Development of Evidence-Based Medicine Clinical Practice Guidelines

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Clinical practice guidelines are the statements developed on the basis of a certain methodology and meant to assist a doctor and a patient to make a decision on the effective treatment in various clinical situations.

Why do we need Guidelines?

To transfer evidence into recommendations on best medical practices as the basis of quality improvement.

1. Biomedical Research
2. Clinical Trials
3. Outcomes and Effectiveness Research
4. Evidence Based Information
5. Clinical Practice Guidelines
6. Quality Measurement
7. Quality Assurance
8. Quality Improvement
Cycle of Clinical Therapeutics (New Model)

Clinical Trials

Guidelines

Concept

Outcomes

Education & Feedback

Quality Indicators

Performance Measures
He who corrects the ingrowing toe-nail receives a few shillings: he who cuts your inside out receives hundreds of guineas, except when he does it to a poor person for practice.

Scandalized voices murmur that these operations are unnecessary. They may be. It may also be necessary to hang a man or pull down a house. But we take good care not to make the hangman and the housebreaker the judges of that. If we did, no man's neck would be safe and no man's house stable. But we do make the doctor the judge, and fine him anything from sixpence to several hundred guineas if he decides in our favor.

Thus everything is on the side of the doctor. When men die of disease they are said to die from natural causes. When they recover (and they mostly do) the doctor gets the credit of curing them.

Shaw, George Bernard. The Doctor's Dilemma, preface. 1913
Evidence-based medicine

Clinical practice guidelines

- Individual patient
- Patient groups
-Politicians
- Health administrators
- Manufacturers of drugs and equipment
- Professional doctor associations
- Individual doctors
- Insurance companies
- Politicians
Directions on Development of Clinical Practice Guidelines: state of the art


- National Health and Medical Research Council. *A guide to the development, implementation and evaluation of clinical practice guidelines*. Canberra (Australia), 1999

International Documents on Development of Clinical Practice Guidelines


Main Objectives of the Clinical Practice Guidelines

- Implement the standards based on proven scientific data in the clinical practice
- Facilitate the decision-making process
- Provide the basis for evaluation of the level of professionalism and quality
- Improve the cost effectiveness of health expenditures
Main Functions of Clinical Practice Guidelines

- Critical overview of the current data
- Basis for the development of standards, indicators, and evaluation criteria
- Basis for the development of secondary documents (forms, lists of essential pharmaceuticals, etc.)
Negative Impact of the Clinical Practice Guidelines (actual and potential)

- Guidelines may reflect the opinions of biased experts at the expense of scientific data, and legalize the doubtful practices
- Risk of standardization of average rather than the most optimal approach
- May become the tool for legal dictatorship
- May hamper the innovations and discourage an individual approach to each patient
- Guidelines developed for the national level may ignore the local problems
- Guidelines developed for specialized care may not take the specific features of the primary health care into account
How do the Clinical Practice Guidelines Affect Health Practices?

- Analysis of 11 randomized clinical trials on implementation of clinical practice guidelines, involving 1,848 doctors (Freemantle et al. The Cochrane Library, Issue 4, 2000)
  - Implementation effects are minimal and statistically insignificant with substantive fluctuations (from -16% to +176%)

  - Clinical outcomes improved in 5 out of 13 trials (38%)
  - Outcomes improved in 4 out of 9 cases of local clinical practice guidelines and in 1 out of 4 cases of implementation of the national clinical practice guidelines
Characteristics of 431 Clinical Practice Guidelines Developed by Various Professional Medical Associations

- The specialists who developed them are mentioned along with the audience the guidelines are meant for in 33% of them
- Information search strategy is described in 12% of guidelines
- The extent to which each guideline is based on evidence is identified in 18% of them
- All above is mentioned in 5% of the guidelines

Methodology Standards for Clinical Practice Guidelines Development: What for?

Each methodology principle is aimed at the elimination of possible sources of constant bias (removal of a preconceived opinion)

• Bias caused by the selection of the data:
  • obsolete,
  • incomplete
  • selectively chosen

• Bias caused by the developers’ qualities

• Bias caused by the values and preferences
  • values underlying the guidelines are frequently implicit (but always present even if they are less obvious)
Evidence-based clinical practice guidelines is a document where the association between each statement and scientific data is detailed, clear and unambiguous and the scientific information prevails over the experts’ opinions.
What does evidence-based medicine approach mean when applied to the development of clinical practice guidelines?

- Use of proven sources and advanced technologies for the information search
- Systematic and regular overviews are the basis for the development of clinical practice guidelines
- Use of clinical epidemiology principles as the methodology basis for the quality assessment of clinical trials
Questionnaire on Appraisal and Certification of Guidelines

The questionnaire was translated and customized for the use in the Russian language by Evidence Clinical and Pharmaceutical Research at the request of Of the Russian Department of the Northern Europe Center of Cochrane Cooperation
AGREE: Quantitative Characterization of 100 Clinical Practice Guidelines from 11 Countries

1. **The area and objectives of application** (items 1—3). Description of a major goal, typical clinical issues and patient populations where the guidelines would apply. 69.3; SD = 21.3

2. **Stakeholder participation** (items 4—7). Assessment of compliance of these guidelines with the views of the people they are meant for. 36.1; SD = 18.9

3. **Stringency of development methods** (items 8—14). Assessment of a process used to accumulate and summarize the evidence; methods used for the development of clinical practice guidelines and methods to be used for their update. 40.7; SD = 25.0

4. **Intelligible description and the form of presentation** (items 15—18). Assessment of a description and a form of presentation of the guidelines. 65.8; SD = 14.1

5. **Applicability** (items 19—21). Assessment of organizational, behavioral and financial aspects related to the implementation of the clinical practice guidelines. 36.9; SD = 23.2

6. **Independence of the authors** (items 22—23). Independence of the authors of the guidelines and information on the potential conflict of interests. 30.3; SD = 22.4
Number of Members as of April 2003:

42 organizations from 23 countries from all continents
GIN Activities

- Exchange of information, transfer of knowledge, and cooperation
- Improvement and harmonization of development methodology of clinical practice guidelines, their dissemination, implementation and evaluation
- Support of research in this area
- Coordination with other international initiatives in improvement of quality of health care
- Creation of a single international registry (database) of clinical practice guidelines already developed and to be developed, to avoid a duplication of efforts
- Creation of a resource library on tools for development of clinical practice guidelines and training methodologies
- Integration of evaluations of medical technologies and clinical practice guidelines
- Public involvement in the work on clinical practice guidelines
- The world-wide coordination of clinical practice guidelines development and availability
The Central Scientific and Research Institute on Health Administration and Information Support Systems

Inter-Regional Society of Evidence-Based Medicine Experts

Training and Methodology Manual on Development of Clinical Practice Guidelines

Moscow, December 2003
Clinical Practice Guidelines Development Principles

2 Working Group
2.1 Stakeholder participation
2.2 Conflict of interest declaration
2.3 Roles and responsibilities of the participants
2.4 Patient involvement

3 Evaluation of Evidence
3.1 Identification of key problems and issues
3.2 Search and evaluation of existing guidelines
3.3 Additional unresolved issues
3.4 Systematic overview of evidence
3.5 Critical review of evidence
3.6 Evidence summary

4 Formulation of guidelines
4.1 Summarized statement
4.2 Resource support
4.3 Evidence level scale
4.4 Methods for achieving consensus

5 Discussion and appraisal
5.1 Discussion
5.2 Appraisal

6 Publishing and dissemination

7 Implementation
7.1 Implementation strategy
7.2 Clinical and organizational algorithms

8 Monitoring, evaluation and auditing
8.1 Quality indicators for auditing
8.2 Update of guidelines
Determine the purposes of guidelines and key clinical issues

Find and evaluate existing guidelines

Decide what issues need further adaptation and update

Systematic overview

Critical assessment of scientific data

Summarize results and update the evidence table

Formulate recommendations

Patients
Intervention
Comparison
Outcome

www.guideline.gov
www.osdm.org
www.guidelines-international.net
опросник AGREE

Existing guideline:
High quality? Up-to-date?
Applicable to local conditions?

Detailed search strategy
Information selection criteria
Methodological evaluation
Evidence scale

Use a formalized questionnaire for each type of research

Design, sample size, and quality
Interventions compared
Evaluation criteria (outcomes)
Effect level
Different scenarios depending on the characteristics of available guidelines and systematic overviews

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Available guidelines</th>
<th>Options for Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality</td>
<td>Novelty</td>
</tr>
<tr>
<td>1</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
<td>+</td>
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<tr>
<td>3</td>
<td>+</td>
<td>-</td>
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<tr>
<td>4</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>?</td>
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</tbody>
</table>
### QUALITY REVIEW SCALE USING THE STRUCTURED QUESTIONNAIRES

<table>
<thead>
<tr>
<th>QUALITY LEVEL</th>
<th>Criteria Compliance Level:</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>All or majority of the criteria from the questionnaire are met. Even if some criteria are not met they are not likely to change the results of the trial (research).</td>
</tr>
<tr>
<td>+</td>
<td>Some of the criteria from the questionnaire are met. If some criteria are not met, they are unlikely to change the results of the trial.</td>
</tr>
<tr>
<td>− (minus)</td>
<td>Majority of the criteria from the questionnaire are not met. It is very likely that the failure to meet these criteria may change the results of the trial.</td>
</tr>
</tbody>
</table>
Factors Determining the Evidence Basis of the Guideline

- Type (Design of a trial (more often the optimal design – randomized clinical trial))
- Number of trials and the number of patients covered (often a meta-analysis is required)
- Heterogeneity of results (outcomes) (optimal when all results are unidirectional)
- Clinical significance of effect and its variations (optimal when a confidence interval is narrow)

- Applicability (transferability, summarability) of trial results to the population in question
# Evidence Basis Scale

| A | • High quality meta-analysis, systematic overview of a randomized clinical trial or a major randomized clinical trial with a **very low probability** (++) of a constant bias, where the results may be propagated to the relevant Russian population. |
| B | • High-quality (++) systematic overview of cohort or case control trials with **very low probability** (++) of a constant bias, or  
• Randomized clinical trials with a **low** (+) risk of a constant bias, where the results may be propagated to the relevant Russian population. |
| C | • Cohort or case control trial or controlled trial without randomization with a **low risk of a constant bias** (+) where the results may be propagated to the relevant Russian population, or  
• Randomized clinical trial with a **very low or low risk of a constant bias** (++) or (+), where the results **may not be** directly propagated to the relevant Russian population. |
| D | • Descriptions of a series of cases, or  
• Uncontrolled trial  
• Experts’ opinion |
<table>
<thead>
<tr>
<th><strong>Индексор качества помощи (intervention quality indicator)</strong></th>
<th><strong>Критерий оценки (review criterion)</strong></th>
<th><strong>Стандарт (standard)</strong></th>
<th><strong>Установленный стандарт (target standard)</strong></th>
<th><strong>Definition</strong></th>
<th><strong>Example</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>An element of a medical intervention overview measured in retrospect, known to change in relation to the quality of the intervention as proven by evidence or supported by the qualified opinion.</td>
<td>Statements regarding the application of an individual element of a medical intervention. The review criteria are clearly worded and registered in the medical documentation.</td>
<td>The level of compliance with indicator or review criterion.</td>
<td>It sets up a quality level advised for achievement.</td>
<td>Patients with blood pressure &gt;160/90 mm Hg should have it retaken within 3 months</td>
<td>If a patient’s blood pressure was registered as &gt;160/90 mm Hg, had it been remeasured within 3 months?</td>
</tr>
</tbody>
</table>
Main Features of Medical Intervention Quality Indicators

- **How important is the indicator?**
  - Significant for the stakeholders
  - It measures the aspect important for health status
  - The subgroups may be analyzed to determine whether the health care is equally accessible
  - There are reasons to expect improvements
  - Results of changes may form the reasons for changes in the system

- **Scientific basis**
  - There is reliable evidence to confirm the relation of the indicator to the quality of health care
  - Reproducibility of the indicator is demonstrated
  - Reliability – the proof that the indicator is measuring what it is supposed to measure
  - Ability to analyze and standardize using the varying source characteristics
  - Easy interpretation – an indicator shall be self-explanatory

- **Technical features**
  - Detailed description of a nominator, denominator and the source of data
  - Availability and accessibility of the data, reasonable costs of obtaining the data
## Sources and Data Bases of Clinical Practice Indicators

<table>
<thead>
<tr>
<th>Name of a Source</th>
<th>Developer with an Internet address</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Library of Quality Indicators and ORYX Programme</td>
<td>Joint Commission on Accreditation of Healthcare Organizations (<a href="http://www.jcaho.org">www.jcaho.org</a>)</td>
</tr>
<tr>
<td>Health Plan Employer Data and Information Set (HEDIS®)</td>
<td>National Commission for Quality Assurance (<a href="http://www.ncqa.org">www.ncqa.org</a>)</td>
</tr>
<tr>
<td>FACCT Quality Measures</td>
<td>Foundation for Accountability (<a href="http://www.facct.org">www.facct.org</a>)</td>
</tr>
<tr>
<td>Quality Indicator Project®</td>
<td>Association of Maryland Hospitals &amp; Health Systems (<a href="http://www.qiproject.org">www.qiproject.org</a>)</td>
</tr>
<tr>
<td>NHS Performance Indicators</td>
<td>National Health Service Executive (<a href="http://www.doh.gov.uk">www.doh.gov.uk</a>)</td>
</tr>
<tr>
<td>Clearing House Databases</td>
<td>UK Clearinghouse on Health Outcomes (<a href="http://www.leeds.ac.uk/nuffield/infoservices/UKCH/home.html">www.leeds.ac.uk/nuffield/infoservices/UKCH/home.html</a>)</td>
</tr>
<tr>
<td>Züercher Indikatoren-Set</td>
<td>Verein Outcome Züerich (<a href="http://www.vereinoutcome.ch">www.vereinoutcome.ch</a>)</td>
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Информация для пользователей и разработчиков клинических практических рекомендаций

Клинические практические рекомендации (clinical practice guidelines) - утверждения, разработанные с помощью определенной методологии и призванные помочь врачу и больному принять решение о рациональной помощи в различных клинических ситуациях.

**Подробнее...**

<table>
<thead>
<tr>
<th>НОВОСТИ</th>
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<tbody>
<tr>
<td>1 Базы данных клинических рекомендаций</td>
</tr>
<tr>
<td>2 Подготовка клинических рекомендаций</td>
</tr>
<tr>
<td>3 Оценка качества клинических рекомендаций</td>
</tr>
<tr>
<td>4 Библиотека публикаций, посвященных клиническим рекомендациям</td>
</tr>
<tr>
<td>5 Программа стандартизации МЗ РФ</td>
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