

**EUROPEAN REGION OF THE
WORLD CONFEDERATION
FOR PHYSICAL THERAPY**



Framework for Clinical Guideline Development in Physiotherapy

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Summary

This document describes a framework for the development of clinical practice guidelines within the European Region of WCPT. The framework has been developed in a collaboration of The Chartered Society for Physiotherapy (CSP) and the Royal Dutch Society for Physical Therapy (KNGF). The methods for guideline development of CSP and KNGF have been used as well as several other international guideline programmes.

Guidelines are systematically developed statements designed to help practitioners and patients to make decisions about appropriate health care for specific conditions. Guidelines contribute to the development of the profession of Physiotherapy: to reduce differences in Physiotherapy treatment and enhance uniformity in the profession; to show the tasks and responsibilities of the profession; and to stimulate collaboration with other health care professions.

This framework for clinical guideline development is written to create a common basis for the development of guidelines in Physiotherapy. This framework aims to assist Member Organizations of the European Region of WCPT for several purposes:

- To assist Member Organizations who may be considering, or already involved in, the development of a clinical guideline.
- To set out the methodology for clinical guideline development as a standard for Guideline Development Groups (GDG)s in the European Region of WCPT.
- To assist Member Organizations in their understanding of clinical guidelines and their development.

The development of clinical guidelines in this framework is divided into six main areas: (1) Organization and structure of guideline development; (2) Preparation; (3) Guideline Development; (4) Validation; (5) Dissemination and Implementation and (6) Evaluation and Revision. In each phase we describe the steps to take, based on current insights. The AGREE instrument is used as reference for describing the development process.

1. Introduction

This framework for clinical guideline¹ development is written to create a common basis for the development of guidelines in Physiotherapy². In the European Region of WCPT several countries have a history of guideline development in Physiotherapy (e.g. UK, Netherlands), while other countries are considering starting, or have recently started, a Guideline programme (e.g. Denmark, Norway). This framework aims to assist Member Organizations of the European Region of WCPT for several purposes:

- To assist Member Organizations who may be considering, or already involved in, the development of a clinical guideline.
- To set out the methodology for clinical guideline development as a standard for Guideline Development Groups (GDG)s in the European Region of WCPT.
- To assist Member Organizations in their understanding of clinical guidelines and their development.

This document is not meant as a complete handbook for guideline developers. More detailed (English based) handbooks are listed in the references. This framework provides a broad outline for guideline development that can be developed in more detail by Member Organizations if they want to start a guideline programme.

Background

Guideline development shows a dramatic increase during the last 10 years. Worldwide in Health Care several multidisciplinary programmes exist. One of the results of increasing the body of knowledge in guideline development internationally, is the opportunity it brings for collaboration to improve the quality of clinical practice guidelines. This resulted in the foundation of the AGREE collaboration (Appraisal of Guidelines, Research and Evaluation), who published an instrument to appraise the quality of clinical practice guidelines (1).

In Physiotherapy guideline development is also becoming more prominent. In order to avoid discrepancies between guidelines, to enhance collaboration in guideline development and to increase cohesion in international guideline development in Physiotherapy, a common framework for guideline development may assist in achieving these goals.

This framework is based on the Guideline Development Protocol of the Royal Dutch Society for Physical Therapy (2) and the Guidance for Developing Clinical Guidelines document of the Chartered Society for Physiotherapy (3). Several international protocols and handbooks are used as reference (4 - 8).

¹ The words guidelines, clinical guidelines and clinical practice guidelines are used as synonymously throughout this document.

² The words Physical Therapist and Physiotherapist are interchangeable. In this document we use Physiotherapist.

What are Clinical Guidelines?

Field and Lohr (9) provided a widely accepted definition of clinical guidelines: "Guidelines are systematically developed statements designed to help practitioners and patients to make decisions about appropriate health care for specific circumstances."

The key characteristics of Clinical Guidelines are that they:

- Present a clear picture of the 'best available evidence of effectiveness' for a particular condition or set of clinical circumstances.
- Provide recommendations about the most effective interventions in particular circumstances, derived from considering the 'best available evidence of effectiveness' in the context of clinical practice.
- Provide a resource for decision making for health care professionals and for patients about the most effective care for specific patient populations in particular clinical circumstances.
- Are developed in a rigorous and systematic way in order to minimize bias and maximize the validity of their recommendations.

Guidelines contribute to the development of the profession of Physiotherapy: to reduce variations in Physiotherapy treatment and enhance consistency across the profession; to show the tasks and responsibilities of the profession; and to stimulate collaboration with other professions.

The principal benefit of guidelines is to improve the quality of care received by patients. Woolf et al (10) describe the potential benefits, limitations and harms of clinical guidelines. They state that the greatest benefit of guidelines is to improve health outcomes. Another aspect is to inform the patient about the care he may expect, especially if guidelines are accompanied by consumer versions.

Woolf also warns of the danger of unbridled enthusiasm for guidelines and the unrealistic expectations about what they will accomplish. Scientific evidence about what to recommend is often lacking or misinterpreted. Therefore recommendations that do not take due account of the evidence can result in sub-optimal, ineffective or harmful practices.

Topic of guidelines

The topic of a guideline will concern a health care problem of patients in relation to their daily functioning. To describe the functioning of patients we use the International Classification of Functioning, Disability and Health (ICF) (11). The topic should be related to a well-defined disease, condition or set of clinical circumstances.

Not a recipe or cookbook

Clinical guidelines are not recipes for practice that must be followed in all circumstances, nor do they negate the need for Physiotherapists to use their clinical reasoning skills or discuss choices with patients. However, where a guideline recommendation is based on strong evidence of effectiveness, there would need to be an explicit reason for not implementing it for a particular patient, such as other complicating conditions or patient preferences and this should be documented.

2. Framework of Guideline Development

In this framework we distinguish six main areas (table 1) based on the structure by Shekelle (12) and on several international programmes (4-8) : (1) Organization and structure of guideline development; (2) Preparation; (3) Guideline Development; (4) Validation; (5) Guideline Dissemination and Implementation and (6) Guideline Evaluation and Revision. In each phase we describe the steps to take, based on current insights. The AGREE instrument (1) provides an excellent reference for describing the development process.

Table 1: Six areas in guideline development

1. Organization and structure
2. Preparation
3. Guideline development
4. Validation
5. Dissemination and Implementation
6. Evaluation and revision

2.1 Organization and Structure

The structure for the development of guidelines varies for each programme, although most are directed from a central organization . Burgers (13) did an international survey of 18 guideline programmes. The programmes were mainly carried out by governmental agencies or professional societies, based on a structured programme. We recommend a certain degree of central coordination in developing guidelines, although individual groups may also develop guidelines, which may be endorsed by the professional body when the guideline meets the criteria.

Guideline Development Group

The Guideline Development Group (GDG) actually develops the guideline. A GDG should consist of experts from the field with clinical skills/expertise and people with skills relevant to guideline methodology (systematic reviewer, information scientist, epidemiologist, chairman, project leader, author). It is desirable to include relevant stakeholders and patients (or patient representatives) in the GDG. It is also an option to involve stakeholders and patients (or patient organizations) in a reference group or specific focus groups.

People with clinical skills/expertise: It will be important to include expertise from a range of different 'schools of thought' or approaches.

People with skills in guideline methodology: One person may be able to offer more than one of the necessary skills, but the GDG should ensure it has access to all of them.

Stakeholders: The number and background of stakeholders may vary per topic. Relevant stakeholders may be other health care professionals, insurers or government agencies.

Patients (and/or carers): Patients and carers have different perspectives on health care to health professionals. Their involvement in clinical guideline development will ensure the guideline reflects these perspectives, including patients' needs and concerns.

For the best result we recommend that the actual process of writing the guideline is done by a small group within the GDG. Usually these are the experts in guideline methodology and are (employed) staff of the responsible organization. This small group may consist of the project leader, systematic reviewer and first author. The other members of the working group comment on the draft versions, advise on and bring in relevant literature, formulate recommendations for practice based on the available evidence and agree on the final draft. One of the group members acts as chairman.

2.2 Preparation/ Initiation

Prioritising topics

In prioritising and deciding on a topic a number of criteria can be used. There should be an expectation that change is possible and desirable and that there is potential to improve the quality of care and/or patient outcomes.

Criteria for selection of topics are:

- The topic concerns a problem or controversy in current practice for which a solution is desirable.
- There is evidence of variation between actual and appropriate care.
- Consensus about diagnosis and treatment is expected to be attainable.
- The topic area should help practitioners and patients to make decisions about appropriate care.
- The scope of the guideline must be attainable.
- Scientific evidence should be available to support recommendations in the guideline.
- Population of patients can be clearly described and there should be sufficient number of patients to make the development of the guideline worthwhile.
- Topic should be relevant to areas in which Physiotherapists are working (primary care, in-patient care, specific interest areas).
- Topic should fit with guidelines developed in other disciplines.
- Topic should fit with relevant developments in society (strategic, political).
- Possibilities for funding for the development of the guideline must be available.

Developing the scope of the guideline

Prior to the actual guideline development an initial literature search is carried out to identify existing systematic reviews and guidelines. A check with key groups representatives, Physiotherapists and patient organizations may take place to refine the subject area. The first draft of a scoping document will include details of the aspects of care the guideline will cover, the background epidemiology, the population, the healthcare settings, the interventions and treatments that will be included, and the relevant outcomes for determining clinical and (if possible) cost effectiveness.

2.3 Guideline development

Refining subject area and defining questions

The first draft of the scoping document will be discussed at the first meeting of the GDG. The GDG will then produce a second draft and also define the research questions to be answered. Questions should include the following components: population, intervention or group of interventions, outcome of the intervention. The author within the GDG will continue to work on the subject area, to be agreed at the second meeting of the GDG.

Identifying the evidence

One of the most crucial phases in the clinical guideline development process, which contributes much to its validity, is the systematic identification of relevant evidence on which to base the formulation of recommendations for practice. The process, as well as being systematic, must be carried out in such a way that the potential for any bias is minimized. Literature will be identified according to an explicit search strategy, selected according to defined inclusion and exclusion criteria and summarized using methodological standards where these are applicable.

It is recommended that the following databases are minimally searched:

- MEDLINE
- CINAHL
- Cochrane Library, including the Rehabilitation and Related Therapies field
- PEDro database

Normally the information specialist and the systematic reviewer carry out the search process, but partnership with the other members of the GDG is essential to ensure the clinical relevance and accuracy of the review. Detailed documentation of the search strategy within the guideline document is important for transparency towards the readers of the guideline and to make it possible to use the same procedures when updating the guideline.

Assessing and synthesizing the evidence

The assessment of the literature is systematically done by assessing the methodological quality (content analysis) and summarized in a review of the evidence (qualitative analysis). The Cochrane Collaboration produces robust systematic reviews (qualitative analysis) and meta-analyses (qualitative and quantitative analysis) that can save a lot of work in assessing the literature. When a review is

already performed by Cochrane or another research group, the review is assessed to investigate whether the inclusion criteria meet the subject area of the guideline, whether the outcome measures are adequate and whether the conclusions are relevant for the guideline.

In order to assess the evidence a critical appraisal tool or quality assessment criteria will be used to assess the quality and reliability of the individual studies. Several tools exist to assess the evidence. No one tool is recommended over another but the tools(s) used should be explicitly stated in the guideline document. The outcome of the systematic review can be summarized in evidence tables. The evidence tables should provide enough information to allow the reader to understand any issues about the quality of the study that will impact on the weight given to it when summarizing the evidence and formulating recommendations.

Ideally two systematic reviewers should independently critically appraise the evidence. Any disagreements between the reviewers should be discussed with the whole GDG.

Grading of the evidence is important so that the GDG and the reader/user of the guideline are able to weigh up the relative importance (weight) of the evidence. Usually, hierarchies are used that reflect a good systematic review as being the strongest evidence, followed by RCT's, non-randomised studies, then cohort studies. However, sometimes qualitative studies are the most appropriate methodology for the question the study is attempting to answer, where a quantitative approach could either be inappropriate or unethical. Unfortunately no grading system currently reflects the appropriateness of the study, as well as the study design.

A possible hierarchy of evidence for use in clinical guidelines is listed in table 2. It must be noted though that differences occur in grading systems throughout the world. Other systems may be used, but it is important to be explicit about grading system that has been used.

Table 2: Hierarchy of evidence in four levels (source: NICE (6))

Level	Type of evidence
Ia	Evidence obtained from systematic review or 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 experience of respected authorities.

Translating the evidence into recommendations

Once the evidence is identified, checked for quality and reliability and summarized, the whole GDG must consider its relevance and applicability to practice or service delivery, in order to formulate recommendations. Recommendations need to take account of:

- The strength of the evidence (type of evidence, quality of the studies, how many studies there are with similar results, how similar were the study populations to the population defined in the guideline)
- Clinical relevance and applicability of the evidence (for example are the settings and context of the studies similar enough to those encountered in the areas of clinical practice relevant to the guideline topic)
- Acceptability to patients. It is important that the guidelines discuss a range of options for patients and professionals, but that the relative benefits and risks of each of these is clearly stated, which will assist in decision-making for the patient and Physiotherapist.

The guideline document should reflect some of the discussion that went on within the GDG during the process of formulating the recommendation. The document should clearly describe the link between the evidence review and recommendations, and describe the rationale for the formulation of those particular recommendations. SIGN (8) describes the process of formulating recommendations as 'considered judgement' and has developed a specific form for this.

Recommendations in guidelines are usually subject to a system of grading, based directly on the level of evidence. A wider debate about the development of a grading system for recommendations that takes account of their significance for practice as well as the strength of the evidence is needed within the guideline community. An example for grading recommendations is presented in table 3. As with the hierarchy of the evidence, other systems may be used but it is important to clarify the grading system used.

Table 3: Grading of recommendations (source: NICE (6))

Grade	Evidence
A	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 and Ib in table 1).
B	Well-conducted clinical studies but no randomised clinical trials on the topic of recommendation (evidence levels IIa, IIb, III in table 1).
C	Expert committee reports or opinions and/or clinical experience of respected authorities. This grading indicates that directly applicable clinical studies or good quality are absent (evidence level IV in table 1).
Good practice point Recommended good practice based on the clinical experience of the GDG	

Structure of the guideline

The content and structure of the guideline is based on the clinical reasoning process of the Physiotherapist. Most guidelines are divided into diagnosis and treatment parts. CSP guidelines focus mainly on the evidence review and recommendations relating to specific interventions or treatment, but also consider assessment and making a clinical diagnosis. The guidelines suggest outcome measures that can be used to evaluate the effectiveness of the interventions in terms of health gain for patients. KNGF guidelines seek applicability in describing the intervention process from physician's referral up to the evaluation with the patient, based on the clinical reasoning process. Each guideline is divided into diagnosis and treatment. Diagnosis is divided into (a) history taking, (b) physical examination and (c) analysis and diagnosis. Treatment is divided into (d) treatment plan, (e) treatment, (f) advice and prevention, and (g) evaluation. KNGF guidelines cover two parts. The first part is the practice guideline in which recommendations for diagnosis and treatment are described. The second part is the review of the evidence in which the evidence and the 'considered judgement' are described, on which the recommendations are based.

At the same time the guideline should make clear what methods and procedures were used. The AGREE instrument offers a framework for a structured and rigorous development methodology which should be incorporated into the procedure.

Apart from the guideline itself a summarized version may be produced (e.g. in a flowchart) and patient brochures may be developed. An example of the possible outline of a clinical guideline and its by-products is given in table 4.

Table 4: Possible outline of a guideline

Summary	Two page summary (usually flowchart)
Practice guideline	<ul style="list-style-type: none"> - Introduction: Aim, Scope, Epidemiology - Diagnosis: Referral, History taking, Assessment, Measurement instruments, Analysis, Conclusion - Therapy: Objectives, Intervention, Outcome measures, Evaluation
Review of the evidence	<ul style="list-style-type: none"> - Introduction: Aim, Clinical questions, Development procedure, Review methodology - Diagnosis - Therapy - Legal perspective - Updating procedure
Annexes	<ul style="list-style-type: none"> - Measurement instruments/ Outcome measures - Evidence tables
Patient brochure	<ul style="list-style-type: none"> - Information about disease/ condition - Advice - Role of Physiotherapy

2.4 Validation

In the validation phase the draft guideline should be tested or reviewed. The draft guidelines can be sent to potential users to test practicality and clarity of the guideline, and acceptability of the recommendations. Patients and stakeholders can also review the draft guideline. The comments should be used by the GDG to adjust the draft guideline.

Ideally, draft guidelines should be tested in daily practice by means of actually using them by practitioners. However, this is very expensive and time consuming. Most guideline programmes do not include such a testing phase. An external review by an (independent) committee of reviewers is recommended. The reviewers should be experts with experience in guideline development and can use the AGREE instrument to check the rigour of the development process.

The endorsement of a guideline may differ in each country. The endorsement/ratification may be carried out by individual Member Organisations of the European Region of WCPT. In the future, perhaps nationally developed guidelines could be subject to endorsement at European level by the European region of WCPT, in order to create European guidelines.

2.5 Dissemination and Implementation

For the dissemination and implementation of guidelines a standard strategy can be developed, which can then be tailored to the specific requirements of each individual guideline. Relevant factors for the successful implementation of a guideline can be identified during the development of guidelines. After defining the implementation plan, projects can be carried out in a number of sites to facilitate implementation.

A standard implementation strategy may consist of the following products and/or activities:

Dissemination:

- Publication of guideline
- Organize workshops
- Presentations at congresses

Implementation:

- Continuing Professional Education
- Audit packs
- Specific activities related to the topic of the guideline
- Reminders

No evidence exists for the best implementation strategy. Several systematic reviews or overview studies have been published concerning the effectiveness of implementation strategies (14-17). It is clear that sending guidelines to potential users in itself has no effect, yet this is a prerequisite for further implementation. Actual change of practice is possible, but requires a rigorous strategy with different activities, targeted at potential users.

2.6 Evaluation and Revision

The guideline document should include a date on which it will be reviewed/ updated in the light of new evidence that might be available. An acceptable timeframe for a review would be five years. A brief review of the literature should be performed to investigate new evidence, similar to the review of the literature carried out for selecting topics. Additional feedback from users can give information about changes in practice that might stress the need for updating the guideline.

When an update of the guideline is undertaken, the original scope of the guideline and clinical questions should be reviewed to see whether they are still valid. Based on the collected material (new evidence, change of practice, additional feedback) the recommendations from the original guideline need to be reviewed and revised if necessary.

3. Implications of guideline (development)

3.1 Resources for guideline development

Guideline development is a lengthy process and one that requires technical as well as clinical skills. Significant resources, both in terms of people with particular skills and attributes and funding are required to ensure a quality product is developed within a reasonable time period. A realistic estimate of the length of the guideline development process is 18 months, assuming the resources discussed in this section are available.

3.2 Legal implications for guideline users

Nationally approved (endorsed) clinical guidelines become a recognised source of evidence of best practice, which could be used in court by an expert witness as the 'benchmark' of good practice. However, clinical guidelines are a vehicle to assist patient and professionals in decision making - they do not deal with every eventuality and they do not replace clinical judgment, they facilitate it. Physiotherapists will need to use their experience and clinical reasoning skills to consider the relevance of a particular guideline to particular patients, taking account of the patient's condition, circumstances and wishes. If the recommendations of a high quality clinical guideline are not implemented for a particular patient, the rationale for this should be documented in the patient record.

4. Conclusion

Clinical guidelines are a valuable resource for effective clinical practice, providing systematically developed syntheses of the 'best available evidence' of effectiveness. Clinical guidelines become important tools for clinical effectiveness and evidence-based practice and have the potential to improve the quality and consistency of patient care.

The development process of clinical practice guidelines has reached a high degree of consensus within the international guideline community. Although some differences occur, it is possible to create a common framework for guideline development. This framework may assist (Member Organisations of) the European Region of WCPT in the further development of clinical guidelines . Collaboration is even more important given the considerable amount of resources necessary to develop guidelines.

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