

DEVELOPMENT OF GUIDELINES IN REHABILITATION MEDICINE IN THE NETHERLANDS

RAZVOJ SMERNIC ZA REHABILITACIJSKO MEDICINO NA NIZOZEMSKEM

J. D. Martina, MD

President of the Dutch Society of Physical and Rehabilitation Medicine

Medisch Spectrum Twente Hospital, Enschede

Rehabilitation Centre Het Roessingh, Enschede

Summary

Clinical guidelines are systematically developed statements with recommendations to support care givers and takers, aiming to improve the quality of care, based on scientific research and supplemented with experiences from professionals and care customers. Their impact concerns not only the process of production but also the process of dissemination. Creating support during the phase of development and making a plan for implementation is crucial. The Dutch Society of Physical and Rehabilitation Medicine issued in 2013 a handbook that describes the process of guideline development in rehabilitation, as well as the methodological requirements and implementation issues. Guidelines are part of the professional standard and therefore have legal significance: the professional must follow the guidelines in clinical practice and may deviate from the recommendations only with motivated and valid arguments. The methodology that is applied to the guideline development process needs to meet rigorous scientific criteria and must comply with the latest evidence-based requirements. However, during the development process it might appear that robust evidence for certain topics is not available. When this is the case, consensus development among experts can be an alternative method to produce clinical recommendations.

This paper describes the process of Rehabilitation guideline development and implementation in the Netherlands.

Povzetek

Klinične smernice so sistematično razvite izjave s priporočili, namenjene podpori izvajalcem in prejemnikom oskrbe s ciljem izboljšati kakovost oskrbe, ki temeljijo na znanstvenem raziskovanju in jih dopolnjujejo izkušnje strokovnjakov in prejemnikov oskrbe. Vpliv smernic ni povezan le s postopkom njihove izdelave, pač pa tudi njihovega razširjanja. Bistveno je zagotoviti podporo v fazi razvoja in izdelati načrt za uvajanje. Nizozemsko združenje za fizikalno in rehabilitacijsko medicino je leta 2013 izdalo priročnik, ki opisuje postopek razvoja smernic na področju rehabilitacije, metodološke zahteve in vprašanja uvedbe. Smernice so del poklicnih standardov in imajo torej pravni pomen: strokovnjak se mora v klinični praksi držati smernic in lahko od priporočil odstopa le z utemeljenimi in veljavnimi razlogi. Metodologija postopka razvoja smernic mora ustrezati strogim znanstvenim merilom in mora biti v skladu z najnovejšimi zahtevami, podprtimi z dokazi. Toda v postopku razvoja smernic se lahko izkaže, da trdnih dokazov za določena področja ni na voljo. V tem primeru je možno izdelati klinična priporočila na podlagi oblikovanja soglasja med strokovnjaki.

Prispevek opisuje postopek razvoja in uvedbe smernic za področje rehabilitacije na Nizozemskem.

INTRODUCTION

Clinical practice guidelines are systematically developed statements to assist practitioner and patient in making

decisions about appropriate health care for specific clinical circumstances.¹ In addition, guidelines can play an important role in health policy formation^{2,3} and have evolved to cover topics across the health care continuum (e.g., health promotion, screening, diagnosis).

E-naslov za dopisovanje/E-mail for correspondence (JDM):

J.Martina@mst.nl

For the development of medical rehabilitation guidelines it is important to determine which role the scientific society should play and to give an answer to the following questions:

- How does a guideline come into being?
- In which way are the members of the scientific society involved?
- What does a guideline mean to the individual member?
- How can the use of guidelines be stimulated?

The impact of guidelines can be assessed in terms of their influence on practice or whether they affect patient's outcome. It is important to recognize that their impact concerns not only the process of production but also the process of dissemination. Creating support during the guideline development process and making a plan for implementation demand particular attention. In this regard the Society's special interest groups play a crucial role in the cooperation with other scientific societies when there are common interests. The Guidelines Committee of the Dutch Society of Physical and Rehabilitation Medicine (VRA) issued in 2013 a handbook that describes the process of guideline development, the methodological requirements and implementation issues.⁴ This handbook follows the requirements established by the National Society of Medical specialists (OMS) in 2011 and the rapport from the Council for the Quality of Care "Guideline for Guidelines" (2011). The handbook shall periodically be revisited according to new insights and developments on the field of guideline development and implementation.

The potential benefits of guidelines are only as good as the quality of the guidelines themselves. Appropriate methodologies and rigorous strategies in the guideline development process are important for the successful implementation of the resulting recommendations.^{5,6,7} The quality of guidelines can be extremely variable and some often fall short of basic standards.^{8,9,10} Therefore, the VRA determined that the criteria as formulated in the *Appraisal of Guidelines for REsearch & Evaluation (AGREE) Instrument* must be used for the evaluation of the quality of the rehabilitation guidelines. AGREE was developed to address the issue of variability in guideline quality. To that end, the AGREE instrument is a tool that assesses the methodological rigour and transparency in which a guideline is developed.^{11,12} The purpose of the AGREE, is to provide a framework to:

1. assess the quality of guidelines;
2. provide a methodological strategy for the development of guidelines; and
3. inform what information and how information ought to be reported in guidelines.

VRA'S GUIDELINES COMMITTEE⁴

Task description

The Board of Directors of the VRA appointed in 2001 a dedicated committee for the development and actualisation

of rehabilitation guidelines. This committee holds twice a year in a plenary meeting and has the following tasks:

- To monitor the procedures and the timeline of the guideline development.
- To keep track of an overview of guidelines initiated and owned by VRA and guidelines to which VRA as invited participant has contributed to their development.
- To advise the Board of Directors and other relevant committees and working groups within the VRA on the development of new guidelines and necessary activities to promote the implementation of guidelines in clinical practice.
- To advise the Executive Board of Directors on updating guidelines (older than five years) and to maintain contact with the person from the working group that has received mandate to represent the society in the original development process.
- To advise the Board of Directors on topics within the realm of rehabilitation medicine for which a guideline is needed.
- To maintain an up-dated guidelines handbook.

DEFINITIONS

Besides guidelines there are other quality instruments such as protocols, clinical pathways, standards for care, algorithms and indicators which are important for the rehabilitation field. This paper deals only with the concept of guidelines.

Guidelines

'A clinical guideline is a document with recommendations to support care givers and takers, aiming to improve the quality of care, based on scientific research and supplemented with experiences from professionals and care customers.' This formulation is called the Brummen-definition and is cited in the "Guideline for guidelines" from the Council for the Quality of Care in The Netherlands.¹³

The primary goal of guideline development is the improvement of the quality of care by supporting the clinician and the consumer in the decision making process. At the same time guidelines contribute to reduce the diversity and the differences of therapeutic approaches and help making diagnostic and treatment activities more transparent.

Guidelines are part of the professional standard, contain normative statements and have therefore legal significance. The professional must apply the guideline in his or her medical practice. Since the recommendations given in guidelines are particularly directed towards the "average patient", and daily practice can be more complex than indicated in the guideline, the professionals may, in individual cases deviate from these recommendations. However, this

must be properly motivated with valid arguments in the medical records.

GUIDELINE DEVELOPMENT⁴

The development of a clinical guideline takes an average of two years. This paragraph gives an overview of the different phases of the guideline development process, based on the rapport “Medical specialists guidelines” 2.0 (2011) published by the Dutch Association of Medical Specialists and the rapport “Guideline for Guidelines” (2011) issued by the Council for the Quality of Care.¹³ Furthermore, adaptations of foreign or international guidelines and maintenance and review of existing guidelines are discussed.

Preparation phase (4 months)

The preparation phase starts from the moment that the need for the development of a guideline is brought upon. In this phase the topic is defined, the chairman is appointed and the organisations that should be involved are identified. The preparation phase lasts until the composition of the working group or panel of experts that is going to produce the guideline has been determined.

Development phase (14 months)

The development phase starts from the moment that the panel of experts has been formally appointed by the executive board of the scientific society. This phase also involves a thorough analysis of evidence gaps and clinical bottlenecks, with involvement of a broad group of experts of different disciplines and patients organisations through an invitational conference, the kick-off meeting. During the development phase it is important to permanently have focus on future implementation (possible stimulating or obstructive factors). A crucial step in this phase is a sharp definition of the subject area. The topic for guideline development will usually need to be refined before the evidence can be assessed in order to answer exact questions. The usual way of refining the topic is by a dialogue among clinicians, patients, and the potential users or evaluators of the guideline. Discussions about the scope of the guideline will also take place within the guidelines development panel. If the topic is not refined, the clinical condition or question may be too broad in scope. For example, a guideline on Spasticity could cover a wide range of underlying conditions, such a stroke, traumatic brain injury, multiple sclerosis, cerebral palsy, spinal cord injury, etc. It could also cover primary, secondary and tertiary care elements of management, such a screening, diagnosis, drug therapy risk factor management or indications for referral to a consultant. Though all these could legitimately be dealt with in a guideline, the task of developing such a guideline would be considerable and eventually unmanageable. There-

fore the group has to be clear which areas are and are not within the scope of their activities. It is possible to develop guidelines that are broad in scope and evidence based, but to do so usually requires considerable time and money, both of which are frequently underestimated by inexperienced developers of evidence based clinical practice guidelines. The development phase ends when the working group has completed a draft of the guideline.

Completion phase (6 months)

This phase begins after the delivery of the first guideline draft. It starts with the comment phase wherein the input from external parties (for example other scientific societies, patients organisations, etc.) is encouraged and it ends with a definitive guideline that is authorized by the participating organisations, accompanied by an implementation plan.

ADAPTATION OF GUIDELINES

When the evidence-based methodology for the development of a foreign guideline has been strictly applied, this guideline can serve as input for the production of a Dutch guideline. The quality of the guideline must be assessed in advance according to the AGREE-instrument.^{4,11,12} The literature can be adopted only if it is sure that there has been a thorough systematic search and it can be supplemented with the results of an up-dated search. In this way existing guidelines can be utilized and adapted to the local situation. This makes possible that Dutch organisations can be able to apply scientific insights in clinical practice in a faster and more efficient way, preventing double work.

A good method for adaptation of guidelines is ADAPTE, developed by the ADAPTE Collaboration, which is available via www.adapte.org.

MAINTENANCE AND REVIEW OF GUIDELINES

All guidelines must be kept up-to-date in order to inform the professionals about the current situation and new recommendations. The development of guidelines imposes therefore a commitment for periodical actualisation. It is usual to indicate in the guideline a term for its up-dating. The scientific societies are the owners of the guidelines and only they are entitled to decide when a guideline must be reviewed, in alignment with other parties for the multidisciplinary topics.

In order to keep the guidelines as much up-to-date as possible, it is allowed to review and adapt parts of the guideline. An on-line database is very useful for this purpose. The structure of an on-line database offers the possibility to update clinical questions one by one.

The operational administration for the maintenance of the guideline can be conveyed to one of the special interest groups of the society.⁴

IMPLEMENTATION OF GUIDELINES

Implementation is the process-based and planned introduction of innovations or changes of proven value in order to assure that these changes get a proper place in the professional conduct and acts, in the functioning of organisations or in the structure of healthcare.¹⁴ Attention for the implementation of guidelines lags behind compared to the attention that is paid to the development process. There is a great deal of activities on the field of guideline development and quality, but its application in practice is insufficient.

Requirements for guidelines of good quality are formulated by AGREE. The objective and the delimiting (especially the clinical question and the patient population) of the guideline must be clear, the development method of the guideline must be valid and the recommendations must be concretely formulated. Furthermore, the guideline must be easy to use in the daily clinical practice of the professional and the independence of the developers must be transparent. Besides, it is important to prevent that the guideline is seen as a "new set of rules" that is imposed to the professionals. The strength of guidelines needs to be emphasized: the objective of a guideline is to support the professional in the decision making process for his patients.

Dissemination is part of the implementation process of guidelines. It implies the distribution of the guidelines among all those involved in the topic. Placing a guideline or an adaptation on a website is not enough. Here there is a task for the scientific society: the society can present the guidelines during its conferences and publish them in newsletters and in the scientific journal. When guidelines are up-dated the changes should be particularly emphasized for the implementation

Good organisation of care

During the guideline development an estimate can be made of possible obstacles that can affect the implementation in the healthcare system. Based on this estimate, professionals can initiate discussions with hospital managers and other parties in order to find solutions for the realisation. Hospitals contribute a great deal to the implementation success. Early identification of possible organisational and financial consequences and sharing these with decision makers is important to gain adhesion and facilitate cooperation. The collaboration between the different specialisms on the workplace is crucial for the realisation of changes within the organisation. In order for the implementation to be successful, the jointly developed guideline must also jointly be implemented. The hospital management can play an active role in the imple-

mentation of guidelines and should at least facilitate the process both with human and material resources.

Alignment with third parties

Beside the specialists there are also other parties that can play an important role at the implementation of guidelines. These are for instance the patient organisations or the care insurers.

Distinction can be made between guidelines that are initiated and developed by the Dutch Society of PRM and those initiated by other scientific societies. There are different applicable procedures for VRA guidelines and non-VRA guidelines.

Topics in the realms of rehabilitation expertise qualify for a national guideline under ownership of the VRA. VRA is then (financially) responsible for the development of the guideline. Financing of medical specialist guidelines in The Netherlands can be obtained from a subsidy granted by the Quality Fund Medical Specialists (SKMS).

VRA can also be requested to participate in the development of national guidelines initiated by another scientific society that has the ownership of the guideline. A VRA member gets mandate from the VRA Executive Board to participate in the expert panel that is in charge of the development of the guideline.

All guidelines go through a comments phase in which the guideline draft is presented for comments to the scientific societies involved. After the comments are processed by the working group, the definitive version of the guideline is then submitted to the participating scientific societies for approval and authorisation.

An important task of the society's Guidelines Committee is to monitor the implementation and give advice regarding eventual problems.

DEVELOPMENT OF GUIDELINES THAT ARE OWNED BY VRA

Topics for which a guideline seems to be necessary usually arise from the working field. These topics are submitted to the Executive Board for approval. In the case that the Board gives its approval, a request for subsidy grant may be submitted to the Quality Fund Medical Specialists (SKMS). When the financing is assured, the development process can be started. Competent and expert members of the society are then approached to participate in the working group. Likewise, other relevant scientific societies are requested to appoint representatives to participate in the multidisciplinary guideline development.

The definitive guidelines of which VRA is the owner, must be submitted for authorisation to the General Assembly of the Society. After authorisation, the VRA office brings the guideline under the attention of the society members by means of publications in the Newsletter en the website. The working group prepares a summary of the recommendations which then is published in the Dutch Journal of Rehabilitation Medicine (NTR). The working group makes an implementation plan and formulates indicators for monitoring and assessment of the use of the guidelines in clinical practice. The results of the implementation are systematically evaluated during all quality audits held by the Quality Committee of the society.

FINAL REMARKS

The methodology that is applied to the guideline development process needs to meet rigorous scientific criteria and must comply with the latest evidence-based requirements. There are several methods to appraise the scientific evidence. An example of a widely used appraisal system is presented in tables 1 and 2.^{15,16} However, during the development process it might appear that robust evidence for certain topics is not available. When this is the case, consensus development among experts can be an alternative method to produce recommendations. Three main

approaches have been used in the health field: the Delphi method, the nominal group technique (NGT) and the consensus development conference. Altogether it is essential to be clear about what the purpose of consensus development is and what it is not. It is a process for making policy decisions, not a scientific method for creating new knowledge. At its best, consensus development merely makes the best use of available information, be that scientific data or the collective wisdom of the participants.¹⁷ This information may be processed in the recommendations of the guidelines, making clear that it derives from consensus statements and not from evidence-based findings. Sometimes this can be the only way of generating valuable information that professionals can use when making decisions for the treatment of their patients.

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Table 1⁽¹⁵⁾

LEVEL OF EVIDENCE	
Rating of Study Design	Type of Study
I	Systematic Review and or meta analysis (where statistical techniques are used to pool the results of included studies)
IIa	Randomized Controlled Trial (with definitive results that do not overlap the threshold clinically significant effect)
IIb	Randomized Controlled Trial (with non definitive results i.e. a point estimated that suggests a clinically effective effect with confidence intervals that overlap the threshold clinically significant effect)
III	Cohort Studies (Two or more groups are selected on the basis of differences in their exposure to a particular agent and followed up to see how many in each group developed a particular disease or other outcome)
IV	Case Control Studies (Patients with a particular disease or condition are identified and matched with controls, like cohort studies case control studies are generally concerned with the etiology of a disease)
V	Cross Sectional Survey (Data are collected at a single time point but may refer retrospectively to health experiences in the past)
VI	Case Reports
VII	Expert Opinion

Table 2⁽¹⁶⁾

GRADE OF RECOMMENDATION	
A	Directly based on Category I or IIa evidence, at least one meta analysis.
B	Directly based on Category IIb, III or IV or extrapolated from Category I or IIa evidence.
C	Directly based on Category V or VI evidence or extrapolated from Category I, II, III or IV.
*	Good practice point, recommended best practice based upon clinical experience of the guideline development group.

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