
Philip J. Van der Wees, Ann P. Moore, Christopher M. Powers, Aimee Stewart, Maria W.G. Nijhuis-van der Sanden, Rob A. de Bie

Clinical practice guidelines are "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." In health care services, clinical guidelines are considered important instruments to improve and manage the care process. Important goals in developing and implementing guidelines are higher quality and improved cost-effectiveness of interventions, ideally resulting in improved health outcomes. Additionally, guidelines address the need to decrease variability and increase transparency in clinical practice and practitioners' desire to legitimize their profession in the eyes of external stakeholders.

Development and implementation of guidelines are major focus areas of health care policy in many countries, and thousands of guidelines have been published worldwide. However, guidelines are criticized due to the lack of definitive research evidence to guide clinical practice and to the variability of methods for guideline development, resulting in potential bias. Further refinement of the development process is currently the subject of debate.

Low- and middle-income countries are facing unique health care problems, for which the development of guidelines is a challenging process. In many instances, the evidence is neither relevant nor applicable, and resources to develop guidelines are lacking. Therefore, guideline development in these countries depends heavily on international guidelines with local adaptations to provide relevancy.

Clinical Guidelines in Physical Therapy

In the last 2 decades, the physical therapy profession has rapidly increased its body of knowledge, and the introduction of evidence-based clinical guidelines was a logical step in this respect. In 2007, the Physiotherapy Evidence Database (PEDro) contained 478 evidence-based clinical guidelines. At the international level, the World Confederation for Physical Therapy (WCPT) has prioritized the development and implementation of clinical guidelines in its policy. The European Region of WCPT (ER-WCPT) has developed a framework for the development of clinical guidelines, and its database shows that, in 2010, eight European countries had physical therapy-specific guideline programs.

There are specific problems related to the use of guidelines by physical therapists in low- and middle-income countries. Physical therapy management is confronted with a high patient-to-physical therapist ratio, low accessibility to health care, lack of facilities and equipment, and short hospital stays. In addition, cultural and language differences mean that well-known outcome measures developed within a Western model are not suitable locally. Furthermore, roles and responsibilities of physical therapists may be different, with consequences for physical therapy diagnosis and decisions for treatment modalities or prevention. There is a need to develop an appropriate local body of evidence to address the specific circumstances. By so doing, suitable clinical guidelines can either be adapted from existing ones or established for low- and middle-income countries.

International Collaboration

The growing body of knowledge in the field of clinical guidelines has provided opportunities for international collaboration. In 2002, the Guidelines International Network (G-I-N) was founded to provide a network and partnerships for guideline organizations, implementers, researchers, and other stakeholders in health care. Despite the existence of several national programs for guideline development, to date they have not resulted in a structured international debate on the specific characteristics of clinical guidelines in physical therapy and possible consequences for methods of guideline development.
The purposes of this article are: (1) to explore methodological considerations for guideline developers and researchers in addressing specific physical therapy–related issues when developing guidelines for physical therapy diagnosis and treatment and (2) to provide a perspective for further harmonization of methods for guideline development, shared use of resources, and production of international evidence statements for physical therapist practice. These evidence statements would include considerations for formulating recommendations at the national level, with a specific focus on the identified challenges in low- and middle-income countries.

Methods for Guideline Development

Methods for guideline development have been harmonized to a certain degree,30,31 for which the AGREE (Appraisal of Guidelines, Research and Evaluation) instrument provides an important framework.32 This instrument can be used to assess the quality of clinical practice guidelines and helps guideline developers to structure and improve the process of guideline development. Core elements of the development process are: formulation of clinical questions and patient-important outcomes, systematic identification and summarizing of relevant evidence, synthesis of the evidence by grading its quality, and formulation of recommendations for daily practice.31 The different steps in guideline development are described in Table 1. Several instruments have been developed to support developers in producing valid clinical guidelines. Table 2 provides a brief overview of characteristics of these instruments.

To explore methodological considerations for guideline development in physical therapy, we analyzed the core elements of the development process, with the aim of stimulating a structured debate on international harmonization of guideline methods in addressing specific characteristics for physical therapist practice. We compared handbooks of national coordinating guideline programs in Australia, the Netherlands, the United Kingdom, and the United States, as well as the World Health Organization (WHO) program for international guidelines.33–56 These handbooks are summarized in Table 3. We did not intend to provide an extensive overview of national or international guideline programs and based our selection on the availability of published handbooks and authors’ background.

In addition, we compared characteristics of clinical guidelines for physical therapy diagnosis and treatment for patients with osteoarthritis of the hip or knee. We searched the PEDro database,40 the International Guideline Library,9 and the US National Guideline Clearinghouse10 for guidelines in English, German, or Dutch language that were aimed at physical therapy diagnosis and treatment, as well as for multidisciplinary or medical specialty guidelines that included physical therapy treatment. The initial search resulted in 27, 26, and 32 hits, respectively, for these 3 databases. Based on the inclusion criteria and after extraction of doubles, we identified 4 physical therapy guidelines41–44 and 12 multidisciplinary guidelines.45–56 Characteristics of physical therapy guidelines and multidisciplinary guidelines for patients with osteoarthritis of the hip or knee are presented in Tables 4 and 5, respectively.

### Table 1. Elements in Guideline Development

<table>
<thead>
<tr>
<th>Element</th>
<th>Specification</th>
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</thead>
<tbody>
<tr>
<td>1. Organization and structure</td>
<td>National or professional coordinated program. Development by multidisciplinary working groups, including health care practitioners, systematic reviewers and methodologists, and patients.</td>
</tr>
<tr>
<td>4. Validation</td>
<td>External review of draft guidelines by peers and stakeholders and if feasible by field test.</td>
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<tr>
<td>5. Dissemination and implementation</td>
<td>Print or electronic publication on paper via journal or Web site. Further implementation via tailored strategy to promote the actual use of the guideline.</td>
</tr>
<tr>
<td>6. Evaluation and revision</td>
<td>Regular update based on scheduled review (every 3–5 years) and updating procedure.</td>
</tr>
</tbody>
</table>
analysis of problems that physical therapists encounter in daily practice. A problem analysis is necessary for the formulation of clinical questions, as well as for the identification of possible barriers and facilitators for implementation.4,5 Two of the assessed guideline programs have specified methods for conducting such a problem analysis.34,37 Based on the identified problems, clinical questions can be formulated for use in diagnosis and treatment of the target group of patients. Each clinical question should be specified for its purpose to support decision making by subsets of clinicians. Clinical questions should include elements that will guide the literature review: patient population, intervention (diagnostic or therapeutic), comparison (alternative intervention), and outcomes of diagnosis and treatment. These aspects are reflected in the guideline programs described in Table 3. However, the identified physical therapy and multidisciplinary osteoarthritis guidelines hardly reflect on specific problems in clinical practice in formulating clinical questions.

Outcomes may be differentiated as critical, important, and not important for decision making.57 In physical therapy, diagnostic testing and treatment objectives usually are aimed at the functioning of patients in daily activities and participation, as well as primary bodily functions. This focus differs from that of the traditional medical field where out-

### Table 2.

Instruments to Support Guideline Developers

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Purpose</th>
<th>Content</th>
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</thead>
<tbody>
<tr>
<td><strong>AGREE II</strong>32</td>
<td>To assess quality of guidelines and provide methodological strategy for development of guidelines</td>
<td>6 domains (23 items): - Scope and purpose - Stakeholder involvement - Rigor of development - Clarity of presentation - Applicability - Editorial independence</td>
</tr>
<tr>
<td>Guideline adaptation53</td>
<td>Systematic approach for adaptation of existing guidelines to be used in a different cultural and organizational context</td>
<td>9 modules (reflecting 3 phases): - Preparation - Scope and purpose - Search and screen - Assessment - Decision and selection - Customization - External review - Aftercare planning - Final production</td>
</tr>
<tr>
<td><strong>GRADE</strong>59</td>
<td>To provide a common, sensible, and transparent approach to grading quality of evidence and strength of recommendations</td>
<td>Quality of studies: - High - Moderate - Low - Very low Recommendations: - Strong (for or against) - Weak (for or against) Factors that influence recommendations: - Quality of evidence - Desirable and undesirable effects - Variability in values and preferences - Use of resources</td>
</tr>
<tr>
<td><strong>GLIA</strong>71</td>
<td>To assess characteristics of guideline recommendations for relative ease of implementation</td>
<td>10 dimensions (31 items): - Global - Decidability - Executability - Presentation and formatting - Measurable outcomes - Apparent validity - Flexibility - Effect on process of care - Novelty/innovation - Computability</td>
</tr>
</tbody>
</table>

Development and Evaluation. Patient, Intervention, Control, Outcome, Time; GRADE PICO

Agency for Healthcare Research and Quality; WHO World Health Organization; United States Preventive Service Task Force; AHRQ Excellence; USPSTF

Comparison of National and International Multidisciplinary Guideline Programs

<table>
<thead>
<tr>
<th>Guideline Program</th>
<th>Clinical Questions and Patient Outcomes</th>
<th>Identification and Summary of Evidence</th>
<th>Synthesis of the Evidence</th>
<th>Formulation of Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (NHMRC)</td>
<td>Questions based on clear problems for clinical decision making or organization of care. Outcomes in different categories: short-term, relapse, return to work, functioning, quality of life.</td>
<td>Use existing systematic reviews if possible. Most rigorous and systematic review methods as feasible should be conducted. Results presented in summary table.</td>
<td>Quality of studies in 4 levels using methodology checklists. Synthesis of evidence described in matrix using 4 levels.</td>
<td>Four levels based on evidence base and consistency of evidence, using an evidence-statement form. Wording of recommendations expressed as “must/should” or “might/could.”</td>
</tr>
<tr>
<td>The Netherlands (CBO)</td>
<td>Questions based on analysis of problems in current care (eg, focus groups, surveys). Diversity of patients considered. Outcomes not specifically described.</td>
<td>Use existing systematic reviews and adaptation of published guidelines. Additional review using PICO, if necessary. Summarized in evidence table.</td>
<td>Quality of studies in 4 levels using methodology checklists. Synthesis of evidence using 4 levels.</td>
<td>Four levels based on evidence and considerations, labeled as “strong,” “moderate,” “weak,” or “none.” Checklist for considerations (eg, relevance, safety, preferences, availability, costs).</td>
</tr>
<tr>
<td>United States (USPSTF supported by AHRQ)</td>
<td>Analytic framework used to present clinical questions in structured format, related to interventions and relevant outcomes for clinical preventive service in primary care.</td>
<td>Reviews conducted via designated Evidence-based Practice Centers. May include full reviews for every key question, targeted reviews to update evidence, and staged reviews to detect gaps in evidence.</td>
<td>Quality of studies in 3 levels using methodology checklists. Synthesis of evidence using 3 levels.</td>
<td>Four levels plus statement for insufficient evidence. Worded as “for or against.” Based on evidence and magnitude of benefits. Information provided in 4 domains when evidence is insufficient.</td>
</tr>
<tr>
<td>International (WHO)</td>
<td>Questions described in 3 categories (definition, facts, and recommendation) using PICOT framework. Key outcomes identified for recommendations and evidence retrieval.</td>
<td>Use existing systematic reviews and update if &gt; 2 years old. Additional databases used for studies from developing countries. GRADE approach to create evidence profiles and summary of findings.</td>
<td>Quality of studies using methodology checklists. Synthesis of evidence using GRADE approach and with 4 levels.</td>
<td>GRADE approach used for strength, worded as “strong or weak” or “for or against.” Allowance for adaptation to local values.</td>
</tr>
</tbody>
</table>

Table 3.
Comparison of National and International Multidisciplinary Guideline Programs


comes usually are aimed at diagnosis and treatment of the disease. The International Classification of Functioning, Disability and Health (ICF) provides a framework to identify relevant outcomes at the levels of patient functioning and to determine the relative importance of outcomes. The ICF has been used in 2 of the osteoarthritis physical therapy guidelines in formulating clinical questions for physical therapy diagnosis and treatment in osteoarthritis guidelines (Tab. 4). When developing guidelines in physical therapy, the ICF can be used to identify relevant universal outcomes, as well as specific outcomes relevant in the context of health care settings in low- and middle-income countries.

Other issues to be considered in guidelines are the clinical importance of the effectiveness of interventions by estimating the magnitude of effects for the relevant outcomes and whether the desirable effects (benefits) outweigh the undesirable effects (harms). The Ottawa Panel considered patient outcomes clinically important when relative difference of effect was more than 15%.

Identifying and Summarizing the Evidence
The literature review process must be carried out in such a way that the potential for any bias is minimized. Eligible studies are identified according to a prespecified search strategy. The search strategy should focus on
the specifications of the clinical questions to identify evidence for the specific circumstances of the selected patients and may be related to multiple aspects such as risk factors, diagnostic testing, prognosis, and interventions. The WHO Handbook for Guideline Development provides specific guidance for retrieving studies from low- and middle-income countries.

The results of the included studies then are summarized in evidence tables. For all 4 physical therapy osteoarthritis guidelines, a systematic literature review was conducted (Tab. 4), and in 3 of the physical therapy guidelines, evidence tables were used to present the results. The G-I-N has produced standard templates for data summaries for diagnostic and intervention studies in guideline development. The objective of these templates is to define a minimum data set for inclusion in evidence tables, with the aim of sharing work among guideline developers. These templates also are very useful for the physical therapy community to reduce duplication of effort.

Some guideline developers choose not to commission their own literature review but instead rely upon

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Evidence Synthesis</th>
<th>Recommendations (LoE, SoR)</th>
<th>Specification and Tailoring (LoE, SoR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APA, 2005</td>
<td>L: literature review; guidelines; evidence tables S: PEDro score for quality of studies LoE: I–II included</td>
<td>Recommendations for treatment: ● Exercise therapy (I) ● Multimodality treatment ● Acupuncture (I) ● TENS (I) Recommended under certain circumstances: ● Knee taping (II) ● Elastic bandaging (II) ● Brace (I) ● Laterally wedged insoles (I) ● Unclear benefits of gait aids (II) ● Weight loss program (II) ● Ice if swelling is problem (I) ● Unclear benefits of laser therapy (I) ● Electromagnetic therapy may be useful adjunct (I) ● Unable to clearly state benefits for NMES (II) Not recommended: ● Ultrasound (I) ● Shortwave therapy (II) No level I or II evidence found: ● Interferential therapy, massage, mobilization techniques</td>
<td>Most efficacious exercise regimen to be determined; aerobic exercise as effective as strengthening exercise; supervised group programs as effective as individual treatments; home programs may be less effective (I) Therapy as recommended under certain circumstances used only with evidence of improvement in subjective and objective outcomes (I–II)</td>
</tr>
<tr>
<td>APTA, 2009</td>
<td>L: systematic review of literature, Oxford Centre for Evidence-based Medicine for study quality LoE: I–IV SoR: A–F</td>
<td>Recommendations for diagnosis: ● Assess impairments in mobility of hip joint and strength of surrounding muscles, especially hip abductor muscles (II, B) ● Use ICD and ICF to classify patients with hip pain (I–II, A) ● Consider other diagnostic classifications when symptoms are not consistent (V, E) ● Use validated functional outcome measures such as WOMAC, LEFS, HHS (I, A) ● Use physical performance measures such as Six-Minute Walk Test, self-paced walk, stair measure, Timed “Up &amp; Go” Test to assess activity limitation and participation restrictions (I, A) Recommendations for treatment: ● Patient education (I–II, B) ● Functional, gait, and balance training (II, C) ● Manual therapy in patients with mild OA (I, B) ● Flexibility, strengthening, and endurance exercises (II, B)</td>
<td>Risk factors related to age, race, sex, genetics, developmental disorders, previous hip joint injury (I–III, A) Detailed description of measurement instruments for activity limitations and participation restrictions (I, A) Patient education should include teaching of activity modification, exercise, weight reduction, methods of unloading the arthritic joints (I–II, B) Gait training may include assistive devices such as canes, crutches, and walkers (II, C)</td>
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(Continued)
### Table 4.
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<table>
<thead>
<tr>
<th>Guideline</th>
<th>Evidence Synthesis</th>
<th>Recommendations (LoE, SoR)</th>
<th>Specification and Tailoring (LoE, SoR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>KNCF, 2009&lt;sup&gt;44&lt;/sup&gt;</td>
<td>L: systematic review of literature; published guidelines; PEDro score for study quality; evidence tables &lt;br&gt;LoE: A–D &lt;br&gt;SoR: I–IV</td>
<td>Use ICF to identify health problems (D, IV) &lt;br&gt;Identify “red flags” (D, IV) &lt;br&gt;Identify treatment factors based on ICF (D, IV) &lt;br&gt;Use performance measure (Timed “Up &amp; Go” Test) and survey (patient-specific complaints) to assess health problems (D, IV) &lt;br&gt;Use outcome measures that reflect relevant aspects of ICF domains, such as HOOS, KOOS, WOMAC, AFI (D, IV)</td>
<td>Exercise therapy should include strengthening, aerobic capacity, gait training, functional training (A1, IV) &lt;br&gt;Mode and intensity of exercise therapy should be tailored to individual goals for activities and participation (A2, IV) &lt;br&gt;Reduce frequency of treatment sessions over time to stimulate independence (A1, IV) &lt;br&gt;Encourage sport and leisure activities after supervised exercise therapy (D, IV) &lt;br&gt;Patient education and self-management support should contain specified aspects (A1, IV) &lt;br&gt;Treatment under certain circumstances used as adjunct mainly when pain, lack of joint mobility, or muscle tension are prominent (A1, IV)</td>
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<td></td>
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<td>Recommendations for treatment: &lt;br&gt;Exercise therapy (A2, I) &lt;br&gt;Supervised exercises (A2, IV) &lt;br&gt;No specific type of exercises or intensity (B, III) &lt;br&gt;Self-management support (A1, II)</td>
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<td>Recommended under certain circumstances: &lt;br&gt;Unclear benefits of TENS (A1, I); consider as adjunct (knee) (IV) &lt;br&gt;Unclear benefits of hydrotherapy (A1, I); consider as adjunct (IV) &lt;br&gt;Consider heat or ice as adjunct (knee) (A1, IV) &lt;br&gt;Consider mobilization techniques as adjunct (A2, IV) &lt;br&gt;Brace (knee) (A1, III) &lt;br&gt;Wedged insoles (A1, III) &lt;br&gt;Knee taping (A1, II)</td>
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<td></td>
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<td>Not recommended: &lt;br&gt;Ultrasound (knee) (A1, II) &lt;br&gt;Electromagnetic therapy (knee) (A1, I) &lt;br&gt;NEMS (knee) (B, II) &lt;br&gt;TENS (hip) (B, III) &lt;br&gt;Massage (A2, II)</td>
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<td></td>
<td>Laser therapy not recommended (A1, IV), despite evidence (knee)</td>
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<tr>
<td></td>
<td></td>
<td>Exercise therapy should include strengthening, aerobic capacity, gait training, functional training (A1, IV)</td>
<td></td>
</tr>
<tr>
<td>Ottawa Panel, 2005&lt;sup&gt;41&lt;/sup&gt;</td>
<td>L: Cochrane criteria for study quality; evidence tables &lt;br&gt;LoE: I–II, SoR: A–C (clinically important benefit to no benefit)</td>
<td>Lower-extremity strengthening (knee) (A–C+) &lt;br&gt;Lower-extremity isometric strengthening (knee) (I, A–C) &lt;br&gt;Isotonic resistance training (knee) (I, C) &lt;br&gt;Isokinetic resistance training (knee) (I, C) &lt;br&gt;Eccentric resistance training (knee) (I, C) &lt;br&gt;Concentric resistance training (knee) (I, A–C) &lt;br&gt;Concentric–eccentric resistance (knee) (I, A) &lt;br&gt;Home strengthening program (knee) (I, A–C) &lt;br&gt;General lower-extremity exercise program (I, A–C) &lt;br&gt;Progression lower-extremity strengthening (knee) (I, A–C) &lt;br&gt;Whole-body functional exercise (knee) (I, A–C) &lt;br&gt;Walking program (knee) (I, C–C+) &lt;br&gt;Jogging in water (I, A–C) &lt;br&gt;Water exercises (I, C) &lt;br&gt;Manual therapy (I, A–C)</td>
<td>Clinically important benefits specified when more than 15% relative difference in comparisons &lt;br&gt;Benefits for each recommendation specified and related to outcome measures &lt;br&gt;Example: lower-extremity strengthening exercises are effective for pain getting down to and up from floor (I, A, clinically important benefit); effective for pain during walking, pain while climbing and descending stairs, arthritis activity, functional tasks, and quadriceps muscle torque (I, C+, clinically important benefit)</td>
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<tr>
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<td>Recommendations for treatment: &lt;br&gt;Lower-extremity strengthening (knee) (A–C+) &lt;br&gt;Lower-extremity isometric strengthening (knee) (I, A–C) &lt;br&gt;Isotonic resistance training (knee) (I, C) &lt;br&gt;Isokinetic and isometric resistance training (knee) (I, C)</td>
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<tr>
<td></td>
<td></td>
<td>Recommended under certain circumstances: &lt;br&gt;Unclear benefits of TENS (A1, I); consider as adjunct (knee) (IV) &lt;br&gt;Unclear benefits of hydrotherapy (A1, I); consider as adjunct (IV)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not recommended: &lt;br&gt;Ultrasound (knee) (A1, II) &lt;br&gt;Electromagnetic therapy (knee) (A1, I) &lt;br&gt;NEMS (knee) (B, II) &lt;br&gt;TENS (hip) (B, III) &lt;br&gt;Massage (A2, II)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laser therapy not recommended (A1, IV), despite evidence (knee)</td>
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</table>

<sup>a</sup> P—patients; Q—question, O—outcomes used; L—literature identification and summary; LoE—levels of evidence; SoR—strength of recommendation; OA—osteoarthritis; TENS—transcutaneous electrical nerve stimulation; NMES—neuromuscular electrical stimulation; ICF—International Classification of Impairments, Disability and Health; ICD—International Classification of Diseases; HOOS—Hip Disability and Osteoarthritis Outcome Score; KOOS—Knee Injury and Osteoarthritis Outcome Score; WOMAC—Western Ontario and McMaster Universities Osteoarthritis Index; AFI—Algofunctional Index; LEFS—Lower Extremity Functional Scale; HHS—Harris Hip Score.
existing, recent, high-quality systematic reviews (Tab. 3). The Cochrane Collaboration produces robust systematic reviews that can save a lot of work in assessing the literature.61 Other initiatives currently under development can be of importance for guideline developers in physical therapy. The Agency for Healthcare Research and Quality (AHRQ) in the United States is developing a systematic review data repository, and an international initiative has been launched for the registration of systematic review protocols.62 Another option for guideline developers is to identify evidence in existing guidelines, a method specifically described in developing 2 of the physical therapy osteoarthritis guidelines.42,44 Because databases of guidelines are growing,9,10,40 existing guidelines can be used to

Table 5. Physical Therapy Interventions in Multidisciplinary Guidelines for Hip or Knee Osteoarthritis

<table>
<thead>
<tr>
<th>Organization</th>
<th>SoR</th>
<th>PT</th>
<th>Recommendations (Strength)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAOS, 2008 (United States),46 knee OA</td>
<td>A–C</td>
<td>Y</td>
<td>Self-management education (B); low-impact aerobic exercises (A); mobility exercises optional (C); quadriceps muscle strengthening suggested (B); patellar taping suggested (B); insoles/lateral wedges not recommended (B); braces unable to recommend</td>
</tr>
<tr>
<td>AGS, 2001 (United States),49 OA pain</td>
<td>None</td>
<td>Y</td>
<td>Patient education; flexibility exercises; strength training; aerobic training; modalities (heat, cold, sound, electricity) as adjunct</td>
</tr>
<tr>
<td>AKdÄ, 2008 (Germany),47 OA</td>
<td>LoE</td>
<td>N</td>
<td>Strengthening exercises, water exercises, mobility, gait training, manual therapy (no specific LoE indicated)</td>
</tr>
<tr>
<td>CBO, 2007 (the Netherlands),44 hip and knee OA</td>
<td>LoE</td>
<td>Y</td>
<td>Exercise therapy, TENS as adjunct (knee), braces or insoles unable to recommend (knee)</td>
</tr>
<tr>
<td>DGOOC/BVO, 2009 (Germany),50 hip OA</td>
<td>A–C</td>
<td>Y</td>
<td>Exercise therapy and strengthening exercises; modalities (thermal, hydrotherapy, electrotherapy, ultrasound) may have positive influence (C)</td>
</tr>
<tr>
<td>EULAR, 2003 (international),51 knee OA</td>
<td>A–D</td>
<td>N</td>
<td>Education (A), exercise (A), insoles/lateral wedges (B), braces (B), laser therapy (B), electrotherapy (B), spa therapy (C), TENS (B), ultrasound (C)</td>
</tr>
<tr>
<td>EULAR, 2005 (international),55 hip OA</td>
<td>A–D</td>
<td>N</td>
<td>Education (A), exercise (no specific evidence), insoles/stick (D)</td>
</tr>
<tr>
<td>MOH, 2008 (Singapore),52 knee OA</td>
<td>A–D</td>
<td>N</td>
<td>Knee strengthening and aerobic exercises (A), water-based exercise (A), TENS (B), interferential current therapy (B), tapping (A), braces and insoles/lateral wedges (B), manual therapy (A), heat and ice</td>
</tr>
<tr>
<td>NICE, 2008 (United Kingdom),53 OA</td>
<td>LE</td>
<td>Y</td>
<td>Core treatment: education and self-management, strengthening exercise, aerobic training. Adjuncts: heat or cold, assistive devices, manual therapy, TENS, insoles, braces</td>
</tr>
<tr>
<td>OARSI, 2008 (international),54 hip and knee OA</td>
<td>0%–100%</td>
<td>N</td>
<td>Information, education (97); aerobic, strengthening, mobility, water exercises (hip) (96); walking aids (90); braces (knee) (76); insoles/lateral wedges (knee) (77); thermal modalities (64); TENS (58)</td>
</tr>
<tr>
<td>Philadelphia Panel, 2001 (United States),56 knee OA (selected)</td>
<td>A–D</td>
<td>Y</td>
<td>Therapeutic exercise (knee) (A), cold therapy (knee) (C), ultrasound (C), TENS (A), electrical stimulation (C)</td>
</tr>
<tr>
<td>RACGP (Australia),54 hip and knee OA</td>
<td>A–D</td>
<td>Y</td>
<td>Exercise (B), aquatic therapy (C), multimodal physical therapy (C), self-management education (C), cold (knee) (C), TENS (knee) (C), patellar taping (knee) (D), massage therapy (D), laser therapy (D). Not recommended: braces and orthoses (knee) (B), electromagnetic fields or electrical stimulation (knee) (B), ultrasound (C).</td>
</tr>
</tbody>
</table>

*a* PT=physical therapists involved in guideline development group or consensus rounds; OA=osteoarthritis; SoR=strength of recommendation; LoE=levels of evidence used without strength of recommendation; TENS=transcutaneous electrical nerve stimulation; NMES=neuromuscular electrical stimulation; AAOS=American Academy of Orthopaedic Surgeons; AGS=American Geriatrics Society; AKdÄ=Arzneimittelkommission deutschen Ärzteschaft; CBO=Kwaliteitsinstituut voor de gezondheidszorg; DGOOC=Deutschen Gesellschaft Orthopädie Chirurgie; BVO=Berufsverbandes Ärzte für Orthopaedie; EULAR=European League Against Rheumatism; MOH=Ministry of Health; NICE=National Institute for Health and Clinical Excellence; OARSI=Osteoarthritis Research Society International; RACGP=Royal Australian College of General Practitioners.
enhance efficiency. A manual for guideline adaptation has been published; it explains how to use existing clinical guidelines as an alternative to de novo guideline development. This manual may be very useful for physical therapy guidelines in low-and middle-income countries, based on their specific problems in developing guidelines.

Synthesis of the Evidence by Grading Its Quality

The identified studies are systematically appraised by assessing their methodological quality and relevance of the clinical context. Describing the quality of the evidence is important so that users of guidelines can interpret the relative importance of the evidence. Each type of evidence (eg, risk factors, diagnostic testing, prognosis, prevention, treatment) should be reviewed against a set of methodological criteria and systematically applied within study types. For evidence on treatments, high-quality randomized clinical trials (RCTs) are considered the strongest evidence, followed by cohort studies, case-control studies, and nonanalytic studies such as case reports or case series. Based on the quality of individual studies, an overall synthesis of the evidence will result in evidence statements expressed in levels of evidence. The PEDro scale was used in 2 of the physical therapy osteoarthritis guidelines to study the internal validity of clinical trials, where high scores on the 11-item quality scale indicate a low risk of bias. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system is increasingly being adopted by guideline development organizations worldwide and is used by 2 of the 5 programs presented in Table 3. This approach includes the rating of evidence as high, moderate, low, or very low quality. Randomized clinical trials are rated as high quality and observational studies are rated as low quality. Several factors may reduce or increase the quality of the evidence: limitations of design and execution (internal validity), inconsistency (or heterogeneity) of results, indirectness of evidence (applicability), imprecision of results (number of events and confidence intervals), and publication bias. Three factors are described that increase the quality of the evidence: large magnitude of effect, plausible confounding, and dose-response gradient.

In the field of physical therapy, the GRADE approach may be very interesting because it involves not only judging the internal validity of clinical trials but also weighting the relative importance of other designs such as observational studies. The typical randomized trial in physical therapy is potentially seriously biased, as blinding of patient and blinding of therapist are absent in the majority of the trials. This concern is inherent to many types of nonpharmacologic intervention research. In addition, evidence from randomized trials may severely limit the validity of guidelines for relevant subgroups of patients. Patients with multimorbidity often are excluded from efficacy studies, and racial and ethnic minorities are underrepresented. The use of observational data has been advocated to create evidence for everyday practice needs, and adaptive approaches have been proposed in order to synthesize evidence using outcomes of both randomized trials and observational research. International collaboration to address these issues is important for building a body of knowledge in the field of physical therapy.

Formulation of Recommendations

Once the evidence is identified, the guideline development group must consider its relevance and applicability to practice in order to formulate recommendations. Guideline developers must make a considered judgment about the generalizability, applicability, consistency, and clinical impact of the evidence to create a clear link between recommendations and the underlying evidence. This is a crucial part of the development process, and Table 3 shows that a variety of approaches and considerations are being used. The strength of recommendations in guidelines usually is subject to a system of grading, taking into account the quality of the evidence and the considered judgment of the guideline developers. Recommendations in the GRADE approach are formulated as strong or weak, based on the evidence as well as desirable and undesirable effects, variability in values and preference, and use of resources.

Transparency of the considered judgment of guideline development groups is important to understand the arguments for specific recommendations. Exercise therapy was recommended in physical therapy guidelines as a core treatment for patients with hip and knee osteoarthritis, although the levels of evidence and strength of recommendations varied among the different guidelines (Tab. 4). Similar findings were identified in the multidisciplinary guidelines, where physical therapy usually was described as part of nonpharmacological treatment modalities. Some differences were found among physical therapy guidelines (eg, where transcutaneous electrical nerve stimulation for knee osteoarthritis was recommended as a core treatment in one guideline and as an adjunct in another guide-
Clinical guidelines have been criticized for ambiguous recommendations using vague and nonactionable language. In addition, recommendations in guidelines are still largely based on lower levels of evidence or expert opinion, which compromises the validity and acceptability of guidelines. When developing guidelines in physical therapy, we should keep these critiques in mind because evidence-based and precisely defined recommendations are more likely to be adhered to in practice. Most guideline programs describe informal consensus procedures to translate the evidence into recommendations for daily practice, although examples of formal consensus procedures such as Delphi or nominal group techniques have been described. The GuideLine Implementability Appraisal (GLIA) can be of assistance in formulating actionable and precisely defined recommendations, with the aim of improving the applicability of guidelines.

Recommendations in guidelines should be aimed specifically at the target group of users. The analyzed guidelines for patients with osteoarthritis showed that the physical therapy guidelines were specific and focused on both physical therapy diagnosis and treatment, whereas most of the multidisciplinary guidelines provided only general recommendations for physical therapy treatment. In 5 of the multidisciplinary guidelines, physical therapists were not involved during the development process (Tab. 5). One multidisciplinary guideline also used the ICF as framework to formulate recommendations in a patient-centered holistic approach. Obviously, it is important that physical therapists be involved in the development of multidisciplinary guidelines when recommendations for physical therapy management are included.

One of the challenges is to provide guidance for modification of care to the specific circumstances of patients. Guideline recommendations usually are formulated for “average patients,” and sociodemographic information (eg, sex, age, race or ethnicity, socioeconomic status) to guide modification of care for patients at risk is limited. In addition, guidelines often do not address patients with multimorbidity. These limitations may hamper the actual use of clinical guidelines in daily practice and might be addressed by providing information on relevant multimorbidity and sociodemographic characteristics for the concerned conditions and discussing the possible consequences for physical therapist practice. Addressing these limitations could be done at the international level, allowing for further specification at the national or local level. The GRADE approach allows for modification of direction and strength of recommendations based on specific considerations for low- and middle-income countries, such as resource use implications.

**Implications for Further Strategy in Physical Therapy**

Stimulating evidence-based practice will remain a core strategic element for the further professionalization of physical therapy, and clinical guidelines can play an important role. International collaboration in the field of physical therapy can avoid duplication of work and will stimulate uniformity in the presentation of the evidence base for physical therapist practice. The current international initiatives for registries of systematic reviews and evidence tables provide an excellent basis for shared use of resources. Participation in these international initiatives is important to ensure the relevance of such registries for the development of guidelines in physical therapy, to increase efficiency in guideline development in physical therapy, and to strengthen the position of physical therapists in their participation in multidisciplinary guidelines.

An international standard for guideline development would enhance the validity of clinical guidelines in physical therapy by addressing aspects of guideline development that are specific and unique to the physical therapy setting. It would also stimulate acceptance of guidelines by physical therapists as a result of a valid process and recognizable output. An international standard for guideline methods should include agreements on the core elements to ensure a valid development process, but also should allow for tailoring to national agreements on guideline methods.

The production of full clinical guidelines is complex and usually requires a national or local approach to address circumstances related to the specific health care setting and context. However, the production of evidence statements as the basis for the formulation of recommendations should be universal. These international statements then can be used for developing specific national guidelines. They also provide potential benefits for professional bodies in physical therapy in terms of empowerment to challenge pre-
scripitive pronouncements from national health services and funders that are not in line with the international evidence statements for physical therapist practice. A formal, international collaborative using a valid standard of guideline development under auspices of WCPT would ensure recognition and acceptance of the international evidence statements.

The physical therapy osteoarthritis guidelines show the feasibility of establishing evidence statements for physical therapy diagnosis and treatment, and osteoarthritis might be used as a topic for pilot testing the development of a first set of international evidence statements.

A Model for Developing Evidence Statements

We propose to establish a collaborative for the production of international evidence statements for physical therapist practice. The purpose of these evidence statements is to provide a universal starting point for the further specification and contextualization of recommendations for physical therapist practice at a national level. Tailoring of recommendations at a national level is important to enhance implementation and may be related to characteristics of physical therapy service, available resources, and patients.

The first step is to establish an international standard for guideline development in physical therapy. The core elements of the development process then will be used for formulating a limited number of clinical questions and identifying evidence from high-quality clinical guidelines and systematic reviews in a standardized, systematic procedure. Evidence will be synthesized by producing evidence statements with grading of the evidence quality. Finally, relevant aspects for applicability of the evidence in daily practice will be considered, with a specific focus on low- and middle-income countries. This considered judgment section will discuss generalizability, consistency, and clinical impact of the evidence to a specified range of parameters (type of health care system, available resources, type of patients, aspects of treatment dose, and expertise of the clinicians). The statements aim to provide a basis for physical therapy diagnosis and treatment in terms of function, activities, and participation, based on the ICF. These statements will allow for further tailoring of recommendations at the national and local levels. A summary of the process and format is presented in the Appendix.

We expect that this simplified approach will lead to the production of concise documents using published guidelines and systematic reviews or a parallel approach when a guideline is being developed by a professional organization. An international steering group will initiate and coordinate the development of evidence statements. The actual development of evidence statements will be conducted by small project groups of 4 to 6 guideline developers, using a reference group of 10 to 15 clinicians from different countries. Delphi techniques can be used to reach consensus during various phases. After initial selection of a topic, an online survey will be distributed among members of the WCPT with the aim of identifying relevant clinical questions and participants for the reference group. The development group will identify, summarize, and appraise the evidence and formulate a draft version of an evidence statement for physical therapist practice and considerations for applicability. The statement will be reviewed by the reference group, and their comments will be used to finalize the statement. The statement then will be ratified by the steering group and published in a peer-reviewed journal, in existing databases, and on relevant Web sites.

What Is the Business Case?

The current momentum in the international field of guideline development is the basis for our initiative. The G-I-N Allied Health Community recently issued the development of a position paper to address the importance of patient functioning and quality of life in clinical guidelines. The ER-WCPT is a member of G-I-N and participates in the projects of the Allied Health Community, which momentum provides an excellent opportunity to address physical therapy–related issues in the harmonization of guideline methods. The international standard could be developed by professional bodies that develop national guidelines in physical therapy and endorsed at the international level by WCPT. Commitment by guideline development organizations to use the international standard is essential to ensure implementation of the developed methods. The WCPT supports this initiative for the development of international evidence statements, which was launched at a focused symposium during the World Physical Therapy 2011 Congress. The ER-WCPT recently adopted a project to develop a European guideline on Parkinson disease, supported by the Royal Dutch Society for Physical Therapy (KNGF). This is a unique situation in that 18 member organizations of the ER-WCPT are actively participating and financially contributing to the project, showing the considerable amount of commitment to international collaboration.

The actual business case lies enclosed in the question as to whether it is feasible to establish an international organization and infra-
structure and to find the means for the development of evidence statements. A preliminary steering group, with the authors of this article as members, has been established to launch the initiative, resulting in the establishment of an international collaborative including a permanent steering group. The steering group will initiate and coordinate the development of evidence statements by seeking funding and establishing project plans. The steering group will invite working group members and reference group members from the established international collaborative to participate in specific projects.

Some small-scale funding is needed to create and maintain an infrastructure to coordinate the development of evidence statements. The steering group will ask for this support from the WCPT and from the organizations representing the members of the steering group. Funding for projects will be sought in 2 ways: (1) requesting main guideline development organizations in physical therapy to add an international perspective to their projects and (2) small contributions from individual national professional bodies in physical therapy. The European physical therapy guideline for Parkinson disease is a successful case example for the feasibility of this approach. In conclusion, we think we have a good rationale and model for pursuing this initiative, as well as a promising business case, as presented to launch this initiative at World Physical Therapy 2011.

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Dr Van der Wees, Dr Stewart, Dr Nijhuis-van der Sanden, and Dr de Bie provided concept/idea/project design. All authors provided writing. Dr Van der Wees provided data collection, data analysis, and project management. Dr Nijhuis-van der Sanden provided facilities/equipment. Dr Moore and Dr Nijhuis-van der Sanden provided consultation (including review of manuscript before submission).

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Appendix.  
Process and Format for Evidence Statement

Title  
Title of the evidence statement.

Introduction  
Introduce the topic and epidemiology. Present identified problems in physical therapist practice. Briefly discuss possible barriers related to culture, health care systems, and resources. Formulate specific clinical questions relevant for international physical therapist practice.

Methods  
Briefly describe the development process, methods for identification of literature (clinical guidelines, systematic reviews, randomized clinical trials), and assessment of the quality of included studies. If possible, included literature will be limited to published clinical guidelines and systematic reviews. Make reference to the grading system used for evidence synthesis.

Presentation of results  
Present the results from the literature study referring to published clinical guidelines and systematic reviews or present an evidence table.

Conclusion: evidence statement

Conclusions from the literature using grading system for best evidence synthesis.

Considered judgment  
Discuss generalizability, applicability, consistency, and clinical impact of the conclusions for daily physical therapist practice. Consider differences for physical therapist practice around the world with respect to patient populations, health care systems, and resources and how this diversity may affect daily practice. Include specific considerations for low- and middle-income countries.