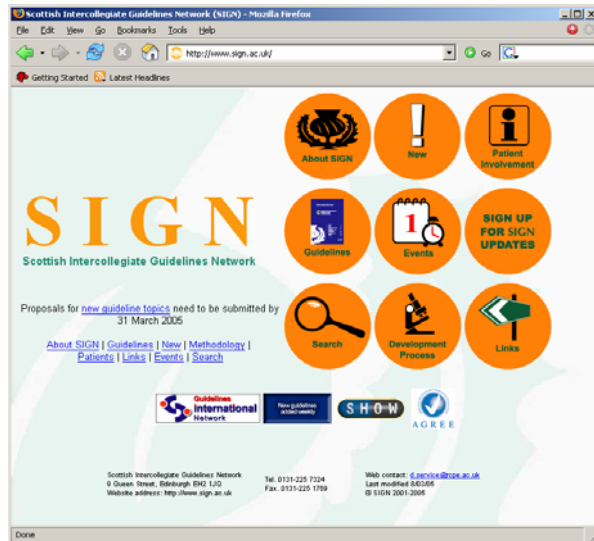
To view a guideline summary, click on a title below.

[Limit Search](#) [Select All](#) [Add to My Collection](#) [Next 20](#)

Items 1 to 20

Title
<input type="checkbox"/> <a href="#">Pressure ulcer prevention and treatment following spinal cord injury</a> . Consortium for Spinal Cord Medicine - Private Nonprofit Organization Paralyzed Veterans of America - Private Nonprofit Organization. 2000 Aug (reviewed 2005). 80 pages. NGC:001815 <a href="#">Other Guidelines from this Developer</a>
<input type="checkbox"/> <a href="#">Clinical practice guidelines for sustained neuromuscular blockade in the adult critically ill patient</a> . American College of Critical Care Medicine - Professional Association American Society of Health-System Pharmacists - Professional Association Society of Critical Care Medicine - Professional Association. 1995 (revised 2002). 15 pages. NGC:002396 <a href="#">Other Guidelines from this Developer</a>
<input type="checkbox"/> <a href="#">Clinical practice guidelines for the sustained use of sedatives and analgesics in the critically ill adult</a> . American College of Critical Care Medicine - Professional Association American Society of Health-System Pharmacists - Professional Association Society of Critical Care Medicine - Professional Association. 1995 (revised 2002). 23 pages. NGC:002397 <a href="#">Other Guidelines from this Developer</a>

# Scottish Intercollegiate Network (SIGN)



<http://www.sign.ac.uk>

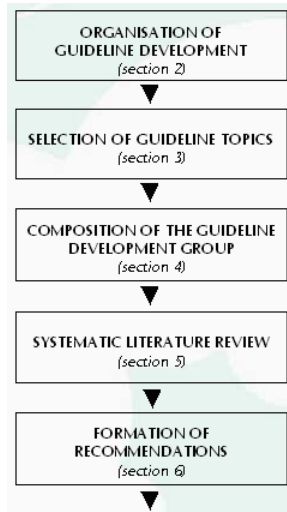
# Scottish Intercollegiate Network (SIGN)



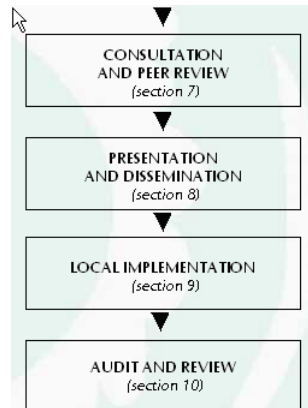
## Formed in 1993

## Aim

Development and Dissemination of National Clinical Guidelines Containing Recommendations for Effective Practice Based on Current Evidence



## Overview of the Sign Guideline Development Process



## Average Timescale for SIGN Guideline Development

Group composition	Systematic review and drafting recommendations	Consultation and peer review	Publication
— 6 months —	----- 12 months -----	----- 9 months -----	3 months
<b>Elapsed time (months)</b>	<b>0</b>	<b>12</b>	<b>21</b>
			<b>24</b>

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



The Guidelines International Network is formally constituted as a Scottish Guarantees Company under Company Number SC243691 and recognised as a Scottish Charity under Scottish Charity Number SC039292P with its registered office at 1, 4th, Mitchell W.C., 55 Abbot Road, Pilchery, Panmure PH16 5BY, Scotland.



## 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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