Development and Implementation of Clinical Practice Guidelines in physical therapy

Introduction to the method of guideline development

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Summary

The development of national practice guidelines (NPGs) is an issue of much concern in healthcare policies world-wide to guarantee and to improve the quality and efficiency of care. The development and implementation of NPGs constitutes an important part of the quality of care policy of the Royal Dutch Physical therapy Association (KNGF). This interest is due to pressure from society (policy-makers, healthcare managers, financiers and patients) on physical therapists to ensure quality of care and to justify our position in the healthcare system. The development of NPGs can also be seen as a logical step in the process of professionalization and quality assurance by physical therapists.

An NPG is described as a systematically developed statement, drafted by experts and directed at one aspect of the treatment of a health problem belonging to the domain of the profession. NPGs are based on the different stages of the physical therapy care process, the available clinical evidence and expert consensus. Priority is given to a cost-effective approach and multidisciplinary consensus on diagnosis, treatment and primary or secondary prevention. Recommendations are based on the results of new or recorded systematic reviews or meta-analysis.

NPGs are important state-of-the-art documents, which can guide professionals in their daily practice and make explicit to other relevant people what professionals can do in a certain situation or with a specific condition, and why they do it. NPGs have important functions, including supporting physical therapists in their decision-making process; they are a frame of reference for orientation and educational purposes, they provide criteria for self-evaluation and peer review, and can initiate changes in established practice patterns.

This chapter describes the process and development of NPGs for physical therapists in the Netherlands. In another chapter the method and strategies for the implementation of NPGs and the need for evaluation of their outcome will be discussed.

Introduction

Healthcare policies all over the world consider quality of care to be of paramount importance.

Healthcare consists of those activities that are directed at the prevention and treatment of health problems (impairments, disabilities and restriction on participation) and the promotion of independence.[1]

The major keyword of quality of care in the policy of those who fund healthcare is cost-effective (or efficient) care.[2-8] To be able to make justifiable choices in financing healthcare activities it is essential to know what treatments are clinically proven and cost-effective.

Professionalization is the key aspect of quality of care for healthcare providers. The definition of 'professionalization' most commonly used is 'becoming a profession'[5], referring to the process by which any new group takes on the characteristics of a

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profession.[9,10] Moreover, professionalization also stands for the position of the professionals in society, including their legal status, and being able to show scientific evidence for the effectiveness of applied techniques. The phenomenon of an ageing society and a shift from secondary to primary care, and more complex primary care pathology, speeds up the process of professionalization, for healthcare is becoming a scarce commodity and demands efficient use of limited means. Professional healthcare providers should therefore be able to define their area of expertise in which assessment (diagnosis), therapy and effectiveness of care are clarified.[11]

In the context of this paper professionalisation also implies paying attention to good healthcare, which should be focused on the needs and demands of individual patients. Negotiations with patients are an important prerequisite to ensure provision of adequate care.

There is some evidence that evidence-based guidelines are one of the instruments to provide insight, quantitatively and qualitatively, in the delivery of healthcare.[2-4,6-8,12-16] Ideally, guidelines are a state-of-the-art review of current knowledge about the diagnostic and therapeutic possibilities for a certain health problem – knowledge synthesis – and should be readily accessible to healthcare providers. It has been suggested that guidelines are adequate management instruments for continuous quality improvement and assurance[5,12,17-20] and the structuring and sustainability of healthcare processes.[5,20,21]

The development and implementation of national practice guidelines (NPGs) constitute an important part of the quality of care policy of the Royal Dutch Physical therapy Association (KNGF).[13-16] Current interest in the development of NPGs is to some extent due to pressure on physical therapists, from health policy makers, legislation and insurance brokers, to improve quality and efficiency of care. NPGs also help practitioners in decision-making but, more importantly, are also needed to legitimate our position in the healthcare system. The interest in NPGs is also stimulated by epidemiological studies that show wide variations in practice patterns and use of physical therapy services.[11,22-25] Research has revealed examples of inappropriate use of physical therapy services and there is often little or no evidence about the efficacy and effectiveness of therapeutic interventions.[11,26,27]

Guidelines may play an important role in the process of professionalization by demonstrating the value of physical therapy to governments, healthcare financers, patients, professional bodies and individual healthcare providers.

The term ‘clinical guidelines' and how it is to be distinguished from other terms used in the field of quality improvement have been obscured for many reasons. However, a useful working definition may be derived from the Institute of Medicine.[5] It defines practice guidelines as being systematically drafted by experts, on the basis of best evidence and/or consensus developed statements, then field-tested, and directed at performing diagnostic and/or therapeutic interventions in persons with definitive, suspected or health-threatening conditions, or directed at areas which have to do with good management and administration of the profession and its members.[5,13-16] NPGs are defined as guidelines developed under the auspices of a professional organization. The distinction between this and other terms lies in the level of specificity of the information and the degree of operational detail. Eddy[4] makes a distinction between standards, guidelines and options: ‘Standards are intended to be applied rigidly; they must be followed in virtually all cases. Guidelines are intended to be more flexible; they should be followed in most cases. Options are neutral and leave the practitioner free to choose any course.'

In 2002, four years after the KNGF published the Method for the Development and Implementation of National Practice Guidelines, it issued eight evidence-based clinical practice guidelines. Nine are to follow in the near future (table 1) according to the updated Method for Development and Implementation (expected in 2003), based on new insights and practical experiences. The purpose of this chapter is to provide general information about the development and function of NPGs for physical therapists in the Dutch healthcare system and to describe the phases that can be distinguished in the process of development of a guideline. In a companion paper, important aspects which deal with the method and strategy of their implementation and outcome-evaluation are discussed.[28]

Table 1. National practice guidelines published or being developed in The Netherlands.

Subject	Date published or expected
Guidelines concerning the organisation of physical therapy practice	
Physiotherapeutic documentation and report (KNGF)	1993
Communication and information report to the general practitioner 29	1997
Guidelines concerning the process of physical therapy practice	
Acute ankle sprains	1998
Stress urinary-incontinence in adults	1998
Chronic obstructive pulmonary disease	1998
Osteoporosis	2001
Cardiac rehabilitation	2001
Osteo-arthritis of hip and knee	2001
Whiplash	2001
Low back pain	2001
Chronic ankle sprains	2003 (in press)
Intermittent claudication	2003 (in press)
Acute knee sprains	2003 (exp.)
Repetitive strain injury	2003 (exp.)
Pelvic pain	2003 (exp.)
CVA	2003 (exp.)
Parkinson	2003 (exp.)
Rheumatoid arthritis	2004 (exp.)
Neck pain	2004 (exp.)

Method

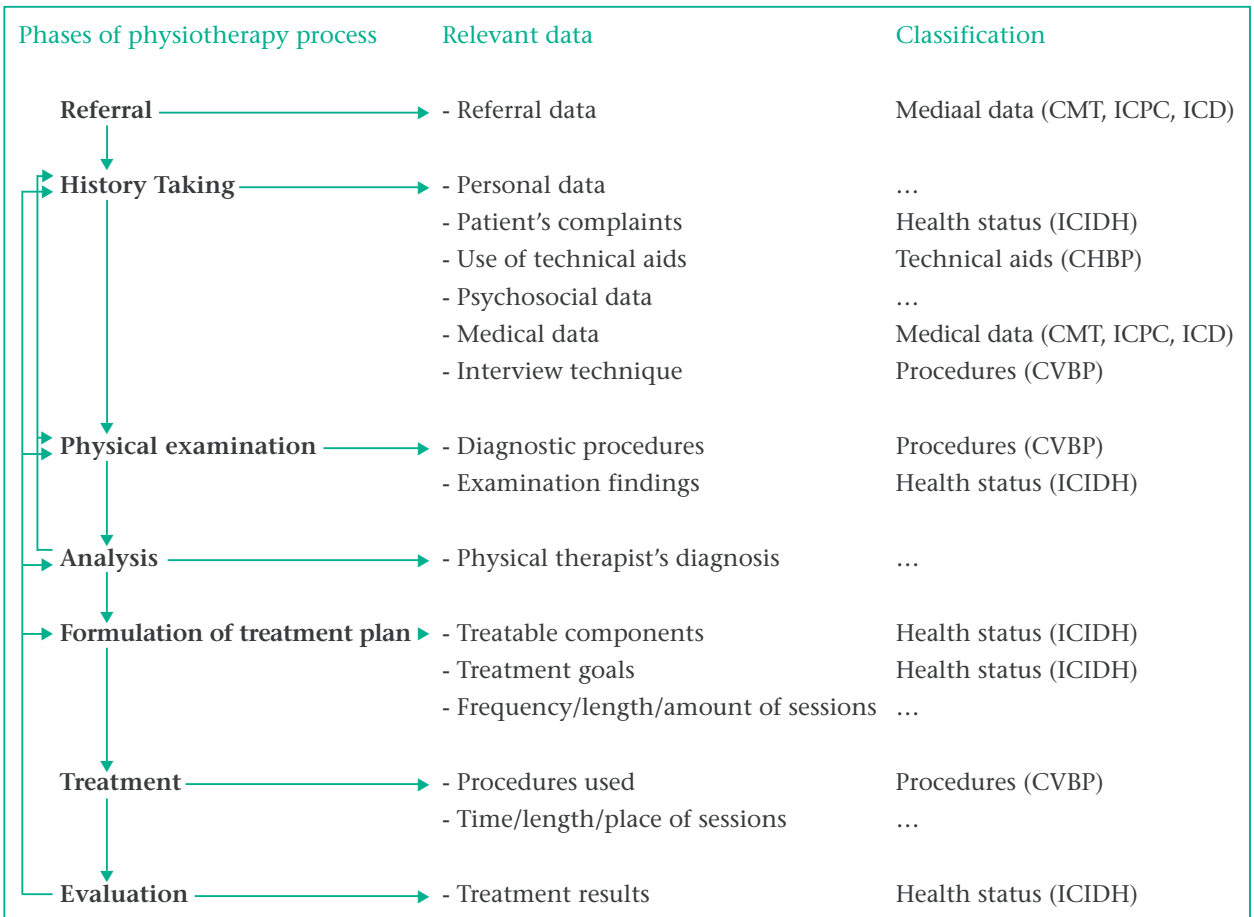
The method for the development and implementation of NPGs for physical therapists in the Netherlands is based on the method developed by the Dutch Association of General Practitioners[30] and guiding principles from international authorities.[2-4,5-7,9,31-37] A literature review did not reveal a methodology that was developed for, and used by physical therapists.[15] The literature about the philosophy and development of guidelines was also studied and embedded in the method used for guideline development.[38] Important guiding principles for development of an NPG are:

- The subject matter is clearly delineated on the basis of a clear medical diagnosis of health problems and related conditions that can be addressed by physical therapy.
- The guidelines should be structured according to the phases of the physical therapy process (table 2) as laid down in a guideline by the professional organization.[39]
- A uniform professional language is used. Whenever indicated use is made of available (international) classifications and accepted terminology, in particular the International Classification of Impairments, Disabilities and Handicaps[40,41,42] but also the International Classification of Diseases[43], the Dutch Classification of Procedures[44] and Medical Terms for Health Professionals[45] (fig 1).
- Uniform and valid diagnostic and responsive outcome measurements are used.
- The guideline should be based on the best available clinical evidence if possible, and if none is available, on consensus between experts.
- Clinical considerations have priority over cost-effectiveness.
- The guideline should be consistent with guidelines produced by other professions or groups of professions. The physical therapy guideline can then often be considered as an appendix to those guidelines, in which the

Table 2. The different phases of the process of physical therapy practice

1. Examination of the referral data
2. History taking
3. Physical examination and evaluation of the patient's funrtional status
4. Formulating the physical therapist's diagnosis and deciding whether or not physiotherapy is indicate.
5. Formulating the treatment plan
6. Providing the treatment
7. Evaluating the changes in a patient's functional status and one's own course of action
8. Concluding the treatment period and reporting to the referring discipline

Figure 1. The physical therapy process, relevant data and necessary classifications



Source: Heerkens et al.[42]
CMT= Classification of Medical Terms (for allied health professions)[45]
ICPC=International Classification of Primary Care[49]
ICD=International Statistical Classification of Disease and Related Health Problems[43]
CVBP=Classification of Interventions and Procedures (for the allied health professions)[44]
ICDH=International Classification of Impairments, Disabilities and Handicaps[40,41]

physiotherapeutic contributions to a health problem are identified.[46,47]
- The guideline should be based on integration and coherence of care. Physical therapy may be one of the possible interventions in the total care of a patient. It should be evident at which point and why physical therapy may become appropriate.
- The guideline should be patient-oriented and in agreement with the policies of patient organizations. Individual patients also need to have a voice in determining care.[48] Are the expectations and treatment goals of patients the same as those of physical therapists?
- The necessary expertise and knowledge that is required from physical therapists should be made clear.

Phases of the physical therapy process

There are four important stages in the development of a clinical guideline:
1. The preparatory phase.
2. The design phase, encompassing the draft guideline and the authorization phase.
3. The implementation phase.
4. The evaluation updating phase.

The preparatory phase involves the selection of a topic based on certain criteria[5,6,20,36,50] (table 3).
The design phase should guide the task group in the development of the guideline. This phase is, for educational reasons, based on the different stages of the physical therapy process (fig 1, table 2). In the process of physical therapy practice a number of interrelated phases can be distinguished[28] : a patient is seen by a physical therapist with a medical referral and a request for professional help. The physical therapist takes the patient's history, examines the patient, draws conclusions, and finally informs the patient about the therapist's findings and conclusions. Together with the patient the physical therapist formulates a treatment plan and treatment goals when indicated.
During and after a course of treatment the therapeutic process and results are evaluated. The data obtained during the care process are recorded according to the national guideline for documentation that has been developed to ensure systematic and uniform record keeping.[15,16,39,51]
The implementation phase comprises the dissemination and specific strategy to implement the developed NPG, based on the general method of implementation.
The effectiveness of the guideline needs to be evaluated at the level of professionals and patients. The NPG should be updated every two to five years after the guideline is put into practice, or whenever new scientific insights make an update necessary.

Design phase

Five groups contribute to the development of an NPG: the Royal Dutch Physical Therapy Association (KNGF) and four collaborating partners (the Dutch Institute

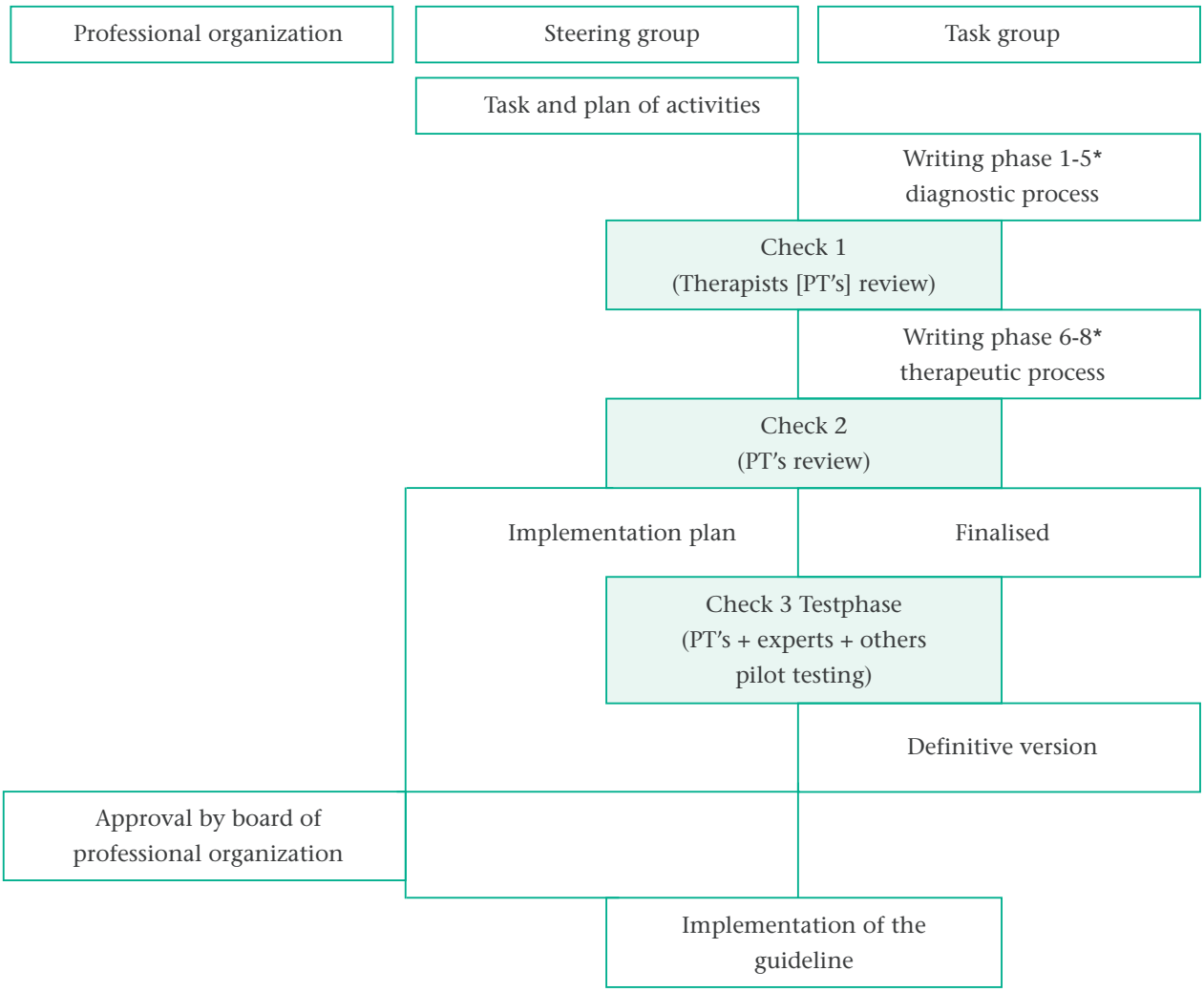
Table 3. Possible criteria to select a subject for development of a guideline.

- Subject concerns a problem or controversy in health care tor which healthcare providers are seeking a solution.
- It is anticipated that consensus about the procedure/intervention is possible.
- Health care providers await guidelines because they need a state-of-the-art document about a subject/topic.
- The Subject is relevant because it has an impact on costs of health care in terms of prevention of health problems or saving of costs.
- There is enough scientific evidence.
- There is a genuine expectation that guidelines fit within existing norms, values and routines.
- The Subject matter can be reasonably delineated.
- It is possible to collect data about the care.

Sources: Grol et al.,[20] Grimshaw and Russel[6] and Field & Lohr[5]

of Allied Health Professions and the Dutch Organisation for Quality Assurance (NPi and CBO) which initiate and eventually endorse the guideline; the steering group which plans and co-ordinates the activities; the task group which develops the guideline; a group of clinical experts in the subject matter of the guideline which comments on it or on parts of it as the practice guideline is developed; and a randomly selected group of physical therapists who pilot test the guideline in clinical practice (figure 2).
Following the formulation of a plan of activities and basic algorithms, systematic literature searches, reviews and/or meta-analysis are conducted into the efficacy of possible interventions,[52-58] diagnostic procedures and measurements,[8,55,56,59,60] prognoses,[55,61] prevention,[62] patient preferences,[63] and current practice.[8,64,65]
The strategy described in table 3 is used. The purpose of these rigorous literature reviews is to document the evidence to justify the recommendations in the guideline.[7,35,66,67] Where scientific evidence in the form of meta-analyses or systematic reviews is not available, the guideline is formulated on the basis of consensus agreement by the task group and the clinical experts.
The task group first develops the diagnostic part of the guideline that may include an algorithm of the process of care and clinical decision-making, to formulate treatment goals and a treatment plan. This part of the guideline is reviewed by 25 practicing physical therapists who have special interest and expertise in the problem area.

Figure 2: Method of guideline development



** The different phases of the process of physiotherapy practice (table 2) within the process of guideline development*

Table 4. Guides for selecting articles that are most likely to provide valid results

Therapy
- Was the assignment of patients to treatments randomised?
- Were all of the patients who entered the trial properly accounted tor and attributed at its conclusion?

Diagnosis
- Was there an independent blind comparison with a reference standard?
- Did the patiënt sample include an appropriate spectrum of the sort of patients to whom the diagnostic test wil be applied in clinical practice?

Harm
- Were there clearly identified comparison groups that were similar with respect to important determinants of outcome (other than the one of interest)?
- Were outcomes and exposures measured in the same way in groups being compared?

Prognosis
- Was there a representative patiënt sample at a well-defined point in the course of disease?
- Was the follow-up sufficiently long and complete?

Sources: Oxman et al.,[55]; Sackett et al.,[8]

Following the plan of activities the task group continues with the therapeutic part of the guideline that, if indicated and possible, should include the recommended intensity, frequency and duration of the intervention(s). This part is reviewed by the same group of therapists who were consulted in the previous phase.
When both the diagnostic and the therapeutic parts of the guideline are completed, the first draft is sent for comments to 60 randomly selected physical therapists for pilot testing. Additional comments are obtained from clinical experts in relevant professions. Based on the comments and experiences of the physical therapists the draft is rewritten. The modified draft is then discussed by the 'Authorisation Committee' (fig 2). Following approval of this committee the guideline is published in a scientific journal and introduced and implemented in the field. A specific strategy is developed for implementation, based on the preliminary experiences of the physical therapists who tested it and identified obstacles to successful implementation as a result of the literature searches, new insights in the process of physical therapy practice, the recommended measurement instruments for diagnosis, and evaluation of patient outcome, and discrepancies between actual practice and optimal practice as reflected in the guideline.[64,65] This implementation strategy will be described in another chapter.[28]
The final product, as a result of the method of guideline development, consists of four parts:
- The practice guideline itself.
- A summary or algorithm on an A4 laminated chart for easy reference.
- A scientific justification with references.
- A specific strategy and instruments for implementation of the guideline (eg a knowledge check to test for discrepancies between the actual and the recommended practice as stated in the guideline).

Characteristics and functions of NPGs

Generally speaking it can be said that most NPGs help in the decision-making process. They are goal-directed and when applicable form a guide with respect to the interventions and procedures needed to reach the goals.
The characteristics for quality practice guidelines are listed in table 4. For NPGs to be effective they should fulfill most if not all of these criteria. Guidelines should be valid and should result in qualitatively better healthcare.[6,7]

The following functions of guidelines are formulated:[20,68]

- Providing an up-to-date state-of-the-art document, which helps in taking diagnostic and therapeutic decisions and is a practical guideline in daily practice.
- Revealing the reasons for and reducing variations in clinical management (both inter- and intra-therapist) and giving insight into working methods of a profession. It is thereby possible to see where there are differences and similarities between different health professions.
- Reducing costs for health insurance companies, government and public health agencies and helping in negotiating contracts and budgets.
- Improving patient outcomes and cost-effectiveness and providing a tool to formulate criteria that can be used in evaluation of care.

NPGs can be considered as an up-to-date knowledge synthesis in a nutshell for pre- and postgraduate education that is an incentive for change. An important guiding principle in the development of our NPGs is that the guidelines are primarily developed for the benefit of practicing physical therapists and the professional organization. They are not yet intended to be used as criteria for registration or re-registration or certification, nor for use by third parties such as legislative bodies or insurance companies. They contribute to professionalization by quality enhancement and assurance.

At the level of individual physical therapists, the most important aspect of NPGs is their effect on everyday practice. They will have state-of-the-art documents, well researched and endorsed by experts, to guide them. It is not possible for the 'average' physical therapist to keep up with all new developments and insights in the profession. NPGs should support decision-making, provide criteria for self-evaluation, peer review and clinical audit, and be an incentive for physical therapists to change or modify their usual care and use of specific modalities or interventions. Guidelines will facilitate up-to-date care, reflecting current insights from societal, scientific and professional viewpoints, and thereby improving its quality.

For the profession, guidelines further the process of professionalization. They show what the profession stands for, demonstrating its scope of practice, and reduce differences in practice, thus enhancing uniformity. Evidence-based guidelines may serve as state-of-the-art documents and can serve as important reference documents in undergraduate and postgraduate education. NPGs will also be helpful in making tasks and responsibilities of physical therapists explicit and in distinguishing their professional domain from those of other healthcare professionals. In addition, the guidelines may reduce the risk of legal liability for inadequate or insufficient care. Guidelines make healthcare transparent and verifiable, thus ensuring surveillance and improvement of quality of care.

The method of development and implementation of NPGs described here has been tested in The Netherlands with the development of three practice guidelines for specific patient categories: stress urinary incontinence in adults,[69,70] acute ankle sprains[71] and chronic obstructive pulmonary disease.[72,73] These guidelines are based on summarized evidence from randomized clinical trials described in systematic reviews[26,74-78] and have been authorized by the professional organization.

Discussion

The development of guidelines in general, and NPGs in particular, can be seen as an important step in the process of professionalisation and they are promoted as vehicles for continuous quality improvement and assurance in physical therapy practice.

The availability of NPGs does not however guarantee their use in physical therapy practice. This, highlights one of the prerequisites of an NPG: the guideline should be the translation of scientific knowledge in actual practice behavior. Implementation is not however mandatory. Guidelines should as their name implies guide practice in order to improve the quality of care, but they are developed for treatment of the health consequences of diseases and improvement quality of life, and not for treatment of diseases themselves. Physical therapists may therefore deviate from the guidelines if this can be justified.

Critical evaluation of the effectiveness of NPGs includes continuous monitoring of clinical processes and outcomes to improve the quality of care provided. However, following evidence-based guidelines founded on documented efficacy will not

Table 5. Quality criteria for national practice guidelines

Validity
- Resulting in expected outcomes (health, cost containment, justifiable satisfaction).
- Based on careful and systematic analysis of the research literature.
- Relation between research findings and guideline is clear.
- Strength of evidence is given (consensus versus evidence-based including experts' judgement behind them).

Reproducibility
- Another task group produces comparable recommendations.
- Guidelines are interpreted and applied consistently by different professionals.

Clinical applicability
- They are written trom the perspective, needs and questions of the target population.
- Integration in general practice is relatively simple.
- They specify patiënt populations and situations to which they apply.

Differentiated
- They take important factors into account which may influence the guideline.

Clinical flexibility
- Frequently occurring exceptions are listed.
- There is room for own judgement, patients' preferences and adjustments to relevant circumstances in the work setting.

Clarity
- Adequate and uniform use of professional language.
- Presentation is logical.
- Important terms are defined.

Didactic
- Design follows usual way of werking and decision making.
- Recommendations are concrete.
- Focus is on essential aspects of intervention.
- Most important points stand out clearly.
- Translation to educational aids and evaluation of instruments are relatively simple.

Attractiveness
- Lay-out attracts attention.
- Field test, justification and explanation are included.

Sources: Grol et al.,[20] Grimshaw and Russel[6] and Field & Lohr[5]

lead automatically to a desired outcome. The effectiveness of putting NPGs into practice, on the level of both the patients' health status and practitioners' behavior, should be evaluated.

The effect(s) of the implementation of guidelines can be evaluated only when therapists record what they actually do. Although in the method of guideline development control points are described to find out

to what extent guidelines are adopted and adhered to by physical therapists, structural information is needed to investigate and evaluate to what extent the guidelines are followed. This will be dealt with in the near future. In our ongoing prospective cohort studies the developed NPGs will be evaluated on the level of patients (eg patient outcome and patient satisfaction) and therapists (eg experiences with the guideline - Do physical therapists act in accordance with the recommendations? [process of care] How does this affect the nature and volume of the care provided?) However, a continuous monitoring system is essential to provide necessary data on the process and outcome of care for benchmarking, clinical audit, and individual feedback and self-evaluation.

Problems have been noticed with respect to the process of development and implementation of NPGs.[13,15] Some of these were known and could have been anticipated:

- Lack of evidence about commonly used diagnostic and interventional procedures within physical therapy. Not all recommended interventions and procedures in physical therapy practice are evidence-based. But this also applies to the work of doctors and other allied health professions.[5,12] For users of the guideline, however, it is important to know which parts are evidence-based, including the strength or level of evidence and grade of recommendations; which parts are based on consensus by experts; and where clinical uncertainty is indicated. For example, the strength of evidence can be indicated as described by Bigos et al.,[79] Grimshaw et al.,[7] or the Canadian Task Force.[80]
- Lack of an organised infrastructure (network) to test and implement NPGs.
- Lack of widespread use of a uniform professional language.
- Unexplained variations in practice in diagnosis and treatment and use of health services. This is, of course, a very important reason to develop guidelines.

In the method of development and implementation of NPGs the different stages of physiotherapeutic care are described to produce uniform evidence-based or at least research-based guidelines. These phases 'guide and guard' the process as has been explicitly expressed by the various groups, which have been involved in development of the guidelines.

There are three stages in development of a guideline when feedback from the field is required. The information from physical therapists in the pilot testing phase has been extremely important for modification of the guidelines and has shed light on their applicability. At the same time it provides the opportunity to discuss progress and difficulties in their development. These pilot studies also provide valuable insight into when and why actual practice differs from the optimal care as proposed in the guidelines.[15] For the first two NPGs retrospective reviews of historical data of clinical practice were carried out to facilitate this comparison, which provided important information to enable us to refine the guidelines and identify specific areas that might need special attention when putting them into practice.[64,65]

The physical therapists were pleased to help by testing the guidelines.[15] The fact that practicing physical therapists have been involved in development of the guidelines will certainly encourage their acceptance and implementation.

Recently multidisciplinary guidelines have been advocated. These describe mutual starting points around policy making in certain disorders, while monodisciplinary guidelines describe the treatment process (eg minimal referral data, physical therapists' diagnosis, treatment and evaluation).

Multidisciplinary guidelines are a professional body of knowledge and can be used to develop monodisciplinary guidelines. (It is very difficult for physical therapists to initiate the development of multidisciplinary guidelines from within the physical therapy profession.)

To make sure that all relevant disciplines tune in with each other, our NPGs are checked by external experts such as general practitioners, medical specialists, and patient group representatives. In the Netherlands evidence-based physical therapy guidelines are seen as a body of knowledge of our profession and used as input for the development of multidisciplinary guidelines in, for example, acute ankle sprain[46] and osteoporosis.[47]

The development of guidelines for physical therapy practice is gaining momentum and the acceptance and implementation of guidelines is welcomed by

most therapists.[15,16,81] Despite initial problems in development of the first three guidelines, there is confidence that the development of other national guidelines will proceed more smoothly.

To maximize the effect of guidelines the method for development and implementation of a specific guideline must be strictly followed. The guideline should be a document with an adequate and appropriate balance of scientific evidence, clinical applicability, and feasibility. All guidelines should be clear, understandable and attractive.[5,6,7,15,16,20]

Finally, it should be emphasized that the methodology for development of an NPG and strategies for its implementation are strongly interrelated. Both are linked to the initial purposes for the development of guidelines.

Particular attention should be paid to the implementation of guidelines that should be specifically directed at the problems experienced by practicing physical therapists. It is important to identify the 'performance gap' between actual practice and practice as proposed in the guideline. The development of guidelines will be successful only when they are used by practicing physical therapists and affect their behavior.

It should be noted that nationally developed practice guidelines alter practice patterns positively, they can be effectively implemented at local level. To quote Eddy:[4] 'Implementing national guidelines as a practice policy deserves whatever effort is required to ensure that all the work that preceded it is put to the best use.'

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