APTA Clinical Practice Guideline Process Manual

American Physical Therapy Association

2022 Edition

Acknowledgments

APTA Sections With Representatives for Clinical Practice Guidelines

These sections have identified a representative as a liaison with APTA for development of CPGs. The names and contact information of the current representatives can be found on APTA's website at www.apta.org/EvidenceResearch/EBPTools/CPGs/Update/.

Academy of Geriatric Physical Therapy	Home Health Section
Academy of Acute Care Physical Therapy	Academy of Neurologic Physical Therapy
Cardiovascular and Pulmonary Section	Academy of Oncologic Physical Therapy
Academy of Clinical Electrophysiology and Wound Management	Academy of Orthopedic Physical Therapy
Academy of Physical Therapy Education	Academy of Pediatric Physical Therapy
Federal Physical Therapy Section	Academy of Physical Therapy Research
Academy of Hand and Upper Extremity Physical Therapy	Academy of Sports Physical Therapy
Health Policy and Administration Section	Academy of Pelvic Health Physical Therapy

For more information contact:

Practice Department

American Physical Therapy Association

3030 Potomac Ave

Alexandria, VA 22305

800/999-APTA (2782)

703/706-3175 (direct)

practice-dept@apta.org

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Evidence-Based Practice and CPGs

The physical therapy profession recognizes the use of evidence-based practice (EBP) as central to providing high-quality care and decreasing unwarranted variation in practice. EBP includes the integration and application of best available evidence, clinical expertise, and patient values and circumstances related to patient and client management, practice management, and health policy decision-making. Below is how APTA has embraced the 3 core elements of EBP as defined originally by Sackett.[1]

Best-Available Evidence. Although EBP encompasses more than just applying the best-available evidence, many of the concerns and barriers to using EBP revolve around finding and applying evidence from the literature.

Clinician's Knowledge and Skills. The knowledge and skills of the physical therapist (PT) and physical therapist assistant (PTA) are key parts of the evidence-based process. The PT's personal scope of practice and the PTA's personal scope of work consist of the activities undertaken for which the individual is educated, trained, and competent to perform. Using clinical decision-making and judgment is key.

Patient's Wants and Needs. The patient's wants and needs are the third key part of the evidence-based process. As described in the guiding principle "Consumer-centricity" within APTA's Vision for the Profession, the values and goals of the patient, client, or health care consumer are central to all efforts in which the physical therapy profession engages.[2] Incorporating a patient's cultural considerations, needs, and goals is a necessary skill in providing best-practice care. (See Cultural Competence in Physical Therapy on www.apta.org.)

Many types of evidence and resources are available, yet a large gap remains between the synthesis of evidence and its application in clinical practice. APTA is committed to helping PTs and PTAs develop, synthesize, and use credible evidence. Clinical practice guidelines (CPGs) are essential tools in this process.

In March 2011, the National Academies of Science, Engineering, and Medicine (then named the Institute of Medicine, IOM, and abbreviated as such in this manual when referring to materials produced under the IOM name) published *Clinical Practice Guidelines We Can Trust*. Following is the definition it provides.[3]

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. Rather than dictating a one-size-fits-all approach to patient care, clinical practice guidelines offer an evaluation of the quality of the relevant scientific literature and an assessment of the likely benefits and harms of a particular treatment.

CPGs enable PTs, PTAs, other clinicians, and the public to understand the state of the evidence and its application to clinical decision-making. They extend beyond a summary of evidence by providing explicit, graded recommendations for actions the clinician can consider. CPGs, combined with clinician knowledge and skills, and patient values and goals, have great potential to yield the highest-quality physical therapy to all patients by decreasing unwarranted variations in practice and decreasing the gap in knowledge translation. Providing the most effective physical therapist management guidance to every clinician and patient can have a massive impact on the population by optimizing movement and minimizing unwarranted or inefficient practice variations, thereby improving health, quality of life, and overall quality of care.

As part of the effort to help develop, synthesize, and use credible evidence, APTA supports the development, understanding, and implementation of CPGs.

Purpose of APTA's CPG Manual

This manual provides guidance for APTA and its sections (named either sections or academies but referred to as sections in this manual) to develop high-quality, trustworthy CPGs by describing a consistent and reliable process. The manual also may be useful to people of interest in the development process, includingbut not limited to other health care providers, patients and clients, payers, and policy makers.

This manual strives to meet or exceed national and international standards for CPG development, while recognizing the practical and financial contexts of volunteer production and updating. The key organizations that provide guidance for CPGs include the National Academies of Science, Engineering, and Medicine (formerly Institute of Medicine, IOM), the Agency for Healthcare Research and Quality (AHRQ), and the Guidelines International Network (G-I-N). IOM published 2 foundational reports for CPG development: the previously mentioned _Clinical Practice Guidelines We Can Trust_ and _Finding What Works in Health Care: Standards for Systematic Reviews_. G-I-N is a global network that supports evidence-based health care and improved health outcomes by striving to develop and share best practices in CPG development throughout the world. The AGREE Enterprise also provides guidance on CPG quality through its CPG appraisal tool, AGREE II, and training resources.

While this manual cannot address every item or step possible in the development of a CPG, it can help to streamline and standardize some of the processes so that APTA and its sections can more efficiently create CPGs, as well as help the physical therapy profession's readership more easily recognize CPG processes in order to digest the evidence and related recommendations. While there are many types of evidence-based documents, a listing and description of these are not part of this manual.

Evidence-based practice and CPG development methods are an evolving form of scholarship. This manual will be a live document, updated as newer options and more rigorous approaches become available and feasible for members to use. Each CPG development team likewise will need to determine what skill sets and expertise they have, and which methods best satisfy their guideline needs.

This manual is organized into 4 sections that parallel the phases of CPG development and dissemination, with appendices at the end. The 4 phases are:

- Planning and resources for developing CPGs
- The CPG development process
- Dissemination, implementation, and evaluation
- Updating and affirmation of currency

References

1. Davidoff F, Haynes B, Sackett D, Smith R. Evidence based medicine. _BMJ_. 1995;310(6987):1085-6.

2. Vision Statement for the Physical Therapy Profession and Guiding Principles to Achieve the Vision. American Physical Therapy Association. http://www.apta.org/Vision/. Accessed July 28, 2017.

3. Graham R, Mancher M, Wolman DM, et al, eds. Clinical Practice Guidelines We Trust. Washington, DC: The National Academies Press; 2011. http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx. Accessed May 20, 2017.

Section Organization for CPG Development

There are many ways to organize a team to develop a CPG, and not every team will be the same size or composition. APTA supports the prioritization and development of CPGs at the organization(s) level. Thus, the section, and not an individual or individuals, is the key driver and should have ultimate oversight of the CPG. The following terms describe the groups, individuals, and organizations that may be involved in guideline development and implementation. An individual CPG team may or may not use all of these potential roles, or may describe different lines of communication; however, each team, in consultation with the section, should ensure that it has the personnel needed to complete the tasks and represent each area described below.

The CPG development process should start with an Oversight Committee (defined below) to ensure coordination of section and association priorities, to gain intraprofessional input during the development of the guideline, and to coordinate implementation and evaluation processes. Upon completion of the guideline, the Oversight Committee may be responsible for ensuring its clarity and quality prior to publication or for coordinating implementation efforts.

In providing direction for the section, these Oversight Committee members do not have the same extensive time commitment as those who are doing the actual comprehensive work of guideline development. This is the responsibility of the guideline development group (GDG). The individuals in the GDG engage relevant audiences and ensure successful publication of the guideline. They also participate in, collaborate with, or support other groups responsiblefor dissemination, implementation, continuous review, and evaluation of the guideline. The following considerations are identified in IOM's *Clinical Practice Guidelines We Can Trust* for determining GDG composition:[1]

- The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG.
- Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG.
- Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.

Below is a list of common roles and definitions adapted from the GIN-McMaster Guideline Development Checklist[2] to describe typical APTA section(s) and groups involved in the process.

CPG Oversight Committee
Sections are encouraged to create a CPG Oversight Committee to facilitate and coordinate the work of the section's GDGs. This body oversees the guideline development and implementation process for the section. Tasks may include priority setting or confirmation, selection of potential guidelines for development from proposed topics, recruitment and appointment of members for specific groups, setting of section policies (methods, budget, publication guidance), arbitration of issues within or across GDGs, and/or approval of final guidelines for publication, dissemination, implementation, and evaluation. A key role of the Oversight Committee is to standardize style and methods across GDGs, sothat CPGs are published with some level of structural consistency to aid readability by section members. The OversightCommittee may include representatives from 1 or more APTA sections. A CPG section representative, defined below, typically chairs the Oversight Committee.

CPG Section Representative
Most sections will identify a CPG section representative to chair their CPG Oversight Committee or equivalent group. This position will be the primary liaison with APTA on the development of CPGs, be a resource for developing GDGs, coordinate with sections to ensure their priorities are being considered, and advance the use of CPGs by PTs, PTAs, and people of interest. The CPG section representative is responsible for communication of section activities with APTA

and other sections. Working with GDG chairs, the representative ensures that APTA has timely updates on activities for each of the section's GDGs.

CPG section representatives are critical for ensuring that the section has processes to prioritize CPG topics (see Topic Selection in Phase 1) that are useful, that guideline development groups are appropriately staffed with qualified members, that conflicts of interest are managed (see Conflicts of Interest in Phase 1), that the style and methods used by GDGs follow consistent and transparent standards, that the section provides resources to support CPG development, and that the section has methods for disseminating the CPGs to its readership and the greater physical therapy community. Section representatives are invited to a meeting at APTA's annual Combined Sections Meeting (CSM), where the association addresses challenges, provides support, promotes coordination among sections, and updates them on progress among the sections.

Depending on the structure within the section and the specific responsibilities of the section representative, frequency and content of communication will vary. It is strongly recommended that the GDG and the section representative determine early on when and what to communicate. If the section representative has a CPG oversight role (for example, in the Academy of Orthopaedic Physical Therapy this is called the CPG editor), the GDG should communicate regularly about the design and conduct of the CPG including systematic review questions, search, review and data extraction methods, and overall design. Getting methodologic feedback early and often will allow the GDG to uncover gaps or concerns expediently.

Guideline Development Group
The GDG is the authoring group of the CPG. It typically includes a team leader or CPG chair, clinical and content specialists, a methodologist, ideally a patient/consumer representative, and possibly support staff who produce the guideline document. For additional guidance on defining role of authors and contributors, see the International Committee of Medical Journal Editors "Defining the Roles of Authors and Contributors."

The GDG determines the scope of topics to be covered within the identified guideline, formulates questions, develops, and agrees on the recommendations, synthesizes the literature, writes the recommendations, and organizes the CPG for draft review and final publication. Group members work directly with consultant and people of interest groups and journal editors to develop the final guideline document.

Specific duties typically include formulating PICO(T)/PECOT questions (see PICO(T)/PECOT in Phase 2), conducting systematic reviews, rating quality of evidence, preparing evidence summaries and background documents for recommendation discussions, making recommendations, developing, and writing the guideline, and reviewing comments from people of interest and public consultation. They also may be responsible for designing and conducting surveys of people of interest to inform the CPG scope and may present or publish those results as intermediate products.

The GDG works closely with the Oversight Committee to ensure goals and objectives for the guideline are completed. The GDG works directly with the content experts, critical appraisers, consumers, implementers, and evaluators to ensure the exchange of inclusive, consistent, feasible, and accurate information.

GDG Chair
The chair of the GDG is typically a neutral party who has expertise in coordinating groups of health care professionals, patients, and caregivers. The chair should be someone who is qualified and experienced in strategies and facilitation of optimal group processes, ensuring all members of the GDG and advisory groups have equal opportunity to contribute and freely express their opinions without feeling intimidated. This individual is not necessarily an expert in any specific clinical domain but typically *is* familiar with the CPG topic. The chair is the primary contact for correspondence for the GDG during the development process and is listed on APTA's website as the point of contact for active groups. APTA hosts a meeting at CSM with GDG chairs to identify challenges, offer advice, provide support, and share updated approaches.

Consultants
These individuals or groups may be formed to provide assistance to the GDG with the development of the guideline. They may include content experts, critical appraisers, and implementation experts:
- **Content Experts.** These are the experts on the guideline topic. They may be health care providers, patients or consumers, policy makers, payers, or others who are recruited to read, edit, or comment on any aspect of the

CPG while under development or in its full draft stage. They have direct interactions with the GDG.

- **Critical Appraisers.** This group of readers is trained to use and complete the chosen critical appraisal tools necessary for determining the levels of evidence across the body of evidence. These readers come from both the academic and clinical settings and may be responsible for completing the appraisal tool as well as abstracting selected types of information from articles.

- **Implementers.** These individuals facilitate the development of materials to ensure clinical use of the guidelines. This may include but is not limited to development of education modules, clinical decision support tools, resources for APTA's website, and inclusion of core data elements in the Physical Therapy Outcome Registry.

People of Interest

People of interest could be individuals, informal groups, or organizations that are involved in the delivery of health care and will have an interest in the content or the outcome of a CPG. People of interest may include health care providers, professional societies and colleges, experts in a disease or condition, research institutions, policy makers, and payers.

Consumers

Consumers of health care include: (a) individual patients; (b) caregivers, including patients' family and friends; (c) potential patients; (d) voluntary and community organizations that represent the interests of patients, caregivers, and the public; and (e) advocates representing the interests of patients, caregivers, and other client groups. They are described collectively as consumers (without implying consumerist assumptions about health services) and are distinct from other users of guidelines such as health professionals, commissioners, and providers of services. A resource for this group is <u>Consumers United for Evidence-Based Healthcare</u> (CUE).

Sponsoring Organization

The sponsoring organization funds the development of a CPG. Typically, the organization will endorse it and assist with publication and dissemination. For example, multiple sections that support the GDG by sponsoring travel of the GDG member would be considered sponsoring organizations, as would APTA when it funds a grant request for costs associated with the development of a CPG.

When the Oversight Committee identifies which groups and roles to include in the development of a CPG, and the best individuals to fill them, each role's function and potential conflicts of interest should be considered. Note that some individuals may be members of more than 1 group (eg, a physical therapist may be a member of the GDG and an implementer). <u>Figure 1</u> represents the potential parties involved during the CPG development process.

FIGURE 1.
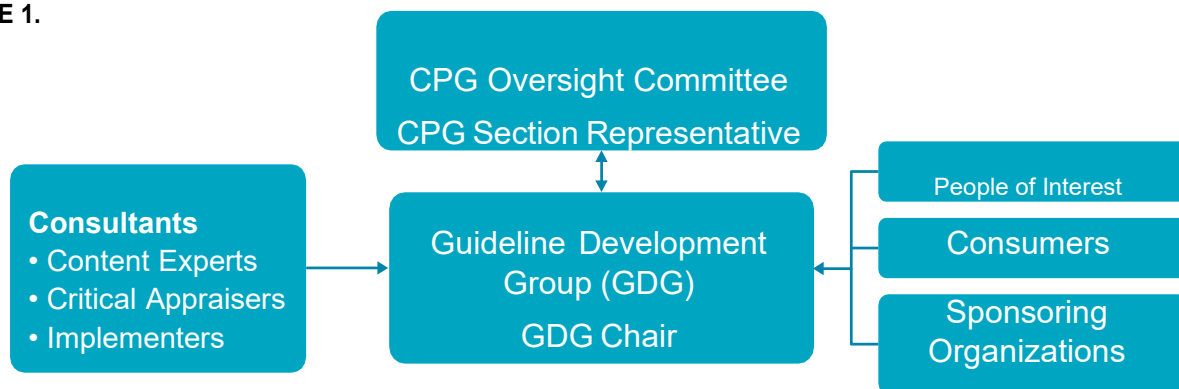
Conflicts of Interest

The 2009 IOM report *Conflicts of Interest in Medical Research, Education, and Practice* stated, "A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[3] Although conflicts of interest (COI) most often are thought of as related to financial gains, they also are related to areas of scholarship and practice. The GDG should declare and discuss any activity that could present the perception of bias in review of evidence and development of recommendations. For example, a GDG member who teaches a specific therapeutic approach would likely be, or be perceived, to be biasedtoward it. An approach that mitigates bias should be developed. This may or may not remove the individual from any input. The conflict management plan should be discussed with section CPG leadership, such as the CPG editor or section representative. To ensure the development of a CPG that can be trusted, a great amount of attention must be paid to identifying and limiting COI. This section describes a process to identify the presence of COI and provides anexample of how to deal with them.

The IOM *Clinical Practice Guidelines We Can Trust* provides the following standards related to the management of COI[1(78,82)]:

1. Establishing Transparency
    1.1 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible.
2. Management of Conflict of Interest
    2.1 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.
        - Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG.
    2.2 Disclosure of COIs Within GDG
        - All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.
        - Each panel member should explain how their COI could influence the CPG development process or specific recommendations.
    2.3 Divestment
        - Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations.
    2.4 Exclusions
        - Whenever possible GDG members should not have COI.
        - In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
        - Members with COIs should represent not more than a minority of the GDG.
        - The chair or co-chairs should not be a person(s) with substantial COI.
        - Funders should have no role in CPG development.

To be transparent about any potential COI, all GDG members must complete a Conflict of Interest Disclosure Form and sign a Conflict of Interest and Confidentiality Statement. (See Appendixes A and B for APTA examples of these documents.) As part of managing COI, the GDG must develop awareness of their own members' biases; understand how to balance bias among GDG members and others who will be involved in the development; and ensure that the interpretation of the literature is conducted as objectively as possible. This process may differ between the GDG

members and all other participants in the CPG development process. Below are the recommendations for the GDG.

- **Guideline Development Group.** The GDG COI form should be reviewed annually by the Oversight Committee. While it is understood that not all conflicts of interest can be avoided, the level and balance of conflict must be transparent and managed. (See Appendix C for a COI management form that can be used as a tracking document). The Oversight Committee will make an overall judgment on bias or make recommendations to eliminate bias. A discussion of the COI for each member will occur at the initial meeting of the GDG. Any changes in potential COI must be communicated to the Oversight Committee and the additional members of the GDG immediately. An oral review, an overall judgment on bias, and any actions taken will be documented at face-to-face meetings and prior to each meeting that involve drafting recommendations or action statements.

The published CPG is expected to state disclosure of any potential conflicts of interest, based on the completed disclosure forms and conflict of interest and confidentiality statements.

APTA Support of the Sections
APTA supports its member sections in the development of CPGs by facilitating and coordinating communication; structured training; opportunities for funding; and dissemination, implementation, and evaluation of the CPGs.

Coordination of Communication
Communication of a section's activities in developing a CPG is vital to the success of the guideline. APTA and its member sections have identified certain roles for communication of CPG activities. As mentioned above, the CPG section representative collaborates with APTA on the general development of section-developed CPGs and identifying resources for them. The GDG chair is the point of contact for any communication specific to the GDG. Both the CPG section representative and the chair of each individual GDG are listed on APTA's website as the point of contact for their respective roles.

Structured Training
Workshop. APTA hosts a workshop to help new GDGs successfully develop a CPG by explaining the process, helping the GDG refine the CPG's scope and structure, and organizing the GDG's processes.

GDG Chair Meeting. APTA hosts a meeting at the annual Combined Sections Meeting (CSM) with GDG chairs to identify challenges, offer advice, provide support, and share updated approaches. Participants are encouraged to exchange their own strategies to work together to resolve specific problems.

Section CPG Representative Meeting. APTA hosts a meeting of section CPG representatives and coordinators at CSM to provide support for organizing CPG development within the sections and to update sections on APTA CPG initiatives.

APTA Funding for CPG Development
Workshops. There is no registration fee for APTA's CPG workshop for members of a new GDG. APTA also provides travel and housing support for up to 2 members of each section. When a group will benefit from the attendance of additional GDG members, sections are encouraged to provide their travel and housing support.

Financial Support. GDGs can apply for APTA financial support of up to $9,000 to augment the section's support of developing CPGs that are important to the practice of physical therapy. APTA also provides financial support for CPG revisions and CPG implementation efforts of $3,000. Proposals are accepted annually and must be submitted jointly by APTA sections and their GDGs. The annual deadline for submission is in September, and APTA issues a request for proposals in summer preceding the submission date. Each proposal is considered individually through a peer-review process and is awarded in part or in full depending on the priorities of the association and competition with other submissions. Recipients of financial support are required to submit annual reports on the progress of the CPG, or sooner if significant milestones are achieved, such as publication. The GDG chair is responsible for this activity. (For more details, contact the APTA Practice Department at practice-dept@apta.org.)

Use of Covidence: APTA provides GDGs with Covidence, a systematic review management system. To receive this

benefit, the GDG Chair must contact APTA Practice Department for access.

Assistance With Dissemination, Implementation, and Evaluation of Guidelines

APTA Endorsements. As part of the association's effort to increase the awareness and use of CPGs, the APTA Board of Directors adopted a process to endorse them. APTA sections and other professional organizations are eligible to seek APTA endorsement. The CPG endorsement process involves a review by APTA staff, AGREE II (Appraisal of Guidelines for Research and Evaluation Instrument) review, and review by the Scientific and Practice Advisory Committee (S-PAC) and review by the APTA Board of Directors to confirm that the protocols for endorsement have been followed. (See Appendix D for the APTA Board clinical practice guideline endorsement process.)

APTA Evidence-Based Practice Resources. APTA has evidence-based practice resources on APTA.org. It has many easy-to-use tools to help PTs and PTAs find clinically related information on typically treated conditions, including CPGs that are relevant to physical therapist practice. CPG+ offers highlights and suggestions based on the CPG that PTs and PTAs can use to check their practice. Additional resources are being developed, and the GDG should work with the APTA Practice Department on posting the completed CPG.

Professional Development. There are many ways for a GDG to educate PTs about a CPG and its recommendations. This includes presentations at section conferences, CSM, and other professional development opportunities such as courses on the APTA Learning Center. GDG members are encouraged to communicate directly with their CPG section representative and the section's education programming chair to coordinate presentation and online course opportunities. For more information on professional development opportunities and the Learning Center, visit https://learningcenter.apta.org or contact learningcenter@apta.org.

Physical Therapy Outcomes Registry. There will be future opportunities for published CPGs to be part of the Physical Therapy Outcomes Registry (Registry). This would include the collection of data elements that are identified during the CPG development. (See Evaluation in Phase 3 for details on inclusion of key data elements that are part of the Physical Therapy Outcomes Registry.) GDGs that will have guidelines included in the Registry will be provided data on clinical utility and outcomes. In addition, there will be future opportunities for quality measure development and support. GDG members are encouraged to communicate directly with their CPG section representative and APTA Registry staff to discuss opportunities for involvement. For more information about the Physical Therapy Outcomes Registry, visit www.ptoutcomes.com or contact registry@apta.org.

Endorsement by Other Professional Organizations. A GDG may wish to have other health care organizations endorse the CPG. The GDG should communicate with the section representative and the APTA Practice Department to determine if a relationship exists with the targeted organization. In this way, outside organizations are not fielding individual requests from a variety of GDGs but rather can maintain a coordinated communication process with key section or APTA leadership.

Resource Assessment

The Oversight Committee and GDG chair have numerous considerations when assessing the resources needed to develop a CPG. In particular, providing realistic time commitment estimates can help ensure that volunteers are able to manage their time and balance it successfully between the CPG project and their other current obligations.

Time Commitments

The overall time to produce a CPG is estimated at 9-12 months if evidence is already synthesized, and 3-4 years (or more) if no synthesized products exist. Communication between team members likely will consist of in-person meetings, online sessions, and phone calls, the frequency and duration of which will vary with each role on the team. Below is a list of considerations and estimated commitments for various roles:

Guideline Development Group
- Frequent conference calls and online meetings (often weekly)
- In-person meetings

- Initial meeting (2 days, often as part of APTA's CPG workshop)
- Meeting at annual APTA Combined Section Meeting (1-3 hours)
- Meeting to develop recommendation/action statements (often 2 days, 1-3 hours per recommendation)

- Screening articles, appraising quality of literature, building evidence tables, writing (100 hours or more over the duration of the project)
- Writing literature syntheses for each recommendation (1-6 hours or more per recommendation, depending on the amount of literature and the need for topical evidence tables)
- Proofreading drafts of other authors in the group (1-4 hours per recommendation)

Librarian/Methodologist
- Conference calls and online meetings with authors during planning stage (20-30 hours)
- Search and deduplication (80 hours)
- Document search process (2-5 hours)

Consultants
- Critical Appraisers
  - Training to use critical appraisal tools (approximately 3 hours per tool)
  - Review, calibration, and form completion for articles (up to 1 hour per tool per article; dependent on the number of articles reviewed)
  - Content experts
  - Conference calls and online meetings (1 hour each; frequency dependent on GDG)
  - Review of final draft with recommended edits and other feedback for authors to incorporate before draft goes to people of interest and public review (3-5 hours)

People of Interest
- Review of first complete draft with recommended edits and other feedback to authors (5 hours)
- Review of public draft after people of interest feedback is addressed (3-5 hours)

Consumers
- Training (1-5 hours, depending on prior experience and intended roles)
- Conference call or online meeting for PICO development (1-4 hours)
- Review of recommendations and final draft (3-5 hours)
- Potential participation or leadership in development of consumer-language versions or educational materials (time is dependent on level of participation)

Financial Commitments
In addition to human resources, fiscal and other resources need to be assessed. Any and all anticipated expenses within a budget or calendar year should be submitted to section leadership annually. Given that completing a CPG often takes more than 1 year, there may be multiple budget submissions. Section leadership also should receive an overall estimate of total costs over the life of the project. If multiple sections are collaborating on a CPG, then the leadership of each section will need to approve a formal agreement on shared expenses that outlines the fiscal implications. Following are expenses to be considered:

- Meetings, such as CSM, writing retreats, monthly and weekly conference calls, and calls or webinars to train appraisers and article reviewers (conference call line charges and potential travel expenses)
- Document management, such as storage, project management systems, and reference software (see Document and Reference Management below for further details)
- Access to medical librarian(s), library databases, and full-text collections
  – Librarians, if there is not a librarian resource available at an institution ($15-$40 per hour)

- Procurement of articles (approximately $35 per article)
- Contracts for evidence summaries
- Journal-publishing expenses such as manuscript formatting, overage fees for exceeding any journal page limits, licensing for free public access to the CPG, and reprint fees (costs vary among journal publishers)
- Clerical assistance and/or use of student helpers to organize screening of articles or critical appraisals of literature ($15-$20 per hour)
- Systematic review tools, such as Covidence
- Guideline authoring tools such as Magicapp or GradeProGDT and related training or support

Document and Reference Management

To maintain transparency and stay organized, it's important to have separate storage or support methods—one to house references and reference libraries and another for all documentation of the guideline development process, appraisal tools, and project documents.

The GDG will need to determine a strategy for maintaining document currency. Consideration should be given to cost, availability, and group accessibility.

Following are good questions to answer:

- Will the group have a single editor or will it share editors? (Some groups may choose to use project manager software, such as Asana.)
- How will reviewer and editorial involvement be staged?
- What file naming and dating conventions will be used?
- Which collaboration and storage system does the majority of the group already use (and so are familiar with it)? (Some examples are Google Docs, Microsoft OneDrive, DropBox, and Zoho Docs.)

The group also will need to determine a strategy for managing references in the CPG manuscript. Options include choosing a reference management tool, ensuring that all contributors have the same tool but use only 1 library; *or* assigning 1 person, typically a librarian or author, to enter all references. The reference tool you choose can be web-based or downloaded software and can be used to help with article screening through data extraction. (Some examples are Endnote, Zotero, Mendeley and RevMan.) Keep in mind that the journal you are targeting for publication may strongly encourage you to use the same reference tool, if any, that it uses.

Topic Selection

Section leaders should set the priorities for evidence-based document topics and have a clear rationale for creating CPGs. Each section should have an advisory panel, advisory committee, or editorial board that works with section leadership to help identify, prioritize, and refine evidence-based document topics. Multiple people of interest (representingvaried professional disciplines and consumers) should be consulted beginning with the topic-selection phase.

Section leadership should consider the following factors in setting priorities and identifying topics:

- Identify section initiatives and refer to the section's strategic plan for topic compatibility.
- Consider topics that have the potential to impact large numbers of clients. Topics should be of high priority, should address problems associated with a high burden of illness, and should address an important quality improvement, such as high variation in care, for which there are no existing recommendations.
- Consider the feasibility of the topic—the existence of sufficient high-quality evidence and clear definitions of the condition or procedure. Also consider the availability of implementation resources and the likelihood that any barriers to change can be overcome.[4]
- Topics should align with IOM priority-setting criteria such as disease burden, controversy, cost, new evidence, potential impact, public or provider interest, and variations in care.

- Additional factors to include in the decision-making process are translation of clinical currency and knowledge, reimbursement policies, risk management, interprofessional collaboration, consulting with policy makers and third-party payers to identify their needs, identifying the presence of knowledge leaders, and evaluating the clinical talent of the section and those likely to participate in the development of evidence-based documents (ie, determining what is feasible given the human resources).

Preliminary Literature Search

Once a potential topic has been identified, the GDG should conduct preliminary searches to ensure that there is a reasonable body of evidence. The amount and quality of evidence will dictate the type of evidence-based document, but for the purposes of developing CPGs, the GDG should ensure that, minimally, enough high-quality level 1 and 2 evidence is available to support some recommendations. If too little exists, it may mean that additional research is needed before recommendations can be made or that the topic is too rare to warrant an evidence-based CPG. If that is the case, the GDG, in consultation with the sponsoring sections, might want to instead consider developing a consensus document or other form of guidance on that topic.

Topic Refinement

Identifying and refining a topic area is the first step in the initial development of an evidence-based document. Validation of the breadth and depth of the content also can be achieved through formative work including interviews and formal surveys of patient/consumer groups, PTs, and other clinicians or professionals who may work with patients who have the selected diagnosis. (As an aside, these surveys, if done well, can be worthy of publication in their own right, thus increasing the overall publication rate for the GDG and serving to alert readers about the CPG under development.)

The GDG should identify what already has been done and estimate the likelihood that the planned CPG topic will accomplish its aims, which typically are to fill a gap in the literature, address an identified deficiency in clinical

practice, and/or synthesize wide-ranging evidence to provide direction for clinicians. People of interest should be surveyed for their priorities. This is an important validation process for ensuring that the work of the GDG will be useful to its membership. Systematically collected information from physicians, consumers, and clinicians about their needs for guidance can inform the breadth and/or depth of the CPG scope. Feedback about the importance of the topic and the need for clinical guidance should be ascertained. Include clinicians who work with patients who have the condition, physicians who typically refer patients with the condition, and consumers or patients of physical therapist services who have or care for someone with the condition.

Development of the Project Plan

Having a clear and defined schedule of activities will enable the GDG to deliver the CPG on time and within the planned project scope. This project plan includes 4 phases: Planning and Resource Organization; Drafting and Publication; Post-production: Dissemination, Implementation, and Evaluation; and Revision, Updating, or Affirmation. Table 1 shows the 4 phases and the activities within each. The key to the plan is setting milestones and completion dates for the major CPG activities within each phase. Figure 2 is a template for setting a timeline of milestones.

TABLE 1. PROJECT PLAN PHASES AND MILESTONES FOR DEVELOPMENT AND DISSEMINATION OF A CPG.

Phase 1: CPG Planning and Resource Organization	Phase 2: Drafting and Publication	Phase 3: Postproduction: Dissemi- nation, Implementation, and Evaluation	Phase 4: Revision, Update, or Affirmation

• Identify the question the CPG will answer • Conduct preliminary literature search • Validate the CPG need and scope • Identify people of interest • Identify the Guideline Development Group (GDG) • Address conflicts of interest • Determine methods	• Perform systematic review for PICO(T) questions/topics for which recommendations will be made • Draft recommendations and determine the level of evidence, and synthesize supporting evidence • Document methodology • Secure review of the CPG • Submit the CPG for publication	• Disseminate the CPG • Implement the CPG • Evaluate the CPG	• Determine the need for updates based on the evaluation • Either revise the CPG or affirm its currency

FIGURE 2. TEMPLATE FOR SETTING MILESTONES AND DEADLINES FOR EACH PHASE OF THE CPG PROJECT PLAN.

PHASE 1: CPG Planning and Resource Organization

Month	Milestone	Activities
0-1	Identify question	• Oversight Committee identifies the key question the CPG will address.
1-2	Identify people of interest	• Oversight Committee identifies people of interest that will be impacted by the CPG.
1-3	Identify GDG members	• Oversight Committee identifies GDG chair(s) and consultant groups. • Oversight Committee addresses conflicts of interest.

PHASE 2: Drafting and Publication

Month	Milestone	Activities
3-24 3-4	SYSTEMATIC REVIEW Refine PICO(T)/PECOT	• GDG determines the specific questions the CPG will address (typically an in-person meeting). • GDG or Oversight Committee communicates with target journal editor. • GDG discusses authorship. (see ICMJE guidelines on roles)
3-10	Conduct initial literature search	• GDG sets inclusion/exclusion criteria. • Librarian runs search and documents search strategy and process. • GDG trains reviewers and appraisers. • GDG trains members in writing evidence syntheses and recommendations. • GDG screens articles (title and abstract review). • GDG reviews articles (full text review). • GDG ensures article search is documented.

10-24	Appraise evidence, extraction data	• GDG conducts critical appraisal of included studies (eg, establishing the quality of the article). • GDG conducts data extraction from included studies. • GDG ensures completeness and accuracy of critical appraisal of the literature. • GDG ensures completeness and accuracy of data extraction.
24-25	Draft recommendations and determine levels of evidence	• GDG writes evidence syntheses and recommendations.
25-27	Document methodology	• GDG ensures accurate documentation of the methodology used to develop the CPG and recommendations.
27-28	Document practice variables for evaluation of CPG implementation and for Registry	• GDG chair(s) ensure(s) that the CPG recommends measures to address key practice variables that will be used for evaluation of CPG implementation and for future use in the Physical Therapy Outcomes Registry.
27-32	Review CPG draft	• GDG communicates with editor of target journal to ensure specifications/ requirements of the journal are met. • GDG ensures the completed CPG draft is ready for review by Oversight Committee, followed by external review. • GDG responds to and documents all reviewer comments. • GDG or Oversight Committee oversees public review of the CPG draft. • GDG finalizes the CPG based on feedback and presents to the Oversight Committee. • GDG works with implementation team on implementation plan.
32-36	Publish CPG	• GDG works with journal to submit and publish the CPG manuscript. • GDG develops plan to maintain CPG currency.

PHASE 3: Postproduction: Dissemination, Implementation, and Evaluation

Month	Milestone	Activity
36-40	Disseminate CPG	• GDG chair(s) and appropriate groups post the CPG in the relevant databases, such as ECRI Guidelines Trust or PEDro. • GDG chair(s) and appropriate groups work with Practice staff to add the CPG to its library. • GDG chair(s) and appropriate groups notify people of interest of thecompleted CPG. • GDG chair(s) and appropriate groups develop educational materials or presentations on CPG content.
36-48	Implement CPG	• GDG chair(s) and appropriate work groups: • Work with APTA and member sections to ensure implementation tools, such as accompanying pocket guides, are available. • Work with external people of interest such as health professional andconsumer groups to ensure implementation tools are available. • Work with EHR vendors to ensure clinical decision support implementation tools are integrated.
36-	Evaluate CPG	• GDG chair(s) and appropriate work groups: • Work with the Physical Therapy Outcomes Registry to develop CPG modules for future implementation. • Develop quality outcomes to evaluate CPG implementation in clinical practice.

PHASE 4: Revision, Update, or Affirmation

Month	Milestone	Activity
36-	Evaluate use of CPG	GDG chair ensures continuous review of real-time data of CPG adherence and patient outcomes from Physical Therapy Outcomes Registry or other mechanisms. .
36-	Revise, update, or affirm currency	GDG chair ensures continuous review of published evidence and recruitment of additional members to GDG, including implementing method of literature surveillance and appraisal in preparation for updates.

Tracking Action Items and Budgets

To help ensure delivery of the CPG within the defined timeline and budget, action items and expenses must be tracked throughout the project. Appendix E is a template for creating a tracking form for action items and incurred expenses over time. Appendix F is a template for identifying and tracking expenses. All documents should be stored in the agreed-upon central repository (see Document and Reference Management in Phase 1). Having the tracking form available on all GDG calls and meetings can ensure that no action items are lost or missed, and it provides transparency to all GDG members of when items need to be completed and by whom.

Following a meeting or call, the tracking form should be distributed to all GDG members, with meeting notes indicating progress, obstacles (if any), and accommodations made to respond to any obstacles. The GDG should communicate plan updates to other participants, such as the Oversight Committee, section representative, and publishing journal.

References

1. Institute of Medicine [now National Academies of Medicine, Health and Medicine Division]. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011. https://www.nap.edu/read/13058/chapter/1. Accessed May 31, 2017.

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3. Institute of Medicine [now National Academies of Medicine, Health and Medicine Division] Board on Health Sciences Policy Committee on Medical Research, Education, and Practice. Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: The National Academies Press; 2009. DOI 10.17226/12598. https://www.nap.edu/catalog/12598/conflict-of-interest-in-medical-research-education-and-practice. Accessed February 1, 2018.

4. Rosenfeld R, Shiffman R, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. *Otolaryngol Head Neck Surg.* 2013;148(15):S1-S55. http://journals.sagepub.com/doi/pdf/10.1177/0194599812467004.

Determining the Scope of the Guideline

The process of determining the scope of the CPG is informed by many factors, including the needs of the target audiences and sponsoring section, the quality of the available literature, the time and resources available to the GDG, and the opportunities for improving the quality of practice.

Target Audience

The GDG will need to specify target audience(s) beyond physical therapists. These might include other health professionals who can implement aspects of the guideline or who participate in the care of patients with the diagnosis, consumers and patients, researchers, and policy makers. Inclusive language and appropriate background material may be needed to make the document user friendly for all potential audiences.

Breadth and Depth of Content

Within the topic selected, the GDG must carefully consider the aspects of particular relevance, and how the CPG will address the topic, including the breadth and depth of information that will be included. The time and resources needed to develop a guideline may not be justified if it replicates existing guidelines or if there is not enough evidence to support helpful recommendations. Guidelines can address very specific questions, such as the efficacy of an individual treatment approach, or be as broad as addressing the entire process of patient management. The intended scope can be changed in the planning stage as the quality and amount of the available evidence becomes clearer to the GDG. When there is strong evidence on a narrow scope of practice, the GDG may consider combining recommendations on that scope of practice with systematic reviews on the remaining topics.

PICO(T)/PECOT Question Generation

A list of clinical questions in PICO(T)/PECOT format may be useful for organizing the content, recommendations, and evidence syntheses, whether the scope is narrow or broad. Components of the acronyms for PICO(T)/PECOT are defined in Table 2 below.[1,2]

TABLE 2. PECO(T)/PECOT DEFINITIONS.

Problem	Condition or patient population
Intervention/**E**xposure	What is done to the patient (eg, diagnostic tests, outcome measures, treatments, education, recommendations)
Comparison	The alternative(s) (optional or may have >1)
Outcome	The intended result planned to accomplish (eg, a measurable improvement in status)
Time	Time frame for the outcomes (optional)

Considerations for the Physical Therapy Outcomes Registry

CPGs often include recommendations on measures that should be used to guide clinical decision making and outcome measurement. The GDG has the opportunity to support quality improvement and research, and to advance the physical therapy evidence base by identifying the core data elements that all physical therapists should document. The APTA Physical Therapy Outcomes Registry (Registry) collects electronic health record (EHR) data from participating practices to allow physical therapists to track their treatments and outcomes, benchmark against national data, and contribute data to strengthen the physical therapy evidence base.

Future development of the Registry will include topic-specific modules based on physical therapy-related CPGs. Therefore, for CPGs that include recommendations on measures, the GDG should consider the core data elements

that all physical therapists should document at least at baseline and at discharge. These measures should include key dimensions across relevant ICF domains and relevant prognostic variables. For example, for body functions and structures, it may include pain, swelling, joint range of motion, strength, and coordination; for activity and participation, it may include relevant physical performance and self-report measures. The core data elements would necessarily be a subset of the full range of measures recommended in the CPG and identifying them should not limit the GDG from recommending the full range of measures to capture a complete picture of patient function. (See Evaluation in Phase 3 for details on inclusion of key data elements that are part of the Physical Therapy Outcomes Registry.)

Pivot Point: Determine the Document Type

"To CPG or not to CPG; that is the question." After engaging a librarian to conduct the preliminary search, the GDG must evaluate the quality of the body of evidence to determine if it will support a physical therapy-focused CPG with moderate to strong recommendations. If the body of evidence is weak, the GDG should consider conducting a systematic review to identify the areas of research that need to be filled in order to write a CPG in the future. If an abundance of CPGs exist on the topic, the GDG should consider whether any can be adapted using the G-I-N process (see below) or if a synthesis of the existing CPGs into a guidance document might be more appropriate. Dagenais et al provide a helpful example.[3] Once the GDG determines the type of document that is most appropriate, it may be necessary to refine the document's aims or scope.

Adaptation of Existing CPGs

If CPGs exist on the chosen topic, the GDG should determine if the recommendations are appropriate to guide PT decision making or if there are gaps in the patient management process that still need to be addressed. If the CPGs address PT management of patients, the GDG should conduct a critical appraisal of the quality of the CPG(s), using the AGREE II instrument to determine its rigor and acceptability. If deemed acceptable, the GDG can use the CPG(s) to develop a document that synthesizes the findings across the reference CPG(s). This ADAPTE process is clearly outlined in the ADAPTE Resource Toolkit V2, 2010.[4]

Moving Forward With a CPG

Once the GDG has decided to move forward with developing a CPG, it should determine what support it will need for the organizational processes. This includes expansion of the GDG to include non-PTs, formation of an advisory group if none exists in the section, and coordination with other CPG groups in the section to align processes with prior decisions or to clarify departures or changes from prior methods used.

Additionally, GDG members should read through the AGREE II instrument and the ECRI Guidelines Trust's TRUST Scorecard to gain a clear understanding of the methodological standards on which the CPG will be reviewed. This will ensure that the GDG's methods for CPG development are aligned with national and international conventions.

Validation of the Content and Processes

External parties can offer many benefits in the CPG development process. They can provide validation of the questions that will be addressed, identify topics or language that might be overlooked by the GDG, and impact the overall scope of the CPG. To the greatest extent possible, external parties should include patients and other consumers of the relevant services, and they should reflect the diversity of the wider population.

A range of approaches can be used to elicit people of interest input. Focus groups of 6-8 people take advantage of the opportunity for shared viewpoints and discussion. When focus groups are not feasible, interviews can be conducted.People of interest surveys of clinicians, referral sources, and/or consumers of services can inform the scope of the CPG, can validate the top issues that are of common interest to different survey groups, and can identify issues that the GDG may not have thought critical.

Advisory groups can provide routine feedback on each phase of the CPG development, from the identification of the questions or topics that should be addressed, through draft production, to draft review. Multidisciplinary advisory groups can provide a balance to the inherent conflict of interest that PTs have as the ones writing physical therapy guidelines that recommend physical therapist services.

Consumer/People of interest Involvement

International and IOM standards strongly support the inclusion of patients, patient representatives, and/or consumers in the CPG development process. As the ultimate endpoint of guideline-directed care, this constituency can help shape the questions and priorities addressed by a CPG. Their perspectives can increase the validity of any recommendation or implementation strategies by introducing patient realities that clinicians might have overlooked, or that are not clearly represented in current literature. They help to ensure that the document is understandable to non-health care providers, enhance methodological transparency, and reduce the perception of conflicts of interest. In addition to surveying a cohort of patients and other consumers about their content preferences for a CPG, the GDG ideally should attempt to include 2 to 3 consumers throughout the development process.

The GDG might solicit representatives from group members' relevant patient or referral base or seek referrals for willing participants through professional contacts. If the GDG seeks endorsement by another professional organization, the group should consider inviting—or might be required to include—a sanctioned representative from that organization. These invitations should be coordinated through the section representative in cooperation with the APTA Department of Practice. Whether or not the professional organization requires a representative as a term of endorsement, such a representative can enhance awareness of the published CPG.

The level of consumer involvement may range from intermittent participation as part of the advisory team to being a critical appraiser of literature, to full membership on the GDG. These participants could be lead authors on lay translations of the CPG or of complementary implementation products, such as educational slides, videos, brochures, or FAQ sheets.

<u>Consumers United for Evidence-Based Healthcare</u> (CUE) is an organization that provides training and support for consumers to participate in the development of evidence-based documents, including CPGs. CUE provides resources for training patients and consumers on critical appraisal, participation on GDGs, peer review, and ways to serve onadvisory panels. Training is available both in person and online, with several free online presentations that provide an overview of the CPG process and consumer roles. The CUE Partnership Clearinghouse helps match interested patients and other consumers with guideline developers.

Selecting a Vehicle for Publication

The CPG's target audience will determine which journals are best suited to publish the CPG. In most cases, section-sponsored CPGs are destined for publication in the section's journal, especially if the audience is a limited, specialized group represented by the section. However, certain factors might warrant alternative publication options—something broader, such as *Physical Therapy (PTJ)* or other physical therapy or rehabilitation journals when CPGs are collaborations among 2 or more sections, or something narrower, such as a monograph that is available for download via the section website.

Ideally, journal publication will provide the largest possible exposure to the appropriate people of interest. This includesPTs who treat patients with the condition, other clinical professions who treat those patients, professional PT education programs, clinical residency and fellowship programs, payers and reimbursement policy makers, regulatory agency representatives, and health care consumers. To reach these external and a wider readership in general, the GDG should consider if and where the journal is indexed. Indexing will enhance access to the target audiences as well as provide publication credits for the CPG authors, many of whom are academicians for which publication productivity is important.

Communication With Section Leadership

As part of the selection process, the GDG should consult with the leadership of the section that represents the CPG. Discussions should address the value to the section, as well as to all target audiences, of publishing a CPG in its journal. The positive impact on section readership might be apparent, but the impact on external people of interest must also be considered.

Communication With the Journal Editor

Before submitting to a target journal for publication, the GDG should have consultative sessions with the journal editor. Issues to clarify with the editor include the following:

- Each journal has its own publication processes and constraints, such as the allocated pages per edition, number of editions per year, and database listings. Others may require that a proposal be sent prior to submission for publication (eg, *PTJ* requires prospective submission of the project proposal). Understanding these practical constraints may help the GDG and the section determine the best method of publication to enhance reader awareness and implementation. Options include publication in the journal as an individual article, as part of a special edition, as a supplement in hard copy or digital format, or as an electronic-only publication (eg, a downloadable monograph via the section website).

- If the end product will be a journal publication, the GDG will need to make arrangements with the editor to stay in contact throughout the CPG development process, so that an appropriate allocation for space can be made as close as possible to the finalization of the guideline. This will avoid finalizing a CPG that may then need to wait out several editions of the journal due to publication backlog.

- Lead time for publication needs to be clear to the GDG. All journals have a typical waiting period between the acceptance of a manuscript and release of the actual formatted publication issue, and the GDG should be made aware of the expected waiting period. Publication ahead of print may be an option to distribute the document more quickly and will need to be negotiated with the journal editor.

- Layout and enhanced options should be discussed. This may include the following questions:
  – Does the target publication support full-color images and graphics, and audio or video attachments?

  – Does the publication have a design "template" for special submissions such as CPGs that will draw more reader attention, or can one be created for this submission?

  If the target publication is a section journal that does not routinely support these options, the GDG needs to determine if the section can cover the extra cost or if the GDG would need to find alternative formats as it develops the guideline. If costs cannot be covered, and color and/or electronic enhancements are considered essential to the CPG, other journals might need to be targeted.

- The journal's editorial process should be discussed. In general, prior to journal submission CPGs undergo review by informed people of interest who are knowledgeable about the topic and methods, as well as public review open toall PTs. The discussion should confirm whether or not these levels of peer review will suffice, with editorial reviewat the journal focusing more on formatting and language to be consistent within the journal's culture, rather than a critique of methodology or content organization. Delineating these expectations early in process may save alot of stress closer to the publication date.

- Open access to the CPG is optimal. APTA recommends that all CPGs be published as free open access. While member support is provided to create these documents, free access means that they are available to improve practice within and outside of APTA membership. This is especially important for international parties that may have less access to evidence-based documents and for other professions that manage the same condition. Free access also means that there is a reduced likelihood of CPG duplication; this occurs when the same topic is studied by 2 different organizations, wasting time and money to derive similar recommendations. Free access will need to be planned with the journal editor and possibly section leadership.

Drafting the Proposed Outline

The GIN-McMaster Guideline Development Checklist is a comprehensive list of steps and considerations for planning and organizing CPG development. The GDG is strongly urged to review this checklist to determine which steps are important for their CPG development.[5] Of particular importance is the section on Considering the Importance of Outcomes and Interventions, Values, Preferences and Utilities.

Below is an abbreviated list to start the content outline.

Sample Proposed CPG Outline

To guide its focus the GDG should begin by identifying the quality-improvement opportunities that are being addressed; in other words, "what will change in practice as a result of this CPG?"

With that in mind, to assist with defining the scope of the CPG, organizing the PICO(T)/PECOT questions, and to inform the literature searches, it is helpful for the GDG to brainstorm a proposed outline of the CPG sections and content. The following are required of all CPGs, and use of the bulleted headings is recommended (absent parenthetical phrases added here for explanation):

- Title page
- Summary of graded recommendations
- Introduction
  - Aim or purpose and scope of the guideline, and intended audience
  - Statement of intent (escape clause)
- Defined levels of evidence and recommendation grades
- Methods (consult with publication editor as to what is supplemental/online versus in print.)
  - Search strategy and databases
  - Search results
  - Article review: inclusion and exclusion criteria
  - Appraisal process (training/reliability of appraisers)
  - Procedure for assigning and definitions of levels of evidence and grades of recommendation
  - Review procedures (people of interest, public, and editorial)
  - Conflict of interest management
  - Updating process (plans to maintain currency)
- Content—graded recommendations with a synthesis of the relevant sources that provide a transparent rationale for the assigned recommendation strength, with evidence tables in text or as appendices, on the following possible topics:
  - Examination tests and measures
  - Classification of subtypes or severity
  - Differential diagnosis/screening
  - Treatment types:
    · Definition of the approach
    · Frequency, intensity, time, and type (FITT) if known
    · Contraindications
    · Variables for risk adjustment
    · Modifying variables or conditions
  - Outcomes measures
- List of authors and reviewers with affiliations, and acknowledgments
- Appendixes or online supplements
  - PRISMA article flow chart (follow the link to see the Word template)
  - Table of excluded articles with reasons for exclusion

Note: Evidence tables and/or a synthesis of the evidence from the included studies are a requirement for acceptance on ECRI Guidelines Trust. Evidence tables may be published within the manuscript, as appendixes, or as onlinesupplements. This may be dictated by journal page limitations. Topical evidence syntheses typically follow each recommendation.

The GDG should consider the following to determine the desired format:

- The "look" of models you have seen
- Spreadsheets available to set up the text (for example, see www.nhlbi.nih.gov/guidelines/obesity/ob_evtbl.htm)

Searching the Literature

The literature search occurs in 2 phases. First, preliminary searches help to determine the amount and quality of evidence that currently exists to support a CPG, illuminates the search skills of the GDG, and identifies a body of literature for validation of a future formal search strategy. The second phase, a formal systematic search, is then conducted and documented. Descriptions of each follow.

Preliminary Searches

Once the CPG topic has been identified, preliminary searches should be conducted in primary databases to determine if there is a reasonable body of evidence to support the guideline or if the scope is too broad. Most important, the GDG should determine if there are any existing guidelines or systematic reviews on the chosen topic, what is missing in the available literature, *and* whether a CPG is still the right product to fill the gap.

The following sites are provided as a convenience but *are not fully inclusive* of all sites that might contain relevant sources of evidence.

Resources to identify existing guidelines:

- APTA Evidence-Based Resources
- Diagnosis-related professional organization websites (eg, American Heart Association, American Academy of Neurology)
- ECRI Guidelines Trust
- Guidelines International Network (G-I-N)
- National Institute for Health and Care Excellence (NICE)
- Physiotherapy Evidence Database (PEDro)
- Scottish Intercollegiate Guideline Network (SIGN)

Resources to identify systematic reviews or other forms of synthesized evidence:

- AHRQ Systematic Review Data Repository
- BMJ Best Practice
- The Cochrane Library
- International prospective register of systematic reviews (PROSPERO)
- McMaster Health Systems Evidence
- Physiotherapy Evidence Database (PEDro)

Primary databases for physical therapy literature:

- APTA Evidence-Based Resources
- CINAHL
- The Cochrane Library
- EMBASE
- MEDLINE or PubMed
- Physiotherapy Evidence Database (PEDro)
- SPORTDiscus

APTA Evidence-Based Resources:

APTA offers valuable resources to members for literature searches. <u>Article Search</u> includes the following databases:

- CINAHL Complete
- Cochrane Central Register of Controlled Trials
- Cochrane Clinical Answers
- Cochrane Database of Systematic Reviews
- Cochrane Methodology Register
- ProQuest Health & Medical Collection
- ProQuest Nursing & Allied Health Database
- Rehabilitation Reference Center
- SPORTDiscus With Full Text

Grey literature (conference proceedings, PowerPoint presentations, unpublished manuscripts):[6]

- <u>Agency for Healthcare Research and Quality</u>
- Clinical Trials Database
- <u>G-I-N Database</u>
- <u>National Institute for Health and Care Excellence (NICE)</u>w York Academy of Medicine
- <u>New Zealand Ministry of Health</u>
- NTIS (1964–present): A resource for accessing the latest research sponsored by the United States and select foreign governments
- <u>Scottish Intercollegiate Guideline Network (SIGN)</u>

Systematic Searches

Following the preliminary search, the GDG should design the formal systematic search strategy with the assistance of a librarian with systematic review expertise. It is strongly recommended that the GDG work with a librarian or other information specialist experienced in searching medical literature: a librarian can lessen the risk of bias in the CPG by ensuring that the search is designed and executed appropriately. To help you prepare for the meeting with the librarian, here are some of the topics that will be covered in your work with them. They will want to know the main questions, the concepts involved, key terms and MeSH headings if already known, examples of critical articles, databasesto be searched, time frames, and any filters. If they are not familiar with rehabilitation literature, there will be a higher burden on the GDG to think through all of the possible ways that concepts are described in the literature. It is alwayshelpful to provide them with a set of articles that are seminal to the area; this is where the results of a preliminary literature search are useful. It can also be helpful to provide the librarian with the section on interventions from the<u>Guide to Physical Therapist Practice</u> for an overview of physical therapist practice and specific terminology.

The search documentation should include the databases searched, start and end dates, terms used, and the results (ie, number of articles identified).

The goal of the systematic search is to find all studies relevant to the CPG topic in order to minimize bias in the recommendations. This requires searching multiple databases, hand-searching journal issues (manually turning pages of printed journals), reviewing citations in relevant studies, and documenting the search process so it is reproducible. Guideline developers should follow IOM standards for systematic reviews (<u>see box on p. 22</u>) to the extent possible to produce a trustworthy CPG.

The following select standards, adapted from the IOM Standards for Systematic Reviews, are particularly important for physical therapy CPG developers:[7(pp48-49,84-85)]

Standard 2.1	Establish a team with appropriate expertise and experience to conduct the systematic review	
2.1.3	Include expertise in searching for relevant evidence	
Standard 2.6	Develop a systematic review protocol	
2.6.4	Describe the search strategy for identifying relevant evidence	
Standard 3.1	Conduct a comprehensive systematic search for evidence	
3.1.1	Work with a librarian or other information specialist trained in performing systematic reviews to plan the search strategy	
3.1.2	Design the search strategy to address each key research question	
3.1.3	Use an independent librarian or other information specialist to peer review the search strategy	
3.1.4	Search bibliographic databases	
3.1.5	Search citation indexes	
3.1.6	Search literature cited by eligible studies	
3.1.7	Update the search at intervals appropriate to the pace of generation of new information for the research question being addressed	
3.1.8	Search subject-specific databases if other databases are unlikely to provide all relevant evidence	
3.1.9	Search regional bibliographic databases if other databases are unlikely to provide all relevant evidence	
Standard 3.2	Take action to address potentially biased reporting of research results	
3.2.1	Search grey literature databases, clinical trial registries, and other sources of unpublished information about studies	
3.2.4	Hand-search selected journals and conference abstracts	
3.2.5	Conduct a web search	
Standard 3.4	Document the search	
3.4.1	Provide a line-by-line description of the search strategy, including the date of every search for each database, web browser, etc.	

A caveat regarding searches for physical therapy measures: CPG authors should be aware that current IOM standards focus on minimizing bias and are based on high-stakes medical and surgical topics, and on the effects of interventions and the accuracy of tests. Because physical therapy CPGs often address the use of tests and measures throughout the episode of care, CPG authors should carefully consider the appropriate methods for searching and reviewing the literature on relevant outcome measures. Whereas the IOM guidance focuses on standards for systematic reviews and critical appraisal, alternative approaches may be more appropriate for identifying *measures*, in order to avoid unmanageably large searches. For example, a consensus process or expert panel could be used to identify relevant measures in the CPG topic area, and targeted searches could be conducted to identify articles on those measure's properties in the target population, rather than more general, scoping reviews on each measure.

Working With the Librarian

Prior to building any searches for the CPG, the librarian will gather information from the GDG regarding the project. In preparation, the GDG should draft a search protocol that includes the following:

- Well-defined research question(s) or PICO(T)/PECOT questions.
- The CPG's inclusion and exclusion criteria for articles. Examples include:
  - Study types/designs (eg, case series, RCTs)
  - Human
  - Gender
  - Age groups
  - Settings
  - Publication date
  - Language
- Citations of key articles from a preliminary search determining whether systematic reviews, CPGs, or other literature already exist on the topic. The preliminary search also should identify how much literature is available on the topic and if the scope should be expanded or narrowed down.
- An approximation of how many citations it is feasible for the group to screen at the title/abstract level (for example, 5,000 citations vs 15,000). Although the search should be designed to retrieve as many relevant articles as possible, it is important to create a search protocol that the group can realistically execute.
- Suggestions for what bibliographic databases the GDG would like to search. At a minimum, IOM recommends searching the Cochrane Library, MEDLINE, and EMBASE (if available). It will likely be necessary to add additional subject-specific databases to find physical therapy-related literature, such as CINAHL, PEDro, ProQuest Nursing & Allied Health Database, REHABDATA, SPORTDiscus, or Index to Chiropractic Literature.
- A plan for managing additional searching:
  - Conduct a web search (eg, Google Scholar)
  - Search grey literature (eg, clinical trial registrations, conference abstracts, dissertations, reports)
  - Hand-search (eg, manually turn each page of a printed journal and review the content)
  - Review citations within included studies
- Names of the tools you will use to manage the search results (eg, EndNote, Covidence).
- Whether or not the librarian will remove duplicate citations from the searches (as opposed to the group doing so).
- How you will obtain full-text articles and store them for team access.
- A timeframe for search completion.
- Whether or not the CPG team will include the librarian as a coauthor on the published CPG.
- A plan to update searches if the CPG development and production takes a significant amount of time, and initial searches potentially become outdated.

From the UK National Health Service, the article "The Literature Search Process: Guidance for NHS Researchers Developed by Thames Valley & Wessex Healthcare Librarians" also can help the GDG prepare for the initial consultation with a librarian.

Once the librarian has the information needed to build a search, the search process will likely follow this process:

1. The librarian will begin harvesting terms that can be used in the search. (See Appendix G for Example search terms.)
2. Depending on how the librarian and the GDG decide to work together, the librarian will send a list of possible search terms to designated members of the group to review and refine.
3. Once the list of search terms is finalized, the librarian will begin testing each search term in a primary database (most likely PubMed or MEDLINE). Based on the search tests and ongoing discussion with the group, the librarian will determine which terms to include in the search strategy.

4. Once the search strategy is complete, the librarian will send the preliminary search results to the group to review and will modify the strategy based on feedback.

5. After the group agrees that the search is final, the librarian will begin translating the search into the other databases selected for searching. (Each database has its own terminology and syntax.)

6. The librarian will run all the searches in the databases individually.

7. Depending on the arrangement, either the librarian will remove duplicates from the search results prior to transferring them to the group, or the group will remove duplicates.

8. The librarian can document all the steps of the searches (eg, databases searched, date(s) of searches, number of results in each database, number of duplicates, and exact search strings) throughout the process and draft the search methodology section for the CPG.

9. Once the group completes the title and abstract review, the librarian may be involved in obtaining full-text articles, if this is an available service.

In addition, APTA staff librarians provide the following services to members:

- User support for Article Search databases on APTA's website
- Consultation on searching physical therapy literature
- Peer review of search strategies for CPGs produced by APTA components
- Consulting on bibliographic management software for GDGs (eg, EndNote, RefWorks)

For assistance, email inforesources@apta.org with a detailed message of the services needed and return contact information.

The Cochrane Handbook on Systematic Reviews of Interventions is a good reference source for the GDG.

Decisions that need to be made:

- What will be your inclusion criteria?
- What will be your exclusion criteria?
- What will be your method of providing the GDG with access to full-text articles?
- Will you distribute responsibility for developing the collection among the GDG or are others included?
- How will you ensure that the literature review is up-to-date, relative to the publication date? Setting up an automated push from your search strategies may ensure timely updates of newly published articles relevant to the CPG.
- How extensive is the body of primary literature?
  - If extensive, should you consider limiting the scope of your CPG?
  - If limited, should you consider expanding the scope of your CPG or changing to a guidance statement? (For example, if textbook guidance is the primary evidence, the topic may not be ready for a guideline.)

Note: Because APTA and its sections are not academic institutions, under copyright law APTA cannot be treated as an interlibrary lender. The association must pay a permission fee for each selected article that is not available free of charge in the public domain (the average fee is $50 per article). Because CPG searches are thorough and expansive, it is cost-prohibitive for APTA to purchase each article. Article purchases should be considered in section or grant budget requests. (Language adapted with permission from the American Academy of Neurology Institute.)

Screening Process for the Systematic Review of Literature
Once the literature search for titles and abstracts is completed, the GDG will need to screen the articles to determine which are relevant for full text review. The following list of standards is provided as methodological guidance. The GDG will need to determine how closely to align with each of these standards and with the section's prior methods for previously published guidelines.

IOM Standards for Systematic Reviews related to screening and selecting studies[7(pp84-85)]

Standard 3.3	Screen and select studies
3.3.1	Include or exclude studies based on the protocol's prespecified criteria
3.3.2	Use observational studies in addition to randomized clinical trials to evaluate harms of interventions
3.3.3	Use two or more members of the review team, working independently, to screen and select studies
3.3.4	Train screeners using written documentation; test and retest screeners to improve accuracy and consistency
3.3.5	Use one of two strategies to select studies: (1) read all full-text articles identified in the search or (2) screen titles and abstracts of all articles and then read the full text of articles identified in initial screening

Literature Organization and Storage

Before the body of evidence starts accumulating, the GDG will need to determine how it will store PDFs and citations, and organize the data extraction/syntheses to support the writing process. Software repository options include:

- EndNote for both a repository and "cite while you write" ability
- Zotero for both a repository and "cite while you write" ability
- Mendeley for both a repository and "cite while you write ability"
- Dropbox or other cloud storage

Options for organizing data extraction with the citations include:
- Excel or similar spreadsheet software
- Covidence, which automatically tracks articles through the systematic review stages
- AHRQ's Systematic Review Data Repository

Appraising the Evidence

Measures of Bias and Quality

A fair and unbiased synthesis of the evidence is a key process in transparent and trustworthy CPGs. Below are key IOM standards and concepts underlying the critical appraisal process in the systematic review for the CPG.

The IOM Standards for Systematic Reviews related to critical appraisal include:[7(p85)]

Standard 3.6	Critically appraise each study
3.6.1	Systematically assess the risk of bias using predefined criteria
3.6.2	Assess the relevance of the study's populations, interventions, and outcome measures
3.6.3	Assess the fidelity of the implementation of interventions

Bias is systematic deviation from the truth in the results or inferences from research. It can cause underestimation or overestimation of the effect. Reviewers must consider the impact of the design and implementation on individual studies results and on the body of evidence addressing the question of interest. The extent of bias cannot be known with certainty, hence the term "risk of bias." This is why reviewer judgment is needed to assess bias in critical appraisal.

Reviewers also must consider the **relevance** of the evidence to the specific question posed by the GDG; this means assessing how relevant the populations, interventions, and outcome measures used in the study are to directly answering the question(s) addressed in the CPG.

For interventions, it also is critical for reviewers to consider **fidelity and quality**, which involves whether the interventions were delivered as planned and with necessary skill.

Finally, the precision of the estimates from the research must be assessed. Estimates of uncertainty (standard errors and confidence intervals) should be in an acceptable range to answer the question with confidence. More detail on these concepts can be found in the _Cochrane Handbook for Systematic Reviews of Interventions_.

Sources of bias are summarized in Table 3 (adapted from Higgins and Altman as published in the IOM Standards for Systematic Reviews[7(pp124),8]).

TABLE 3. SOURCES OF BIAS IN CLINICAL TRIALS

Type of Bias	Definition
Allocation or selection	Participant characteristics are associated with prognosis
Attrition	Differences in withdrawal are associated with outcome
Performance	Differences in treatment or care provided impact outcome
Detection	Differences in outcome assessment by group impact outcome
Reporting	Differences in planned and reported results impact outcome

Approaches to minimizing risk of bias are summarized in Table 4 (based on the Cochrane Collaboration Risk of Bias Tool and adapted from Higgins and Altman as published in the IOM Standards for Systematic Reviews[7(pp124),8]).

TABLE 4. BIAS TYPES AND RELEVANT DOMAINS OF STUDY DESIGN

Potential Bias	Goal	Relevant Domains in Cochrane Risk of Bias Tool
Allocation or selection	Select groups similar except for intervention	• Sequence generation • Allocation concealment
Attrition	Maintain follow-up on everyone throughout study	• Sequence generation • Blinding of participants, study personnel providers, assessors • Incomplete outcome data
Performance	Maintain comparable conditions throughout study	• Blinding of participants, study personnel providers, assessors
Detection	Use valid, reliable outcome measures and consistent measurement methods across groups	• Blinding of participants, study personnel providers, assessors
Reporting	Measure, analyze, and report all outcomes as planned	• Selective outcome reporting • Selective analysis reporting

These issues will be included in any critical appraisal process to some degree. The goal is to assess them systematically and consistently across reviewers and CPG domains.

The Appraisal Process
The bases of a rigorous systematic review are the exhaustive literature/evidence search and the systematic critical appraisal of the resulting relevant literature. The 2 most common approaches for critical appraisal of literature are (1) the use of critical appraisal tools (CATs) for reviewing individual studies combined with assigning levels of evidence, and (2) using the GRADE system (Grading of Recommendation, Assessment, Development, and Evaluation, https://gradepro.org/), which appraises a body of evidence by outcome. While both processes will result in an appraisal of bias for the body of evidence, GRADE requires more formal training. Therefore, APTA workshops encourage the use of CATs, given that the GDG typically uses section volunteers to assist with the appraisal process. Using volunteers

may increase participation within sections, facilitate awareness of the CPG topic among section members, support members' professional development of EBP skills, and help to minimize bias by GDG members in their interpretation of the literature. However, using multiple readers creates a challenge in collecting standard, consistent results. CATs facilitate the needed standardized approach to appraising the literature for the CPG under development.

Using Critical Appraisal Tools
There are many benefits to using CATs, also described as checklists. CATs provide more reliable and complete appraisals than do informal appraisal processes.[9] The appraisal process is more structured, standardized, and straightforward when using a CAT.[10] The focus on empirical, verified criteria provided by CATs can improve the focus on risks of bias,[11] as appraisers target those items in a publication rather than get sidetracked by the results of a study. CATs may improve communication among raters on a guideline development team since members are using the same operational definitions for the criteria, and differences of opinion about risks can be focused on specific items.

Challenges and Caveats When Using CATs
There are some challenges to selecting and using CATs. While use of a particular CAT for appraising the literature within an individual CPG development project provides standardization within that project, there is no standardization of included items or criteria among the many instruments that exist for appraising the same types of studies.[9,10] This results in significant item variability among tools, making careful selection of the right tool important.[12-14] Many CATs are developed by consensus[14] but lack reliability and validity.[15] Existing tools may or may not apply to the field or patient population related to the CPG under development.[16] It has been shown that even if different CATs are designed for the same type of study (eg, diagnosis or intervention studies) they will generate different quality ratings for the same evidence.[11,14,17]

On the other hand, a checklist designed for multiple types of studies loses detail or granularity that might help a GDG make more accurate decisions about the level of the evidence for an outcome.[9]

CATs typically include a single criterion for determining if the outcome measures are reliable and valid, but if a study uses several outcome measures, they necessarily are all appraised together under a single criterion. Emphasis needs to be placed on separately evaluating the individual outcome measures in the critical appraisal process.[18] Except for GRADE and the APTA Critical Appraisal Tool for Experimental Interventions (CAT- EI), current approaches do not allow for separately appraising the evidence from different outcomes in the same study. In addition, while CATs or checklists can identify whether something is reported in an article, they do not evaluate the quality of those items.[17] In other words, a CAT can identify whether the information is reported but cannot assess whether what is reported reflects sound research methodology or even what was necessarily done. Some items may have been completed that are not reported due to publication space limits.

Items included in a CAT are not typically weighted for their contribution to bias. It is not clear which missing items may be considered fatal flaws and which may not, by themselves, affect the risk of bias. Thresholds for bias also are influenced by the nature of the question being asked. Studies of diagnostic tools or interventions on life-and-death conditions might require higher thresholds than studies of tools or interventions that do not have such critical outcomes. For example, the threshold for risk of bias of an intervention that could cause death (eg, a medication) may be higher than one that will not (eg, exercise for deconditioning).

Guideline groups should discuss these issues for consensus on troubling articles and document their decisions. Transparency about the decisions is critical.

Recommendations for Using CATs
There are several benefits to using the same CATs within and across sections when developing CPGs. Use of the same tools within a section allows readers to assume that the levels of evidence assigned to articles are based on the same scales or appraisal criteria, making it easier to compare and synthesize recommendations on related patient issues. Using the same tools across sections enables clinicians who train to be critical appraisers for one section to more easily review literature for another section; many PTs are members of several sections, and this would increase their participation and potentially increase consistency in appraisals across CPGs. Finally, when the same tool is used across sections, training opportunities for the critical appraisal process and for application of appraisals in CPG development can be more focused and resource efficient.

APTA recommends the following CATs for the study designs listed in Table 5.

TABLE 5. RECOMMENDED CATS FOR DIFFERENT STUDY DESIGNS.

Study Design	Appraisal Tool	Training Resources
Clinical practice guidelines	AGREE II	www.agreetrust.org/resource-centre/agree-ii-training-tools/
Systematic reviews	AMSTAR 2	Detailed instructions are provided in the CAT review form.
Intervention	APTA CAT-EI	http://apta.adobeconnect.com/p6qi3mk2e2w/
Diagnosis	SIGN checklist	Recommend use of the SIGN check list. Detailed instructions are provided in the review form.
Measurement tools	COSMIN	www.cosmin.nl/images/upload/files/COSMIN%20check-list%20manual%20v9.pdf
Prognosis	Best BETs: Best Evidence Topics	http://bestbets.org/ca/pdf/prognosis.pdf
Cohort	SIGN	www.sign.ac.uk/checklists-and-notes.html
Case-control studies	SIGN	Notes www.sign.ac.uk/checklists-and-notes.html
Case series	Joanna Briggs Institute Reviewers' Manual: 2020 edition • Checklist for Case Reports • Checklist for Case Series	Training resource is included with the tool.

Data Extraction

Having completed the search and determined which articles are to be critically appraised for use in the CPG, the GDG should identify a method of organizing the extracted data that will be synthesized for the recommendations. A *data extraction spreadsheet* is the working document for the GDG. It can organize the extracted data relevant to the CPG topics or PICO(T)/PECOT questions and can keep track of all articles that are reviewed, who did the review, when the review was sent out and received back, and its assigned level of evidence by outcome of interest. In contrast, *evidence tables* are streamlined tables that present the relevant evidence from the data extraction spreadsheet to support specific recommendations designed for publication.

A spreadsheet such as Microsoft Office Excel is useful for the data extraction spreadsheet. Each article is added as a new row, and endless new or more detailed variables can be added as columns. For example, if article extractions include types of baseline measures for a condition, the GDG will have derived a list of potential measures it expects to see in the literature. Each measure is given its own column. As the GDG reads each article and fills in the desired information under the existing tools, a new measure may be identified that was not previously in the spreadsheet. A new column can easily be added at the location that most makes sense. As a rule, if a column starts out as a generic "measures" column, once the same measure or variable is used in 2 different studies, it is more efficient to pull out the information about that unique measure or variable into its own column. By keeping all column headings in the first row and not merging any cells, the spreadsheet retains a sorting function that can speed the evidence synthesis process. In other words, no cells should be merged for nesting titles, as this will remove the option of sorting by columns of content, thus reducing the efficiency of writing content summaries.

Evidence Table Design
A simplified version of the data extraction spreadsheet will be useful for formatting evidence tables that are incorporated into the CPG. The G-I-N Working Group on Evidence Tables has published a suggested list of items[19] to include in an evidence table.

Sample extraction forms can be found in <u>Appendix H</u>; however, the GDG will need to tailor all literature grids to their own topic and PICO(T)/PECOT questions. Additionally, the CAT-EI is provided as a fillable PDF; Adobe Acrobat Pro DC enables exportation of the filled fields into a spreadsheet, thus partially populating a data extraction spreadsheet with items from the CAT-EI.

Summaries From Data Extraction Spreadsheets and Evidence Tables

Reports of systematic evidence reviews must provide enough detail to allow readers to follow the judgments that were made in crafting the recommendations. The GDG will need to provide enough of a synthesis of the literature so that clinicians understand the strength of the evidence underlying the grade of the recommendation, the evidence for the conditions specified in the recommendation, as well as the clinical rationale for the recommendation. A synthesis of the evidence that communicates the rationale for the recommendation by intervention or outcome is preferable to individual reviews of separate studies. This synthesis should help the clinician to summarize the evidence for recommendations in explanations to others.

The <u>PRISMA statement</u> provides standards for reporting of systematic reviews, and the <u>AMSTAR 2 systematic review checklist</u> provides key dimensions on which systematic review quality may be judged. Finally, given that the summaries are part of an application for a new or updated CPG, ECRI Guidelines Trust provides <u>criteria for inclusion</u> in the ECRI Database. Additional information can be found in Cabanne et al.[19] Development of evidence tables also allows future GDGs to build on the evidence for updates to the CPG.

The above steps lead to a systematic review which includes design (identifying PICO(T)/PECOT questions, databases, grey literature, time frame and inclusion and exclusion criteria), conduct of search, title and abstract review, full text review, data extraction, and interpretation that will be used to make the recommendations.

Determining the Levels of Evidence

APTA suggests using the definitions in Table 6 for levels of evidence and recommendation grades, adapted from the Oxford Centre for Evidence-Based Medicine—Levels of Evidence.[20]

TABLE 6. LEVEL OF EVIDENCE DEFINITIONS.

	Types of Studies				
Level of Evidence	Intervention/ prevention	Pathoanatomic/ risk/ clinical course/ prognosis/ differential diagnosis	Diagnosis/ diagnostic accuracy	Prevalence of condition/ disorder	Exam/ outcomes
I. Evidence obtained from high-quality systematic reviews, diagnostic studies, prospective studies, or randomized controlled trials (RCTs)	Systematic review of high-quality RCTs (a) High-quality RCT (a)	Systematic review of prospective cohort studies High-quality prospective cohort study (b)	Systematic review of high-quality diagnostic studies High-quality diagnostic study with validation (c)	Systematic review of high-quality cross-sectional studies High-quality cross-sectional study (d)	Systematic review of prospective cohort studies High-quality prospective cohort study

II. Evidence obtained from lesser-quality diagnostic studies, prospective studies, or RCTs (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, less than 80% follow-up)	Systematic review of high-quality cohort studies High-quality cohort study (b) High-quality outcomes research High-quality quasi-experimental study (g) High-quality single-subject design (h) Lower-quality RCT (e)	Systematic review of retrospective cohort studies Lower-quality prospective cohort study High-quality retrospective cohort study Consecutive cohort study Outcomes study or ecological study (f)	Systematic review of exploratory diagnostic studies or consecutive cohort studies High-quality exploratory diagnostic study Consecutive retrospective cohort study	Systematic review of studies that allows relevant estimate Lower-quality cross-sectional study	Systematic review of lower-quality prospective cohort studies Lower-quality prospective cohort study
III. Case-controlled studies or retrospective studies	Systematic review of case-controlled studies High-quality case-controlled study Outcomes study or ecological study (f) Lower-quality cohort study	Lower-quality retrospective cohort study High-quality cross-sectional study Case-controlled study	Lower-quality exploratory diagnostic study Nonconsecutive retrospective cohort study	Local nonrandom study	High-quality cross-sectional study
IV. Case series	Case series	Case series	Case-controlled study		Lower-quality cross-sectional study
V. Expert opinion	Expert opinion	Expert opinion	Expert opinion	Expert opinion	Expert opinion

(a) High quality includes RCT>80% follow-up; blinding; appropriate randomization procedures.

(b) High-quality or dramatic effect cohort study includes >80% follow-up.

(c) High-quality diagnostic study includes consistently applied reference standard and blinding.

(d) High-quality prevalence study is a cross-sectional study that uses a local and current random sample or censuses.

(e) Weaker diagnostic criteria and reference standards, improper randomization, no blinding, <80% follow-up may add threats to bias and validity.

(f) High-quality outcome or ecological studies use instrumental variable(s) or other control for confounding factors.

(g) High-quality comparative study without random assignment to groups.

(h) Must have a minimum of "a" and "b" phase.

Procedures for Assigning Levels of Evidence

The assignment of specific levels to the evidence in a study is based on the critical appraisal process that identifies risks for bias, the GDG's assessment of those identified risks of bias, and the importance of those risks to the procedures or specific outcomes of interest.

The GDG uses the levels of evidence table(s) to assign 1 of the 5 levels to each study based on the study design *and* outcome interest, assuming "high quality" (eg, randomized clinical trial for intervention) starts at level I. This means that a single study might generate several levels of evidence, as an outcome measured with valid and reliable measurement tools may receive a higher level of evidence than an outcome measured with a less-reliable tool or procedure.

Thus each study is assessed using the critical appraisal tool combined with the GDG's judgment about its overall quality. The study can then be assigned 1 of the 4 overall quality ratings listed below—which identify the amount of confidence in the assigned evidence level (between I and V). The level-of-evidence assignment may need to be adjusted based on the overall quality rating factors.

High quality. The study/outcome remains at the assigned level of evidence. For example, if a randomized clinical trial was assigned to level I, its final assignment is level I. A high-quality rating includes:

- Randomized clinical trial with greater than 80% follow-up, blinding, and appropriate randomization procedures
- Cohort study with greater than 80% follow-up
- Diagnostic study with consistently applied reference standard and blinding
- Prevalence study that is a cross-sectional study using a local and current random sample or censuses

Acceptable quality. Weaknesses in the study identified in part through the critical appraisal process limit the confidence in the accuracy of the estimate by a downgrade of 1 level. For example, a study/outcome originally assigned to level I has a final assignment of level II.

Low quality. The study has significant limitations that substantially limit confidence in the estimate by a downgrade of 2 levels. For example, a study originally assigned to level II has a final assignment of level IV.

Unacceptable quality. The limitations in the study are so serious that it should be excluded from consideration in the guideline.

Grades of Recommendation or Action Statements

Assigning grades to the recommendations requires the GDG to weigh the quality of the collective evidence and potential benefits against potential harms and costs of implementing the recommendation. Because this requires the GDG to make judgments, the transparency built into the process through documentation and literature synthesis is critical. Additional information on grading recommendations can be found at IOM's *Clinical Practice Guidelines We Can Trust*.

The grades and definitions in Table 7 were developed through consensus by this manual's authors. Ideally, CPGs developed within an APTA section would use the same definitions for levels of evidence and recommendation grades to provide consistency within and across sections. However, evidence-based practice is an evolving area, and levels of evidence and recommendation grade conventions change over time. Additionally, when 2 sections collaborate, alternative definitions may need to be used to provide consistency between the developing CPG and the sections' journals or prior publications. Finally, within a section, evolution can occur and changes in convention are permissible. It might be helpful to have an editorial note about such changes within a section so that people of interest knowledge about the CPG process is current.

TABLE 7. GRADE ASSIGNMENTS FOR LEVEL-OF-EVIDENCE RECOMMENDATIONS

Letter Grade	Level of Obligation	Definition
A	Strong	A high level of certainty of *moderate to substantial* benefit, harm, or cost, or a *moderate* level of certainty for *substantial* benefit, harm, or cost (based on a preponderance of Level 1 or 2 evidence with at least 1 level 1 study)
B	Moderate	A high level of certainty of *slight to moderate* benefit, harm, or cost, or a *moderate* level of certainty for a *moderate* level of benefit, harm, or cost (based on a preponderance of level 2 evidence, or a single high-quality RCT)
C	Weak	A moderate level of certainty of *slight* benefit, harm, or cost, or a weak level of certainty for moderate to substantial benefit, harm, or cost (based on Level 2 thru 5 evidence)

D	Theoretical / foundational	A preponderance of evidence from animal or cadaver studies, from conceptual/theoretical models/principles, or from basic science/bench research, or published expert opinion in peer-reviewed journals that supports the recommendation
P	Best practice	Recommended practice based on current clinical practice norms, exceptional situations in which validating studies have not or cannot be performed yet there is a clear benefit, harm, or cost, expert opinion
R	Research	An absence of research on the topic or disagreement among conclusions from higher-quality studies on the topic

Common sources of evidence tables and recommendation grades include:

- Center for Evidence-based Medicine (CEBM)
- *Journal of Orthopaedic & Sports Physical Therapy* (Academy of Orthopaedic Physical Therapy and Academy of Sports Physical Therapy)
- *Pediatric Physical Therapy* (Academy of Pediatric Physical Therapy)

Linking Grades of Recommendation and Evidence Levels via Language of Obligation

After the level of evidence is determined for a body of evidence to support a recommendation or action statement, care should be taken to align an appropriate term of obligation within the recommendation statement. That is, if the evidence supports a Grade A or strong recommendation, it would be expected that clinicians "must" or "should" do that action, with "must" being the required term of obligation when harm might occur if the action is not followed. If the recommendation grade is a B or moderate strength, then the term of obligation would be no higher than "should." A Grade C recommendation reflects evidence that is weaker than for Grade B, and the terms of obligation would be "may" or "could." In this way, the clinician's obligation to implement the recommendation is aligned with the strength of the evidence and consistent across statements. Table 8 links the language.

TABLE 8. LINKING LEVEL OF EVIDENCE, GRADES OF RECOMMENDATION, AND LANGUAGE OF OBLIGATION

Level of Evidence	Preponderance of Benefit or Harm	Balance of Benefit or Harm	Level of obligation to follow the recommendation	Level of obligation against an action	Potential letter grades based on highest level of evidence
I	Strong	Option	Must or Should	Must not or Should not	A or Strong
II	Moderate	Option	Should	Should not	B or Moderate
III	Weak	Option	May	May not	C or Weak
IV	Weak	Option	May	May not	C or Weak
V	Option	No recommendation	May	May not	P or Practice R or Research
Best practice	Varies	No recommendation	Should or May	Should not or May not	P or Practice

Best Practice Recommendations

The GDG should use the "P-Best Practice Recommendation" for current clinical practice norms; exceptional situations where validating studies have not or cannot be performed and there is a clear benefit, harm, or cost; or when expert opinion is needed to support the clinical decision-making process. This could include situations of conflicting evidence or when the GDG wants to specify conditions under which select actions may be taken.

Suggested language for these recommendations might include in the case of conflicting values: "When patients do not respond to first choice or higher-level recommended approaches, or have conflicting values with the recommended approaches, PTs may use the following approaches [FILL IN], and must document objective baseline data, dosage if applicable, and outcomes to demonstrate patient response to the approach."

Or, when defensible documentation and clinical norms are expected, but the GDG wants to reinforce a particular behavior, suggested language is: "PTs should conduct and document a routine blood pressure screen prior to implementing the recommended interventions."

Research Recommendations

As the GDG synthesizes the available evidence, it will inevitably identify topics or issues for which high-quality studies have conflicting results or there simply are no studies. If research is needed to clarify a particular aspect of patient management, the GDG might consider using the "Research Recommendation" to specify the questions and types of evidence that are needed. Such recommendations inform researchers as well as section leadership, which may influence allocation of grants and support for needed studies.

Drafting Recommendations or Action Statements

There are different approaches to formatting recommendation statements, and the GDG will need to coordinate with the section CPG coordinator and the editor of the targeted journal on this decision. Ideally, all CPGs produced by a section are structured consistently to enable the section's membership to digest these documents. Regardless of the format used, the recommendations and supporting literature should meet the IOM standards for articulation[21(p8)]:

Standard 6.	Articulation of recommendations
6.1	Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed.
6.2	Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.

APTA recommends the use of BRIDGE-Wiz for writing implementable action statements and recommendations.

(Labels are in **bold**, sample data are in regular text, and comments are in brackets.)

Date: 7/1/2020

Key Action Statement [or "Recommendation," if preferred]

Evidence Quality: IV, **Recommendation Strength:** Weak

Action: [Includes data submitted from the initial recommendation construction.]

Aggregate Evidence Quality: IV

Benefits:

Risk, Harm, Cost:

Benefit-Harm Assessment: [Preponderance of benefit]

The GDG fills in the remaining components after the outline is produced:

Value Judgments: Describe ethical issues, guiding principles, and values of the GDG that impact the action statement/recommendation.

Intentional Vagueness: Acknowledge or explain any vagueness in the action statement/recommendation.

Role of Patient Preferences: Indicate how patient preferences might impact the action statement/recommendation. Generally, weaker evidence will require greater patient participation in shared decision making.

Exclusions: Specify conditions or situations in which the recommendation should not be followed.

Quality Improvement: Identify what aspect of practice will improve as a result of following the recommendation.

Implementation and Audit: Identify specific strategies for implementing this particular recommendation and how its implementation might be measured for adherence.

Notes: This component is for the GDG's notes and is not published in the final CPG.

Supporting Evidence and Clinical Interpretation: Synthesize the summary of the literature that supports the action statement/recommendation.

The GDG should address these 2 issues:

1. How should each recommendation be managed in patients with multiple comorbidities/conditions, particularly when there are multiple recommendations?

2. Will the recommendations apply equally to underrepresented patient groups; that is, are there health inequities in access, application, or response to treatment that may modify the implementation of a recommendation?

Guidance for CPG consumers and people of interest on how to prioritize recommendations may help to improve implementation and may impact the language used to craft recommendations. These explanations may fit underSupporting Evidence or under Role of Patient Preferences.

The GDG may want to review the CPG and the individual action statements/recommendations for ability to implement using the <u>AGREE II checklist</u>. The AGREE II checklist focuses on the overall methodological processes used. Having non-GDG readers assess the CPG draft with the AGREE II prior to public review is helpful for identifying processes that were used but not adequately explained, or explanations that are not clear to outsider readers. By addressing these items prior to public review, the GDG can enhance the levels of transparency and ease of implementation for the CPG.

Documenting the CPG Methods and Development Process

Throughout the project, the CPG authors must document the methods, decision-making rules, processes, and results of their work. The documentation for CPGs is analogous to that of systematic reviews, with some additions. CPG authors must include the following materials along with their CPG manuscript when submitting for publication:

- Literature search (search terms, dates, and results for each database, including result totals both before and after removing duplicate records)
- Article inclusion and exclusion criteria
- Article FLOW diagram
- Critical appraisal instruments, processes, and decision rules
- Critical appraisal results
- List of included articles
- List of excluded articles and reason for exclusion
- Description of the consumer/patient roles in the CPG development

Documentation of Practice Variables

As a result of writing the examination and discharge or outcome recommendations, the GDG should be able to identify a minimum data set for the condition addressed by the CPG. Clearly identifying items that *must* be documented on all patients with the condition will allow easier clinical implementation and evaluation of the CPG's clinical utility and effectiveness. The practice variables are not meant to be all-inclusive for the CPG. The variables that are identified will inform providers of their adherence to CPG recommendations and outcomes for selected patient populations and will help developers better evaluate the effectiveness of the CPG. The GDG should consider the following items for documentation.

Specific Outcomes Measure

- Global representation of identified patient population
- Recognition and acceptance by internal and external people of interest
- Representation of all movement dysfunctions of the identified patient population as it relates to activities and participation
- Use and distribution not limited by fees and copyright laws

Patient Classification/Diagnosis

- Use of recognized movement-related terms to describe the condition or syndrome of the movement system
- Inclusion, if deemed necessary, of the name of the pathology, disease, disorder, anatomical or physiological terms, and stage of recovery associated with the diagnosis
- Succinct and direct language to improve clinical usefulness
- Movement system diagnoses that span all populations, health conditions, and the lifespan, using, whenever possible, similar movement-related terms to describe similar movements, regardless of pathology or other characteristics of the patient

Variables for Risk Adjustment

- Items that have demonstrated impact on the outcomes for the identified patient population
- Clear identification and definitions

Examination (Test and Measures)

- Findings from the examination that are integral to 1 or more of the following for the identified patient population:
  - Correct patient classification/diagnosis/prognosis
  - Intervention to be performed
    - Clear identification and definitions
    - Consistent with the Guide to Physical Therapist Practice

Interventions

Activities performed by the PT or, when appropriate, by the PTA

- Clear identification and definitions
- Consistent with the Guide to Physical Therapist Practice

When the GDG identifies multiple acceptable measures, some effort should be made to further identify which measure is preferred. In this way, the CPG will more clearly outline the clinical decision process for choosing one measure over another and help reduce unwarranted variation in practice. The decision process should be based on the measures' psychometric properties, the sample patients they have been tested on, and the pragmatics of enhancing widespread use, including costs, time to administer, required clinician training, and usefulness of the information to clinicians and patients alike.

There are opportunities for CPGs to be included as modules in the Physical Therapy Outcomes Registry. (See Evaluation in Phase 3 for details on inclusion of key data elements that are part of Considerations for the Physical Therapy Outcomes Registry.)

Draft Review Process

It is not too early to consider which people of interest the GDG can or should invite to review the first draft. This might be by profession if specific names are not identified. Early identification may inform the writing process, and somereviewers may be appropriate for the advisory group that starts the process with the GDG. The manuscript review process includes:

- First-level review/editing/formatting by section CPG coordinator
- Potential second-level review by content experts
- Potential third-level review by people of interest
- Public comment
- Journal editorial review by a designated editorial board member and/or the journal editor

People of interest options include: section CPG advisory panel members, clinical researchers on the topic, claims reviewers, coding and reimbursement experts, physicians in specialty area(s), academic institution educators, clinical residency educators, clinical practitioners, guidelines methodologists, and consumers.

When the draft goes out for review, ensure that all interested people of interest been notified. Posting on the section website and social media, for example, are good vehicles to solicit input on the draft. Consider inviting other professional groups, patient advocacy groups, and policy makers to review the document. Using a program such as Survey Monkey to collect and organize responses of external reviewers will allow the GDG to more easily respond tothe variety of comments on a particular recommendation that might be submitted. Use the dedicated email address for the CPG to collect all reviews. Log all comments and the GDG's response to each suggestion, including edits to accept and decisions not to accept each comment.

Manuscript Submission

One person from the GDG should be responsible for shepherding the final manuscript through the publication process, including uploading all related documents and files to the manuscript submission system, identifying supplemental files for online access, and responding to the editorial comments and edits. This person should discuss with the journal the option of electronic publication ahead of print as a means of publishing the guideline in a timely manner. This is most important for journals that have historically long waiting periods between final acceptance and print production. Further, APTA supports free open-access publishing for all CPGs, so that any clinician, whether or not an APTA member or even a PT, can access the CPG to inform clinical decision making.

Celebrate the Publication!
Once you have finished the final edits and the journal has released the publication, take a moment to celebrate this major accomplishment before the CPG transitions to the post publication activities described in Phases 3 and 4.

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PHASE 3: POSTPRODUCTION: DISSEMINATION, IMPLEMENTATION, AND EVALUATION

As part of the process of CPG development, it is recommended that each section have an "implementation team" that works in consultation with the section Oversight Committee and the GDG to facilitate the development of the activities or products identified for the dissemination, implementation, and evaluation of the CPG. Many of these tasks extend beyond the initial development of the CPG, and, while it may not be the role of the GDG to complete all of them, it is the GDG's role to identify and support strategies for CPG dissemination, implementation, and evaluation.

Dissemination is a multipronged process that includes publication in refereed journals and commonly used responsibilities of CPGs (eg, ECRI Guidelines Trust, PEDro, APTA evidence-based resources, G-I-N), and notifying people of interest groups of the published document (eg, section members, providers at large, patient groups, external groups, payers).Implementation, which commonly is referred to as knowledge translation, includes education for all people of interest andincorporation of the CPG into the PT's everyday clinical practice. Finally, evaluation encompasses development of a systematic way to identify the continued use and effectiveness of the CPG. Figure 3 identifies potential components of the postproduction phase and may be used in knowledge transitions teams as they plan activities.

FIGURE 3. CLINICAL PRACTICE GUIDELINE POSTPRODUCTION COMPONENTS.

Dissemination	Implementation	Evaluation
Publisher (published guideline)	APTA	Key data elements (Registry)
Communication by section	Evidence-based resources	Module development
APTA	CPG+	Data collection
Posted on apta.org	Tests and measures	GDG feedback
Endorsed by APTA	Member news	Clinical feedback
ECRI Guidelines Trust	ChoosePT fact sheet	Development of quality measures
Communication by section	APTA Learning Center	Process
Communication by APTA	Background and overview	Outcome
External community	Performing outcome measures and interventions	Structural (eg, # of patients seen)
Endorsement by APTA	Quality improvement application	Clinical quality evaluation
Consumers	National meetings	Use of CPG at patient level
People of Interest	Combined Sections Meeting	Therapist use
Notification	Section	Faculty use
PEDro	National meeting	Organizational use
Communication by section	Regional meetings	Population health
	Web resources	GDG
	Health care providers and payers	Continuous review of published evidence
	Synthesized material	Review of real-time data from Registry, if available
	Consumer groups	
	EHR vendors	
	Clinical decision support algorithms	
	Data points	

Dissemination

As described in Phases 1 and 2, the GDG should identify the optimal location for publishing the guideline and communicate with the target journal early in the development process. The conversation should include the costs associated with publishing, which may depend on the length of the CPG and the level of access to journal subscribers vs the public; formatting considerations (any specific needs to accommodate graphic or multimedia elements); the review process; and promotion of the published CPG to all people of interest groups (eg, press releases,articles for newsletters, social media announcements).

Notification of people of interest also may include requesting endorsement by an organization. Each organization willindependently decide if and how they endorse a CPG.

APTA Endorsement

Endorsement by APTA is a 3-step system. It begins with an APTA staff review to ensure the proposed CPG's accessibility, currency, and consistency with APTA policy. CPGs that pass this review advance to a staff work group, which conducts a critical appraisal (AGREE II) to determine quality level and provides the AGREE II assessment. The SPAC reviews the staff report, the CPG, and the AGREE II assessment to determine endorsement. The SPAC recommendation is provided to the Board for approval. For questions, please contact practice-dept@apta.org.

Inclusion in Guideline Databases

Once the CPG has been published and is available for download, the GDG should focus on disseminating the CPG to guideline databases such as APTA's Evidence-Based Resources, ECRI Guidelines Trust, Guidelines International Network, and PEDro. (See below for further information on each database.) It is recommended that the GDG designate an individual responsible for determining submission requirements to each database and then submitting the CPG. This can be 1 person per GDG or 1 person within the section who handles this for all CPGs. CPGs typically are open for free access upon publication, and the designated person should coordinate with the publishing journal to ensure there are no copyright issues with disseminating the CPG outside of the journal. The Implementation group should pursue every opportunity to share the CPG, and any supporting documents, templates or information products, when the CPG is posted to a repository (eg, press release, articles for newsletters, social media announcements).

APTA Evidence-Based Resources

APTA's Evidence-Based Resources are available exclusively to association members. Its clinically related resources on typically treated conditions includes a repository of CPGs. Links to CPGs relevant to physical therapist practice follow the inclusion criteria of the ECRI Guidelines Trust (see criteria below) such that the guideline was:

- Based on a systematic review of the evidence;
- Published by APTA sections or by other health care associations, organizations, and societies, and not by individuals; and
- Created to assist in clinical decision making, not to take the place of clinician judgment.

Any CPGs subsequently found to have insufficient quality to guide practice are removed from the collection. CPGs posted have not been reviewed for consistency with APTA policies.

There are also resources for implementation that will be discussed later. For more information contact practice-dept@apta.org.

ECRI Guidelines Trust

The ECRI Guidelines Trust is a U.S. repository for CPGs. For inclusion, CPGs must meet the following criteria:

- The full-text guideline is available in English, online (for free or for a fee), and published within the last 5 years.
- The guideline includes recommendations providing guidance on patient care.
- The guideline must be produced by a medical specialty association, professional medical society, or other relevant CPG development organization.
- The guideline is based on a verifiable systematic review of the evidence that includes search strategy, study selection, and evidence analysis.

To submit, the GDG designee downloads the <u>Permission Agreement Form</u> from the ECRI website.

PEDro
PEDro is the Australian physiotherapy database for CPGs, systematic reviews, and clinical trials.

To submit, the GDG designee <u>contacts the site editor</u> and sends the published CPG for consideration.

Guidelines International Network
The Guidelines International Network (G-I-N) has the world's largest international guideline library. Comprising individuals and organizations interested in guidelines, G-I-N strives to lead the field of guideline development and implementation. To submit, the GDG designee contacts the APTA Practice Department at <u>practice-dept@apta.org</u>, as APTA is an organizational member of G-I-N and posting of the CPG is performed by the organizational member.

Promotion to Other Professional Groups
Some professional groups may not endorse or promote CPGs that did not have their own representatives participating in the development process, or a CPG published in a section journal may not reach PTs outside the section who should be aware of it. When it is important for clinicians of other professions or sections to be aware of the CPG, the GDG might consider submitting a companion article to the other profession's journal (or to *PTJ* in the case of a CPG published in a section journal). This companion article should be submitted very close to the publication time of the CPG to educate these other clinical parties on how the CPG recommendations might influence their roles in managing patients with the selected condition. In this way, more clinicians are made aware of the CPG or the parts of a CPG that are most relevant to that party.

Implementation

Knowledge translation is key to the successful integration of the CPG into clinical practice. The GDG should identify strategies for individual clinicians and the section for preparing educational materials and resources that help with that integration. The key component to implementation is developing clear and actionable recommendations. The overall implementation strategies should be strategic and specific to each people of interest group (eg, PTs, other health care providers, patients, and clients, and EHR vendors). Below are resources and examples of implementation strategies that may be used by people of interest groups. All efforts should coordinate through the CPG section representative or Oversight Committee to prevent duplication of efforts and to facilitate development of consistent materials.

APTA
APTA offers several ways to share summarized information as well as more detailed explanations of specific components of a CPG. Use of APTA's evidence-based resources, APTA*'s* magazine and email newsletter, ChoosePT.com, the APTA Learning Center, and national conferences are discussed below.

Evidence-Based Resources
Selected CPGs included in APTA's evidence-based resources are reviewed for CPG+, a translation aid for applying CPGs to practice. CPG+ features brief appraisals of full CPGs performed by 3-4 PTs and methodologist authors. They include quality ratings (using AGREE II), highlights of the CPG, and "Check Your Practice" tips for clinicians. See <u>"Physical Therapy Management of Congenital Muscular Torticollis: An Evidence-Based Clinical Practice Guideline"</u> as an example. As the CPG nears completion, a designee of the GDG should communicate with APTA staff by emailing <u>practice-dept@apta.org</u>, and entering "CPG+" in the subject line.

APTA's Rehab Reference Center can inform the physical therapist's management of a specific condition.

APTA's evidence-based resources also offer summaries of tests and measures, and access to the full tools frequently used by physical therapists. The tests and measures database summaries include applicable conditions and populations, administration instructions, measurement properties, interpretation, and clinical relevance. The GDG should con- tact APTA staff to create a plan to ensure that a summary is developed for any tests or measures that are recommendedby the CPG**.**

Member Communications
APTA's member communications can announce new CPGs to all APTA members. When a CPG is published, the GDG should contact staff at publicrelations@apta.org.

ChoosePT.com
ChoosePT.com is APTA's official consumer information website. Material developed by the GDG, such as consumer-friendly summaries, lay translations of the CPG, or clinical decision aids may be appropriate to be shared here. To submit materials for consideration to post on ChoosePT.com, contact APTA staff at publicrelations@apta.org. For more information on resources to create consumer-oriented materials, see Consumer Groups below.

APTA Learning Center
CPGs are linked to appropriate learning activities as a resource for implementation. As the CPG nears completion, a designee of the GDG should contact Learning Center staff to help identify the best courses for the CPG topic. Email learningcenter@apta.org with "CPG" in the subject line.

National Meetings
The GDG should anticipate when the CPG will be ready for journal submission and, near to that time, consider submitting abstracts for educational presentations of the content at national meetings such as the APTA Combined Sections Meeting. This is a great opportunity to have direct interaction with members.

Sections
Meetings and Web Resources
Each section's Implementation/Knowledge Translation Team and Oversight Committee should identify their strategies for implementation related to meetings and web resources. The GDG should coordinate efforts with the section's resources to prevent duplication of efforts and facilitate development of consistent materials. Early planning and working with the section's resources to identify opportunities to share and disseminate materials with section members about the CPG to facilitate implementation is critical. Some additional items that the GDG, Implementation/KnowledgeTranslation Team, or Oversight Committee should consider developing include:

- Documentation templates that incorporate recommended measures or data (see Evaluation below)
- Algorithms for clinical decision making
- Flowcharts describing clinical steps or processes
- Quick reference charts for PTs
- Case reports
- Patient-oriented clinical decision aids
- Slide presentations for academic and clinical educators

Health Care Providers and Payers
CPGs represent how PTs should manage the care of an identified population. The implementation team, in consultation with the GDG, should make efforts to ensure that other health care providers, payers, claims reviewers, and policy makers understand the recommendations and how they should be used. The creation of brief summaries, presentations, and other high-level resources should be incorporated and disseminated. In addition, sharing the development of a CPG also may involve publishing a summary or collaborative article for a closely related professionthat may direct its readers on the portions of a CPG that are important for that profession. The GDG should review identified author guidelines of the targeted journals for more details.

Consumer Groups

The development of resources for patients and consumers helps to ensure meaningful implementation of the CPG. Patient and consumer representatives who have participated in the CPG development may be a resource for writing or otherwise helping to develop patient-centered, plain-language materials, including a summary of the CPG, FAQ sheets, brochures, slide/presentation programs, or patient decision aids. Once the resources are developed, informing the consumer groups and providing easy access to the material is critical.

Examples include:

- The Academy of Orthopaedic Physical Therapy's Perspectives for Patients series on such topics as frozen shoulder (May 2013), low back pain (April 2012), and heel pain (February 2017)
- The American Academy of Neurology's Summary of Evidence-based Guideline for Patients and Their Families
- The Academy of Neurologic Physical Therapy's handouts for patients, physicians, and rehabilitation professionals

EHR Vendors

Development of a standardized documentation template that incorporates the key data elements for the identified patient population will increase effectiveness and improve communication. When basing these templates on evidence, the profession takes a large leap toward decreasing unwarranted variation in practice. Further, by incorporating these data standards into documentation quality metrics, they can become a part of normal clinic activities that can be used in the evaluation of the CPG uptake and patient outcomes. (Specifics on the identification of "key data elements" to assist in evaluation are discussed below.) The GDG is encouraged to share the documentation templates with EHR vendors to assist with this process.

The actionable activities that are inherently part of a CPG's recommendations lead to the natural development of algorithms. These algorithms—"if-then" statements—can inform the PT what interventions should be done if specific observations are made. With clear directions to EHR vendors, clinical decision support can be incorporated into the normal workflow of the therapist.

Evaluation

CPG recommendations are developed to guide practice, which ideally will reduce unwarranted practice variation and facilitate best practices. While it may not be the role of the GDG to enforce uptake, it is the group's role to identify strategies for the individual clinician and/or an implementation team to use to encourage adoption and user evaluation. This component includes information on how to identify key data elements that will be used to clinically describethe use of the CPG. See below for key data elements and a brief explanation of opportunities to integrate with the Physical Therapy Outcomes Registry.

Key Data Elements

Key data elements or quality indicators for the CPG can provide the GDG with quality feedback about the CPG's recommendations. In addition, they can be used to increase the understanding of how the guideline is used in practice. PTs can use this information to better understand the care they provide, and the GDG can use the collection of de-identified data for updating the CPG. There will be opportunities for the GDG to work with the section to have these data elements (see Documentation of Practice Variables in Phase 2) included as a future module of the Physical Therapy Outcomes Registry.

Finally, the GDG should establish methods for preserving the procedural work of the team and supporting documents and tables in order to pass them on to the updating team 2 to 4 years later—this process is described more fully in Phase 4.

The responsibility for maintaining the currency of a CPG lies with the section. The CPG section representative and Oversight Committee, in consultation with the GDG, must establish the process for CPG revision and updating.

The GDG should discuss whether the members are interested in continuing their work to maintain currency and to develop updated recommendations as appropriate. Often some of the team members will be interested in continuing, while others will want or need to rotate off of the project. Consider whether the entire team will be involved in monitoring the literature on a regular basis, or specify a time point at which a review will take place. *Before you complete the CPG it is best to develop a plan for currency, and identify roles and responsibilities and timelines.* An advantage of this approach is that the group responsible for updating can store and benefit from all of the documentation that you have developed to date—so no recreating wheels!

Although there is broad agreement that recommendations must be reviewed and, as necessary, updated regularly or when evidence supports changes in the recommendations, there is no consensus on the timing for revision or updates of existing CPGs. The work of Shekelle et al has contributed to the discussion empirically and conceptually. He has proposed "situational" criteria for changes in recommendations[1]:

1. Changes in evidence on the existing benefits and harms of interventions
2. Changes in outcomes considered important
3. Changes in available interventions
4. Changes in evidence that current practice is optimal
5. Changes in values placed on outcomes
6. Changes in resources available for health care

In addition to Shekelle's conceptual criteria, IOM's *Clinical Practice Guidelines We Can Trust* has specific recommendations regarding CPG currency[2]:

Standard 8. Updating	
8.1	The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.
8.2	Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.
8.3	CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm; that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective; or that a recommendation can be applied to new populations.

Following are some considerations for decisions that need to be made:

- Knowing that the CPG will need to be endorsed, revised, or updated within 5 years, the GDG should select an author on the original CPG team who will be willing to lead the process.
- Individuals' training, energy level, and time availability all will affect commitments of authors.
- One revision coordinator position can be created for the section if there will be several CPGs.
- The CPG revision coordinator should work with the publishing journal's editor and staff for developing the format of the revision. Reviewing other updates (eg, Academy of Orthopaedic Physical Therapy, SIGN, NICE) can provide guidance.
- A plan will be needed for monitoring the literature and deciding when changes need to be made.
- As with the original CPG, communication plans need to be developed for alerting users, patients, and other people of interest of updated guidelines.

Vernooij et al[3] provide a checklist for updating CPGs that resulted from a collaboration across international guideline methodologists, based on CPG development checklists and quality assessments. A downloadable and fillable PDF version with 16 items is available from Equator-Network.org. Updating groups will find it helpful to review the recommendations for best practices listed in this document prior to formatting the updated document.

The critical question is whether to conduct a full literature review at a specified time (eg, 2-3 years before the 5-year time frame) and revise the entire CPG (as did the Academy of Orthopaedic Physical Therapy for its heel pain, Achilles tendon, and hip pain CPGs) or to take a more limited approach. One limited approach might be to conduct focused systematic reviews using agreed-upon search methods on the evidence available since the last CPG publication to determine if changes are needed; these reviews would be published, and the GDG would base CPG update decisions on those publications. Another approach is sometimes called surveillance. Under surveillance, the search strategy developed during the initial CPG development is adjusted to include randomized trials and systematic reviews. The titles and abstracts are screened according to the existing inclusion and exclusion criteria, and a working spread-sheet is populated with key evidence and constructed so that the evidence can be sorted by recommendation.

The spreadsheet can be sent to the GDG, with questions to assess whether the evidence requires a change in the current recommendations. If yes, an update or revision would be triggered. If no, the CPG would be certified as of the search date for currency and necessary paperwork submitted to the appropriate people of interest (eg, section, APTA). This approach stops short of a manuscript but allows updated evidence tables to be provided online.

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Websites for Guidelines, Systematic Reviews and Methods Resources

ECRI Guidelines Trust https://guidelines.ecri.org/

Agency for Healthcare Research and Quality http://www.ahrq.gov/

Scottish Intercollegiate Guidelines Network http://www.sign.ac.uk/

National Institute for Health and Care Excellence http://www.nice.org.uk/

Physiotherapy Evidence Database http://www.pedro.org.au/

OT Systematic Evaluation of Evidence http://www.otseeker.com/

Guidelines International Network http://www.g-i-n.net/

Turning Research Into Practice Database http://www.tripdatabase.com/

American Academy of Neurology
https://www.aan.com/policy-and-guidelines/guidelines/

Academy of Orthopaedic Physical Therapy–*Journal of Orthpaedic & Sports Physical Therapy*
https://www.jospt.org/topic/clinpracguide

https://www.orthopt.org/content/practice/clinical-practice-guidelines/cpg-framework-history

Critical Appraisal Checklists
Knowledge Translation Program https://ebm-tools.knowledgetranslation.net/worksheet
Scottish Intercollegiate Guidelines Network https://www.sign.ac.uk/checklists-and-notes
Fetters L, Tilson J. Evidence Based Physical Therapy. 2nd ed. FA Davis; 2019.
https://www.fadavis.com/product/physical-therapy-practical-guide-evidence-based-practice-fetters-tilson-2

Manuals on How to Write Guidelines
SIGN 50: A guideline developer's handbook https://www.sign.ac.uk/sign-50
Developing NICE guidelines: the manual https://www.nice.org.uk/process/pmg20/chapter/introduction-and-overview
Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. Otolaryngology—Head and Neck Surgery. 2013;148(1 Suppl):S1-55. doi:10.1177/0194599812467004. http://oto.sagepub.com/content/148/1_suppl/S1.

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Conflict of Interest Disclosure Form

Name:

(Every panelist must complete a separate form)

Guideline name and chapter (if known):

Date:

The American Physical Therapy Association (APTA) and its member sections strive to produce high-quality, unbiased evidence-based guidelines. As such the policy requires full disclosure by all guideline authors, editors, and reviewers of all potential conflicts of interest (COI) related to APTA activities, real or perceived, including those that are unrelated to the guideline topic.

APTA, section, or Oversight Committee reviews the disclosures and either recommends approval, approval with management, or disapproval to the Guideline Development Group. It is the full Oversight Committee's responsibility to issue the final vote on each candidate for a Guideline Development Group and oversight of others involved in the guideline development process.

Examples of COIs that clearly disqualify a nominee include employment by a pharmaceutical or device manufacturer, particularly if the drugs or devices manufactured are related to a specific guideline topic. Nominees who serve as consultants or participate on advisory boards should provide as much information as possible in order for the Oversight Committee or appropriate subcommittee to evaluate the potential COI accordingly.

It is not the goal of Oversight Committee to preclude all individuals with COIs. Rather, the goal is to ensure full transparency while protecting the integrity of the guidelines, the guideline panelists, and the APTA. It is not the role of the Oversight Committee to serve as a policing body for its guideline panels. However, if the committee or its members discover through other means that nondisclosed COIs exist, then the nomination in question can be revoked.

Category of Conflict of Interest	Mark "Yes" or "No" to indicate whether each listed circumstance applies to you or to your parents, siblings, spouse, life companion, or children. Consider the *36 months* before the date of this form and known future commitments. Provide details for all "Yes" answers (including dollar value, which will not be disclosed).	
	No	Yes (dates, dollar amounts, and other details)
Nonprofit (NIH, AHA) or university (pilot) grant		
Device /pharmaceutical/ company grant that is not clinical research (eg, educational)		
Other grant		
Royalties or in-kind benefits (eg, travel, accommodations) from a commercial entity		
Share (or stock-option holder) of a device or pharmaceutical company		
Employee, officer, or director of a pharmaceutical or device company		
Consultant to a pharmaceutical or device company (specify interaction with FDA, financial analysts)		
Employee, officer, or director of an institution or employer that, to my knowledge, has a financial relationship with a commercial entity having an interest in the subject of the guideline		
Money for patient enrollment or other aspect of research		
Hold patent rights or have a patent application pending for research related to the subject		
Participate in speaking activities, advisory committee, or other activities related to guideline topic, with or without receiving honoraria or in-kind benefits a. Sponsored by a nonprofit (university grand rounds, annual meeting symposia) b. Sponsored by a for-profit (pharmaceutical company, for-profit health education company)		
Published article(s) on guideline topic		
Make public statements related to the subject of the guideline		
Provide expert legal assistance related to any litigation related to the subject of the guideline		
Anything else that could affect the perception by others of my objectivity and independence		

DEFINITION

For purposes of APTA and this disclosure form, a COI or competing interest is a financial relationship or other set of circumstances that might affect, or might reasonably be thought by others to affect, an author's judgment, conduct, or other work. A COI exists based on the author's circumstances. The author's behavior, subjective beliefs, and outcomes are irrelevant. In other words, the author must disclose a COI, even if the circumstances do not actually influence the author's services, and even if the author believes that the circumstances cannot or will not affect the author's actions. In parentheses below are some, but not all examples.

Draft a COI disclosure statement related to yourself, by summarizing all "yes" answers listed above in general terms (excluding specific monetary amounts):

ATTESTATION

I attest that my answers are true, that I have disclosed all conflicts of interest in accordance with the conflicts of interest policy and that the disclosed conflicts of interest (if any) will not bias, or in any way impact the integrity of, my work.

SIGNATURE

If I choose to submit this form electronically, I agree that keying in my name and corresponding date at the top of this form indicates my assent to its terms and is equivalent to my signature.

Signature:

Updates must be submitted online until the date of the final proof of the manuscript. Submit this form electronically or send it to:

[ENTER DELIVERY INFORMATION]

Conflict of Interest and Confidentiality Statement

The American Physical Therapy Association (the "Association" or "APTA") conducts all of its activities in accordance with the highest ethical standards. In this regard, each individual assisting APTA on an Association matter (an "Individual") shall scrupulously avoid any conflict between their respective personal, professional, or business interests and the interests of the Association, in any and all actions taken by them on behalf of the Association in their respective capacities. This Conflict of Interest and Confidentiality Statement (the "Statement") is designed to assist Individuals and APTA.

This Statement is intended to supplement but not replace any applicable state and federal laws governing conflict of interest applicable to nonprofit organizations. In addition, this Statement is intended to supplement and not supersede any existing APTA conflict of interest policy. In the event of any divergence or conflict between this Statement and a more specific APTA policy, the provisions of the more specific policy shall control.

I. GUIDELINES

A. *Disclosure of Financial, Personal, Professional or Business Interests*

As each Individual is most familiar with their unique situation, it is each Individual's continual responsibility to alert APTA to any conflict of interest situation, whether real or apparent, that may impact their discussions/decisions. Accordingly, if any Individual has: any ownership, employment, volunteer, agency, or business interest in a commercial entity or nonprofit organization that is the subject of the Association matter discussions or decisions; a position as a spokesperson, consultant, employee, or agent for a commercial entity, nonprofit organization, or an individual that is the subject of the Association matter discussions or decisions; or any other interest that is likely to bias the discussions or decisions on the Association matter; such person shall give notice of such interest or relationship to APTA, which will take appropriate action as needed, and, if deemed necessary, such Individual shall thereafter refrain from voting, writing, discussing, or making decisions on matters in which he or she has an interest, or otherwise attempt to exert any influence on the discussion or written material, or to affect a vote or decision on matters in which he or she has an interest. The above is not an exhaustive list of all situations that may pose a conflict of interest between the Individual's financial, personal, professional, or business interests and the interests of APTA.

B. *Use of Inside Information for Personal Gain; Confidentiality*

In the course of assisting on an Association matter, Individuals will have access to information that is confidential or proprietary to APTA or other entities. This information may include, but is not limited to, financial information, business plans of APTA or other entities, policy proposals, recommendations, policy development plans, confidential membership plans, and other information which would impede implementation of APTA or other entities' activities if it were disclosed ("Confidential Information"). Individuals shall not disclose any Confidential Information and shall make best efforts to prevent such disclosure. Additionally, Individuals shall not use information gleaned from assisting on an Association matter, which is proprietary, confidential, or otherwise not generally known to the public, for personal or professional gain.

In the course of assisting on the Association matter, Individuals will be asked to render opinions, and provide information, advice, or written materials based upon their unique knowledge. Individuals shall not offer opinions, information, advice, or written material for personal gain.

C. Interpretation and Application

This Statement is intended to provide guidance in resolving conflicts, but APTA anticipates that there will be questions about the interpretation and application of this Statement. APTA staff may provide answers to those questions. This Statement will evolve as it continues to be subject to review and revision.

ATTESTATION

My signature below certifies that I have read the APTA Conflict of Interest and Confidentiality Statement. During such time as I continue to assist on the Association matter, I agree to notify APTA promptly if and when I determine that any actual, apparent or potential conflict of interest arises. I agree that, upon request, I will return to APTA all materials supplied to me by APTA, including agendas, minutes, and supporting documents.

Clinical Practice Guideline: _____

Name in print: _____

Signature: _____

Sample Conflict of Interest Management Form

Name	Role	Date	ICMJE form* for disclosure of potential conflicts of interest				
			Receive payment for services related	Receive payment for services unrelated	Intellectual property	Other relationships	Generated disclosure statement

*International Committee of Medical Journal Editors Conflict of Interest Form is available at http://www.icmje.org/conflicts-of-interest/.

APTA Board-Adopted Procedure for Clinical Practice Guideline Endorsement Process

CLINICAL PRACTICE GUIDELINES ENDORSEMENT BOD Y03-19-06-09 [Policy]

The Board of Directors (Board) or Executive Committee (EC) approves all clinical practice guidelines (CPGs) submitted to APTA for endorsement.

The Scientific and Practice Affairs Committee (SPAC) will make recommendations for endorsement of CPGs to the Board or EC per the process outlined in Clinical Practice Guideline Endorsement Procedure. SPAC will conduct an annual review of this process and modify it as necessary.

Process

Step 1: APTA staff performs policy and administrative review in order to:

- Ensure consistency with APTA policies
- Ensure the guideline is available for free access
- Ensure the guideline is less than 5 years old
- If the CPG meets these criteria, the CPG moves to the next step:

Step 2: APTA staff request member experts to perform a scientific review to ensure that the guideline is of high quality.

- At least 2 member experts, who do not have conflicts of interest, will use a standardized critical appraisal tool (AGREE II– Appraisal of Guidelines for Research and Evaluation Instrument) to assess the methodological rigor and transparency with which a guideline was developed.
- The member expert reviewers will send the results from the CPG critical appraisal tool and recommendations for or against endorsement to APTA staff. Both externally developed and academy/section-developed CPGs may undergo the above process.
- Staff will prepare a report for the Scientific and Practice Affairs Committee (SPAC) reflecting the recommendations of the member experts.

Step 3: The SPAC reviews the report to ensure that the CPG review process outlined above has been followed.

- The SPAC reviews the report and will make recommendations for endorsement of CPGs to the Board or EC.
- The SPAC will conduct an annual review of this process and modify it as necessary.

Step 4: The Board of Directors or Executive Committee approves all Clinical Practice Guidelines (CPGs) submitted to APTA for endorsement.

- If the CPG successfully meets all criteria for endorsement, formal notification with the APTA president's signature will be sent to the organization or individual that requested endorsement. This notification will be archived as an official statement from APTA.
- If the CPG does not meet all criteria for endorsement, formal notification with the APTA president's signature will be sent to the organization or individual that requested endorsement with a rationale for non-endorsement. This notification will be archived as an official statement from APTA.

Tracking Form for Action Items

Project		Project #	
Project manager		Sponsor	
Project artifacts		Updated	

ID	Action Item (What is the item to be completed?)	Owner (Who manages this issue?)	Status	Date Entered	Planned Completion	Actual Completion	Comments
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Outline of CPG Expenses

Budget				
CPG		Revision or New		
Team Leader		Sponsor Section(s)		
CPG Coordinator		Updated		

Budget Status

Approved Budget	Planned Expenditures to Date	Actual Expenditures to Date	Variance	
$0.00	$0.00	$0.00	$0.00	
	Planned Remaining Budget	Actual Remaining Budget	Variance	
	$0.00	$0.00	$0.00	
Additional $ needed				

Budget Details

Internal Expenses

Salaries	Hourly Rate	# Hours	Total Cost	
Type of resource	$0.00	0	$0.00	
Type of resource	$0.00	0	$0.00	
Type of resource	$0.00	0	$0.00	
Type of resource	$0.00	0	$0.00	
Type of resource	$0.00	0	$0.00	
Type of resource	$0.00	0	$0.00	
Other Internal Expenses			Total Cost	
Type of expense			$0.00	
Type of expense			$0.00	
Type of expense			$0.00	
Total Internal Expenses				$0.00

External Expenses

Consulting Costs			Total Cost	
Type of consulting			$0.00	
Type of consulting			$0.00	
Type of consulting			$0.00	
Capital Expenditures			Total Cost	
Type of expense			$0.00	
Type of expense			$0.00	
Type of expense			$0.00	
Total External Expenses				$0.00

Sample Search Terms

Diagnosis/Classification Related

"algorithms"[MeSH:noexp]
"classification"[MeSH]
"cluster analysis"[MeSH]
"cohort studies"[MeSH:noexp]
"decision making"[MeSH]
"decision Support Techniques"[MeSH]
"diagnostic self evaluation"[MeSH]
"exercise test"[MeSH]
"medical history taking"[MeSH:noexp]
"models, statistical"[Mesh]
"movement/classification"[Mesh]
"palpation"[MeSH:noexp]
"physical examination"[MeSH:noexp]
"sensitivity and specificity"[MeSH]
"severity of illness index"[Mesh]
"treatment failure"[MeSH]
accuracy*[tiab]
algorithm*[tiab]
back screen*[tiab]
categorization[tiab]
categorize[tiab]
classif*[tiab]
classification based[tiab]
classification scheme*[tiab]
classification system*[tiab]
clinical decision*[tiab]
clinical exam*[tiab]
clinical pathway*[tiab]
clinical prediction*[tiab]
cluster analys*[tiab]
cluster*[tiab]
cohort*[tiab]
decision rule*[tiab]
decision support[tiab]
diagnose[tiab]
diagnosing[tiab]
diagnostic classification[tiab]
disability evaluation*[tiab]
exercise test*[tiab]

history taking[tiab]
ICF[tiab]
Mckenzie[tiab]
mechanical diagnosis[tiab]
movement system*[tiab]
movement test*[tiab]
physical exam*[tiab]
predict*[tiab]
predictive model*[tiab]
prognos*[tw]
reliab*[tiab]
screening[tiab]
sensitivity analys*[tiab]
specificity[tiab]
stratif*[tiab]
sub classification*[tiab]
sub group*[tiab]
subclassification*[tiab]
subgroup*[tiab]
subgrouping*[tiab]
subtype*[tiab]
targeted treatment*[tiab]
valid*[tiab]
validation studies[pt]

Physical Therapy Related

"cardiac rehabilitation"[Mesh]
"chiropractic"[Mesh]
"home care services"[Mesh:noexp]
"neurological rehabilitation"[Mesh]
"occupational therapy"[Mesh]
"osteopathic medicine"[Mesh]
"physical and rehabilitation medicine"[Mesh:noexp]
"physical therapy modalities"[MeSH]
"primary health care"[Mesh:noexp]
"rehabilitation research"[Mesh]
"rehabilitation"[Mesh:noexp]
"skilled nursing facilities"[Mesh]
"telerehabilitation"[Mesh]
athletic train*[tiab]
chiropract*[tw]
habilitation[tiab]
home care[tiab]
home health[tiab]
inpatient rehab*[tiab]
occupational therap*[tiab]
osteopath*[tiab]
physiatr*[tiab]
physical medicine[tiab]
physical rehab*[tiab]
physical therap*[all fields]
physical therap*[TW]
physiotherap*[all fields]
physiotherap*[TW]
post acute[tiab]
postacute[tiab]
primary care[tw]
primary health care[tw]
primary healthcare[tw]
rehabilitation program*[tiab]
rehabilitation research[tiab]
skilled nursing facilit*[tiab]
telerehab*[tiab]

Extraction Forms—Sample Headings

APPENDIX H

	Study
	Study Design
	Eligibility Criteria
	Interventions
	Primary Outcome Measure
	Secondary Outcome Measure(s)
	Sample Size
	Randomization Method
	Number Allocated to Each Group
	Sources of Bias
	Effect Size Primary Outcome
	Effect Size Secondary Outcome
	Critical Appraisal Rating and Scale Used Primary Outcome
	Critical Appraisal Rating and Scale Used Secondary Outcome
	Level of Evidence for Primary Outcome: Interventions (List Intervention and Level of Evidence)
	Level of Evidence for Secondary Outcome: Interventions (List Intervention and Level of Evidence)
	Level of Evidence for Diagnosis or Differential Diagnosis (List Exam Procedure and Level of Evidence)
	Level of Evidence for Prognosis (List Risk Factor or Predictive Variable and Level of Evidence)
	Benefits/Harms Tradeoff