

# KNGF guideline methodology 2019

## Development and implementation of KNGF guidelines

Version 2

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This is a publication of the Koninklijk Nederlands Genootschap voor Fysiotherapie (KNGF) [Royal Dutch Society for Physical Therapy] and is available online at [www.kngf.nl/kennisplatform](http://www.kngf.nl/kennisplatform).

This publication should be cited as follows: KNGF Guideline Methodology: Development and Implementation of KNGF Guidelines, version 2, Koninklijk Nederlands Genootschap voor Fysiotherapie (KNGF) [Royal Dutch Society for Physical Therapy], Amersfoort, 2019.

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## 1 Introduction

The KNGF develops a large number of evidence-based products. These are products where scientific evidence is translated into products that can be applied for practical purposes. Guidelines are a known example of this.

The KNGF has developed and revised many guidelines in recent years, which are listed in the table below.

### *Overview of KNGF guidelines*

| Guidelines   | Year |
|--|------|
| Osteoarthritis of the hip and knee                     | 2018 |
| Stroke   | 2014 |
| COPD (revision in 2018–2019)                           | 2008 |
| Ankle injury   | 2006 |
| Physiotherapeutic file-keeping (revision in 2018–2019) | 2016 |
| Cardiac rehabilitation                                 | 2011 |
| Complaints of the arm, neck and/or shoulder (CANS)     | 2010 |
| Lower back pain (revision in 2019–2020)                | 2013 |
| Meniscectomy   | 2006 |
| Neck pain  | 2016 |
| Osteoporosis   | 2011 |
| Parkinson's disease                                    | 2017 |
| Rheumatoid arthritis                                   | 2018 |
| Stress (urinary) incontinence                          | 2011 |
| Symptomatic peripheral artery disease                  | 2014 |
| Pregnancy-related pelvic pain                          | 2010 |

In addition, the KNGF has developed many other evidence-based products, such as evidence statements (Breast cancer (2011); Motor handwriting problems in children (2011); Subacromi-al problems (2011); Anal incontinence (2013); Rehabilitation after anterior cruciate ligament reconstruction (2014); Acute knee injury (2015)), as well as standards for exercise interventions (Chronic obstructive pulmonary disease (2009); Coronary heart disease (2009); Diabetes mellitus type 2 (2009); Osteoporosis (2009); Oncology (2011); Osteoarthritis (2011); Overweight and obesity in children (2013); Chronic pain (2015) and Vulnerable elderly (2015)).

The KNGF also participates in the development of multiple external guidelines every year.

All KNGF guidelines and external guidelines are available at [www.kngf.nl/kennisplatform](http://www.kngf.nl/kennisplatform).

### *Definition, objective and target audience*

A guideline is defined as follows (Management Board for Quality of Care [Regieraad Kwaliteit van Zorg], 2012): *'a document containing recommendations aimed at improving quality of care, based on systematic summaries of scientific research and due consideration of the advantages and disadvantages of various care options, supplemented with the expertise and experiences of healthcare professionals and healthcare consumers.'*

Guidelines are considered to be a tool for healthcare professionals and (potential) healthcare consumers when making healthcare choices. Healthcare professionals can also use the guideline as a means of updating knowledge, for educational purposes and to draw up (multidisciplinary) cooperation agreements.

Guideline recommendations are not mandatory. Healthcare providers can – and in some cases should – deviate from the recommendations in the guideline, provided that the reasons for this are recorded in the patient's medical record (Management Board for Quality of Care, 2012).

The objective of the KNGF guideline methodology is to determine the following:

- *Practical and applicable guidelines*  
The professional field will be explicitly involved in the process, a clear and practical, digital guideline format will be used and an intensive implementation programme will be employed.
- *High-quality guidelines compliant with national and international standards and (legal) requirements*  
The guideline will be developed with a tripartite approach; all relevant stakeholders (healthcare providers, patients, health insurance companies) will be involved in developing the guideline, and the guideline will be submitted to these stakeholders for authorisation (Zorginstituut Nederland ['Dutch National Health Care Institute'], 2018).
- *Efficient process and uniform (development of) guidelines*  
The methodology contains a standardised, clearly described manual, whereby the KNGF has the role of process supervisor, methodology expert and author.

### **KNGF guideline methodology**

Until 2017 the KNGF guidelines were pursuant to the 'Method for developing, implementing and revising KNGF guidelines' ('Methode voor ontwikkeling, implementatie en bijstelling van KNGF-richtlijnen') (Hendriks, 1996; Van der Wees, 2007). In 2017 the 'KNGF guideline methodology' took effect (KNGF, 2017). This methodology is adjusted every year, where necessary, based on the experience gained with applying the methodology and (legal) requirements and criteria with respect to the development and content of quality standards, including guidelines (Healthcare Institute of the Netherlands, 2018). The KNGF guideline methodology is therefore a 'living' document.

The methodology applies exclusively to KNGF guidelines. The other evidence-based products of the KNGF (evidence statements, standards for exercise interventions and external guidelines) have a different function and come about in a different manner. Here one must realise that KNGF guidelines have (appeared to be of) great value for the inclusion of physical therapy in external guidelines<sup>a</sup>.

The present guideline methodology is comprised of the following:

- description of the organisational structure, including a task description of all involved stakeholders (chapter 2: 'Organisational structure');
- description of the execution of the KNGF guideline methodology based on a step-by-step plan (chapter 3: 'Steps of the KNGF guideline methodology');
- reference list (chapter 4: 'References');
- appendices with templates to support guideline development and implementation.

## **2 Organisational structure**

| Stakeholder                        | Role  |
|------------------------------------|---|
| 1. KNGF Board                      | • Commissioner and authorising stakeholder  |
| 2. KNGF, Quality Policy department | • Contractor  |
| 3. KNGF guideline expert(s)        | • Process supervisor, methodology expert and author<br>• Development, dissemination and implementation of the KNGF guideline and (implementation) products  |
| 4. Subject-matter experts          | • Subject-matter expert scientist(s)  |
| 5. Guideline panel                 | • Representation of the physical therapy field<br>• Representation of the exercise therapy field<br>• Representation of the primary involved PA(s)<br>• Representation of the primary involved other professional group(s)<br>• Representation of patient organisation(s) |

<sup>a</sup> External guidelines are multidisciplinary guidelines that are initiated by an external stakeholder, with the KNGF being invited to take part in the development or revision thereof.

|                                |   |
|--------------------------------|---|
| 6. Review panel                | <ul style="list-style-type: none"> <li>• Representation of the physical therapy field</li> <li>• Representation of the exercise therapy field</li> <li>• Representation of secondary involved PA(s)</li> <li>• Representation of secondary involved professional group(s)</li> <li>• Representation of health insurance companies</li> <li>• Representation of the Healthcare Institute of the Netherlands</li> <li>• Possibly: representation of a secondary involved patient group</li> </ul> |
| 7. Therapist and patient group | <ul style="list-style-type: none"> <li>• Representative from the professional field</li> </ul>  |
| 8. External stakeholders*      | <ul style="list-style-type: none"> <li>• Representation in the guideline panel or review panel, participation in a review phase and authorisation by the respective Board</li> </ul>  |
| 9. KNGF, other departments     | <ul style="list-style-type: none"> <li>• Editing of the KNGF guideline</li> <li>• Publication, dissemination and implementation of the KNGF guideline</li> <li>• Development, dissemination and implementation of the KNGF guideline (implementation) products</li> <li>• Answering and archiving of questions from members about the KNGF guideline</li> <li>• Feedback of content-related questions from members about the KNGF guideline to the KNGF guideline expert(s)</li> </ul>          |

PA = Professional Association.

\* External stakeholders are involved professional groups outside of the physical therapy and exercise therapy fields.

### 2.1 KNGF Board

The KNGF Board is the commissioner of the development/revision<sup>b</sup> and implementation of KNGF guidelines. To this end, the Board includes a specific task regarding the guideline policy in the KNGF annual plan, with the KNGF long-term plan being used as the guideline. The Board is advised by the KNGF guideline expert(s) when defining the proposed task.

The specific tasks of the KNGF Board are as follows:

- defining the task for development/revision and implementation of the KNGF guidelines and approving inclusion of this task in the KNGF annual plan;
- creating conditions for implementing the defined task in terms of financial resources and manpower;
- appointing members who serve on the guideline panel and review panel on behalf of KNGF;
- remotely monitoring the progress of the formulated task(s);
- reviewing the concept guideline;
- authorising the final draft.

A KNGF guideline is written for physical therapists and exercise therapists (Cesar/Mensendieck). That is why the Vereniging van Oefentherapeuten Cesar en Mensendieck (VvOCM) [Association of Cesar and Mensendieck Exercise Therapists] is closely involved in the guideline process. In addition to the KNGF Board, the VvOCM Board is a primary authorising stakeholder.

### 2.2 KNGF Quality Policy department

The KNGF's Quality Policy department accepts the Board's task and is responsible for executing this task.

### 2.3 KNGF guideline expert(s)

The KNGF guideline expert(s) are responsible for executing the Board's task.

<sup>b</sup> An existing KNGF guideline can be revised. A revision concerns an update of an existing guideline based on recent literature and insights. A new KNGF guideline can also be developed about a new topic/disorder.

The KNGF guideline experts fulfil an advisory role for the Board regarding the development and revision of guidelines.

To this end, they continuously monitor the field's need for new guidelines or revision of an existing KNGF guideline. They compile a needs assessment – if possible, annually – by surveying members about KNGF guidelines. In addition, the KNGF guideline experts consult with the Wetenschappelijk College Fysiotherapie (WCF) [Scientific College of Physical Therapy] and the professional associations (PAs) of the KNGF and other stakeholders. Based on all the obtained information, the KNGF guideline experts prioritise the existing needs.

They then issue recommendations to the Board about which guideline they believe should be revised or developed the next calendar year.

A guideline that is developed by order of the Board is assigned to a specific guideline expert. In some cases, multiple KNGF guideline experts are involved in the development of a guideline.

Every KNGF guideline expert possesses expertise and experience in guideline development, process supervision, systematic review, epidemiology, development of measurement instruments and implementation strategies (Zorginstituut [Healthcare Institute of the Netherlands], 2017).

When developing the guideline, the responsible guideline expert fulfils the role of process supervisor, methodological expert and author. These roles are explained below.

#### *The role of process supervisor*

The KNGF guideline expert is responsible for the planning, finances and further organisation and coordination of the guideline process and is asked to deliver a specific guideline and its supplementary products and appendices within the set budget and deadline.

The specific tasks of the KNGF guideline expert in the role of process supervisor are as follows:

- recruiting a subject-matter expert scientist and contracting the knowledge institute where the subject-matter expert scientist works;
- setting up the guideline panel and review panel;
- recruiting an independent chair, and acting as the (technical) chair him/herself if no independent chair is available;
- organising a focus group to identify the barriers with regard to the guideline topic (barrier analysis);
- organising guideline panel and review panel meetings (including reserving rooms and catering, sending out invitations, compiling and distributing the agenda, meeting materials and minutes, processing reimbursements for fees and travel expenses);
- acting as a point of contact for members of the guideline panel and review panel;
- monitoring the process during meetings of the guideline panel and review panel;
- ensuring execution of the professional field review cycle;
- informing the Board about the progress of the guideline;
- submitting the guideline for external review and authorisation to the KNGF Board and the VvOCM Board and the other involved stakeholders;
- providing the guideline to the Healthcare Institute of the Netherlands for inclusion in the Dutch Guideline Database of the Healthcare Institute of the Netherlands (hereinafter referred to as: Dutch Guideline Database)<sup>c</sup>;
- ensuring publication, dissemination and implementation of the guideline.

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<sup>c</sup> *The Dutch Guideline Database of the Healthcare Institute of the Netherlands is an official and public database to which a quality standard (including a guideline), information standard or measurement instrument can be added – on the initiative of patient organisations, healthcare providers and health insurance companies jointly, or on the initiative of the Quality Council. The Dutch Guideline Database is available at [www.zorginzicht.nl](http://www.zorginzicht.nl).*



### ***The role of methodology expert***

The KNGF guideline expert is responsible for the methodological guideline process. This process is divided into a preliminary phase, preparation phase, development phase, review phase, editing phase, authorisation phase, dissemination and implementation phase and maintenance phase (see chapter 3).

The specific tasks of the KNGF guideline expert in the role of methodology expert are as follows:

- informing the guideline panel and review panel members about the methodology employed when developing a guideline;
- going through and executing the methodological steps of the guideline development process;
- ensuring the quality of the various methodological steps in the guideline development process;
- if necessary, adjusting the guideline process and/or adjusting the guideline panel or review panel for the purposes of maintaining quality;
- if necessary, consulting with experts, such as an information specialist (search strategy), experienced reviewer (systematic review) or health economist (cost-effectiveness analyses).

### ***The role of author***

The KNGF guideline expert is responsible for writing text for guidelines, supplemental implementation products and appendices in collaboration with the subject-matter expert scientist(s) (see the next paragraph).

The specific tasks of the KNGF guideline expert in the role of author are as follows:

- acting as the main author of the guideline;
- acting as a (co-)author of the supplemental implementation products and appendices.

## **2.4 Subject-matter expert scientist(s)**

For each guideline, at least one scientist is involved who is a subject-matter expert in the area of the respective guideline and works at a knowledge institute (with which the final contract is concluded). This subject-matter expert scientist should preferably be a senior scientific researcher (professor/lecturer) in the respective disorder.

Additionally, a second scientist can be involved as a subject-matter expert.

Together with the KNGF guideline expert involved in the guideline, these scientists are responsible for the development process of a specific guideline, including a systematic review, the guideline panel and review panel meetings and, ultimately, delivery of the guideline.

The systematic review should preferably be conducted within the knowledge institute where the subject-matter expert scientist(s) work(s) in order to make efficient use of the expertise that is available in the area of review and of the supporting facilities at that institute, such as the information specialist and existing licences.

After the guideline has been completed, the knowledge institute – in the form of the subject-matter expert scientist – remains responsible for the continued monitoring of scientific literature and for informing the KNGF guideline expert correspondingly.

The specific tasks of the subject-matter expert scientist(s) are as follows:

- contributing to the barrier analysis;
- preparing and attending guideline panel and review panel meetings;
- conducting the systematic review (searching, selecting, summarising and weighing the importance of the literature) in collaboration with the KNGF guideline expert;
- elaborating clinical questions, with members of the guideline panel and review panel as fellow readers;
- helping develop the quality indicators on behalf of the guideline;
- assisting with the implementation of the guideline (developing e-learning, writing an article for FysioPraxis, giving a presentation at various congresses);
- monitoring the scientific literature after publication of the guideline (maintenance phase) and advising the KNGF guideline experts about the possible need for modular or complete revision of the guideline. If the subject-matter expert is no longer employed at the knowledge institute, the knowledge institute will assume this task.

## 2.5 Guideline panel

In the event of a guideline revision, the authors of the existing guideline are informed about the revision, and their involvement is taken into consideration when setting up the guideline panel. A new guideline panel is set up for each new guideline that is to be developed.

At least the following primary involved stakeholders are represented in the guideline panel (which should preferably consists of eight to twelve persons):

- the physical therapy field: at least two physical therapists with relevant practical experience in the respective disorder;
- the exercise therapy field: at least one exercise therapist with relevant practical experience in the respective disorder;
- the primary involved physical therapy professional association(s);
- the primary involved other professional group(s) (external stakeholder);
- a patient representative; someone who represents the primary involved patient population on behalf of the Patiëntenfederatie Nederland (NPF) [Dutch Patient Federation] (external stakeholder).

Members of the guideline panel represent the perspective of their own constituencies, so that the final draft is adopted and accepted by all relevant primary involved stakeholders. They are mentioned in the guideline by name, job title, professional association, organisation and/or institute where they work.

Guideline panel members make a constructive contribution to the objective and content of the guideline both in guideline panel meetings and outside of them. In addition, they – together with the KNGF guideline expert – perform certain sub-tasks, such as answering a specific clinical question.

The specific tasks of a guideline panel member are as follows:

- contributing to the barrier analysis;
- preparing and actively participating in guideline panel meetings;
- critically deliberating the formulation of clinical questions and the search strategy;
- executing one or more sub-tasks (such as critically deliberating the response to a specific clinical question);
- critically reading and reviewing the concept text of a guideline;
- ensuring continuous feedback of steps and decisions of the guideline panel to his<sup>d</sup> organisation/constituency.

All members of the guideline panel must complete a Declaration of interests form prior to the first meeting (Appendix 1: 'Declaration of interests form' template).

The overview of interests pertaining to the guideline is usually published at the same time as the guideline.

Representatives of a professional association, organisation and/or institute must also submit a completed Mandate form (Appendix 2: 'Mandate form' template).

The guideline panel meets about five times (possibly supplemented with written input or review cycles). The following topics are discussed during the guideline process in any case:

- everyone's role and task;
- the guideline methodology (in this case, brief training);
- the timeline of the guideline development process (Appendix 3: 'Guideline timeline' template);
- the results of the barrier analysis;
- the work plan and definition of the guideline (Appendix 4: 'Work plan' template);
- the clinical questions and the search strategy;
- the selection and weighing of the literature;
- the concept response to clinical questions and the concept recommendations;
- the concept guideline with associated guideline (implementation) products and appendices.

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<sup>d</sup> Use of the masculine form in this document also includes the feminine form.

During every meeting, the guideline panel members should reach a consensus about the steps to be taken at that moment. If they are not successful in this, the consensus must be reached during a telephone or written review cycle.

The guideline panel members receive the regular KNGF reimbursement for travel expenses and fees.

## **2.6 Review panel**

At least the following *secondary involved stakeholders* are represented in the review panel (which should preferably consists of eight to twelve persons):

- the physical therapy field: at least two physical therapists with relevant practical experience in the area of a related disorder;
- the exercise therapy field: at least two exercise therapists with relevant practical experience in the area of a related disorder;
- the secondary involved physical therapy professional association(s);
- the secondary involved other professional group(s) (external stakeholder);
- health insurance companies: one representative of Dutch Healthcare Insurance Companies (external stakeholder);
- Healthcare Institute of the Netherlands: one representative of the Healthcare Institute of the Netherlands (external stakeholder);
- one patient representative; someone who represents the patient population of a secondary disorder on behalf of the Patiëntenfederatie Nederland (NPF) [Dutch Patient Federation] (external stakeholder).

Members of the review panel represent the perspective of their own constituencies, so that the final draft is accepted by all relevant secondary involved stakeholders. They are mentioned in the guideline by name, job title, professional association and/or institute where they work.

The specific tasks of the review panel members are as follows:

- critically reading and reviewing the concept documents;
- ensuring feedback of steps taken and decisions made by the guideline panel and the review panel to the organisation or constituency.

The KNGF guideline expert ensures that the members of the review panel have access to the concept documents. During the meeting the guideline process and the choices made by the guideline panel are explained in more detail by the KNGF guideline expert and/or the subject-matter expert scientist.

All members of the review panel must complete a Declaration of interests form prior to the first meeting (Appendix 1: 'Declaration of interests form' template). The overview of interests pertaining to the guideline is usually published as an appendix to the guideline.

Representatives of a professional association, organisation and/or institute must also submit a completed Mandate form (Appendix 2: 'Mandate form' template).

The review panel meets about four times (possibly supplemented by written input or review cycles). The following topics are discussed during the guideline process in any case:

- everyone's role and task;
- the guideline methodology (in this case, brief training);
- the results of the barrier analysis;
- the work plan and definition of the guideline (Appendix 4: 'Work plan' template);
- the clinical questions and the search strategy;
- the selection and weighing of the literature;
- the concept response to clinical questions and the concept recommendations;
- the concept guideline with associated guideline (implementation) products and appendices.

If the review panel is smaller than the recommended size of eight to twelve persons (e.g. if multiple stakeholders do not cooperate or only wish to provide a written review), then written review panel cycles may be opted for instead of meetings.

During every meeting, the review panel members should reach a consensus about the steps to be taken at that moment. If they are not successful in this, the consensus must be reached during a telephone or written review cycle.

The review panel members receive the regular KNGF reimbursement for travel expenses and fees.

### **2.7 Therapist and patient group**

Therapists and patients ('the professional field'), in the form of their representatives, are closely involved in the development of a KNGF guideline. They play an essential role in developing or revising guidelines during the preparation phase (by indicating and defining barriers), the development phase (by means of representation in the guideline panel and review panel) and the review phase (through the professional field review cycle). They also play a role in the maintenance phase by indicating and prioritising guideline topics.

The primary task of therapists and patients is to monitor the applicability and accessibility of the guideline. Even after the guideline has been published, they can provide continuous feedback to the KNGF about the content and/or implementation of the guideline. This feedback is archived and brought up during the next revision of the guideline.

The specific tasks of the therapist and patient group are as follows:

- having a seat on either the guideline panel (as a primary involved stakeholder) or the review panel (as a secondary involved stakeholder);
- providing barriers for the barrier analysis;
- reviewing the applicability and legibility of the concept guideline based on a representative sampling from the professional field;
- indicating and prioritising topics for new guidelines needed in the professional field;
- indicating barriers in the application of existing guidelines in daily practice (implementation).

### **2.8 External stakeholders**

External stakeholders are interested parties outside of the physical therapy and exercise therapy fields who are ultimately expected to authorise the guideline. External stakeholders represent their constituency in the guideline development process, either in the guideline panel or in the review panel.

The specific tasks of the external stakeholders are as follows:

- representation of one or more members with a mandate in the guideline panel (primary involved stakeholder) or review panel (secondary involved stakeholder);
- reviewing the concept guideline during the review phase;
- authorising or submitting a declaration of no objection for the guideline;
- being a co-applicant when submitting the guideline to the Healthcare Institute of the Netherlands for inclusion in the Dutch Guideline Database.

### **2.9 Other KNGF departments**

Other KNGF departments also play a role in the development, dissemination and implementation of the KNGF guideline and associated guideline (implementation) products.

The Quality Policy department maintains close cooperation with the Marketing & Communications department when developing guidelines and (implementation) products and launching these online. The Account Management Members, Interest Representation and Front Office (member information) departments are also involved during the implementation phase.

The KNGF Front Office department is responsible for archiving questions and comments regarding the KNGF guidelines. This department forwards content-related questions from members about a KNGF guideline to the KNGF guideline expert(s).

### **2.10 Authorship**

The guideline is written by the KNGF guideline expert and the (external) subject-matter expert scientist of the respective guideline. They are mentioned in the guideline with their affiliation.

The primary responsibility for the guideline resides with the KNGF. The guideline is and remains the property of the KNGF.

After publication of the guideline, the KNGF guideline expert(s) and subject-matter expert scientists may jointly publish the guideline in an (international) scientific journal. This article may concern a process description or the review, for example. The KNGF guideline expert(s) and subject-matter expert scientist(s) publish jointly. The KNGF and the respective knowledge institute where the subject-matter expert scientist is employed coordinate and make clear agreements about the publication.

#### Relevant appendices

- Appendix 1 'Declaration of interests form' template
- Appendix 2 'Mandate form' template
- Appendix 3 'Guideline timeline' template
- Appendix 4 'Work plan' template

### 3 Phases in the KNGF guideline methodology

The tasks within the guideline process are described based on eight phases: the preliminary phase, the preparation phase, the development phase, the review phase, the editing phase, the authorisation phase, the dissemination and implementation phase and, finally, the maintenance phase.

The table below contains an overview of these phases of the KNGF guideline methodology and their components.

#### *Phases in the KNGF guideline methodology*

##### 1. Preliminary phase (section 3.1)

- Needs assessment and formulation of a recommendation to the Board
- Inclusion of the guideline policy in the KNGF annual plan

##### 2. Preparation phase (section 3.2)

- Hiring of the subject-matter expert scientist by contracting a knowledge institute
- Setup of the guideline panel and review panel
- Discussion of everyone's tasks and responsibilities
- Execution of the barrier analysis
- Definition of the guideline
- Formulation and determination of clinical questions
- Execution of desk research

##### 3. Development phase (section 3.3)

- Formulation of the clinical questions
- Finalisation of the module
- Combine modules into chapters
- Combine chapters into a concept guideline

##### 4. Review phase (section 3.4)

- Internal review cycle
- External review cycle
- Discussion of the review
- Processing of the review
- Delivery of the final draft
- Start of implementation product development (see Dissemination and implementation phase)

##### 5. Editing phase (section 3.5)

- Editing of the final draft

##### 6. Authorisation phase (section 3.6)

- Authorisation by the KNGF/VvOCM Boards
- Authorisation or declaration of no objection by external stakeholders

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### 7. Dissemination and implementation phase (section 3.7)

- Publication of the guideline on the KNGF knowledge platform
- Communicating about the guideline
- Submission of the guideline for inclusion in the Dutch Guideline Database of the Healthcare Institute of the Netherlands
- Development of supplemental guideline (implementation) products and appendices

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### 8. Maintenance phase (section 3.8)

- Continuous collection of feedback from the professional field
  - Annual monitoring of publications and developments
  - Modification or complete revision of the guideline
  - Execution of a needs assessment and desk research
  - Continuous monitoring by the knowledge institute
- 

### 3.1 Preliminary phase

- 
- Needs assessment and formulation of a recommendation to the Board
  - Inclusion of the selected guidelines for revision or development in the KNGF annual plan
- 

#### 3.1.1 Needs assessment and formulation of a recommendation to the Board

The KNGF guideline experts continuously monitor barriers that occur in daily practice when applying existing KNGF guidelines, or whether there is a need for a full or modular<sup>e</sup> revision of a guideline or for a guideline to be developed about a new topic.

The subject-matter expert scientists of existing guidelines are responsible for informing the KNGF guideline experts about publications that could be a basis for a full or modular guideline revision. The KNGF guideline experts, in turn, monitor which relevant external guidelines are being developed and which other policy developments are taking place that necessitate the revision of an existing guideline or the development of an entirely new guideline.

Based on the acquired information, and possibly after consultation with the WCF and the PAs, the KNGF guideline experts prioritise which existing guidelines are eligible for full or modular revision and about which new topics a guideline should be developed.

Specific content-related and strategic criteria are considered when prioritising topics/guidelines.

#### *Criteria for developing a new guideline*

- the needs of the professional field;
- the prevalence of the health problem in daily practice;
- the scope of the health problem, whereby it can be assumed that physical therapy<sup>f</sup> will result in health benefits;
- the degree of scientific evidence;
- the degree of variation in physical therapy activities;
- the possibility of limiting the topic;
- whether it is realistic to expect the relevant stakeholders to reach a consensus;
- whether the guideline can be included in the short term or can be affiliated with an external guideline or healthcare standard;
- the importance of the guideline for the position of the physical therapy.

#### *Additional criteria for full or modular revision*

- the age of the guideline or module;
- the degree of relevance of new insights and/or scientific evidence;

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*e A guideline can undergo full or modular revision. A guideline consists of multiple clinical questions. The elaboration of a clinical question constitutes a guideline module. All guideline modules together constitute the guideline.*

*f Wherever physical therapy is mentioned, this can also include exercise therapy and vice versa.*

- the degree to which the guideline is employed in daily practice;
- the severity of the barriers that are found when applying the guideline or module;
- a new external guideline about the topic has been published, due to which the (organisation of) physical therapy care must change.

Based on the needs assessment and the recommendations of the WCF, the PAs and possibly other stakeholders, the KNGF guideline experts issue recommendations every fall to the KNGF Board about the development or revision of one or more guideline topics during the next calendar year. The proposed relevant involved and external stakeholders and the global project planning and budget are included in these recommendations.

### 3.1.2 Inclusion of the guideline process in the KNGF annual plan

After approval by the KNGF Board, the KNGF guideline experts ensure that the guideline process (consisting of development or revision of a guideline) is included in the KNGF annual plan for the next calendar year.

The annual plan specifically describes which activities are planned within the guideline process for the coming year and how these activities are aligned with the mission and vision of the KNGF long-term policy plan.

The KNGF Board presents this annual plan to its members for approval in the fall. After being approved by the members, the proposed guideline project is started in the next calendar year.

### 3.2 Preparation phase

- Hiring of the subject-matter expert scientist(s)
- Setup of the guideline panel and review panel
- Discussion of everyone's tasks and responsibilities
- Execution of the barrier analysis
- Definition of the guideline
- Formulation and determination of concept clinical questions
- Execution of orienting review
- Formulation of the concept search strategy

The following table summarises the tasks, activities and who is responsible during the preparation phase.

#### *The preparation phase*

| Task   | Activity   | Responsible party/parties   |
|--|--|---|
| Hiring of the subject-matter expert scientist(s) | <ul style="list-style-type: none"> <li>• Approach subject-matter expert scientists and the knowledge institute where the scientists are employed, document the agreements made with the knowledge institute</li> </ul> | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul>   |
| Setup of the guideline panel and review panel    | <ul style="list-style-type: none"> <li>• Approach members for the guideline panel and review panel and document agreements that were made</li> </ul>   | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul>   |
| Collection and prioritisation of barriers        | <ul style="list-style-type: none"> <li>• Perform a barrier analysis</li> </ul>   | <ul style="list-style-type: none"> <li>• Professional field</li> <li>• Review panel</li> <li>• Guideline panel</li> </ul> |
| Determination of the clinical questions          | <ul style="list-style-type: none"> <li>• Formulate and determine the clinical questions</li> <li>• Formulate the search strategy</li> </ul>  | <ul style="list-style-type: none"> <li>• Guideline panel</li> </ul>   |
| Execution of orienting review                    | <ul style="list-style-type: none"> <li>• Execute orienting review as preparation for the guideline process</li> </ul>  | <ul style="list-style-type: none"> <li>• KNGF guideline expert and subject-matter expert scientist(s)</li> </ul>          |

### **3.2.1 Hiring of the subject-matter expert scientist(s)**

When a guideline is being revised or developed, the KNGF guideline expert decides – after receiving approval by the Board – on a subject-matter expert scientist who has specific expertise in the guideline's field and who is employed by a knowledge institute. Both parties are approached by the KNGF guideline expert and are informed about the proposed tasks, as described in section 2.4.

If the subject-matter expert scientist and the knowledge institute agree, agreements are concluded that are contractually set forth with the knowledge institute.

### **3.2.2 Setup of the guideline panel and review panel**

The KNGF guideline expert – possibly in consultation with the subject-matter expert scientist and any other stakeholders – makes a selection from the proposed stakeholders and/or persons in order to compile a guideline panel and a review panel.

The KNGF guideline expert approaches these parties and/or persons and informs them about the required tasks, as described in sections 2.5 and 2.6.

Members of the guideline panel and review panel who wish to assume tasks receive a declaration of interests form (Appendix 1: 'Declaration of interests form' template) that they must complete, sign and return. Representatives of a professional association, organisation or institute must also submit a completed Mandate form (Appendix 2: 'Mandate form' template).

Based on the declaration of interests, the KNGF guideline expert assesses whether any undesirable conflicts of interest exist, so that another representative can be selected, if necessary. The members of the guideline panel and review panel who serve on behalf of the KNGF are also nominated and officially approved by the KNGF Board.

The members of the guideline panel and review panel receive the following documents:

- the barrier analysis (Appendix 5: 'Barrier analysis' template);
- a list with relevant guidelines/standards, systematic reviews and other key articles, as a supplement, if applicable;
- proposed dates for meetings of the guideline panel or review panel (as applicable).

In the preparation phase the guideline panel and the review panel usually each meet once.

### **3.2.3 Discussion of tasks and responsibilities**

During the first meeting of the guideline panel and the review panel, the members introduce themselves and the KNGF guideline expert describes the proposed tasks and responsibilities. In addition, the KNGF guideline expert explains the guideline methodology. A concept work plan is also composed and discussed in mutual consultation (Appendix 4: 'Work plan' template).

### **3.2.4 Execution of the barrier analysis**

The barrier analysis is carried out by the guideline panel and the review panel based on Appendix 5: 'Barrier analysis' template. In this template the guideline panel members indicate the barriers encountered in the professional field and the points of attention for the respective guideline topic. The members of the guideline panel and the review panel are actively involved in identifying the barriers and the points of attention.

Barriers are also collected by means of focus group meetings, surveys, invitational conferences, personal interviews, etc. This happens by means of a (personal) invitation from the KNGF guideline expert in cooperation with other KNGF departments sent to physical therapists in the professional field, patients, involved professional groups and other stakeholders, including health insurance companies.

### **3.2.5 Definition of the guideline**

Based on the outcome of the barrier analysis and the available knowledge (such as insights and literature) and resources (such as time), the KNGF guideline expert, the subject-matter expert scientist(s), the guideline panel and the review panel aim to reach a consensus about



the definition of the guideline. The definition concerns, among other things, the objective and the target group, the indications and the therapeutic interventions. The definition is decisive for the clinical questions.

### 3.2.6 Formulation and determination of the clinical questions

The clinical questions are compiled by the guideline panel based on the work plan developed for this (Appendix 4: 'Work plan' template) and follow the layout of the guideline in 'General information', 'Diagnostic process' and 'Therapeutic process'.

Other than these general clinical questions, the guideline panel formulates additional clinical questions per chapter based on the barrier analysis. All clinical questions are then prioritised per chapter. The Toetsingskader (Assessment Framework)<sup>g</sup> (Healthcare Institute of the Netherlands, 2015) is also taken into consideration for the formulation.

How many clinical questions are addressed in the guideline is determined by the subject-matter expert scientist(s) and the KNGF guideline expert. The guideline panel selects the final clinical questions in close cooperation with the review panel.

The subject-matter expert scientist(s) and the KNGF guideline expert are also responsible for the methodology. They have to determine which clinical questions will be answered systematically – by means of systematic review – and which ones will be answered narratively (descriptively). The aim is for the guideline to contain 10 systematically elaborated clinical questions.

### 3.2.7 Orienting review

Parallel to the barrier analysis and the meetings in which the guideline panel and review panel discuss the clinical questions, the KNGF guideline expert delves deeper into the guideline's topic by means of orienting review. This way more insight is obtained into the topic and the recent associated developments.

### 3.2.8 Formulation of the concept search strategy

Based on the final clinical questions, the guideline panel formulates the concept search strategy for the review (including search terms, search period and inclusion and exclusion criteria). The guideline panel also compiles a shortlist of key articles that serve as a control of the review. If sufficient evidence is deemed to be available, then the option to conduct the review hierarchically can be considered. Existing evidence-based guidelines, systematic reviews and/or meta-analyses are then used in the first instance. If this strategy ultimately yields insufficient literature, then randomised controlled studies are searched for in the second instance and observational studies in the third instance.

### Relevant appendices

- Appendix 1 'Declaration of interests form' template
- Appendix 3 'Guideline timeline' template
- Appendix 4 'Work plan' template
- Appendix 5 'Barrier analysis' template

## 3.3 Development phase

- 
- Elaboration of clinical questions
  - Finalisation of modules
  - Combine modules into chapters
  - Combine chapters into a concept guideline
  - Compilation of a summary
  - Start of indicator development
- 

<sup>g</sup> Based on the Assessment Framework, the Healthcare Institute of the Netherlands determines whether quality standards, information standards or measurement instruments that are submitted to the Dutch Guideline Database are a justified description of the quality of a healthcare process or a justified way of measuring whether good healthcare has been provided (Healthcare Institute of the Netherlands, 2015).

About four guideline panel meetings and two review panel meetings are held during the development phase. One or more clinical questions are discussed per meeting. The number and scope of the clinical questions determine the final number of meetings.

The elaboration of a clinical question constitutes a module in the guideline. This enables modular revision of a guideline. The modules are combined into chapters, and the chapters together constitute the guideline. Finally, a summary of the guideline is written.

The following table summarises the tasks, activities and who is responsible during the development phase.

#### *The development phase*

| Task  | Activity   | Responsible party/parties  |
|---|--|--|
| Elaboration of a clinical question                          | • Conduct systematic review  | • KNGF guideline expert in cooperation with the subject-matter expert scientist(s) |
|   | • Discuss literature results and considerations                                      | • Guideline panel during the guideline panel meeting                               |
|   | • Determine concept recommendations or description                                   | • Guideline panel during the guideline panel meeting                               |
| Finalisation of the modules                                 | • Approve concept modules<br>• Finalise the modules                                  | • Guideline panel during the guideline panel meeting                               |
| Delivery of a concept guideline                             | • Combine final modules into chapters<br>• Combine chapters into a concept guideline | • KNGF guideline expert  |
| Delivery of a summary of the guideline                      | • Summarise the KNGF guideline   | • KNGF guideline expert  |
| Start development of indicators and implementation products | • Develop concept quality indicators   | • KNGF guideline expert in cooperation with the subject-matter expert scientist(s) |

#### **3.3.1 Elaboration of clinical questions**

It is preferable for a clinical question to be systematically elaborated. If systematic elaboration is not feasible, a narrative elaboration is selected.

The clinical questions are elaborated by a KNGF guideline expert and the subject-matter expert scientist(s). In some cases, a guideline panel member is called in to assist the KNGF guideline expert with this task, based on the field of expertise or interest. It is preferable for this to be done per clinical question.

#### ***Systematic elaboration of a clinical question***

A set methodology is employed for the systematic elaboration. This methodology has three phases:

- Systematic review
- Evidence to decision
- Formulation and determination of the recommendation(s)

#### ***Systematic review***

The systematic review is conducted by a KNGF guideline expert and the subject-matter expert scientist(s).

In addition to the actual systematic literature search, this review also includes selecting, summarising and weighing the literature. Pre-established inclusion and exclusion criteria form the basis for the selection of the encountered literature. If a clinical question concerns an intervention, the desired and undesirable effects of the intervention are also defined. For the ultimate search strategy, advice may be obtained from an information specialist of the knowledge institute. The review is conducted in electronic databases, such as PubMed, EMBASE, PEDRO and Cochrane Library.

The first selection is done based on the title and abstract of the encountered articles. The second selection is done based on a screening of the full articles. The KNGF guideline expert ensures complete documentation and archiving of the search and selection process, enabling replication of these processes. It is possible to check whether the search task is complete with the help of key articles. If this is not the case, the search strategy needs to be adjusted. If multiple studies are found in which a cost effectiveness study has been conducted, a health economist can be hired for a cost effectiveness analysis that summarises the outcomes of various studies.

The review takes place prior to the guideline panel meeting during which the respective clinical question is discussed.

The methodological quality of the included literature is assessed per study. This concerns limitations in the study design and implementation (risk of bias). Then the characteristics of the studies are listed in a table and the outcomes per outcome measure are summarised. The evidentiary value/quality of evidence is assessed by the KNGF guideline expert with the help of the GRADE system (GRADE: *Grading of Recommendations Assessment, Development and Evaluation*). According to this system, the quality of evidence per outcome measure is determined based on five criteria (box 1).

**Box 1. GRADE criteria for adjusting the quality of evidence**

Based on various factors, it may be necessary to adjust the quality of evidence ('body of evidence') downward. These factors are grouped as follows in GRADE:

- *limitations in the study design and implementation*: for example, through randomisation errors or due to a lack of follow-up;
- *inconsistency*: when the results of the various studies vary in magnitude and/or direction and this heterogeneity cannot be explained; the confidence intervals do not overlap or barely overlap.
- *indirectness*: if the found evidence does not (entirely) align with one or more PICO elements, for example, if intermediate or surrogate outcome measures are used (O) or if no direct comparison of the experimental and standard intervention is available (I-C);
- *inaccuracy of the estimated effect*: inaccuracy occurs if the estimated effect is based on a small study group and/or few events, resulting in broad confidence intervals;
- *publication bias*: for example, if it is plausible that studies with negative results are not submitted for publication.

The quality of the evidence can be adjusted upwards based on:

- *the magnitude of the effect*;
- *the dose-response relationship*;
- *a favourable effect of confounders*: if it can be reasoned that correcting distorting factors would lead to a large increase of the effect.

The GRADE system has four levels of quality of scientific evidence: 'high', 'moderate', 'low' or 'very low'. This level indicates how high the chance is that the actual effect will be close to the estimated effect and must be independently determined per outcome measure. If the scientific evidence consists of solely RCT(s), then the assumption is that the quality of the evidence is high; if other studies in addition to RCTs are included, then the assumption is that the quality of the evidence is low.

The results of the GRADE assessment are then displayed in a GRADE evidence profile per outcome measure and per clinical question (Appendix 6: 'GRADE evidence profile' template). This

GRADE evidence profile is sent to the guideline panel with a request to check it for inclusion of all relevant studies.

### **Evidence to decision**

The results of the review are discussed during the guideline panel meeting, under the direction of the KNGF guideline expert.

Subsequently, the considerations are discussed. The evidence-to-decision format includes which considerations can play a role. Considerations are substantiated with scientifically 'grey' literature, where possible. Based on the quality of the literature (determined based on GRADE) and the discussed considerations, the strength (*strong/weak*) and the direction of the recommendation(s) (*positive/negative*) are determined. This process is called *evidence to decision*.

Recommendations should:

1. be a summary of the response to the clinical question;
2. stand on their own and have only one interpretation;
3. be as specific and concrete as possible;
4. where possible, also have an efficiency aspect (with regard to expensive interventions);
5. be compliant with the standard formulation.

Recommendations should preferably be formulated as follows:

– **Strongly positive:**

'Apply...' / 'Implement...' / 'Offer...'

'The guideline panel has concluded that... should be applied.'

– **Weak/conditionally positive:**

'Preferably apply...'

'Take into consideration...' / 'Consider...'

– **Weak/conditionally negative:**

'Preferably do not apply...'

'Take into consideration...' / 'Consider...' / 'Be cautious in ...'

– **Strongly negative:**

'Do not apply...' / 'Do not implement...' / 'Do not offer...'

### **Formulation and determination of the recommendation(s)**

If the guideline panel has achieved a consensus about the strength and direction of the recommendation(s), the concept recommendation(s) is/are determined. The considerations that played a role in determining the concept recommendation(s) are also described.

Clinical questions about the use of measurement instruments are answered on the basis of the 'Raamwerk Klinimetrie' (Clinimetry Framework) (Swinkels et al., 2015). The most suitable measurement instruments are selected in this framework, in a structured manner and based on theoretical and practical arguments. Also, when prioritising measurement instruments as much alignment as possible is sought with the recommended measurement instruments in other (recent) KNGF guidelines.

### **Narrative elaboration of a clinical question**

Not all clinical questions can be systematically elaborated, either because systematic review is not indicated for this or because such a review is not feasible with the available time and resources. This concerns, for example, clinical questions that describe incidence, prevalence and pathophysiology or clinical questions about the organisation of care.

These questions are therefore narratively elaborated.

With narrative elaboration, non-systematic review is performed and, where necessary, 'grey' literature is also included in addition to scientific literature. No systematic evidence to decision process takes place. Instead, considerations are discussed in the guideline panel until a con-

sensus has been reached. A narrative elaboration of a clinical question results in a description, including a description of these considerations, and in some cases in a recommendation.

### **3.3.2 Finalisation of modules**

The complete elaboration of a clinical question, including – if applicable – a summary of the systematic review, a brief overview of the evidence to decision process and one or more recommendations, constitutes a module of a guideline.

The KNGF guideline expert submits each concept module separately to the guideline panel and review panel for approval. If a consensus has been reached in both the guideline panel and the review panel, the module is finalised.

Each module has the same layout and consists of four parts: 'Practice guideline', 'Explanation', 'Justification' and 'References'.

#### ***Practice guideline***

The practice guideline is a brief and concise presentation of all recommendations.

#### ***Explanation***

The recommendations are explained and conclusions from the literature and the most important considerations that led to the recommendation are described in this part.

#### ***Justification***

In this part, a complete description is provided of the results per outcome measure, the assessment of the methodological quality and the other considerations that resulted in the recommendation.

#### ***References***

In this part, all references are provided per module.

### **3.3.3 Combine modules into chapters**

Ultimately, all finalised modules are combined into chapters.

The chapter layout is fixed: 'General information', 'Diagnostic process' and 'Therapeutic process'. All chapters together constitute the concept guideline.

The layout and the modules that describe the background of the disorder are included in the 'General information' part. Modules that describe diagnostics are included in the 'Diagnostic process' part. Modules that describe therapy and completion of the therapy are included in the 'Therapeutic process' part.

### **3.3.4 Combine chapters into a concept guideline**

Lastly, all chapters are combined. This results in the concept guideline.

### **3.3.5 The summary**

A summary is also compiled for every KNGF guideline. All recommendations, subdivided into 'General information', 'Diagnostic process' and 'Therapeutic process', are described in a simple and point-by-point manner and briefly explained in about two pages (Appendix 7: 'Summary' template).

### **3.3.6 Development of indicators and implementation products**

The Assessment Framework states that development of indicators is also a part of the guideline development. Based on the selected core recommendations, concept quality indicators are developed with tripartite involvement<sup>h</sup>. These concept indicators form the basic set of indicators that will be described in the first instance for internal use. The process for determining indicators is still under development and will be described in more detail in a later phase.

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<sup>h</sup> *Tripartite means that three stakeholders are involved in something; in this case, healthcare providers, patients and health insurance companies.*

The indicators are not a part of the guideline but are seen as an implementation product and are included in seminar modules. Development of indicators and other implementation products will commence as soon as the concept guideline has been determined. A more detailed description of this follows in section 3.7.

### Relevant appendices

Appendix 6 'GRADE evidence profile' template

Appendix 7 'Summary' template

### 3.4 Review phase

- 
- Internal review cycle
  - External review cycle
  - Discussion of the review
  - Processing of the review
  - Final draft as the end product
- 

During the review phase the concept guideline is submitted to the involved stakeholders, and they are asked to provide a review. The review phase is further subdivided into the internal review cycle and the external review cycle. During the internal review cycle the concept guideline is shared with the professional field of physical and exercise therapists, the WCF and the KNGF and VvOCM Boards.

During the external review cycle the concept guideline is shared with external involved stakeholders, such as other professional groups and stakeholders involved in the guideline, including health insurance companies. Discussion of the collected reviews with the guideline panel and incorporation of the reviews in order to determine a final draft are also part of the review phase.

The entire review phase takes about three months.

The following table summarises the tasks, activities and who is responsible during the review phase.

#### *The review phase*

| Task                                   | Activity  | Responsible party/<br>parties  |
|--|---|--|
| Collection of internal reviews         | <ul style="list-style-type: none"> <li>• Collect reviews from the professional field</li> <li>• Collect reviews from the WCF</li> <li>• Collect reviews from the KNGF and VvOCM Boards</li> </ul> | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul>                          |
| Collection of external reviews         | <ul style="list-style-type: none"> <li>• Collect reviews from external involved stakeholders</li> <li>• Collect reviews from the review panel</li> </ul>  | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul>                          |
| Summarisation of the collected reviews | <ul style="list-style-type: none"> <li>• Summarise all the collected reviews</li> </ul>   | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul>                          |
| Discussion of the collected reviews    | <ul style="list-style-type: none"> <li>• Present and discuss the summary of the collected reviews</li> <li>• Come to a consensus about the changes that need to be made</li> </ul>                | <ul style="list-style-type: none"> <li>• KNGF guideline expert with the guideline panel</li> </ul> |
| Processing of the review               | <ul style="list-style-type: none"> <li>• Implement the desired changes into the guideline</li> <li>• Resubmit the guideline to the guideline panel</li> </ul>                                     | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul>                          |
| Finalisation of the guideline          | <ul style="list-style-type: none"> <li>• Give final approval of the guideline</li> </ul>  | <ul style="list-style-type: none"> <li>• Guideline panel</li> <li>• Review panel</li> </ul>        |

#### **3.4.1 Internal review cycle**

A professional field review cycle is used in the internal review cycle. During this professional field review cycle, the concept guideline is proposed to the respective physical therapist and exercise therapist professional field. The professional field review cycle is intended to review the concept guideline for practical applicability and legibility of the guideline in a broad, heterogeneous representative reflection of the professional field. A professional field review cycle can take place in various ways: it can be a written/electronic review cycle, a focus group meeting or a practical test. Various departments of the KNGF and the VvOCM cooperate when approaching the professional field.

At the same time as the professional field review cycle, the concept guideline is submitted to the WCF and the Boards of the KNGF and the VvOCM for review.

#### **3.4.2 External review cycle**

At the same time as the internal review cycle, the concept guideline is submitted to the involved external stakeholders for review. The concept guideline is also submitted to the members of the review panel for review.

In general, the response period is about two months. A standard review form must be used for reviews (Appendix 8: 'Review form' template).

#### **3.4.3 Discussion of the collected reviews**

The KNGF guideline expert summarises the received reviews into a review table which shows which party provided which review. This review table is submitted to the guideline panel. The guideline panel is asked to respond to this in writing (electronically) or in a guideline panel meeting.

The guideline panel should reach a consensus about which changes and/or additions are required or desired to be made to the concept guideline and which will (must) be implemented.

In consultation with the guideline panel and per received review, the KNGF guideline expert outlines a substantiated proposal of how this review or the proposed suggestion for changes and/or additions will or will not be incorporated into the guideline. This rationale is added to the review table.

#### **3.4.4 Processing of the received reviews**

The KNGF guideline expert processes the received reviews and the desired changes and/or additions that have been determined by the guideline panel. The manner in which the reviews are processed is also added to the table with reviews.

The modified version of the concept guideline is then resubmitted to the guideline panel and the review panel, but this time only for notification purposes. Reviews stemming from this that require a revision of the guideline are in turn processed by the KNGF guideline expert.

#### **3.4.5 Final draft as the end product**

After approval of the modified version of the concept guideline by both the guideline panel and the review panel, the final draft is ready.

### **Relevant appendices**

Appendix 8 'Review form' template

### **3.5 Editing phase**

- 
- Editing of the final draft
- 

The final draft is sent to the party that is responsible for the (web) editing of the KNGF guideline. The editors check the guideline for readability and layout and modify the guideline in accordance with the KNGF corporate style, in coordination with the KNGF guideline expert. No content changes are implemented to the guideline.

In addition to a digital version, a PDF version of the guideline is also created.

### 3.6 Authorisation phase

- 
- Authorisation by the KNGF/VvOCM Boards
  - Authorisation or declaration of no objection by external stakeholders
- 

During the authorisation phase the final draft is submitted to the KNGF and VvOCM Boards and the involved external stakeholders for authorisation. The authorisation phase lasts about two to three months.

The following table summarises the tasks, activities and who is responsible during the authorisation phase.

| Task                             | Activity  | Responsible party/parties   |
|----------------------------------|---|---|
| Authorisation of the final draft | <ul style="list-style-type: none"> <li>• Submit the final draft to the KNGF Board and VvOCM Boards</li> <li>• Submit the final draft to the involved external stakeholders</li> </ul> | <ul style="list-style-type: none"> <li>• KNGF guideline expert</li> </ul> |

#### 3.6.1 Authorisation by the KNGF Board and VvOCM Board

The final version of the guideline is submitted for authorisation to the KNGF Board and the VvOCM Board.

#### 3.6.2 Authorisation or declaration of no objection by external stakeholders

The final version of the guideline is submitted for authorisation to the Boards of the involved external stakeholders. A standard authorisation form is used for this (Appendix 9: 'Authorisation letter' template).

The complete table with reviews, including summary, rationale and undertaken actions based on the reviews is also submitted. This information allows external stakeholders to see whether and how the reviews have or have not been incorporated.

The external stakeholders are asked to authorise the guideline or submit a declaration of no objection. They generally have a period of two months to authorise the guideline. By authorising the guideline, the external stakeholders also approve the submission of the guideline to the Dutch Guideline Database of the Healthcare Institute of the Netherlands.

#### Relevant appendices

Appendix 9 'Authorisation letter' template

### 3.7 Dissemination and implementation phase

#### *Standard products and steps*

- Publication of the guideline on the KNGF knowledge platform
- Communication about the publication of the guideline
- Submission of the guideline for inclusion in the Dutch Guideline Database
- Development of e-learning
- Development of patient information
- Development of seminar activities

#### *Optional products and steps*

- Development of a factsheet
  - Knowledge gaps
  - Scientific publication
  - Placement of an English translation on international websites
-



The dissemination and implementation phase runs parallel to the development phase of a guideline and is dependent on it. It is the task of the KNGF guideline expert to monitor the progress of the – guideline-specific products and align the dissemination and implementation with the development phase.

For every guideline, a number of standard but still guideline-specific dissemination and implementation products are developed at the same time as the guideline. Non-standard, guideline-specific dissemination and implementation products can also be developed. These are optional.

### **3.7.1 Standard dissemination and implementation products**

#### ***Publication of the guideline on the KNGF knowledge platform***

After authorisation of the guideline by the KNGF Board and the VvOCM Board, a guideline is always published on the KNGF knowledge platform. All guidelines are accessible to members on this website. In addition, a PDF version of all the parts of all the guidelines can be downloaded from this site by both members as well as non-members.

#### ***Communication about the publication of the guideline***

News items and medial channels communicate about the publication of the guideline on the KNGF knowledge platform. For example, a news item is distributed via Fysio-Enieuws, and a news item is placed on the knowledge platform. An article about the new guideline is published in *FysioPraxis*. The article is written in consultation with the KNGF guideline expert and the involved subject-matter expert scientist.

In addition, the available media channels of the KNGF also communicate about the guideline.

If the guideline has also been authorised by external stakeholders, the link to the knowledge platform and the PDF version of the guideline is shared with all involved external stakeholders. A sample news item is also submitted, which these stakeholders can use in their communication with their own constituency.

#### ***Submission of the guideline for inclusion in the Dutch Guideline Database***

The KNGF guideline expert submits the guideline for inclusion in the Dutch Guideline Database of the Healthcare Institute of the Netherlands using the appropriate submission form.

#### ***Development of e-learning***

An e-learning module is developed for each KNGF guideline, for which accreditation is requested from the KNGF's and VvOCM's accreditation committees. The e-learning is made available to all physical and exercise therapists. The goal of the e-learning is to increase knowledge of the guideline's content and allow this knowledge to be applied in case studies. All chapters are discussed, and practice questions are provided at the end of each chapter. Passing the final exam means that the e-learning has been successfully completed.

#### ***Development of patient information***

Patient information is developed for every KNGF guideline – in cooperation with the guideline panel – pursuant to the appropriate format (Appendix 10: 'Patient information').

#### ***Development of seminar activities***

In order to implement the developed KNGF guideline in practice, the KNGF develops and/or facilitates KNGF seminar activities, such as a lecture, a one- or multiple-day class, intervention, on-the-job coaching, etc.

### **3.7.2 Optional dissemination and implementation products**

#### ***Development of a factsheet***

The added value of physical therapy for the disorder that the KNGF guideline pertains to is demonstrated clearly and legibly on two pages. The goal is to inform various target groups about the added value of physical therapy. Target groups include patients, referrers, healthcare purchasers, politicians and policy-makers.

### **Knowledge gaps**

To respond to a gap in knowledge, a list is compiled containing the clinical questions stemming from the barrier analysis and that form a barrier in daily physical therapy practice but for which no or little evidence has been found.

### **Scientific publication**

It is possible to publish physical therapy guidelines in a number of international scientific journals that are aimed at physical therapy. A publication is written by the KNGF guideline expert and the subject-matter expert scientist(s). In addition, the results of the systematic review can be summarised in a scientific systematic review.

### **Placement of the English translation of the guideline on international websites**

If the guideline has not already been translated into English by the subject-matter expert scientist(s) (within the scope of a scientific publication), it is translated by a translation agency or by the guideline expert(s).

The KNGF guideline expert places the English version of the guideline on international websites that deal with guideline development or physical therapy, such as the website of the *Guidelines International Network* (G-I-N), the *ER-WCPT* and/or in the PEDRO database.

## **3.8 Maintenance phase (guideline policy)**

- 
- Continuous collection of feedback from the professional field
  - Annual monitoring of publications and developments
  - Modification or complete revision of the guideline
  - Needs assessment and desk research
  - Continuous monitoring by subject-matter expert scientist(s), and if these are not available, by the knowledge institute
- 

This phase is not described separately within the scope of this methodology. For information, see chapters 1 and 2 of this document.

## **4 References**

### **Beoordelingskader Stand van wetenschap en praktijk 2015 [Evaluation framework of the state of science and practice 2015]**

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### **GRADE**

- Cochrane Canada. *Nancy Santoso demonstrates GRADEpro* [Webinar March 2010]. Available at: <https://www.youtube.com/watch?v=ye6nCYkVLE>.
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### **HARING tools**

- Guideline development knowledge base. *Ondersteunende materialen bij het ontwikkelen van richtlijnen [Supporting materials for developing guidelines]*. Tools. Available at: <http://www.ha-ring.nl/>.

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#### **Methodology development for KNGF guidelines**

- Quality Standards advisory and expert group (AQUA). (2015). *Leidraad voor Kwaliteitsstandaarden [Guideline for Quality Standards]*. The Hague: Healthcare Institute of the Netherlands  
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Available at: <https://www.fysionet-evidencebased.nl/index.php/wcf-homepagina>.

#### **Methodology development for specialised medical guidelines**

- Guideline advisory committee. (2011). *Medisch specialistische richtlijnen 2.0 [Specialised medical guidelines 2.0]*. Utrecht: Orde van Medisch Specialisten [Order of Medical Specialists]. Raad voor Wetenschap, Opleiding en Kwaliteit [Council for Science, Education and Quality].  
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## Appendices

### Appendix 1: 'Declaration of interests form' template

#### Declaration of interest

With the scope of the Code for the prevention of undue influence as a result of a conflict of interests, all those who are proposed to be involved in the development of scientific advisory reports and medical guidelines are asked to complete, sign and return the declaration below. The form will be made public after assessment.

#### Applicant's personal information

Committee .....  
Name of member .....

#### Primary role(s)

If you have multiple roles, please list the scope per role.  
.....  
.....  
.....

#### Ancillary activities

Please briefly list your activities per role and whether these are paid or unpaid.  
.....  
.....  
.....

#### Description of relationships and interests

For a more extensive explanation, see the 'Transparency in relationships and interests' section of the Code.

#### Personal financial interests

Examples:  
• *Member of an advisory committee who operates in the service of a company in the area that the advice/guideline concerns.*  
• *Direct financial interests in a company (shares or options).*  
.....  
.....  
.....

#### Personal relationships

Example:  
• *People in a person's direct environment (such as family members, partner, friends, close colleagues) who could benefit from a certain outcome of a piece of advice.*  
.....  
.....  
.....

#### Reputation management

Examples:  
• *Participation in (unpaid) committees in order to protect or receive recognition for one's own reputation/position, the position of the employer or other interest groups.*  
• *Figurehead role in a patient or professional organisation.*  
.....  
.....  
.....

**Externally financed research**

Example:

- *Participation in research financed by the (semi)public sector, funds or industry, whereby the financier may have an interest in certain results of the research.*

.....  
.....  
.....  
.....

**Knowledge valorisation**

Examples:

- *Special or unique expertise in a (sub)area that the advice/guideline concerns and that offers possibilities of 'marketing'. This can be a medical product, procedure or intervention, but also a new theoretical concept or model, or a new approach to organisation and logistics.*
- *Ownership of a product patent.*

.....  
.....  
.....  
.....

**Other interests**

Are there any other interests on your part or within your environment which, if they were to become known, could embarrass you, your environment or the organisation?

.....  
.....  
.....  
.....

**Signature**

- I. Declares to have taken note of the 'Code for the prevention of undue influence as a result of a conflict of interests'.
- II. Declares that he/she will consider the internal deliberations of the committee as being confidential.
- III. Declares in good conscience to have provided above a summary of all relevant relationships and interests he/she has.
- IV. Declares that he/she will report any new, lost, changed or increased interests in the interim.

*Print the form, sign it and send it to .....@kngf.nl.*

Signature of proposed member .....

Date .....

**Assessment (to be completed by the organisation)**

Name of member

.....

Committee

.....

- No impediments to participation in the committee.
- Participation in the committee under the condition that the person involved recuses him/herself from the deliberations and decision-making process regarding the [FILE NAME] file.
- No participation in the committee possible due to an estimated excessively high risk of undue influence.
- No participation in the committee possible, but contribution of desired expertise to the committee possible by means of a hearing procedure on the deliberations and decision-making process regarding the file.

Name

.....

Role

.....

Date

.....

Initials

.....

Explanation (optional)

.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....  
.....

**Source:** Code for the prevention of undue influence as a result of a conflict of interests. January 2012. Utrecht: Koninklijke Nederlandse Akademie van Wetenschappen (KNAW) [Royal Netherlands Academy of Arts and Sciences]; 2012.

**Appendix 2: 'Mandate form' template**



**MANDATE FORM**  
GUIDELINE PANEL GUIDELINE [*name of guideline*]

**Mandate**

|  |
|--|
| On behalf of   |
| the Board mandates   |
| to serve on the [ <i>name of guideline</i> ] Guideline guideline panel |

**Details of the proposed guideline panel member**

|                   |                      |
|-------------------|----------------------|
| Title:            | First name initials: |
| Last name prefix: | Last name:           |
| Phone number:     | Email address:       |

**Signature of association/organisation**

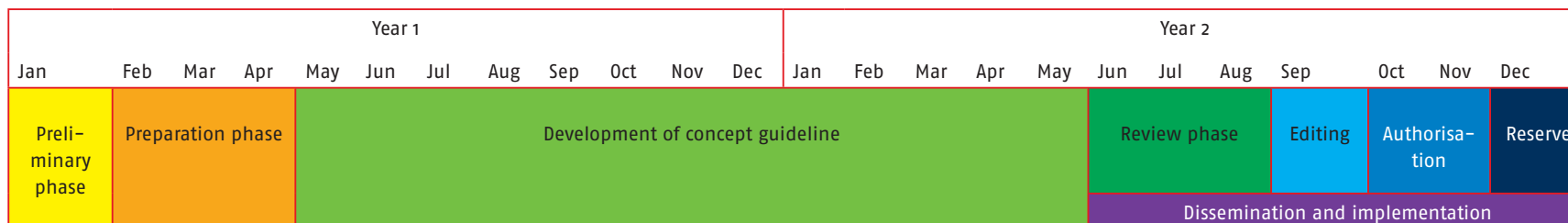
|                           |                    |
|---------------------------|--------------------|
| Association/organisation: | Name of signatory: |
| City:                     |                    |
| Date:                     |                    |

You can return this form by email (.....@kngf.nl) or by regular mail:

KNGF  
Attn [*name of KNGF guideline expert*]  
PO Box 248  
3800 AE Amersfoort

Please return this form as soon as possible.

**Appendix 3: 'Guideline timeline' template**



**Preliminary phase**

Needs assessment  
Recommendation to the Board about the guideline topic

**Preparation phase**

Setup of subject-matter expert scientist(s) and guideline and review panels  
Conduction of barrier analysis  
Definition of the guideline

**Development phase**

Elaboration of clinical questions into literature modules  
Deliver concept guideline

**Review phase**

Submission of concept guideline for review  
Checking of concept guideline in professional field review cycle  
Delivery of final draft

**Editing**

Editing by external agency

**Authorisation**

Submission of guideline for approval to the KNGF Board and to external stakeholders

**Dissemination and implementation**

Publication of the guideline  
Communication about the guideline  
Finalisation of the implementation products



**Appendix 4: 'Work plan' template**

| Chapter – module                   | Clinical question  | Searches* | GP meeting | SMES/GL expert | GP member |
|------------------------------------|--|-----------|------------|----------------|-----------|
| <b>A. General</b>                  |  |           |            |                |           |
| A1. General introduction           | What is the reason for a revision of the guideline [disorder X]?   |           |            |                |           |
|                                    | What is the goal of the guideline?   |           |            |                |           |
|                                    | Who are the intended users of the guideline?   |           |            |                |           |
|                                    | Who are the patients addressed by the guideline?   |           |            |                |           |
|                                    | Reading guide  |           |            |                |           |
|                                    | Most important definitions and terms   |           |            |                |           |
| A2. Background [disorder X]        | Epidemiology and pathophysiology of [disorder X]   |           |            |                |           |
|                                    | Clinical presentation and progression of [disorder X]  |           |            |                |           |
|                                    | Etiological and prognostic factors for the development and/or progression of [disorder X]  |           |            |                |           |
|                                    | Societal impact and developments   |           |            |                |           |
|                                    | How is the diagnosis made?   |           |            |                |           |
| A3. Organisation of care           | What is the role of the therapist in the healthcare process of [disorder X] patients compared to other involved (para)medical professionals?                                 |           |            |                |           |
|                                    | How is multidisciplinary cooperation organised (e.g. in first-line treatment)?   |           |            |                |           |
|                                    | Which information does the physical/exercise therapist need from the referrer?   |           |            |                |           |
|                                    | Which information does the therapist report to the referrer?   |           |            |                |           |
| <b>B. Diagnostic process</b>       |  |           |            |                |           |
| B.1. Diagnostic actions            | Which information at minimum is assessed in diagnostic actions for patients with [disorder X]?   |           |            |                |           |
|                                    | Which information at minimum is collected during the medical history taking for a patient with [disorder X]?   |           |            |                |           |
|                                    | What does the physical examination of a patient with [disorder X] consist of?  |           |            |                |           |
|                                    | When is it necessary to refer a patient with [disorder X] back to the referrer?  |           |            |                |           |
|                                    | When is referral to another specialty necessary (possibly through the primary care physician)?   |           |            |                |           |
| B.2. Customised diagnostic actions | How are diagnostic actions customised if a patient with [disorder X] has a common secondary disorder (and related medication) that impacts his/her the physical functioning? |           |            |                |           |
|                                    | What does the diagnostic process look like?  |           |            |                |           |
|                                    | What do the diagnostic actions of a therapist for patients with [disorder X] consist of?   |           |            |                |           |

**Appendix 4: 'Work plan' template (continued)**

| Chapter – module                              | Clinical question   | Searches*  | GP meeting | SMES/GL expert | GP member |
|---|---|--|------------|----------------|-----------|
| <b>B. Diagnostic process (continued)</b>      |   |  |            |                |           |
| B.3. Patient profiles and indications         | How can the characteristics of patients with [disorder X] that impact diagnostic and therapeutic actions be divided into sub-groups/profiles?                     |  |            |                |           |
|   | What is the indication for physical therapy/exercise therapy for patients with [disorder X]?  |  |            |                |           |
|   | On the basis of which information does a referrer screen and refer a patient for physical/exercise therapy?   |  |            |                |           |
|   | Which screening and possible referral is done by the therapist?   |  |            |                |           |
| B.4. Measurement instruments                  | Which ICF domains are assessed for diagnostic, prognostic and/or evaluative objectives during diagnostic actions (medical history taking + physical examination)? |  |            |                |           |
|   | Which measurement instruments best assess the ICF domains and objectives and for whom (recommended and optional measurement instruments)?                         |  |            |                |           |
| <b>C. Therapeutic process</b>                 |   |  |            |                |           |
| C.1. Therapy per profile                      | What are the routes in therapeutic actions, defined based on the patient profiles (characteristics)?  |  |            |                |           |
| C.2. Counselling and advice                   | Which counselling and advice is given to patients with [disorder X]?  |  |            |                |           |
| C.3. Exercise therapy                         | Frequency   | Which frequency, intensity, type and time span (FITT) of the exercise therapy is recommended for patients with [disorder X]?                     |            |                |           |
|   | Intensity   |  |            |                |           |
|   | Type (training methods and forms)   |  |            |                |           |
|   | Time span   |  |            |                |           |
|   | Supporting interventions  |  |            |                |           |
|   | Exercise therapy with co-morbidity  | How are therapeutic actions customised if a patient with [disorder X] has a common secondary disorder that impacts his/her physical functioning? |            |                |           |
|   | Transfer to activities of daily living (ADL)  | What promotes and guarantees the transfer of training to ADL?  |            |                |           |
| C.4. Non-exercise therapy interventions       | What are the non-exercise therapy interventions that can be offered to patients with [disorder X]?  |  |            |                |           |
| C.5. Promotion of physical activity behaviour | How can the therapist promote physical activity in ADL (physical activity behaviour) in patients with [disorder X]?   |  |            |                |           |

**Appendix 4: 'Work plan' template (continued)**

| Chapter – module                          | Clinical question   | Searches* | GP meeting | SMES/GL expert | GP member |
|---|---|-----------|------------|----------------|-----------|
| <b>C. Therapeutic process (continued)</b> |   |           |            |                |           |
| C.6. Blended care and eHealth             | What is the added value of blended care (eHealth by a therapist in combination with conservative therapy) compared to conservative therapy for patients with [disorder X] and how can this best be applied? |           |            |                |           |
| <b>Appendices</b>                         |   |           |            |                |           |
| 1. Appendices by guideline                | 1. Summary card   |           |            |                |           |
|   | 2. Patient information  |           |            |                |           |
|   | 3. E-learning   |           |            |                |           |
|   | 4. Physical seminars  |           |            |                |           |
|   | 5. Indicator set  |           |            |                |           |
|   | 6. Knowledge gaps   |           |            |                |           |
| 2. Appendices for GL justification        | 1. Barrier analysis (report by therapist and patient focus groups)  |           |            |                |           |
|   | 2. Overview of interests  |           |            |                |           |

\* SMES: Subject-matter expert scientist(s), GL expert: KNGF guideline expert, \*\* GP: guideline panel

**Appendix 5: Barrier analysis template**

**A. Content-related barriers**

- Which barrier(s)/topic(s) with regard to **diagnostics** has/have to be addressed in this guideline at minimum?
- Which barrier(s)/topic(s) with regard to **therapy** has/have to be addressed in this guideline at minimum?
- Which barrier(s)/topic(s) with regard to **evaluation** has/have to be addressed in this guideline at minimum?
- Which barrier(s)/topic(s) with regard to **referral and referral back** has/have to be addressed in this guideline at minimum?
- Other barriers

**B. Barriers in the organisation and process of healthcare**

- Which barriers are there for the *healthcare provider* in the **organisation of healthcare** regarding patients with *[guideline topic]*?
- Which barrier(s)/topic(s) with regard to the organisation of healthcare for patients with *[guideline topic]* must at minimum be addressed *from the patient perspective* by this guideline in your opinion?
- For which improvements regarding **monodisciplinary (physical therapy)** cooperation do you think this guideline can generate good initiatives?
- For which improvements regarding **multidisciplinary cooperation with other disciplines** do you think this guideline can generate good initiatives?
- Other barriers

**C. Barriers in implementation of the guideline**

- Which barriers are there that could impair implementation of this guideline?

**D. Prioritisation**

- What are the three most important barriers according to you?

1. ....
2. ....
3. ....

**Appendix 6: 'GRADE evidence profile' template**

| RCTs                | Quality assessment (depreciation) |               |              |             |                  | Summary of results |                      | Quality |
|---------------------|-----------------------------------|---------------|--------------|-------------|------------------|--------------------|----------------------|---------|
|                     | Study design and execution (RoB)  | Inconsistency | Indirectness | Imprecision | Publication bias | Patients (n)       | Effect size (95% CI) |         |
|                     |                                   |               |              |             |                  | I                  | C                    |         |
| [outcome measure 1] |                                   |               |              |             |                  |                    |                      |         |
| [outcome measure 2] |                                   |               |              |             |                  |                    |                      |         |
| [outcome measure 3] |                                   |               |              |             |                  |                    |                      |         |
| [outcome measure 4] |                                   |               |              |             |                  |                    |                      |         |

\* RCT: randomised controlled trial, n: number, RoB: risk of bias, I: intervention, C: control, CI: confidence interval.

Appendix 7: 'Summary' template

## Summary of KNGF guideline [*guideline topic*]

### Clinical diagnosis

|  |
|--|
|  |
|--|

### History taking

|  |
|--|
| Need for assistance                      |
| Functions and anatomical characteristics |
| Activities                               |
| Participation                            |
| External factors                         |
| Personal factors                         |
| Prognostic factors                       |
| Contra-indications and red flags         |

### Physical examination

|  |
|--|
| Inspection of posture and activity                   |
| Palpation  |
| Functional examination                               |
| Observation of activities – relevant for the patient |

### Determination of the indication

|  |
|--|
|  |
|--|

### Counselling and advice

|  |
|--|
|  |
|--|

### Exercise therapy

|  |
|--|
|  |
|--|

### Frequency, intensity, type and duration van de exercise therapy

|  |
|--|
|  |
|--|

### Non-exercise therapy interventions

|  |
|--|
|  |
|--|



Appendix 9: 'Authorisation letter' template



Return address: PO Box 248 – 3800 AE Amersfoort

PO Box 248  
3800 AE Amersfoort  
Stadsring 159b  
3817 BA Amersfoort

T 033 467 29 00  
F 033 467 29 99  
hoofdkantoor@kngf.nl  
www.kngf.nl  
www.defysiotherapeut.com

ABN AMRO 55.30.44.028  
IBAN NL59ABNA0553044028  
VAT 0025.84.700.B.01  
Chamber of Commerce  
no. 40506528

Date

Topic                    Authorisation guideline [*guideline topic*]

Dear Board,

We are pleased to submit this [revised] guideline [*guideline topic*] for Board approval (authorisation). The guideline panel that revised the guideline consists of representatives of involved professional associations, patient advocacies, healthcare providers and scientists. The Healthcare Institute of the Netherlands and Dutch Healthcare Insurance Companies are also represented in the review panel. For the full list of participating organisations, please refer to the guideline.

Please find enclosed the [revised] guideline, the justification and the summary. We would like to thank everyone for the reviews they provided for the concept version of the guideline. All of the reviews we received have been incorporated to the greatest extent possible in the enclosed version. Patient information, an e-learning module for physical and exercise therapists and an indicator set have also been developed for the guideline.

We are asking you to authorise the guideline in accordance with the usual procedures for your association. Authorisation also entails that you agree to fulfil the role of co-applicant of this guideline when it is submitted for inclusion in the Dutch Guideline Database of the Healthcare Institute of the Netherlands. We would very much appreciate receiving your response at the latest by [*date*]. For any additional questions or comments and authorisation, please send an email to [*guideline expert*] at [*email address*].

Kind regards,

[*name of guideline expert*]



**Appendix 10: 'Patient information' template**

- Patient information [*guideline topic*]
- What is [*guideline topic*]?
- The complaints
- Treatment of [*guideline topic*]
- What you can do yourself
- What physical therapy can do

