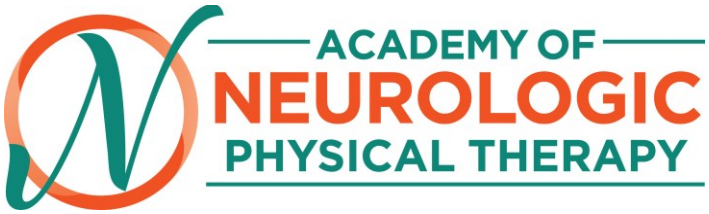

Academy Of Neurologic Physical Therapy
Evidence Based Documents Manual

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Overview of Evidence Based Documents Manual

The ANPT Evidence based documents (EBD) committee oversees the development and updates of ANPT-sponsored clinical practice guidelines, systematic reviews, and EGDE documents to promote the integration of research evidence into neurologic physical therapy practice. This manual serves to guide the development of EBD documents that are overseen by the EBD Committee. The EBD Committee also reviews EBD documents for which ANPT endorsement is sought. Note that just like evidence evolves and advances practice, so does evidence on methodology of EBD development and therefore this manual may change in methods

Definition of Evidence Based Documents

Clinical Practice Guideline (CPG): Clinical practice guidelines are graded recommendations on best practice to optimize movement in individuals with neurological conditions based on the systematic review and evaluation of the quality of the scientific literature. These documents are defined by a stringent methodology and formal process for development. Clinical practice guidelines are required to bridge the gap between evidence and recommendation and are made up of both evidence-based and expert-based information to guide clinical practice decision-making. Although variation can exist, all must meet standard criteria.

Systematic Review (SR): A systematic review is a balanced synthesis of evidence related to a defined clinical question. The systematic review applies an explicit, reproducible methodology and systematic search of the literature. Systematic reviews search, appraise, summarize, and identify gaps in knowledge. SRs do not provide recommendations for practice.

Evidence Database to Guide Effectiveness (EDGE): EDGE documents synthesize evidence using Delphi methodology to provide recommendations for outcome measures used in neurologic clinical practice, research, and entry level physical therapist education.

EBDs endorsed by the ANPT: Documents that have been reviewed and approved for ANPT endorsement by the EBD committee. See ANPT endorsement process on the ANPT website.

Organizational Structure of Evidence Based Documents Work Groups

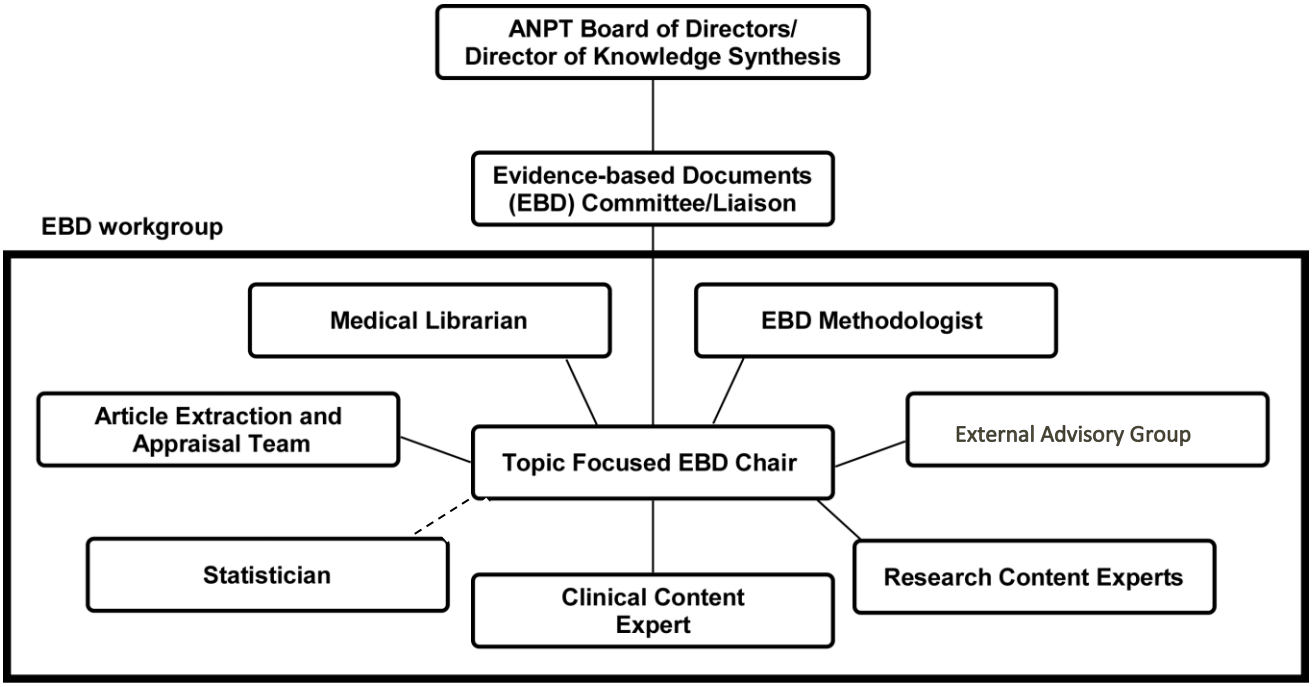

Figure 1. ANPT EBD Organizational structure. The figure above illustrates the composition of each EBD Work Group and relationship with the ANPT Board of Director of Knowledge Synthesis, EBD Committee, and the Liaison. The roles with solid lines are required members of the group and those connected with dashed lines may serve as consultative roles. The scope of the project and EBD type (e.g., CPG, EDGE, SR) will determine how many clinical content and research content members will be needed. Total number of EBD work group members is determined according to ANPT policies and can be modified based on need.

Roles and Responsibilities

ANPT Board of Directors

- Determines the number of Academy-sponsored CPGs and other EBDs to be developed at any one time based on the available financial support for the process and available expertise.
- Academy support for the development of an EBD should be dependent upon the availability and applicability of existing EBDs on a particular topic and availability of qualified and willing EBD development leader and workgroup.
- Determines need for EBD (topic identification) as a bi-directional process from the bottom up (member feedback) and top down (deliberation at the EBD Committee level).
- Approve members of the Evidence Based Documents Committee.

Director of Knowledge Synthesis

- Provides oversight of all ANPT EBDs and related procedures including CPGs.
- Serves as the liaison between the ANPT Board of Directors and EBD Committee.

- Attends EBD Committee meetings.
- Monitors knowledge synthesis related ANPT budget areas throughout the year and in collaboration with the Treasurer. Responds to specific financial inquires related to knowledge synthesis committees and work groups.
- Coordinates and supervises Academy work related to generation and update of CPG and outcome measures (EDGE) documents. Interacts with APTA (Anita Bemis-Dougherty, Senior Advisor for Scientific Affairs and Jeanine Kolman, Specialist for the Practice Department) and/or other external organizations that develop CPGs pertaining to neurologic physical therapy to recommend committee members to the guideline development group and/or provide input on scope of the CPG.
- For a complete list of duties and responsibilities, see ANPT policy and procedure manual

Evidence Based Documents Committee

- **Composition**
  - The ANPT Board of Directors will appoint one chair or two co-chairs and committee members who are ANPT members and represent expertise from adult neurological clinical practice and/or research. The chair(s) and committee members should represent expertise in knowledge translation, EBD development methodology, and/or scientific writing/editing.
  - The total number of committee members will vary according to the demands of the EBD committee and the number of ongoing EBDs that are in process.
  - Term of office is three (3) years. However, for liaisons to Guideline Development Groups (GDGs), the liaison should stay in communication with the EBD committee and GDGs to ensure consistency of communication through CPG development. Appointments are reviewed and renewed annually by the ANPT Board of Directors in June as per ANPT Policy and Procedures.
  - ANPT Board liaison is the Director of Knowledge Synthesis

- **Roles and responsibilities**
  - Meets virtually at least once per month with one in person meeting at CSM each year. If the group is unable to meet or if a committee member is unable to attend a scheduled meeting, updates will be emailed to the Chair, compiled and posted by the Chair for the group to review.
  - With the assistance of ANPT Board and Membership, the committee identifies, prioritizes, and refines EBD topics to be developed (refer to topic identification section below).
  - Organizes and places call to ANPT members for EBD work groups. Works with SIGs, ANPT volunteer list, EBD work group chair to identify content experts as potential members of EBD work groups and encourage these members to apply.
  - Screens CV/resumes to determine qualifications as clinical or research expert for each work group and submits a list of all qualified applicants to the EBD work group chair for final selection. Recommends the final selection of work group leaders and working group members to the Director of Knowledge Synthesis and the ANPT Board of Directors for appointment.
  - Recommends the appointment of EBD work group leader(s), workgroup members (including methodologist and librarian) and liaison to the Director of Knowledge Synthesis and ANPT Board.
  - Works alongside the EBD workgroup liaison to complete their role as the primary point of contact to the EBD workgroup (see EBD workgroup liaison role below)
  - Works with liaison and workgroup to screen and secure additional work group members as needed (can include article appraisal and data extraction team, statistician, stakeholder and expert panel (see Figure 1 dotted lines below) and/or medical librarian).

- Reviews, edits, and approves all EBD documents generated by the EBD workgroup and those listed in the ANPT product review process (see product review process on ANPT website for list of EBD relevant documents) prior to ANPT endorsement (see endorsement process on ANPT website). The review process includes planned and revised methodology at the onset and throughout EBD development as well as the completed manuscript prior to submitting for publication or public comment if applicable.
- Maintains and manages all matters of conflict of interest (see process below).

Evidence Based Documents Committee Liaison

- Member of the EBD committee and the primary point of contact for the EBD workgroup. The liaison may also be an active member of the EBD workgroup.
- Remains on EBD committee throughout the EBD project
- Frequent (at least monthly) communication between EBD workgroup and EBD Committee regarding general overview of the progress of the EBD document's development
- Works alongside the EBD workgroup to ensure that adequate support and resources are met, including budget requests
- Facilitates application of ANPT EBD methodology
- Facilitates communication between EBD workgroup and EBD Committee during the review, editing, and approval processing for the EBD document
- Assists workgroup to identify and refine content areas and scope of the EBD
- Assists workgroups in completion of EBD development in a timely manner

EBD Work Group (CPG, SR or EDGE groups)

- **Chair:**
  - Primary role is manager of group processes, including guiding development process; facilitating communication between group members; delegation and direction of work group tasks, regular (at least monthly) communication with EBD Committee liaison and when changes to methodology are being considered, submitting reports to APTA (if grant funded) and biannual reports to ANPT executive office.
  - **Skills**: efficient, motivated, organized, demonstrated leadership ability, scientific writing. Must have clinical and/or research expertise in EBD topic area. Should have prior experience with EBDs or CPG development.

  Members:
  - Administrative roles for each group member should be decided upon during first group meeting (e.g., organizing meeting times, setting agenda, meeting minutes).
  - Responsibilities of the Work Group include participation in all conference calls, attendance to all meetings with a commitment to teamwork and clear communication, reading all relevant material and doing all necessary background work to fully participate, responding to e-mail communications in a timely fashion, completing all personal assignments to meet deadlines, and maintaining confidentiality.
  - **Clinical Content Expert:** Depending on the type of EBD, it is recommended that at least one member has clinical expertise in the EBD topic. Expertise is determined by experience in a particular setting, years of practice, and degree and certifications. Experience in presentations, teaching, and publications are also considered. Should have prior experience with EBDs or CPG development.

- **Research Content Expert:** Depending on the type of EBD, it is recommended that at least one member has research expertise in the EBD topic. Expertise is determined by experience in research design and methodology, facility in critical appraisal, and scientific writing in the EBD topic area. Should have prior experience with EBDs or CPG development.
- **EBD Methodologist:** A methodologist is experienced in EBD development and is required for all EBDs. This may be a regular member of the work group or a contractual position.
- **Medical Librarian:** A librarian is required to conduct all literature searches based on pre-defined search terms developed in consultation with the EBD work group. This is a contractual position.
- **Statistician:** For EBDs conducted as a meta-analysis, a statistician may be required in a contractual position.
- **Article Extraction and Appraisal Team:** For CPGs, a call will be put forth in the ANPT newsletter for applications to the article extraction and appraisal team. The primary assignments will include critical review of published research for potential inclusion in the CPG. Members of this team must have strong clinical or research background in the topic area. An aptitude for reviewing scientific publications is strongly encouraged. Those with exceptional organizational skills, attention to detail, and demonstration of previous collaborative work is helpful. Responsibilities of these team members include disclosure of conflict of interest, participation in all conference calls (primarily in article appraisal pairs), completion of all trainings with a commitment to teamwork and clear communication, reading all relevant material and completing all necessary background work to fully participate, responding to e-mail communications in a timely fashion, and completing all personal assignments to meet deadlines.
- **External Advisory Group:** For CPG development, an external advisory group should be updated/consulted at all major milestones by the Chair of the guideline development group. See Table 3. This group is made up of the ANPT Director of Knowledge Synthesis, a JNPT representative or another journal representative with clinical or research expertise the CPG content area, a senior clinical and research content expert(s).

Conflict of Interest Forms: ANPT central office requests an annual completion of an online conflict of interest form for all those working on EBD projects. The EBD Committee reviews these forms and manages any identified conflicts at the beginning of each project and annually until the project is completed (accepted by the journal for publication).

Intellectual Property Agreement: Please see the Intellectual Property Agreement in ANPT's Policy and Procedure Manual and Copyright Transfer

Selecting a journal for publication: As the Journal for Neurologic Physical Therapy is the flagship journal of the ANPT the priority is to attempt to publish in that journal first. Communication with the Editorial Board of JNPT should be initiated early during evidence-based document development and should be ongoing at key processes or decision-points regarding evidence-based document development (described below). If the evidence-based document in final draft is not accepted by the journal, the authors and EBD committee should discuss potential other journals, with subsequent communication with the journal editorial board. If the EBD workgroup feels that another journal should be considered, the request must be submitted to the EBD Committee and Director of Knowledge Synthesis.

R**esource for authorship:** Authorship should be discussed at the start of each project. Please refer to the following resource for guidance on authorship. International Committee of Medical Journal Editors/ Defining the Role of Authors and Contributors: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

General Processes for Development of Evidence Based Documents

EBD Topic Identification

- ANPT Board of Directors, EBD Committee, and/or membership can propose a topic for the development of an EBD.
- The procedures for EBD topic identification occur each January as follows:
  a. EBD committee surveys ANPT Research, Practice/ Advocacy Committees and SIGs to help identify topics.
  b. ANPT members submit ideas through the ANPT website. Membership is notified of the link through the Newsletter and other social media platforms.
  c. EBD committee reviews topic suggestions and decides which one(s) should be put forward to the ANPT Board of Directors for final approval.
  d. ANPT Board of Directors and EBD Committee prioritize topics to be transitioned into an EBD.
- Once the review and prioritization of topics is completed, a summary will be posted on the website with the topic(s) selected to move forward along with a rationale for selecting this topic.
- Topic should be based on clinician interest, consumer demand, prevalence of the diagnosis in physical therapy, levels of variability in practice, abundance of literature or conflicting results within the literature, the effect of the guideline in terms of cost of recommended care, or its importance for reimbursement and policy development
  Reasons for setting topic priorities:
    i. Problems associated with a high burden of disability.
    ii. No existing recommendations of good quality.
    iii. A strong likelihood that the developed recommendations will improve health outcomes, reduce inequities, or reduce unnecessary costs if they are implemented.
    iv. Implementation is feasible.
- Considerations (e.g., using ICF and Patient/Client Management as foundation) when discussing topic choices include using ICF language, following patient/client management process or describing a singular aspect (screening, examination, classification, intervention by one or more activities e.g., walking, secondary prevention) for a single setting or across the continuum of care (see Scope).

Determination of EBD Scope

The scope of the EBD is dependent upon two things: The breadth and depth of the EBD and the type of EBD.

> According to Rosenfeld et al., "A well-crafted [EBD] has a clearly defined scope. Defining scope will occupy most of the first conference call and may require a second for completion. Inexperienced [EBD] developers attempt to cover all aspects of a condition, resulting in a broad scope that will stall development efforts. The key to progress is a razor-sharp focus from the start, recognizing that some issues important to some stakeholders will inevitably be left out." (p. S16)

Determination of EBD Breadth and Depth

To determine the scope of the EBD requires that questions 1. "What exactly is the EBD intending to accomplish? 2. What is its focus?" be answered precisely.
The following recommendations and considerations will facilitate decision-making in the process of determining the scope of the EBD:

1. Define the intended audience, target patients or clinical presentation, and the target condition or procedure (it may include assessment or treatment or both) and be able to precisely define the condition or procedure.
   a. To whom is the EBD directed? PTs? All physical therapy professionals? All medical professionals? Patients/caregivers? Etc.
   b. The target patient or clinical presentation can be defined using demographics, signs/symptoms, history, diagnostic tests. The Work Group should be clear to identify what patients or clinical presentations would **not** be included in the EBD.
   c. There may be a single condition or a list of multiple conditions. May use the ICF terminology and model as a basis for the description of the target/health conditions.
   d. Identify the patients' or conditions' level within the continuum of care to which the EBD is directed. The continuum includes practice settings from acute hospitalization to community – based programs. In some instances, the recommendations are more heavily based in one setting and an explanation related to the best practice area to implement the EBD should be included. Furthermore, acuity (hyper-acute, acute, sub-acute, chronic) and severity should also be addressed, defined and consistent between EBDs when it is pertinent to the topic and assists in defining scope. Examples of CPGs that have combined multiple neurological diagnoses include Vestibular Hypofunction, Core Measures, and Chronic Locomotor CPGs.
2. Use the PT management model from the Guide to Physical Therapist Practice (Exam, Eval, Diagnosis, Prognosis, Intervention) and delineate how much of the PT management process will be covered in the EBD.
3. Prospectively identify outcomes to consider. Outcome categories may include health status, functional, quality of life, as well as cost, quality and utilization outcomes. Agree upon standardized outcomes using body structure/function, activity, and/or participation domains and provide MDC and MCID where available. Relate information on the benefit/outcome to society for implementing the EBD. (i.e. cost or cost-effectiveness data, quality of life improvements) to the stakeholders (both the target patients and the target audience).

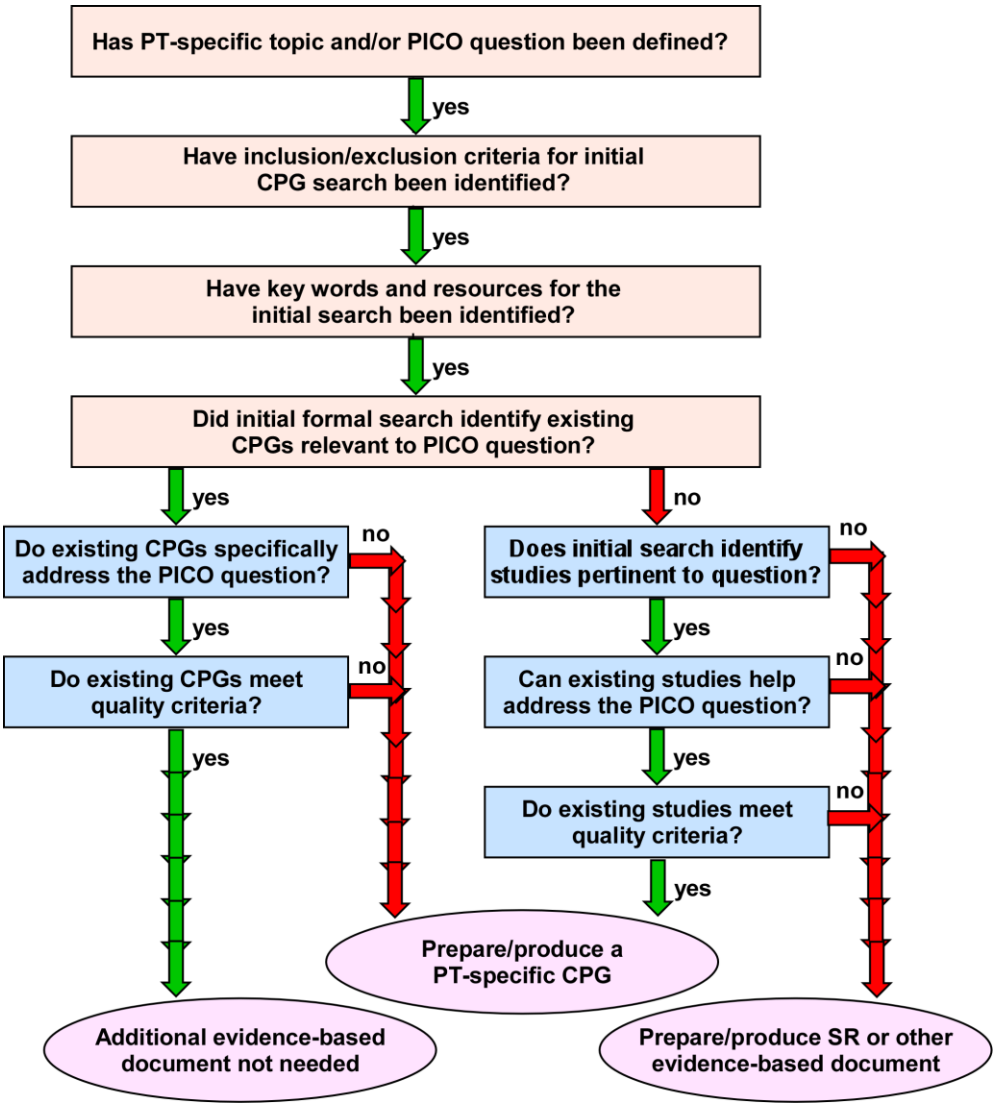

Figure 2. Decision tree for determination of the type of EBD Document should the undertaken.

Determination of Type of EBD

Before the scope of the EBD can be formally defined, the choice of EBD must be established. Figure 2 provides the process for determining type of EBD. The choice of EBD is determined by the **first literature search** to determine if CPGs and/or SRs already exist on the topic or if there is sufficient evidence to support a CPG. If not, a SR may need to be considered. A medical librarian may be needed to assist with the initial search process. The following standard electronic databases should be searched.

- CPG repositories include:
  - http://www.sign.ac.uk/ - Scottish Collegiate
  - http://www.nice.org.uk/ - Nat'l Inst for Health and Clinical Excellence
  - http://www.pedro.org.au/ - Physiotherapy Evidence Database
  - http://www.g-i-n.net/ - Guidelines International Network

- http://www.guidelines-registry.org – Practice Guideline Registration for Transparency (PREPARE)
- https://osf.io/registries/discover - Center for Open Science
- Discipline-specific guidelines (look to professional organization websites)

- Systematic Reviews or other synthesized evidence?
  - http://www.thecochranelibrary.com/view/0/index.html
  - http://srdr.ahrq.gov/ - AHRQ Systematic Review Data Repository (New)
  - http://www.pedro.org.au/- Physiotherapy Evidence Database (PEDro)
  - http://www.crd.york.ac.uk/prospero/ - International prospective register of systematic reviews (PROSPERO)
  - Primary Reference Databases - (PubMed, CINAHL, etc)

Once the first literature search is completed and the type of EBD has been established, the EBD Work Group, in consultation with the EBD Committee, refines and agrees upon a specific scope for the EBD.

Procedures for Clinical Practice Guideline Development

The organizational structure of ANPT CPGs work groups (guideline development group, GDG) is depicted in Figure 1. The CPG procedures and timeline that are followed by the GDG are outlined in detail below and in Table 3. Typically, the development of a CPG takes place over a 5-year period. CPG revisions are then typically conducted every 5 years. A CPG revision typically occurs over a 3-year period, requiring that CPG revision groups start the revision process 2 years following the preceding CPG publication.

Formation of a New GDG

Once a new CPG topic is identified following the process outlined above, the EBD committee organizes the process of GDG formation. First, the chair(s) of the GDG is appointed by the ANPT Board of Directors based upon recommendations from Director of Knowledge Synthesis and EBD Committee. A call for GDG members is then put forth in the ANPT newsletter, which typically runs for 30 days. Applications are then screened by the EBD Committee based on the EBD work group criteria for clinical and research content expertise outlined above. A list of qualified individuals is then sent to the GDG chair(s), who will narrow down the final selections. The EBD committee chair(s) will then send the selections to the Board of Directors for final approval. Typically, GDG members will include three research content experts and three clinical content experts. Once the GDG is formed, the EBD Committee will assign a liaison (defined above) who will interface with the GDG and EBD Committee throughout CPG Development. Roles and responsibilities of the GDG chair and members are outlined above. The process is similar for forming GDG for CPG revisions except that the original GDG will be asked to return to help ensure consistency as well as new members will be asked join as part of a succession plan. Please see the section on CPG Revision for more information.

Preparation

Define Administrative Roles: During the initial GDG group meeting, administrative roles for each group member should be decided upon (e.g., organizing meeting times, setting agenda, meeting minutes). Importantly, a CPG methodologist must be identified either as a group member or as a consultant to the group. In addition, a medical librarian must be identified to assist with literature search terms and searches.

Meet with EBD Committee Liaison and/or EBD Committee Member: GDGs initially meet with the EBD committee liaison and/or EBD committee member for an overview of CPG development or revision processes and EBD committee role. This meeting should be requested by the GDG within the first month after the GDG members are approved.

Attend APTA CPG Workshops: At least two GDG members are required to attend the APTA CPG workshop offered each summer. All GDG members are invited to attend the workshop. At least two GDG members must also attend the APTA CPG meeting that takes place at CSM each February. These workshops are optional for CPG revision groups.

Confirm PICO Question and Scope: Groups must define an overall PICO question, Scope (see Scope section above), and Statement of Intent, which will each be included in the published manuscript. Representative examples may be found in ANPT-supported published CPGs.

Conduct Clinician Survey: A clinician survey should be conducted early in the CPG development process to identify practice preferences related to the CPG topic. The online survey should be sent to the EBD Committee Liaison, who will then assist with submitting to the ANPT central office for posting within the online weekly newsletter. The survey will typically run for 30 days. Results will be compiled and returned to the GDG. These results can then be included as rationale for the overall scope and specific PICO questions within the CPG.

Establish External Advisory: An External Advisory Group must be established early in the CPG development process. The composition of this group is stated above (See EBD Work Group above). GDGs must arrange a meeting with the advisory group within the first 6 months of CPG development to review and discuss the overall PICO question, scope, statement of intent, clinician survey, and general progress to date.

APTA CPG Grant: Within the first year, GDGs will submit a grant proposal to the APTA. The deadline for the APTA CPG grant is usually in October. At least one month prior to this deadline, the draft proposal must be sent to the EBD Committee Liaison, who will then submit to the EBD Committee for review. Within one week, the EBD Committee will return any edits to the GDG through the EBD Committee Liaison. If a discussion is warranted to clarify any methodological processes or concerns, a meeting will be arranged between the EBD Committee Liaison and, if indicated, the EBD Committee chair(s)/Director of Knowledge Synthesis.

CPG Methodology: Once the proposed methods are agreed upon by the GDG and EBD Committee, they will serve as the approved methods for the CPG.

Designate a GDG email account: this email will be used for article extractor/appraisal applications and excel worksheets from the article extractor/appraisal process. Some GDG have set-up a Gmail account for the CPG, although creating a new email account for this purpose is not required.

Establish Software Resources: A mechanism for literature and document storage should be established early. Recommendations/considerations include:

- Establish how abstracts, articles, and other documents will be organized. All group members should have access to the database of all abstracts and full text articles. Some programs to consider are:
  - Covidence – Systematic review management available through the APTA for storage of abstracts and full text articles, abstract and full text screening, data extraction, article appraisals. EBD Committee can assist with training. Website training resources also available (https://www.covidence.org/)
  - Box – Secure cloud content management for all CPG related documents available through the APTA (https://www.box.com/). **All EBD development documents should be stored on ANPT's Box site.**
  - Reference Manager (e.g., Mendeley https://www.mendeley.com/, Zotero https://www.zotero.org/, Endnote https://endnote.com/)

First Literature Search

CPGs undergo a 2-step literature review. The first search ensures that a) sufficient evidence exists for the development of a CPG, and b) no CPGs on the defined CPG topic exist. This search is limited to systematic reviews and clinical practice guidelines. With the assistance of the medical librarian, search terms and databases to search are established. See process for first literature search above. Depending on the results of this first search, a decision is made to move forward with the defined CPG topic, a modified CPG topic, or a different EBD (e.g., systematic review). See Figure 2 for guidance with this decision.

Second Literature Search

At this point in CPG development, a team of article extractors/appraisers should be established. With the help of the EBD liaison and APTA Central Office, a call is put forth in the ANPT newsletter. Applications are sent to a GDG email account and reviewed by two GDG members according to the criteria described in the EBD Workgroup Section above. Eligible applicants are brought forth to the rest of the GDG for a final decision. In general, there are four research content experts and four clinical content experts included on this team. However, these numbers may increase or decrease depending on the number of included articles.

A second literature search for articles that will inform the recommendations within the CPG is then conducted. To manage the large number of articles, separate literature searches may be organized (e.g., based on individual specific PICO questions, neurological diagnoses, outcomes, intervention, etc.)

Assumptions:

1. The PICO question that the group is addressing has been clearly defined. This question may have been modified to align with the literature and need for a CPG after the first literature search.
2. Key conceptual definitions relevant to the proposed EBD have been clearly defined and operationalized (e.g., chronicity post injury, diagnoses, treatment categories)

Steps:

1. Delineate inclusion and exclusion criteria:
   Examples:
   - age range of subjects
   - sample size
   - medical conditions
   - acuity level of subjects (use of standardized definitions for acuity i.e., acute, subacute, chronic whenever possible). As there are varying definitions of these terms depending on diagnosis, we recommend that these terms be operationally defined for a given EBD.
   - level of function (ICF WHO)
   - study setting (community, acute care, rehabilitation, subacute care, long term care, etc)
   - study intent (diagnostic, prognostic, efficacy of intervention, epidemiological, instrument development/clinometric, etc)
   - study design (systematic reviews, randomized controlled trials, controlled cohort trials, etc)
   - type of statistical analysis (relationship, difference, descriptive, predictive etc.)
   - language (e.g., English only, unless medical translators are available to the team)
   - date range for studies

- exclude duplicates, conference proceedings, abstract only, methods only

2. Search: Decisions about which databases and development of key search terms are made with guidance of the medical librarian. At a minimum, the following databases should be included in the search:
    - Pubmed or Medline
    - CINAHL tends to capture more of rehab literature
    - PEDro for PT outcome studies/RCTs

3. Establish system for managing and reviewing articles
    - Examples include Covidence, Redcap, or Excel software to keep track of each abstract that might potentially be included. If using redcap or excel, headings may include primary author, co-authors, title, journal, year, citation, others as determined by intent of search. If using Covidence, this step should be done by the librarian.
    - Keep track of search results (this is done automatically if using Covidence)

4. Screen title and abstracts: Evaluate the title and abstracts based on inclusion/exclusion criteria
    - Judgment categories are Yes or No. If unclear, judgment should be yes to move it forward to full text review.
    - Establish reliability of the review process by having review team members review the same small set of title/abstracts independently, then discuss the process for clarification and consensus
    - Each title and abstract review must be completed by two reviewers. Each reviewer evaluates abstracts independently. Results from the independent reviews are then brought together for consensus. Discrepancies should be discussed and resolved within reviewer pairs with a third GDG member used as necessary. Communication between all GDG members should be maintained throughout this stage to ensure consistency. If using Covidence, abstracts with an agreed upon 'yes' vote will automatically move forward to full text review.

        If using Redcap or Excel,
        - Develop a form based on inclusion/exclusion criteria that reviewers could use to record why they made their recommendations for each article.
        - Provide Excel file cut and pasted from the master with the citations each pair was assigned to use. Pairs come to consensus on each assigned abstract. If this is not possible, the Work Group Chair resolves.
        - Work Group Chair records team decisions on the master file

5. Screen Full Texts: Evaluate the full text article based on inclusion/exclusion criteria
    - Retrieve articles that moved forward to full text review. Upload into article review manager (e.g., Covidence) and reference manager (e.g., Zotero or Endnote).
        - Judgment categories are Yes or No. Avoid use of 'maybe' if possible.
        - Review reasons for exclusion
        - If using Covidence, add to pull down menu (the number of articles excluded for these reasons will automatically be generated into the PRISMA flow chart in Covidence)
        - If using Excel screening form (from title and abstract review), record why an article is excluded.

- Each full text review must be completed by two reviewers. Each reviewer evaluates full text articles independently. Pairs come to consensus on each conflict with a third screener to resolve, if necessary. Note that there may be some conflicts that require further whole group discussion to resolve conflicts. For example, criteria that have not yet been discussed as a group.

6. **A third literature search** towards the end of the CPG development may be warranted if enough time has passed since the last search was completed. Typically, the last literature search should be completed within a year of submitting the manuscript to a journal.

Article Appraisal

Evaluate the included articles based on the appropriate critical appraisal tool: A risk of bias assessment, also called critical appraisal or quality assessment, aims to establish transparency of evidence synthesis results and findings. A risk of bias assessment should be applied to each included study in the CPG. There are numerous critical appraisal tools for every level of evidence. The following is a list of tools and training resources:

- Cochrane Risk of Bias tool for randomized trials, Version 2 (**ROB 2**) - tool to assess the risk of bias in randomized trials
- Information and video training links for use of ROB 2 can be found here: RoB2: A revised Cochrane risk-of-bias tool for randomized trials | Cochrane Bias
- Cochrane Risk of Bias in Non-Randomized Studies of interventions (**ROBINS-I**): The ROBINS-I is a tool developed to assess risk of bias in the results of non-randomized studies that compared effects of two or more interventions
- Information and video training links for use of ROBINS-I can be found here: https://methods.cochrane.org/bias/risk-bias-non-randomized-studies-interventions
- Consensus-based standards for the selection of health measurement instruments COSMIN – Assesses risk of bias in studies evaluating outcome measures
- Information and guidance regarding COSMIN tool selection and use can be found here; https://www.cosmin.nl/
- Cochrane Prognosis Methods Group (PMG) - focuses on the development of methods and guidance for performing reviews of prognosis studies: https://methods.cochrane.org/prognosis/
- Information and guidance regarding the PMG and training materials and workshops can be found here: https://methods.cochrane.org/prognosis/
- A MeaSurement Tool to Assess systematic Reviews, Version 2 (AMSTAR 2) - Critical appraisal when the evidence-based document of choice is a systematic review of RCTs
- Information and guidance regarding the AMSTAR 2 and training materials can be found here: https://amstar.ca/About_Amstar.php
- Case Series Studies: The Institute of Health Economics (IHE) in Alberta, Canada has done extensive work on critical appraisal of case series studies. They developed an 18-point appraisal tool and use a 70% cutoff score for rating high quality studies. Its use would be valuable in situations where a topic/PICO question (or sub-question) was answerable only by a majority of case series evidence. However, appraisal of this type of study would result in a Level IV level of evidence (see Levels of Evidence below) irrespective of the outcome of the critical appraisal.

    - Information and guidance regarding the IHE tool can be found here: https://www.ihe.ca/advanced-search/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique
    - Checklist can be found here: https://www.ihe.ca/publications/ihe-quality-appraisal-checklist-for-case-series-studies
- As the evidence on critical appraisal evolves, new tools may emerge addressing different levels of evidence. If other tools are warranted for the project, these should be discussed with the EBD committee prior to implementing.

  Once risk of bias tool has been selected, the following steps should be conducted:

    - An initial meeting should be held between the GDG and the article appraiser team to introduce the CPG and train on the appraisers selected critical appraisal tool.
    - At the end of this meeting, appraiser pairs (typically researcher and clinician) will be assigned and instructed to independently review and rate two articles. This process is to establish reliability.
    - Each appraiser's rating is compared to the rating established by the consensus rating previously determined by GDG members. A score of 90% is required to move forward to the next steps in the appraisal process. If 90% not achieved, a third article will be assigned and reviewed in a follow up meeting.
    - Once 90% reliability in rating is established, a set of included articles will be assigned to a team of 2 reviewers. Ten articles is generally a good starting point, but the number of articles may vary. Appraisers should complete appraisal of the assigned articles within a 4-week period. After this time, another set of articles will be assigned. Each reviewer evaluates articles independently then must come to consensus within the reviewer pair. Appraisers will not be assigned studies in which they are an author.
    - A method for compiling and storing the article appraisals must be established by the GDG. Typically, this is done by having article appraisers submit documentation via a designated email account. Some GDG have set up a Gmail account for the CPG. Documents are then uploaded to the GDG Box account by a designated GDG member or student assistant.

Data Extraction

Most resources on evidence-based documents recommend that the team leader/review coordinator, in consultation with the workgroup's methodologist or statistician, clearly define the necessary pieces of information (data points) to be extracted from each article to answer the guiding PICO question that is the foundation for the evidence-based document.

Data extraction forms for a CPG on *evaluation of intervention effectiveness*, for example, might include at least the following pieces of information:

- Study ID number (pre-assigned for each article)
- Data extractor initials (if using Covidence, extractor's name is automatically recorded)
- Date data extraction completed (if using Covidence, automatically recorded)
- Complete Reference as follows
    - Primary Author
    - Secondary Authors

    - Full Title
    - Journal
    - Year
    - Volume(Issue):page range
- Objective—the study objective as stated by the authors
- Article type/study design: e.g., meta analyses or systematic reviews, diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, case-controlled studies, retrospective studies, case studies and case series, or expert opinion. Note: This will inform decisions about of levels of evidence.
- Critical Appraisal Tool Summary Scores.
- Population—demographics of the participants in the study
- Intervention—description of the intervention
- Control—description of the control group or alternative intervention
- Outcome measures used
- Types of analyses performed
- Results of the intervention
- Study limitations
- Adverse events

It is important to note that there is no single template for data extraction: the content to be extracted depends on the PICO question/s underlying the EBD development group's goals and purpose. Once key "data points" are defined, the team leader and methodologist must decide how and when the information to be extracted will be documented and stored. A timeline for completion should be developed.

Data Extraction Database Options

There are a number of options to consider in collecting and managing the "data" extraction process, each with its own pros and cons. Regardless of the system used, each reviewer completes one data extraction form for every article on his or her assignment list. Most resources on development of evidence-based documents recommend that two reviewers independently gather relevant information from each article, compare results, and come to consensus/agreement that all key information has been extracted. This strategy helps to reduce potential bias, as well as improve reliability during data collection. Following consensus, the document can be emailed to the GDG designated coordinator (if using excel) or notify the coordinator via email when data extraction is complete (if using Covidence). The coordinator then performs or delegates data entry into a master excel file or other database for further analysis.

- *Covidence Database software:* This is the recommended database. It allows multiple persons to have access, and can be modified as necessary to make data gathering more efficient. When data extraction and article appraisal is complete, the GDG leader or designated coordinator can export reviews to an excel spreadsheet.

- *Spreadsheets / Data Tables:* Tools such as Microsoft's Excel program or Google Docs open access online programs can be developed to meet the specific needs of the workgroup. The decision must be made a priori about whether reviewers enter data directly, or use "pencil and paper" to gather information that a single assigned person (e.g., team leader or review coordinator) enters extracted data into the spreadsheet. If the number of reviewers is relatively small, entering data directly may

be manageable. If the number of reviewers is large, the risk of data entry errors increases substantially. Additionally, spreadsheets with many columns and rows of information to complete can be cumbersome and confusing; this contributes to risk of data-entry errors.

- *Web-based Surveys:* Survey Monkey https://www.surveymonkey.com is a web-based tool that could be used to design a data extraction form. The team leader/review coordinator would need to design a survey that reviewer teams can respond to for each of their assigned articles. Answer format could be designated as a combination of free text or forced choice options. Management of data can be cumbersome if many articles are to be mined for information. Survey results can be downloaded by the team leader/review coordinator into a database, such as Excel. This works efficiently only if response options are well understood and consistent across the review team. Note that there is likely to be a cost for advanced survey tools.

No matter which strategy is selected for data extraction, the initial draft of the "form" needs to be evaluated and revised so that it is efficient and effective. Many data extraction forms undergo several iterations prior to implementation in a final version. Evaluation of the form is achieved by having several knowledgeable reviewers use it on "practice" articles, focusing attention on clarity of instructions, ease of use, and identification of redundant and missing information. The iterative feedback provided by actual use is invaluable, ensuring that the data needed to support synthesis is available in a consistent, interpretable, and high-quality format.

Training for Data Extraction

Once the data extraction strategy and "form" are finalized, the article appraisal/data extraction team of individuals need to be trained so that there is consistency (and therefore less risk of error) across the review team. Because there is great variability in how authors present information and describe methods and results across journals, effective data extraction can be very challenging and time intensive. Having data extractors "practice" on the same article or small set of articles followed by discussion to reach consensus may be a solid strategy to develop inter-rater reliability. It is very helpful to have a manual or notes included within the data extraction template that individuals can refer to as they move from novice to experienced data extractors.

After the team leader/review coordinator is satisfied that there is consistency in process and content across reviewers, pairs of reviewers are assigned a set of articles for data extraction (e.g., 10 articles per 4-week period). Each reviewer independently completes data extraction then compares results with their teammate. Once consensus is reached, the final data set for that article is recorded/saved in the data extraction/data management tool that has been chosen/developed for the project.

Managing the Database (if using redcap or excel)

Errors in data entry in a complex database (e.g. Redcap, Excel) are likely, no matter how careful or experienced the individual/s entering data are. It is important to think about the EBD database in the same way one would a research database. Data extraction forms, the "raw" data used for development of the CPG, should be saved in an e-folder accessible to the individual on the team designated as the database manager. This person should periodically use sort options to scan for out of range or unusual values in any given column, referring to the "raw" data to make corrections. Once the database manager is satisfied that information in the database is accurate, the team is ready to move into the process of synthesis. This process is not necessary if using Covidence software.

Sorting Information in the Database

For the GDG to be able to synthesize evidence contained in the database of extracted data, it is necessary that a sorting process of the information is possible. In this way, information relevant to specific components of the PICO question can be grouped. It may be necessary to add columns within the database so that coding will allow an efficient sorting process. Sorting of the data provides the foundation for development of data/evidence tables as the synthesis process begins. If using Covidence, it is helpful to create lists in which one or more categories (e.g., for various interventions and/or outcomes of interest) or 'yes' 'no' responses can be clicked.

Data Synthesis (Making Recommendations)

The quality of an evidence-based document is determined by the transparency and effectiveness of the synthesis process. Just as in the earlier stages of CPG development, risk of bias can be reduced by use of a consensus building strategy. There are no hard and fast rules about the synthesis process. The EBD Committee recommends that 2-4 individuals (depending on scope of document) be assigned to draft a synthesis outline, present their outline to the group, and then use a consensus or Delphi-type procedure for ratification by larger group to ensure that possibility of bias is minimal. A description of the Delphi method can be found at (http://www.healthknowledge.org.uk/public-health-textbook/research-methods/1c-health-care-evaluation-health-care-assessment/use-delphi-methods
In CPGs, synthesized information leads to a clinical recommendation or "grading". One example of a process to develop recommendations is the "GRADE" process (Grading of Recommendations Assessment, Development, and Evaluation; for example, see Guyatt 2011), developed by an international collaboration as a transparent and structured method for presentation of summaries of evidence and developing recommendations. GRADE methodology was developed to answer questions concerning alternative management strategies, interventions, or health policies.

Assigning Levels of Evidence

Once all included articles are appraised, scores from the critical appraisal are linked to Levels of Evidence. The use of the Center for Evidence-Based Medicine nomenclature is recommended for Levels of Evidence. Depending on which appraisal tool is used, a cut off score/criteria should be established for this purpose. The following indicates how the critical appraisal scores have been integrated into Levels of Evidence using a > or < 50% score for the Critical Appraisal Tool from APTA, although other appraisal tools and criteria can be utilized (e.g., ROB-2 or variations in comparison or control interventions).

I Evidence obtained from high-quality diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, meta-analyses or systematic reviews (
II Evidence obtained from lesser-quality diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, meta-analyses or systematic reviews (e.g., weaker diagnostic criteria and reference standards, improper randomization, no blinding, <80% follow-up)
III Case-controlled studies or retrospective studies
IV Case studies and case series
V Expert opinion

Assigning Quality 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. Individual GDGs can determine which appraisal tool to use and what criteria are utilized to assign a 1-5 level as long as it is generally consistent with professional standards and agreement both within the GDG and from the EBD committee.

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. (for example, a CAT score > 50% of criteria). For example, a high-quality rating for specific article might include some of the following criteria:

- 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. (e.g., critical appraisal score <50 - >25% of criteria).

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 (e.g., critical appraisal score <25% of criteria)

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

Steps in the Synthesis Process

The synthesis process has multiple steps that must be carried out for *each* PICO question that has informed the search for evidence to support the CPG:

1. Assigning levels of evidence based on critical appraisal scores

2. Development of evidence/data tables (evidence profiles) using information in the master database (including quality rating for each study). See next section on Evidence Tables.
3. Review of information in the data/evidence table to identify potential recommendations.
4. Deciding about the direction (pro/con) and strength (strong/weak) of the recommendation. See Evaluating and Grading Evidence Section.
5. Reaching consensus on each recommendation within the entire workgroup. See Writing Recommendations section.
6. Synthesizing recommendations into a single document.
7. Extract information from the articles that meet quality criteria to inform the developing CPG. This step is discussed in the next section on Writing Recommendations.
8. Synthesize evidence across retrieved/appraised studies to come to consensus about recommendation for clinical use.
    - Use of a team discussion / consensus building is recommended
    - Make "strength of evidence" determination for recommendation for clinical use based on the criteria/format group has previously agreed upon.

Evidence Tables (Data Tables, Evidence Profiles, Summary of Finding Tables)

Evidence tables are developed to be able to answer the specific PICO questions posed as well as scope of the document being developed by the CPG workgroup. The information included in an evidence table is selected from the completed database following data entry. A CPG aimed at identifying which outcome measure or combination of measures provides the best information about change in functional locomotion for persons with stroke might design a data table that could be used for each outcome measure identified in the search and review process. A workgroup looking specifically at best-practice interventions for developing postural control necessary for independent sitting in persons with quadriplegic and high paraplegic spinal cord injury might choose to group interventions within a single evidence table. A group looking at physical therapy for a specific diagnosis or movement dysfunction from the viewpoint of an episode of care (from referral to discharge) might organize their data by the categories of the APTA's patient-client management model.

Evidence tables can be developed either in Excel worksheet format (which allows sorting) or as a Word document. Some of the data can be cut and pasted from the master data file once data extraction is complete. The first row in an evidence table contains the headings of interest to the group. In a study focusing on intervention effectiveness, for example, headings might include:

- Primary Author Name
- Year of publication
- Class/Level of evidence
- Study Population (n, gender, mean age, dx as appropriate)
- Intervention
- Outcome measures
- Strength of results.

Each study that has been retrieved, critically appraised and "data-mined" should have its own row in the table. The summary statement considers the "evidence" presented down the columns of the evidence table. (see Appendix 5 in the American Academy of Neurology 2011 *Clinical Practice Guideline Process Manual 2011)*

Evaluating and Grading the Quality of the Evidence

The GDG is charged to determine the strength of each PICO question recommendation (and their related action statements) based on the level of evidence available in the literature. The grade assigned to the recommendation informs the language of action statements related to the/each PICO question. Note that recommendations of B, C, D, or E (aimed at clinicians), may also be accompanied with an R grade (aimed at clinical researchers). The key to drafting a recommendation statement is that it is actionable rather than simply a statement of fact. The following is intended to provide some guidance on the action verb usage with respect to the grades of recommendations (See Table 1). One additional consideration for intervention-based CPGs involving level I and II evidence is to include criteria for the activity of the control group (for example, see Hornby et al.).

- **A-Strong** implies a **"must" or "should"** recommendation that represents best/optimal clinical practice (i.e., state of the art/top of the chart!). This recommendation is clearly aimed at translating top-notch evidence into clinical practice to improve patient care. The strength of the evidence might suggest that more research in this area may not add additional understanding to what is already known.

  The decision to use "must" vs "should" is based on the discussion and consensus within the GDG (see Lomatan 2010).

  From Lomatan et al: ""Must" clearly defines the highest level of obligation, but we anticipate only rare usage of the term… Use of "must" or "must not" may be limited to situations where there is a clear legal standard or where quality evidence indicates the potential for imminent patient harm if a course of action is not followed. "May" is an appropriate choice for the lowest level of obligation. We suggest avoiding any expression using "consider"…
  "Should" is the commonest deontic verb found…and is an appropriate choice to convey an intermediate level of obligation. Alternatively, the intermediate level could be stratified into "should" and "is appropriate." Overlapping ranges of obligation may be acceptable as long as guideline developers make explicit the connection between deontic terms chosen and their intended level of obligation. One strategy would be to link deontic terms to grades of recommendation strength. In this approach, the number of deontic terms used would depend on the particular grading system applied by the guideline developers." p. 513

- **B-Moderate** implies a **"should" or "is appropriate"** recommendation that supports but might not quite fully represent best/optimal practice (i.e., there is some room for improvement). This recommendation is aimed at changing clinical practice, but also identifies where "holes" in existing evidence may exist that need to be addressed by clinical researchers to move the field toward best/optimal clinical practice.

- **C-Weak** implies an **"is appropriate" or "may"** recommendation that represents better (but not quite best; there is definitely room for improvement) clinical practice (i.e., there is a clear need for further research). While it aims to improve practice, it also challenges clinical researchers to provide better evidence such that better evidence can be developed so that the grade may improve in future revisions of the guideline.

  The use of "may" when associated with grades C, D, and E and III, IV, and V levels of evidence suggests that the GDG be very careful to discuss benefits/harms and values in the action statement profile. Higher levels of evidence and stronger grades of

recommendations imply a clear benefit-harm impact while lower levels of evidence and lower grades imply that the balance between benefits and harms plays a greater role in decision making. Toward that end, the clinician must especially be able to weigh the benefits / harms and patient values in these circumstances.

- **D-Theoretical/Foundational** implies an **"is appropriate" or "may"** recommendation that represents good (not quite better) clinical practice (i.e., there is great need for further research). It is a strong signal to clinical researchers that more work needs to be done in evaluating how well theoretical models etc. translate into the clinical realm.
- **E – Expert Opinion** implies an **"is appropriate" or "may"** recommendation that represents good (not quite better) clinical practice. This might be based primarily on review papers, white papers, consensus documents developed by various methodology (e.g., Delphi, RAND) and opinion of the EBD workgroup. It creates an *imperative* for clinical researchers to fill the many "holes" that were identified during the EBD development.

  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."
- **R-Research** can be used individually when there is little or no evidence available to guide practice or in combination with B-E grades (when the existing evidence needs bolstering). It generates either a "must do" or should do" aimed at clinical researchers, rather than clinicians.

Table 1. Grades of Evidence

Grade	Recommendations	Quality of Evidence
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 I or II evidence with at least 1 level I 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 II 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
E	Expert Opinion (i.e., 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

Writing Recommendations

BRIDGE-WIZ (https://digital.ahrq.gov/ahrq-funded-projects/improving-guideline-development-and-implementation/citation/building-better) should be used for constructing the recommendations and accompanying text and should be a group activity (in-person meeting recommended) to reduce bias. If GDG decide not to use Bridge-WIZ, they should still follow the formatting listed below:

- Begin with a statement (Action Statement 1). Action statements will be located on a summary page at the beginning of the EBD and in the body of the text.
- Action statements are typically presented in rank order with the highest recommendations presented first, followed by descending levels of recommendations and ending with research recommendations.
- Follow action statement with elaboration – who should do what, when and where?
- Follow elaboration sentence with level of evidence and strength of recommendation.
- Expanded recommendations are located in the Body of the CPG

    Repeat the action statement verbatim from the summary page.

Elaborate using the following **action statement profile**:

- Date: current date
- Key Action Statement [or "Recommendation," if preferred]
- Evidence Quality:
- Action: [Includes data submitted from the initial recommendation construction.]
- Aggregate evidence quality: This is one to two sentences of specific evidence detail (odds ratios, CIs) or simply an indication of the overall level of evidence based on the data from the evidence tables.
- Benefits: Several sentences or bulleted remarks describing what is accomplished by following the action statement and/or what the action statement offers the patient, family, therapist etc.
- Risk, Harm, and Costs: List any risks, harms, or costs associated with following the action statement.
- Benefit-Harm Assessment: Each group should evaluate this relationship and make a statement (in many cases "Preponderance of benefit"). Use risk – benefit evidence where available.
- Value Judgments*: Identify here when the working group includes value statements (using Guide to PT Practice, Code of Ethics, other value-related documents) within a recommendation. Identify here when the working group adds, modifies, or otherwise changes a recommendation based on values when the evidence is unclear or is a close call. For example, this section may explain why a less reliable measure may be advocated over an overly expensive, time - consuming and costly measure with greater reliability.
- Intentional vagueness*: Elaborate on an action statement that is written with intentional vagueness. For example, examination of a body structure's impairment may be strongly recommended. However, no specific measurement tool is listed. This is an example of knowing unambiguously what to do but the intentional vagueness exists on how to do it.
- Role of patient/caregiver preferences*: Identify if, when, or where preferences and/or role of caregiver impacts decision-making.
- Exclusions*: Identify situations or circumstances where the action statement should not be applied. Clear exceptions will be important when guidelines are adapted to measure clinical performance.

- 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.

*Written after BRIDGE-Wiz generates an action statement.

- This **action statement profile** is then followed by a **Supporting Evidence and Clinical Interpretation** section. This includes 1-3 paragraphs summarizing the literature and providing necessary information on interpretation of results, elements of a recommended process, red flags, and research recommendations/needs. This section should be written by Working Group members with expertise in the topic area.
- Once recommendations, are written, the following steps should be followed
  - Present draft to rest of the GDG group for consensus
  - Send draft recommendations to EBD Committee
  - Send to External Advisory Group to review

Assessing the Implementability of a CPG

The implementability of a CPG is defined as "the ease and accuracy of translation of guideline advice into systems that influence care" (see Shifffman 2005) The GDG can facilitate implementability of the CPG through "pre-emptive identification of potential barriers of recommendations and where possible suggest potential solutions to address them by the guideline workgroup. (from Gagliardi et al. How can we improve guideline use? A conceptual framework of implementability. Implementation Science 2011, 6:26.)

To accomplish this, the GDG should:

1. Identify barriers of current practice at the provider, payer, and patient levels that may affect implementation of a guideline (education/training, required dosage, payment limitations, technological resource needs) and provide suggestions for implementation.
   a. Examples: structural (significant service redesign ie. Redesign business model), organization (lack of facility, equipment or staff or skill mix), individual (lack of knowledge, attitude and skill) (Who handbook on Guideline Development 2010)
2. Elucidate necessary coordination of care with other practitioners and alternative choices that could be made and would require referral to another practitioner (surgery, medication, etc)

One tool to assist in appraising the *implementability* of the CPG is the GLIA: the GuideLine Implementability Appraisal v. 2.0. This tool should be used prior to opening the CPG to expert panel review, public comment and publication. In this step, typically, an external panel comprised of people unfamiliar with the CPG's content and development, are invited to complete the GLIA. Each action statement is appraised across 8 dimensions of guideline implementability:

1. Executability (exactly what to do)
2. Decidability (precisely under what conditions (e.g., age, gender, clinical findings, laboratory results) to do something)
3. Validity (the degree to which the recommendation reflects the intent of the developer and the strength of evidence)

4. Flexibility (the degree to which a recommendation permits interpretation and allows for alternatives in its execution)
5. Effect on process of care (the degree to which the recommendation impacts upon the usual workflow in a typical care setting)
6. Measurability (the degree to which the guideline identifies markers or endpoints to track the effects of implementation of this recommendation)
7. Novelty/innovation (the degree to which the recommendation proposes behaviors considered unconventional by clinicians or patients)
8. Computability (the ease with which a recommendation can be operationalized in an electronic information system) is only applicable when an electronic implementation is planned

Based on the GLIA results, the GDG may modify its content in order improve the ease in which recommendations may be applied prior to publication or assist administrators in identifying potential problems in implanting a CPG within their organizations.

Writing CPG manuscript

- See Table 2 for CPG manuscript preparation checklist
- Ensure use of a consistent labeling system that follows both ICF and ICD taxonomies
- In each published CPG, two dates should be clear:
  - Date of pertinent systematic evidence review
  - Proposed date for review/revision of the document and/or when the document should be considered inactive if an update is not performed. For example,
    "This guideline will be considered for review in (insert based on present publication date plus 5 years), or sooner if new evidence becomes available. Any updates to the guideline in the interim period will be noted on the Academy of Neurologic Physical Therapy website: http://www.neuropt.org/ "
- Complete draft CPG and submit to EBD Committee and Director of Knowledge Synthesis for review and incorporate their feedback into a revised document. This draft must be sent in JNPT format. The back-and-forth review may take several iterations and could take from 1-3 months depending on the extent of revisions that need to be made.
- Send draft CPG to External Advisory Group. Revise as appropriate based on feedback.
- Initiate a call for public review by PTs, MDs, other health professionals, patient advocacy groups, patients/family as appropriate (esp. if CPG, or CGS, may not be necessary for other types of EBD).
- Jury and incorporate public comments into document as appropriate. Maintain a response document for each comment submitted.
- Submit document to journal (priority will be JNPT) for peer review.
- If ANPT-sponsored CPGs are accepted into JNPT, a mechanism is in place to allow open access. The GDG should inquire about this early when writing the CPG. If the CPG is submitted to another journal, the EBD committee and Director of Knowledge Synthesis should make the ANPT Board of Directors aware of this and request funding for open access.

Table 2. CPG manuscript preparation checklist

	DONE?
Title "A clinical practice guideline to…"	
Author list	
Collaborator list (article appraisal and data extraction team)	
Abstract	
Background	
Methods	

Results	
Discussion/Limitations	
Key Words	
Conflict of interest	
Table of Contents	
Introduction	
Summary of Action Statements	
Levels of Evidence and Grade of Recommendations (include tables for Level of evidence, Definitions for recommendations)	
Overall Objective of CPG	
Overview and Justification (include description of GDG group members)	
Overall Scope	
Statement of Intent/Target Audience	
Methods	
Determination of Scope (include initial literature search/stakeholder survey(s))	
Literature Search (include date of pertinent literature searches)	
Screening Articles	
Article Appraisal and Data Extraction (include training process)	
Prisma Flow Chart	
Formulating Recommendations	
Patient Views and Preferences	
External Review Process	
Knowledge Translation and Implementation Plan	
Process for Updating and Revising CPG Include proposed date for review/revision of the document and/or when the document should be considered inactive if an update is not performed	
Action Statements and Research Recommendations	
Action Statement	
For each Action Statement, include the following:	
Action Statement Profile	
Aggregate evidence quality	
Benefits	
Risks, harm, and costs	
Value judgement	
Intentional vagueness	
Role of patient preferences	
Exclusions	
Quality improvement	
Implementation and audit	
Supporting Evidence and Clinical Implementation	
Summary Table of Recommendations and Clinical Implementation Strategies	
Research recommendation	
Additional Studies* (i.e., met criteria, but not included in recommendations)	
Discussion	
Summary of CPG	
Clinical implications	
Implementation of recommendations (include facilitators and barriers)	
Limitations and future recommendations	
Conclusions	

Summary of Research Recommendations	
Acknowledgements	
References	
Appendices: Evidence Tables: One evidence table for each Action Statement	

*Optional section

Stakeholder review: Stakeholders for specific CPGs can be health care providers, patients or consumers, policy makers, payers, or others with a vested interest in the recommended practices who are recruited to read, edit, or comment on any aspect of the Clinical Practice Guideline. while under development or in its full draft stage. They have direct interactions with the GDG (modified from APTA Clinical Practice Guideline Manual).

Following CPG manuscript submission

- Create a succession plan process for revision – Follow the succession plan in Table 1.
- Submit symposium presentation to APTA combined sections meeting
- Work with assembled ANPT knowledge translation group formed for the CPG to support clinical implementation of the CPG recommendations (see below)

Implementation of CPG Recommendations

GDGs should reflect on the following areas when offering recommendations for supporting guideline uptake:

- Use of multiple formats and channels for **guideline dissemination** based on preferences of the target group of health care practitioners.

- Development of **educational resources** adapted in content, and vehicle to meet the needs of each target group of health care practitioners (and other stakeholders, as indicated).

- Identification of the **resource implications** of recommendations, ensuring their availability before starting.

- Use of **data collection** tools (for example, simple audit templates).

Examples of strategies that may support implementation of a CPG by the individual, clinical program, department, or health system include: (Kaplan SL, Coulter C, Fetters L. Physical therapy management of congenital muscular torticollis: an evidence-based clinical practice guideline. Pediatric Physical Therapy. 2013: 348-394.)

- Keep a copy of the CPG in a location that is easy to reference.
- Compare items in the recommended examination/intervention list to determine what should be added to an examination or plan of care to increase adherence.
- Adapt examination forms to include a place to document each of the recommended measures.
- Adapt format of daily notes to include a place to document recommended interventions in the plan of care.
- Seek training in the use of the recommended standardized measures and/or intervention approaches.
- Build relationships with other health providers or referral sources to encourage use of CPG.

- Measure service outcomes of care (eg, patient effect across the ICF domains, costs, and caregiver satisfaction).

These strategies should be included within the "implementation" section of the CPG as a way of guiding individuals, clinical programs, departments, or health systems into implementing CPG.

Assessing CPG Impact on Physical Therapy Practice

Ultimately, adoption and implementation of CPG recommendations occurs through the process of knowledge translation. In communication between the Director of Knowledge Synthesis and the Director of Practice, a Knowledge Translation Task Force for the developing CPG should be formed, and this task force will be responsible for generating tools and products to facilitate knowledge translation. As such, the EBD committee and the GDG are not directly responsible for the development of knowledge translation tools and products. While the EBD committee and GDG should be made aware of the work of the specific task force, it is beyond the scope of the EBD committee or the GDG to facilitate and monitor the success of the knowledge translation process. However, to ensure that the task force is generating products and tools consistent with the published recommendations, the EBD committee and GDG should be made aware of the content of these developed tools and products, and information gained from the task force regarding the impact of the CPG or KT tools and products on practice.

CPG Revisions

The revision process is integral to maintain clear, updated recommendations or guidelines based on the most current evidence. The Director of Knowledge Synthesis and the EBD Committee maintains a policy and procedure for monitoring, reviewing, and updating CPGs. Each CPG should be reviewed/revised at least every five years.

The revision process should begin 3 years after publication to assure completion by the five-year deadline. The following recommendations will support a seamless transition of workflow from the original GDG to the revision GDG:

- Updating the CPG should occur within 5 years of the initial CPG publication. Considerations for revising the document during the 1st 3 years post-publication include:
    - New evidence shows that a recommended intervention causes previously unknown substantial harm
    - A new examination or intervention is found to be significantly superior to a previously recommended intervention
    - A recommendation can be applied to new populations
- Those potentially involved in the CPG revision are responsible for monitoring the literature for new and relevant publications (up to 3 years post-publication of the original CPG). This includes completion of an updated literature search to evaluate available pertinent evidence since the initial publication. The evaluation of the literature should be identical to the "First Literature Search" process discussed above, and the process for CPG revision should be similar to the initial CPG development as described in this manual. Additional information regarding the scope of the CPG revision can also be informed from the work of the knowledge translation task force for the initial CPG.
- To support continuity, the initial GDG should keep clear documentation and notes. For example, clear records may include search terms and strategies, organized evidence tables, etc. These documents should be stored on an ANPT site like Box.

- The Director of Knowledge Synthesis, EBD Committee, and Leader of the initial GDG identify any/all persons from the original/previous workgroup that will work on the revision workgroup. New members may be invited to join the group as part of a succession plan for the next guideline revision. The ANPT Board of Directors appoints the GDG.
- The revision workgroup should work for a 5 year term or may define a more appropriate time frame given the extent of new evidence found.

The EBD Committee will continue to review and edit all submitted CPGs irrespective of their status (i.e, original; revision).

Table 3. CPG Development Timeline[a]										
Objectives (Initial CPG)	**Year 1[a]**		**Year 2**		**Year 3**		**Year 4**		**Year 5**	
Preparation (possible before grant submission)										
Define administrative roles	X									
Meet with EBD committee liaison* and/or EBD committee member for overview of CPG development or revision process and EBD committee role	X									
Attend APTA CPG meeting at CSM in Feb[b]			X							
CPG Workshop in July– all members attend[b]		X		X						
Confirm overall PICO question	X									
Confirm scope	X									
Conduct clinician survey	X									
Establish external advisory group	X									
Meet with external advisory group		X								
Write and submit grant to EBD Committee for review and edits one month prior to deadline		X								
Submit CPG grant to APTA in Oct		X								
Establish software resources - Covidence - Box - Reference manager (e.g., Zotero, Endnote)		X								
Conduct initial literature search for SRs and CPGs to determine need for a CPG (see Figure ?)										
Delineate inclusion and exclusion criteria	X									
Identify and meet with librarian to discuss search strategy and databases for SRs and CPGs	X									
Reach consensus on moving forward with CPG	X									
Conduct second literature search and review	X									
Delineate inclusion and exclusion criteria based on overall and/or sub-PICO questions	X									
Meet with librarian to discuss search strategy	X									
Conduct title and abstract review and reach consensus on included articles		X								
Identify process for uploading full text article (e.g., work study student)		X								
Conduct full text review and reach consensus on included articles		X	X							
Conduct article appraisal and data extraction										
Identify critical appraisal tool		X								
Create processes and forms for critical article appraisal and data extraction			X							
Solicit, screen, and confirm volunteers for article appraisal/data extraction*			X							
Meet with external advisory group			X							
Train article appraisal and data extraction team			X							
Conduct article appraisal and data extraction				X	X	X				
Synthesis										
Develop data/evidence tables							X			
Evaluating and grading quality of evidence							X			
Review data to determine number recommendations							X			
Draft and grade initial recommendations							X			

Reach consensus on recommendations							X			
Submit recommendations to EBD committee and external advisory group for review							X			
Write CPG manuscript										
Prepare draft CPG manuscript (see checklist)								X		
Director of knowledge synthesis engages director of practice for KT group								X		
Send to EBD committee for review								X		
Send to stakeholders for review								X		
Send for public comment								X		
Disseminate final CPG										
Present at APTA CSM/ ANPT annual conference									X	
Submit CPG manuscript to JNPT									X	
Member(s) of GDG consult with KT group									X	X
Succession plan										
Invite EBD committee (ebdcommittee@gmail.com) to all Covidence reviews										X
Identify 1-2 GDG members who will lead the CPG revision										X
Send contact information to EBD Committee Liaison: GDG members, article appraiser/data extraction team members, librarian, external advisory group, stakeholders										X
Send list of literature search terms for overall and/or specific PICO questions to EBD Liaison										X
Send EBD Liaison all CPG documents - Article extractor/appraiser training - Articles if not using Covidence - Appraiser and data extraction forms - APTA final grant proposal - Published CPG										X

*****EBD Committee Liaison will communicate with GDG at least monthly throughout CPG development

[a]CPG revisions will be conducted over a condensed timeline of approximately 3 years

[b]CPG workshops are optional for CPG revision groups

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Appendix 1: Procedures for EDGE Documents Development

Appendix 2: Procedures for Systematic Reviews