

Neurology Section

Procedures for Evidence-Based Document Development

I. Definitions of Evidence Based Documents

Clinical Practice Guideline (CPG) Clinical practice guidelines are graded recommendations on best practice for a specific condition 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.

Clinical Practice Appraisals (CPA)/ Clinical Guidance Statements (CGS) Clinical practice appraisals or guidance statements summarize best practice for an area of clinical practice based upon the integration of available literature from CPGs and expert opinion. These documents are defined by a strong methodology including an analysis of the available research and structured process for development. Variation may exist but 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. Under no circumstance does an SR provide a recommendation for practice. Clinical practice guidelines are required to bridge the gap between evidence and recommendation.

Clinical summary Clinical practice summaries are referenced based and peer reviewed summaries of the evidence. These documents describe what is known so far and focus on clinical application following a standard format which includes overview, classification, screening, examination, diagnosis, prognosis, intervention, medical management, and case examples. These are published on PTNow.

Procedural summary A procedural summary is a variation of a clinical summary for non-clinical population content such as safe patient handling, electrical stimulation, etc. APTA has not formalized a definition for procedural summary beyond this. The Task force interprets this EBD as a step-by-step description.

Position statement/White paper Position statements are intended to set forth a position based on clinical content related to the physical therapists scope of practice. These documents are referenced and peer reviewed. They are intended for a consumer audience.

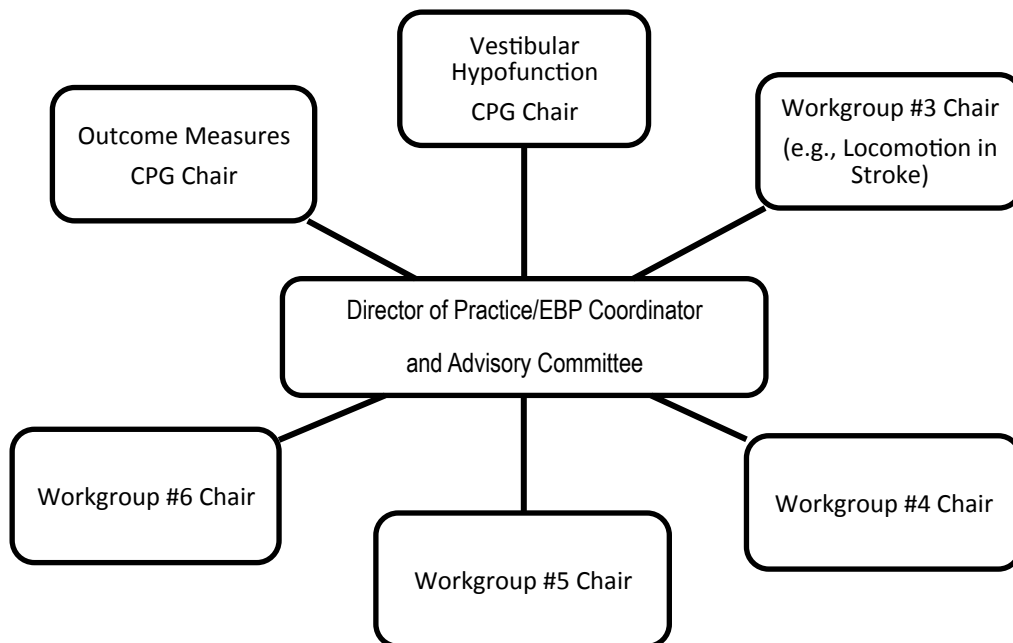
Pocket guide Pocket guides are short summary statements in a portable tool. A pocket guide could be derived from any of the above documents. When pocket guides are developed independent of another document, they are intended to be based on best available evidence and expert consensus and are referenced and peer reviewed.

Consumer documents The APTA is presently talking about this type of document as a companion to CPGs or CGSs.

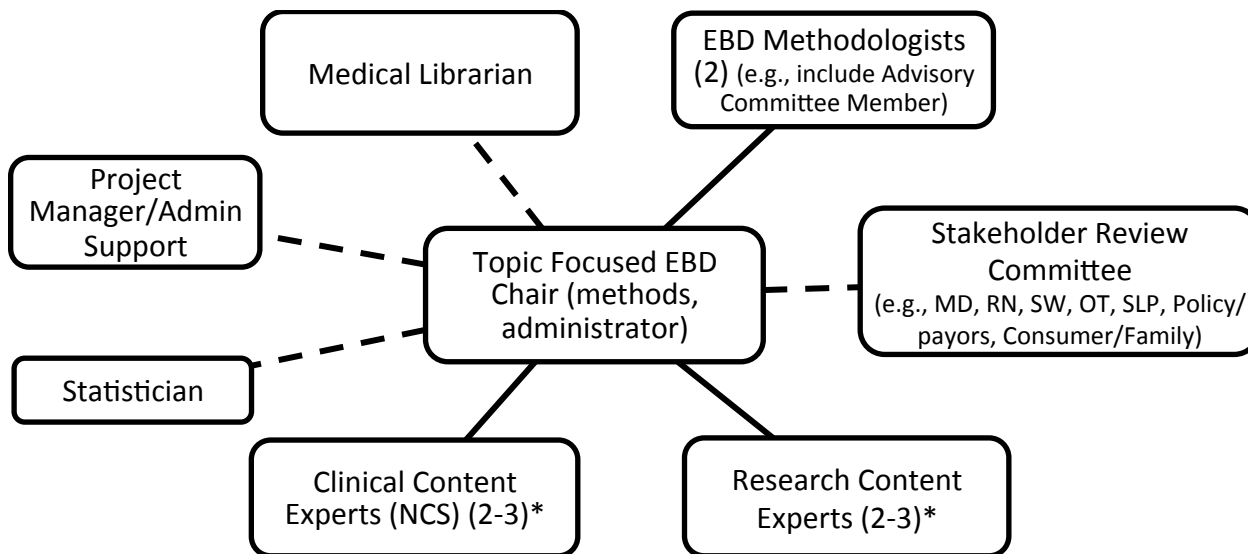
II. Structure and People Needed to Develop Evidence Based Documents (EBDs)

The Neurology Section completes the development of EBDs with the following structure:

1. The Director of Practice along with the 3-5 member Advisory Committee will oversee the process. The Figure below illustrates the relationship of the Director of Practice and Advisory Committee to the EBD work groups. The Section leadership along with the Director of Practice and Advisory Committee will determine how many work groups will be in process at any one time.



2. The figure below illustrates the composition of each EBD Work Group. Those roles with solid lines are required members of the group and those connected with dashed-lines serve consultative roles. The scope of the project and EBD type (CPG, CGS, SR) will determine how many clinical content and research content members will be needed. EBD Work Groups (topic-specific and multiple groups can be working simultaneously)



* scope of project and EBD type (CPG, CGS, SR) determines how many members of a workgroup will be needed

III. Roles and Responsibilities

Neurology Section Board of Directors

Determines the number of Section-sponsored clinical practice guidelines (CPGs) and other evidence-based documents (EBDs) to be developed at any one time based on the available financial support for the process and available expertise.

- Section 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 working group.
- Need for an EBD (topic identification) should be a bi-directional process from the bottom up (member feedback) and top down (deliberation at the Advisory Committee level).
- Selects members of advisory committee.

Director of Practice/Evidence-based Document (EBP) Coordinator

- Possesses background (or has access to training) in evidence based practice and EBD development methodology; demonstrated skill in scientific writing and critical appraisal process; knowledge in the continuum of care and neurological physical therapy.

- Oversees and manages Working Groups (Working Groups are headed by a topic-focused EBP Chair) and Advisory Committee activities.
- Provides expertise and resources on methodology to Working Group Chair and members.
- Along with the Advisory Committee, develops a plan for the update of all published EBDs as needed (but at least reviewed every 5 years).
- Along with Advisory committee, maintains and manages all matters of conflict of interest.

Advisory Committee

- Consists of 3-5 members. Director of Practice/EBP Coordinator and experts in knowledge translation and EBD document development methodology and scientific writing/editing.
- With the assistance of Board of Directors and Neurology Section Membership, identifies, prioritizes, and refines topics to be developed.
- Assists in periodically (as warranted by changes in neurological physical therapy practice and/or policies and as standards for the development of EBDs evolve) conducting needs assessment for topics identification.
- Organizes and places call to Section members, NCS, and/or SIG members for volunteers. Works with SIG to identify content experts as potential members of EBD workgroups. Screens CV/resumes to determine qualifications as clinical or research expert.
- Recommends to the Director of Practice and the Section BoD the appointment of work group leaders, and working group members. Places a call to Section members, NCS, and/or SIG members as appropriate; and screen CV/resume to determine qualification as clinical or research experts.
- Assists work groups with identifying and delineating the content areas of their evidence based documents.
- Assists work groups with securing additional external reviewers.
- Assists Working Group on scope of EBDs.
- Reviews, edits and approves all EBDs (both original and subsequent revisions) submitted by the Working Groups at the request of the Director of Practice/EBP Coordinator. With respect to editing: Edits the CPG submission from the work group so that guidelines have a consistent labeling system that follows both ICF and ICD taxonomies and are formatted for publication in either JNPT or PTJ.
- With director of Practice, maintains and manages all matters of conflict of interest.
- Maintains a list of potential Reviewers with expertise in various content areas.
- Submits any published CPG to National Guidelines Clearinghouse.

Topic Focused EBD Chair and Work Group:

Chair is appointed by Advisory Committee.

- Must declare conflict of interest before approval of appointment.
- Primary role is manager of group process, as well as “tie breaker” during review of abstracts, research papers or other evidence based documents. Guide development process; Facilitate communication; Manage tasks; Delegate and direct team on tasks; Conduct first editorial review

prior to External Review Group; Along with working group members, identify members of external review group and develops timeline.

- Skills needed include efficient, motivated, organized, demonstrated leadership ability, scientific writing, fluent in use of Internet, e-mail, and storage services (eg, Skydrive, Google Docs). Prior experience with EBDs or CPG development would be beneficial.
- Familiar with literature and management of the clinical condition or procedure.
- Decides, along with work group, on the nature of the EBD (eg, CPG, CGS, SR, Clinical Summary).
- Communicate regularly with Advisory Committee

Work Group (see chart: Recommend approximately 6 full-time members)

- Potential members can be identified by the Chair, Advisory Committee, and/or Section leadership.
- Considerations as a clinical expert includes experience in a setting, years of practice, degree and certification, CI experience, publication of case reports and similar documents on the topics, presentation and teaching experience. Recommend 2 members have clinical expertise in the work group.
- Considerations as a research expert includes experience in research design and methodology, facility in critical appraisal, scientific writing in the content area. Recommend 2 members have research expertise in the work group.
- A search specialist (medical librarian) and statistician may be required and it is recommended that these are ad hoc and contractual positions (budgeted through the APTA EBD proposal process or funded through Neurology Section).
- Understanding of EBP and EBD development is critical for success.
- Responsibilities of the Work Group include: disclose conflict of interest, participate in all conference calls, attend 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, maintaining confidentiality.

The next page includes the Conflict of Interest form that each EBD work group member should complete and submit to the Advisory Committee for their review and approval.

CONFLICT OF INTEREST DISCLOSURE FORM

Name: _____ (Every panelist must complete a separate form)

Guideline name and chapter (if known): _____

Date: _____

The Neurology Section (NS) of the American Physical Therapy Association, and the Evidence-based Documents (EBD) Advisory Committee (AC) of the Practice Committee (PC) strive to produce high-quality, unbiased EBDs. As such the policy requires full disclosure by all guideline authors, editors, and reviewers of all potential conflicts of interest (COI) related to NS activities, real or perceived, including those that are unrelated to the guideline topic. The AC and Director of Practice reviews the disclosures and either recommends approval, approval with management, or disapproval to the NS Board of Directors. It is the AC responsibility to issue the final vote on each candidate. 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 EBD topic. Nominees who serve as consultants or participate on advisory boards should provide as much information as possible in order for the AC and Director of Practice to evaluate the potential COI accordingly. It is not the goal of the AC to preclude all individuals with COIs. Rather, the goal is to ensure full transparency while protecting the integrity of the EBDs, the EBD panelists, and the NS. It is not the role of the AC to serve as a policing body for its EBD panels. However, if the committee or its members discover through other means that non-disclosed COIs exist, then the nomination in question can be revoked.

Annual updates must be submitted to the AC until the date of the final proof of the manuscript. COI forms are stored and archived with the NS Board.

DEFINITION: For purposes of the NS 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 contributor's circumstances. The contributor's behavior, subjective beliefs, and outcomes are irrelevant. In other words, the contributor must disclose a COI, even if the circumstances do not actually influence the contributor's actions or manuscript, and even if the contributor believes that the circumstances cannot or will not affect the contributor's actions. In parentheses below are some, but not all, examples.

Within the last 3 years and presently (for you and your parents, siblings, spouses, life companion or children):

COI Topic	NO	Yes (if yes, explain and where applicable provide \$ amount)
Do you have, or are named in, any grants (clinical, educational, research) on EBD topic from any funding body (non-profit, private, corporate)?		
Receive royalties or in-kind benefits (travel; accommodations; per diem; meals) from a commercial or professional entity?		
Own shares (stock option holder) of a device/equipment or company with ties to EBD topic?		
Act as an employee, officer, or director of a device/ equipment or pharmaceutical company? <i>Specify interaction with FDA, financial analysts</i>		

Serve as a consultant to a device or pharmaceutical company or perform advocacy work related to the EBD topic?		
Act as an employee, officer or director of an institution or employer that has a financial relationship with a commercial entity having an interest related to the EBD topic of interest?		
Provide money for patient enrollment or other aspect of research related to the EBD topic?		
Hold patent rights or pending patent application on EBD topic of interest?		
Participate in speaking activities, advisory committee, or other activities related to industry sources, with or without receiving honoraria or in kind benefits (sponsored by a nonprofit university, annual meeting, inservice, symposia; sponsored by a for- profit health company)? <i>Include any participation in CE or related speaking on this EBD topic. If you sit on advisory committees on this EBD topic, include it here.</i>		
Make/Made public statements on this EBD?		
Provide legal assistance (or expert testimony) on litigation related to EBD topic?		
Clinical practice related COI: Do you perform clinical procedures in your clinical practice related to EBD topic of interest? <i>Estimate the percentage of time you treat patients related to EBD topic</i>		
Anything else that could be perceived by others to affect your objectivity? <i>Include any published papers (research, educational, perspective, reviews, etc)</i>		

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. 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:

IV. TOPIC IDENTIFICATION

- Board, Advisory Committee, and/or membership can propose a topic for the development of an EBD.
- Board and Advisory Committee prioritize topics to be transitioned into an EBD.
- 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 (ref: Peds Manual- **Pediatr Phys Ther 2013;25:257–270**).
- Reasons for setting topic priorities (based on **Oxman, Schünemann, and Fretheim**. Improving the use of research evidence in guideline development: 2. Priority setting Health Res Policy Syst. 2006; 4: 14)
 - 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 (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).

V. SCOPE

The scope of the EBD is dependent upon two things: The breadth and depth of the EBD and the type of EBD. Depending on the degree of development of the topic and question(s) these steps are complementary.

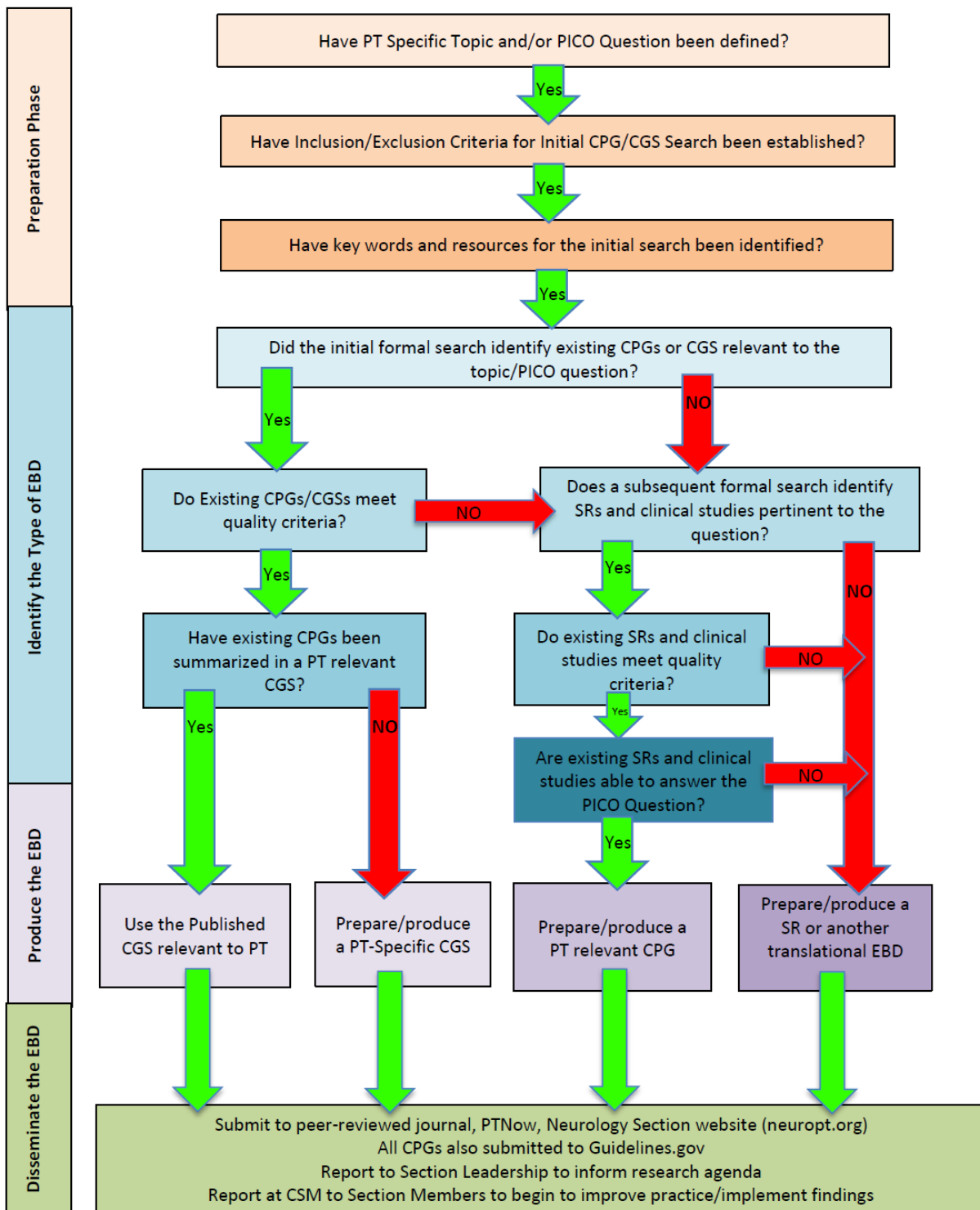
According to Rosenfeld et al.,

“A well-crafted guideline has a clearly defined scope. Defining scope will occupy most of the first conference call and may require a second for completion. Inexperienced guideline 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. Clinicians may have trouble

embracing the concept of a focused guideline with restricted scope and a limited number of recommendations. Instead, the desire will be to include a broad range of topics, similar to what appears in a traditional review article or book chapter. Topics deemed important by the group, but not accommodated in the guideline action statements, may still be discussed in the supporting text or in an appendix, provided it is clearly identified as based on consensus or expert opinion.” (p. S16)

The following figure (Figure 3) provides the process for determining type of EBD.

Figure 3: Decision tree for determination of what type of evidence-based document should be undertaken.



Breadth and Depth of EBD

To determine the scope of the EBD requires that questions “What exactly is the EBD intending to accomplish? 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? Etc.
 - b. The target patient or clinical presentation can be defined using demographics, signs/symptoms, history, diagnostic tests. The Working 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. 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) should also be addressed when it is pertinent to the topic and assists in defining scope.
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. Outcomes categories to consider 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).

Determining the Type of EBD

There are different types of EBDs. The following are EBDs that have been defined by the APTA:

Clinical Practice Guideline (CPG) Clinical practice guidelines are graded recommendations on best practice for a specific condition 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 made up of both evidence-based and expert-based information and as such are intended to facilitate interpretation of research evidence to guide clinical practice decision-making (Fetters & Tilson). Although variation can exist, all must meet standard criteria.

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- Development of a CGS may be prudent when multiple CPGs exist on a particular topic. For the CGS, its scope is to **appraise the existing CPGs and synthesize the CPGs' recommendations into a coherent summary**. The appraisal and synthesis may address much of the topic and scope without the need for a new CPG and also provide an opportunity for a gap analysis. Thus, where applicable, PT-specific action statements should be developed based on a synthesis of levels of evidence and grades of recommendations from the existing CPGs. However, the gap analysis may also provide directives for a refinement of the clinical question and **scope for a future PT-specific CPG**.

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. Under no circumstance does an SR provide a recommendation for practice. Clinical practice guidelines are required to bridge the gap between evidence and recommendation.

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Consumer documents The APTA is presently talking about this type of document as a companion to CPGs or CGSs.

Before the scope of the EBD can be formally defined, the choice of EBD must be established. The choice of EBD is determined by a **first literature search** to determine if CPGs and/or SRs already exist on the topic. A search specialist (medical librarian) may be needed to assist with the search process. At a minimum, National Guidelines Clearinghouse, Guidelines International Network, and standard electronic databases (using “guideline”) should be searched.

- CPG repositories include:
 - <http://guidelines.gov/> - National Guidelines Clearinghouse
 - <http://www.sign.ac.uk/> - Scottish Colleague
 - <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
 - Any discipline-specific guidelines (look to professional organization websites)
- Systematic Reviews or other synthesized evidence?
 - <http://www.thecochranelibrary.com/view/0/index.html>
 - <http://srdp.ahrq.gov/> - AHRQ Systematic Review Data Repository (New)
 - <http://www.pedro.org.au/> - Physiotherapy Evidence Database (PEDro)
 - Primary Reference Databases - (PubMed, CINAHL, etc)

Once the initial search is completed and the type of EBD has been established, the Working Group, in consultation with the Advisory Committee, defines and agrees upon a specific scope for the EBD.

Scope References/ Resources

Fetters L & Tilson J. Evidence-based Physical Therapy. FA Davis. 2012.

Kaplan et al. Clinical Practice Guideline: Physical Therapy Management of Congenital Muscular Torticollis: An Evidence-Based Clinical Practice Guideline from the American Physical Therapy Association Section on Pediatrics. Under review

Rosenfeld RM, Shiffman RN, and Robertson P. Clinical practice guideline development manual, third edition: A quality-driven approach for translating evidence into action. Otolaryngology Head Neck Surgery 2013 148: S1.

Woolf S, Schünemann HJ, Eccles MP, Grimshaw JM and Shekelle P, Developing clinical practice guidelines: types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations. Implementation Science 2012, 7:61

VI. Statement of Intent

All CPGs should have a statement of intent following the scope. Both the Orthopedic and Pediatric Sections have used similar phraseology in their CPGs. As a representative example, the following is taken directly from the forthcoming Pediatric CPG on Congenital Muscular Torticollis. APTA has general language for statement of intent within CPGs as well.

“This guideline is intended for clinicians, family members, educators, researchers, policy makers and payers. It is not intended to be construed or to serve as a legal standard of care. As rehabilitation knowledge expands, clinical guidelines are promoted as syntheses of current research and provisional proposals of recommended actions under specific conditions. Standards of care are determined on the basis of all clinical data available for an individual patient/client and are subject to change as knowledge and technology advance, patterns of care evolve, and patient/family values are integrated. This CPG is a summary of practice recommendations that are supported with current published literature that has been reviewed by expert practitioners and other stakeholders. These parameters of practice should be considered guidelines only, not mandates. Adherence to them will not ensure a successful outcome in every patient, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate decision regarding a particular clinical procedure or treatment plan must be made using the clinical data presented by the patient/client/family, the diagnostic and treatment options available, the patient’s values, expectations and preferences, and the clinician’s scope of practice and expertise. The GDG suggests that significant departures from accepted guidelines should be documented in patient records at the time the relevant clinical decisions are made.”

VII. CRITICAL APPRAISAL OF THE EVIDENCE and LEVELS OF EVIDENCE

Critical appraisal requires the **SECOND LITERATURE SEARCH** and is used for the development of CPGs, CGSs, and SRs. Once the scope(s) using PICO format has been established, the Work group performs a second literature search. The obtained documents will then be appraised for their quality.

Assumptions:

1. the "PICO" question that the group wants to address has been clearly defined
2. key conceptual definitions relevant to the proposed EBD have been clearly defined

Steps:

1. Preparation: Clear delineation of inclusion and exclusion criteria for potential studies

Examples:

- age range, gender, and ethnicity of subjects
- sample size
- medical conditions allowed
- level of function (ICF WHO) or acuity level of subjects
- 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 (cross sectional, longitudinal, descriptive, quasi-experimental, experimental)
- type of statistical analysis (relationship, difference, descriptive, predictive etc.)
- language (English only, unless medical translators are available to the team)
- date range for studies

2. Search: Decisions about which data-bases to use and development of key search terms.

Guidance of a Medical Librarian is very helpful at this step.

- Mesh headings for Pubmed (most up to date with epubs) or Medline
- CINAHL tends to capture more of rehab literature
- PEDro for PT outcome studies/RCTs
- Boolean operators: use of quotations, parentheses, roots*, AND, OR, NOT
(note: goal at this point is to be as inclusive/broad as possible)

3. Search: Conduct the search

- Set up excel database to keep track of each abstract that might potentially be included (headings: primary author, co-authors, title, journal, year, citation, others as determined by intent of search)
- Work Group Chair is the keeper of this file. Note number of duplicates if multiple searches are undertaken

- Record every potential abstract in the database (decisions about inclusion are the next step)
- Retrieve and save abstracts into limited access e-storage (GeriEDGE cut and pasted abstracts, saving files by primary author last name, year, and journal abbreviation; and stored them in a dropbox folder accessible only to members of the team)

4. Appraise Abstracts: Evaluate the abstracts based on inclusion exclusion criteria

- Define judgment categories: ex: retrieve, exclude, “data mine” (if article references might yield additional abstracts)
- Establish reliability of the review process by having all review team members review the same small set of abstracts independently, then discuss the process for clarification and consensus
- Assign a set number of abstracts (alphabetically) to each team of (2) reviewers. Each reviewer evaluates abstracts independently.
 - 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
- Retrieve articles that met inclusion criteria. Save pdfs in a “Articles to be Reviewed” file (save them by primary author, year, journal abbreviation)
- Retrieve articles that fell into “data mine” category; review references titles, and retrieve abstracts that appear to be informative; put these through the abstract review process

Note: When the second literature search results in a large number of documents, the Work Group may want to include additional volunteers for the critical appraisal process. The Work Group should provide an orientation and training session(s) regarding background to the project and the specific critical appraisal process. Reliability should be established for each critical appraisal tool used within the development of the EBD. The Work Group will need to establish an acceptable level of reliability. We recommend a 90% agreement among appraisers. Consensus can be established through discussion. The Work group will be responsible for resolving any scoring discrepancies.

5. Evaluate the articles based on the appropriate critical appraisal tool

- Establish reliability by having entire review team independently review and rate several articles. Use discussion of process and come to consensus on outcome. This should be accomplished in one conference call.
- Assign a set of retrieved articles to a team of 2 reviewers. Each reviewer evaluates articles independently then must come to consensus with team.
- Critical appraisal when the evidence-based document of choice is either a systematic review or a clinical practice guideline.

- **Appraising individual studies:** There are numerous evidence appraisal tools. Center for Evidence based medicine (CEBM) and Scottish Intercollegiate Guidelines Network (SIGN) provide tools for SRs, RCTs, Cohort, Case control, and Diagnostic studies.

From CEBM

- <http://ktclearinghouse.ca/cebm/teaching/worksheets>

From SIGN

- <http://www.sign.ac.uk/methodology/checklists.html>

Case Series Studies: The Institute of Health Economics 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.

<http://www.ihe.ca/publications/library/2012-publications/development-of-a-quality-appraisal-tool-for-case-series-studies-using-a-modified-delphi-technique/> (accessed 1/2014)

<http://colloquium.cochrane.org/fr/abstracts/development-quality-appraisal-tool-case-series-studies> (accessed 1/2014)

Intervention Studies: The APTA has developed a critical appraisal tool for experimental intervention studies and APTA is encouraging its use in all evidence-based document initiatives.

Measurement Studies: Consensus-based standards for the selection of health measurement instruments (COSMIN) provides a tool specific to health measurements. However, this is a very dense tool and may pose challenges for training volunteer reviewers.

Fetters and Tilson (2012) within their text, discuss and provide appraisal tools across the different types of studies: (<http://www.fadavis.com/product/physical-therapy-practical-guide-evidence-based-practice-fetters-tilson>)

TOOL RECOMMENDATION: The Task Force recommends that the **APTA Critical Appraisal Tool for Experimental Intervention Studies** be used for all randomized controlled trials. Work groups should assist APTA with validation of the APTA's Critical Appraisal Tool. As Sections and work groups adopt this tool, there is also the potential for the development of a central repository of critically – appraised intervention studies. At this time, **appraisal tools developed by Fetters & Tilson (2012)** should be used for all other studies. The Task Force evaluated the Institute for Health Economics' critical appraisal tool for case series studies and felt 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.

- **Appraising systematic reviews:** Appraising systematic reviews will be required when the evidence-based document of choice is a clinical practice guideline.

TOOL RECOMMENDATION: The Task Force recommends using **AMSTAR** for the critical appraisal of systematic reviews.

<http://www.nccmt.ca/registry/view/eng/97.html>

- Critical appraisal when the evidence-based document of choice is a clinical guidance statement.
 - **Appraising clinical practice guidelines:** The best tool for appraising CPGs at this time is the AGREEII document. All CPGs should be appraised using **AGREEII**. At least 3 (preferably all) members of the Work group should review each CPG using AGREEII. Training for AGREEII is available here:

<http://www.agreetrust.org/resource-centre/agree-ii/>

<http://www.agreetrust.org/resource-centre/agree-ii-training-tools/>

If time and resources are limited, then a new, short version of the AGREEII (AGREEII – GRS) document may be considered. Each Work Group in communication with the Advisory Committee should decide which version of the AGREEII document should be used.

<http://www.agreetrust.org/resource-centre/agree-ii-grs-instrument/>

- Inter-rater reliability should be established on a sample CPG. Consensus should be established by phone call on all CPG scores.
- Score criteria for each paper. This will be used to determine level of evidence (e.g., Level I versus Level II)

6. Scores from the critical appraisal are linked to Levels of Evidence.

- The Task Force recommends the use of the CEBM nomenclature for Levels of Evidence. The CEBM nomenclature has been adapted by the Orthopedics and Pediatrics Sections and is presently being used by the Vestibular CPG Group. The following indicates how the Pediatric CPG on Congenital Muscular Torticollis integrated critical appraisal scores into Levels of

Evidence using a > or < 50% score. Orthopedics Section did not provide critical appraisal score information.

- I Evidence obtained from high-quality diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, meta analyses or systematic reviews (critical appraisal score > 50% of criteria).
 - II Evidence obtained from lesser-quality diagnostic studies, prognostic or prospective studies, cohort studies or randomized controlled trials, meta analyses or systematic reviews (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, <80% follow-up) (critical appraisal score <50% of criteria).
 - III Case-controlled studies or retrospective studies
 - IV Case studies and case series
 - V Expert opinion
- ***THRESHOLD RECOMMENDATION:*** The Task Force recommends adopting the 50% threshold for appraisals of *individual studies only*.
 - Background on making this recommendation:
 - Presently, there are numerous and variable approaches to critical appraisal which is also dependent upon the type of individual study. There is no established standard for or consensus on choosing 50, 60, or 70% cutoff for delineation of higher versus lower level of evidence. However, one group, the Institute of Health Economics 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 case series studies.
 - The Task Force debated this issue quite extensively and came to the conclusion that 50% was a prudent threshold at this time. With so much variability, our intention is to error on the side of inclusion with the 50% recommendation. However, as the science of critical appraisal evolves, the Advisory Committee should periodically re-visit this issue.
 - The Task Force does not recommend using a threshold for appraisals of CPGs (when the EBD of choice is a CGS)
 - AGREEII provides for a scaled domain score. However, the AGREEII Consortium states “Although the domain scores are useful for comparing guidelines and will inform whether a guideline should be recommended for use, the Consortium has not set minimum domain scores or patterns of scores across domains to differentiate between high quality and poor quality guidelines. These decisions should be made by the user and guided by the context in which AGREE II is being used.” (p. 13 of Brouwers et al). As such, the Task Force does not recommend a formal threshold be established when evaluating CPGs for their inclusion in a CGS. More appropriately based on the purpose of the CPG, a Work Group should decide to include only high quality CPGs and this should be accomplished by consensus discussion following appraisal using AGREEII.

7. Extract information from the articles that meet quality criteria to inform the developing evidence-based document. Enter into an Evidence Table. 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.

References/ Resources

Brouwers M, Kho ME, Browman GP, Cluzeau F, feder G, Fervers B, Hanna S, Makarski J on behalf of the AGREE Next Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J.* Dec 2010, 182:E839-842; doi: 10.1503/cmaj.090449

Fetters L & Tilson J. *Evidence Based Physical Therapy.* FA Davis Company. 2012.

Kaplan SL, Coulter C, Fetters L. *Clinical Practice Guideline: physical therapy management of congenital muscular torticollis: an evidence-based clinical practice guideline from the American Physical Therapy Association Section on Pediatrics.* Under Review.

Moga C, Guo B, Schopflocher D, Harstall C. *Development of a Quality Appraisal Tool for Case Series Studies Using a Modified Delphi Technique.* Edmonton AB: Institute of Health Economics. 2012.

Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, Porter AC, Tugwell P, Moher D and Bouter LM. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Medical Research Methodology* 2007, 7:10

Shea BJ, Hamel C, Wells GA, Bouter LM, Kristjansson E, Grimshaw J, Henry DA, Boers M. AMSTAR is a reliable and valid measurement tool to assess the methodological quality of systematic reviews. *J Clin Epidemiol.* 2009 Oct;62(10):1013-20.

Woolf S, Schünemann HJ, Eccles MP, Grimshaw JM and Shekelle P, Developing clinical practice guidelines: types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations. *Implementation Science* 2012, 7:61.

VIII. STRATEGIES FOR DATA STORAGE, DATA EXTRACTION AND SYNTHESIS OF FINDINGS

For any type of evidence-based document being developed by a workgroup, the next step (after articles have been retrieved and critical appraisal is completed) is to extract relevant information from each article, and begin the process of synthesis.

DATA STORAGE

A mechanism for literature and document storage should be established. Work group members will be performing searches, appraisals, and soon begin drafting the EBD and its associated sections. A clear, easily accessible document storage space will assure that each workgroup member has the tools necessary for these tasks. Recommendations/considerations include:

- Establish how abstracts, articles, and other documents will be organized. Some programs to consider are:
 - Googledocs
 - Mendeley
 - Endnote
 - Zotero
 - DropBox
 - Hardcopy

- Consider different capabilities of the program/software:
 - Accessible and convenient to the users
 - Organization capabilities, including adding information over time
 - Ease of information retrieval
 - Efficient means of preventing duplicate entries; one main repository
 - Flexibility of the system, ie. ability to attach a .pdf document
 - Cost may be a consideration

- Some feedback from previous users include:
 - Googledocs:
 - Different versions of a manuscript were saved, and it was challenging to keep track of the most recent; web-based
 - Mendeley: Mendeley Reference Manager for articles
 - Free version has low storage capacity; \$5-10/mo extra for >3 people and for more than ~150 articles
 - Has potential for multiple projects with various collections of articles for each
 - Endnote:
 - Cost to a student = \$180
 - Has Internet capability- can sync to desktop or work computer
 - Software expires after some time due to new versions
 - Some versions cannot hold PDFs, and some reported trouble with updating the most recent version
 - DropBox
 - Provided limited access to the group (when this is needed)

- Regardless of organization/storage system, *keep track of the search histories* to compile for the Methods section or a future revision workgroup
- Name files with consistent format. For example, use of “author’s last name_year_key word” can make articles easier to find
- Establish a method to provide workgroup member access to full-text publications, as appropriate. All group members should have access to the database of all abstracts. Copyright laws may prevent sharing the full collection of articles to all.

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 in order to answer the guiding PICO question that is the foundation for the evidence-based document.

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

- Study ID number (assigned by review coordinator for each article)
- Data extractor initials
- Date data extraction completed
- 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.
- Level of Evidence (described earlier)
- Critical Appraisal Tool Summary Score.
- 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

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 Options

There are a number of options to consider in collecting and managing the "data" extraction process, each with its own pros and cons:

- *"Paper and pencil"* or standardized forms available as Word documents or functional PDF forms. An example of this type of data extraction tool is the form developed by the Section on Research EDGE group and used by the various NeuroEDGE subgroups; it was designed to gather information on validity, reliability, and measurement characteristics of functional measures used to document outcomes in physical therapy care (<http://www.ptresearch.org/article/84/resources/researchers/edge-task-force-evaluation-database-to-guide-effectiveness/edge-rating-forms>).

Each reviewer completes one 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 review coordinator, who then performs or delegates data entry into an excel file or other database for further analysis.

- *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.
- *Database software:* Tools such as Microsoft Access program can also be developed to meet the specific needs of the workgroup. By setting up a series of screens by content information (e.g., citation info, sample characteristics, study design and statistical analysis, methodological quality, measures used, intervention details, conceptual & operational definitions/outcome measures used, results, etc. as appropriate for the PICO question), risk of data entry errors is greatly reduced. This type of database also allows multiple persons to have access, and can be modified as necessary to make data gathering more efficient. There is a significant learning curve for new Access users however; this option would work best if someone in the group was already familiar and facile with

the software program, or if there was funding to hire an expert to develop the multi-layer interface and train group members in its use.

- *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.
- *Free Online Databases and Software:* The Cochrane Collaboration has data management and analysis software, **RevMan** (Review Manager 5.3) available for download for researchers involved in developing systematic reviews. It may also be useful for other types of evidence-based documents as well. <http://tech.cochrane.org/revman>. *Cochrane also has **GRADEpro** software that helps to create the summary of finding tables necessary for the synthesis process.* <http://tech.cochrane.org/revman/gradepr>. *Users are able to tailor their data forms based on the type of question their EBD is trying to answer: effectiveness of intervention, diagnostic test accuracy, methodology review, overview, or flexible (prognosis, qualitative, or prototype) review. Once the type of review is identified, the software has a defined set of information to gather. Tables, figures and appendices can be downloaded into RevMan. The APTA is in the process of evaluating a critical appraisal/data collection form for studies of physical therapy intervention/outcome studies.*
- *Fee for Service Web-Based Databases and Software:* When there are many articles from which data needs to be extracted, or when there are multiple persons involved in the article review and data extraction processes, there are online services that are designed to assist data management for complex reviews. **DistillerSR** (<http://distillercer.com/products/distillersr-systematic-review-software>) is an example of one such service

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, insuring 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 individuals who will be extracting data need to be trained so that there is as 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/dictionary 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 (ideally) are assigned a set of articles for data extraction. Each independently completes data extraction then compares results with their teammate. Once consensus is reached, the final data set for that article is recorded in the data extraction/data management tool that has been chosen/developed for the project. If there are many articles from which data must be extracted (and if data extractors are experienced), an alternative is to “spot check”, having single data extractor, with a planned dual consensus evaluation on every 15th or 20th article.

Managing the Database

Errors in data entry in a complex database 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 EBD, 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 back 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.

Sorting Information in the Database

In order for the group 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.

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 EBD 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. After reviewing strategies used by EBD workgroups from APTA Sections of Orthopedics and Pediatrics, as well as methodology from EBD workgroups from other disciplines, we recommend 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 clinical practice guidelines, in particular, and other evidence based documents, 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) (see Guyatt G, et al. J Clinical Epidemiology, 2011, 64:383-394), 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.

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:

- For all EBDs:
 - Carefully determining/grading the strength of the evidence of each of the articles to be included in the evidence/data table. This can be accomplished using a consensus process, or by a single group member with expertise in research methodology.
 - Generation of a “best estimate” of effects as well as an index of uncertainty (e.g. Confidence intervals associated with the estimate).
 - Review of the document by the Advisory Committee and External Reviewers
 - Incorporation of recommendations for review groups into the document

- For CPGs:
 - 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.
 - Review of information in the data/evidence table to identify potential recommendations.
 - Deciding about the direction (pro/con) and strength (strong/weak) of the recommendation. See Evaluating/Grading Evidence below.
 - Reaching consensus on each recommendation within the entire workgroup. See BRIDGEWiz section below.
 - Synthesizing recommendations into a single document.

- For SRs:
 - Developing summary of finding (SOF) table. SOF tables are a shorter distillation of the larger evidence tables, focused on findings that make key information more accessible to readers. SOF tables are included in the SR document, providing a summary of key information on which a synthesis decision or clinical recommendation is made.
 - Review of information in the data/evidence table to prepare summary of findings.
 - No recommendations are made in a SR.

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 EBD development workgroup. The information included in an evidence table is selected from the completed database following data entry. A workgroup developing a systematic review or 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" would have its own row in the table. The summary statement considers the "evidence" presented down the columns of the evidence table. Useful references about building evidence tables include Appendix 5 in the American Academy of Neurology 2011 *Clinical Practice Guideline Process Manual* (St. Paul, MN) p. 41, : The American Academy

of Neurology; Mlika-Cabanne et al, Sharing hard labour: developing a standard template for data summaries in guideline development. *BMJ Qual Saf* 2011;20:141-145.)

Evaluating and Grading the Quality of the Evidence

The workgroup 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 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.

- **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. A useful reference on this issue is: Lomatan et al., How “Should” We Write Guideline Recommendations? Interpretation of Deontic Terminology in Clinical Practice Guidelines: Survey of the Health Services Community. *Qual Saf Health Care*. 2010 December ; 19(6): 509–513. doi:10.1136/qshc.2009.032565.

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
- **R-Research** can be used individually when there is really 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.

Grade	Recommendations	Quality of Evidence
A	Strong	A preponderance of level I studies, but least 1 level I study directly on the topic support the recommendation.
B	Moderate	A preponderance of level II studies but at least 1 level II study directly on topic support the recommendation.
C	Weak	A single level II study at less than 25% critical appraisal score or a preponderance of level III and IV studies, including statements of consensus by content experts support the recommendation.
D	Theoretical/ foundational	A preponderance of evidence from animal or cadaver studies, from conceptual/theoretical models/principles, or from basic science/bench research supports this conclusion.
E	Expert Opinion	Best practice based on expert opinion (review papers, white papers, consensus documents developed by various methodology (e.g., Delphi, RAND) and the clinical experience of the guideline development group.
R	Research	An absence of research on the topic, or conclusions from existing studies on the topic are in disagreement.

Use of Bridge-WIZ for Writing Recommendations

BRIDGE-Wiz should be used for constructing the recommendations and accompanying text and should be a group activity (in-person meeting recommended) to reduce bias. If Working Groups 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.
- 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**:

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 Cost: 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.

* 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.

Steps Following Writing of Recommendations

Present draft recommendation to rest of the group for consensus

Complete draft CPG and submit to Advisory Committee for review. Incorporate AC feedback.

Assess CPG implementability (see Implementation Section).

Send draft CPG to multidisciplinary expert review group. Act on external review group feedback as appropriate. Keep a table/spreadsheet of external review group comments and how the GDG acted on these comments.

Submit to Neurology Section through the Advisory Committee to 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).

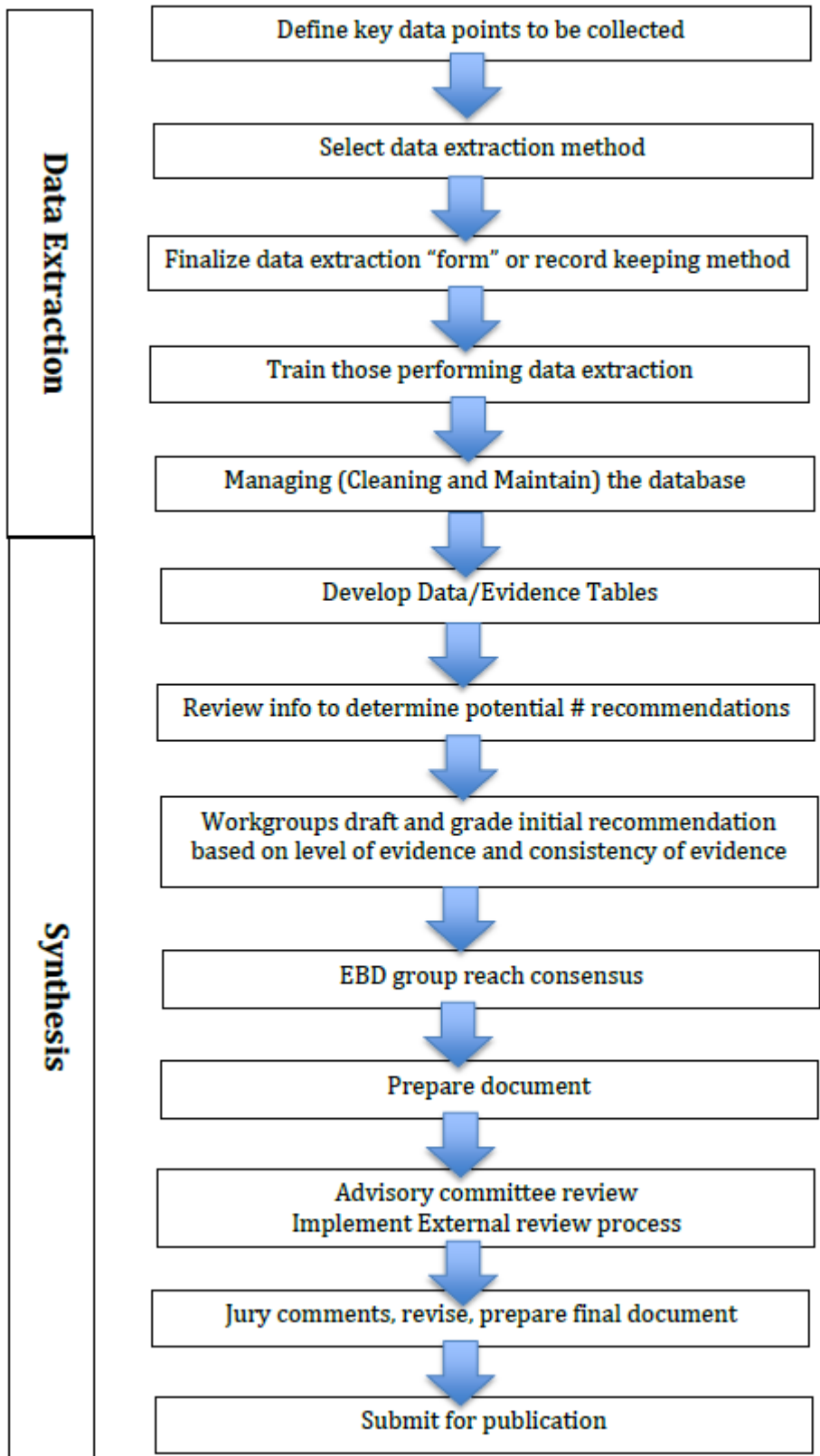
Jury and incorporate public comments into document as appropriate

Submit document to journal/publisher for further peer review, and responds to comments

Submit to appropriate databases for CPG (eg National Guideline Clearinghouse).

Publicize publication of EBD through Neurology Section.

Plan for revision process – see Revision Policy.



IX. Revision of Evidence-Based Documents

The revision process is integral to maintain clear, updated recommendations or guidelines based on the most current evidence. The Director of Practice (DoP) and the Advisory Committee (AC) should maintain a policy and procedure for monitoring, reviewing, and updating any EBD. Each EBD should be reviewed/revised at least every five years (ie. some CPG portals pull the CPG after the 5 year publication date).

In each published EBD, three dates should be clear:

- EBD/CPG publication date
- 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 Neurology Section of the APTA website:
<http://www.neuropt.org/> “

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

- The initial EBD workgroup is responsible for regular monitoring of the literature in order to assess if new and significant evidence is available, and if updating the EBD should occur prior to a formal five year review. Considerations for revising the document prior to the five year time frame 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
- The initial EBD workgroup is responsible for monitoring the literature for new and relevant publications (up to three years post-publication of the original EBD). This includes completion of one final literature search to update the evidence and create a bibliography for the revisions group.
- To support continuity, the initial EBD workgroup should keep clear documentation and notes. For example, clear records may include search terms and strategies, organized evidence tables, etc.
- By the third year, the DoP, AC and Leader of the initial EBD workgroup identify any/all persons from that group that will continue to work on the revision workgroup. The DoP and AC confirm leadership for the revision group, and this group may begin the revision process.

- The revision workgroup should work for a five year term, or may define a more appropriate time frame given the extent of new evidence found.

As additional EBD workgroups are formed, or if the volume of EBDs warrants this, the DoP and AC can opt to add an additional AC member as Revisions Coordinator. This should be examined at least annually to match resources and needs of newly-developing or to-be-revised EBDs. Alternatively, the DoP may opt to assign the Revisions Coordinator role to an existing AC member. The roles and responsibilities of this person would be to:

- Keep track of all CPGs/EBDs and when revisions are due.
- Contact, on behalf of the AC, the original group to identify potential revision members and report to the AC.
- Facilitate hand-off between the original and revision CPG/EBD groups.

The AC will continue to review and edit all submitted CPGs irrespective of their status (ie, original; revision).

X. Implementation of Evidence-Based Recommendations

One of the final responsibilities of the EBD Workgroup is to identify the potential facilitators and barriers to implementing recommendations. “Implementation refers to that part of the guideline lifecycle in which systems are introduced to influence clinicians' behavior toward guideline adherence”. (GLIA, Guideline Implementability Appraisal v 2.0)

This section focuses specifically on CPGs, as one type of EBD, as these inherently provide a set of action statements. For other types of EBDs, that include recommendations or action statements (ie position statement/ white paper), it is suggested that the EBD workgroup, at minimum, identify potential barriers to implementation and consider potential strategies to enhance implementation.

Guideline developers should reflect on the following areas when offering recommendations for supporting guideline uptake: (modified Table 3 in Shekelle et al, originally taken from Gagliardi et al)

- 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, Fethers 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 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”. (from Shiffman RN, Dixon J, Brandt C, Essaihi A, Hsiao A, Michel G, O’Connell R. The GuideLine Implementability (GLIA): development of an instrument to identify obstacles to guideline implementation. *BMC Medical Informatics and Decision Making*. 2005; 5(23)). The CPG development workgroup 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 group 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

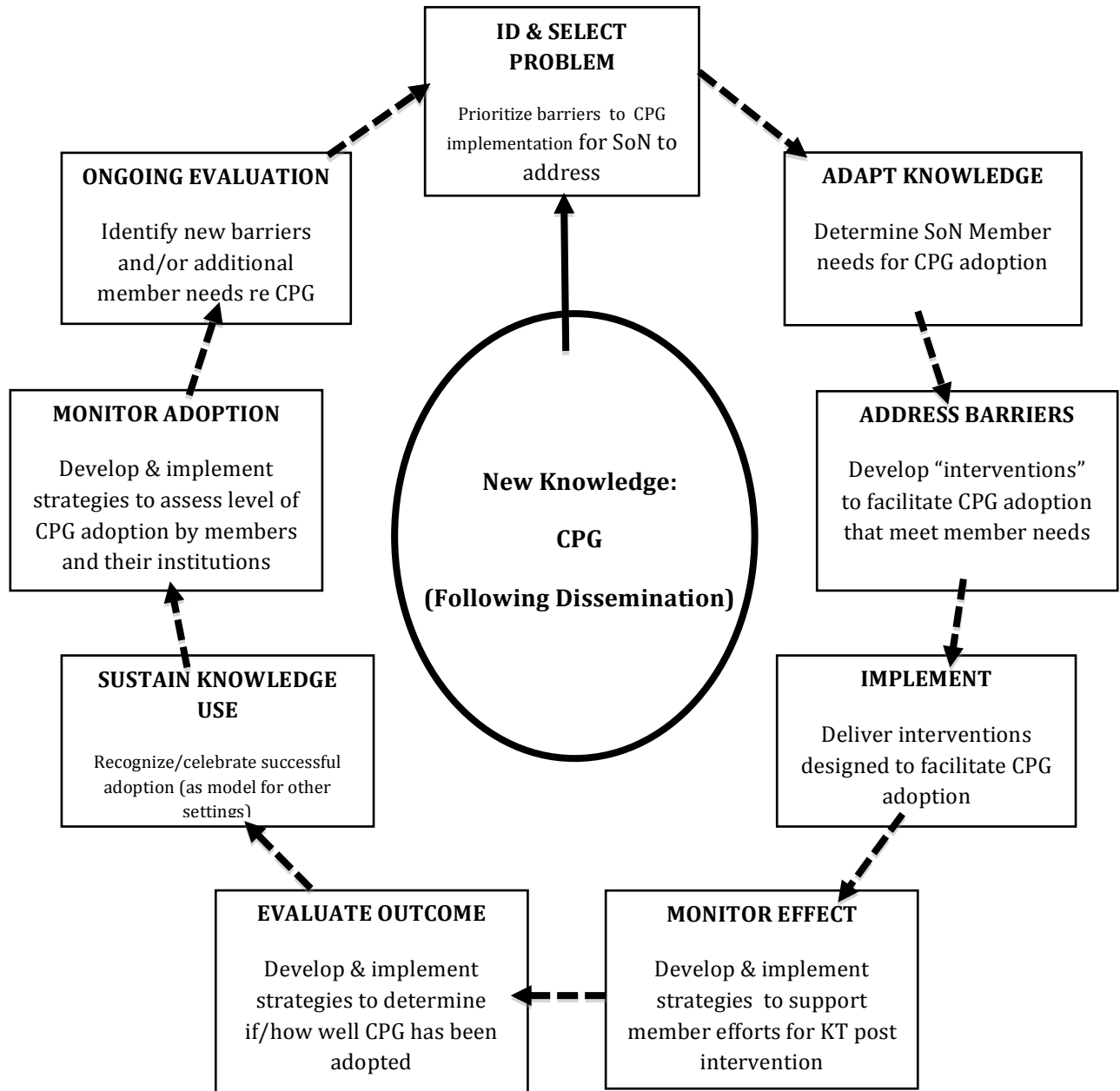
Based on the GLIA results, authors of a CPG may modify its content in order improve the ease in which recommendations may be applied prior to publication or assist administrators in identifying potential problems in implanting a CPG within their organizations.

Assessing whether a published CPG has impact on physical therapy practice

Ultimately, adoption and implementation of CPG recommendations occurs through the process of knowledge translation (Hudon et al). It is beyond the scope of the CPG workgroup to actually facilitate and to monitor the success of the knowledge translation process. Because the Section is encouraging development of the CPG to enhance physical therapy practice, it may fall to the Section to undertake assessment of barriers to implementation at the level of the Section, and to develop and implement strategies to facilitate adoption of the CPG it has sponsored.

Development of a CPG requires a rigorous inquiry and synthesis process that results in “creation” of new knowledge. The Section disseminates this new knowledge via publication in its journal, making it available on its website, and presentations at Combined Sections Meetings. Dissemination alone does not guarantee that the CPG will be adopted at the health care administrative and clinical practice level. If the Section intends newly developed CPGs to change and improve the practice of neurological physical therapy, then it should develop strategies to facilitate the knowledge translation process, and to monitor the impact of CPGs in daily clinical practice. Figure 1 presents a potential model, at the level of the Section, to facilitate the knowledge translation process, such that CPGs supported and disseminated by the Section are “living” and effective documents. (Friedman et al).

Figure 1: Conceptual Model for the knowledge to action process for implementation of CPGs in Neurological Physical Therapy Practice (adapted from Graham ID, Logan J, Harrison MB et al. Lost in knowledge translation: time for a map? J Contin Educ Health Prof, 2006:26:13-24.)



Although the adoption of a CPG as a “living” document can be considered cyclical in nature, the SoN can enter the process by identifying which of the barriers to CPG implementation identified in the new CPG can be best addressed at the level of the Section. Such barriers might include a lack of knowledge about “how to” read/interpret the document among SoN members, lack of understanding on the part of rehabilitation managers about incorporating recommendations into daily operations, or difficulty in changing documentation systems to effectively comply with recommendations.

Once such barriers and member needs have been identified and prioritized, the SoN would begin to consider how best to address the problem/s. The SoN might choose to assemble a group of individuals with expertise in knowledge translation or members of the EBD Advisory Board to develop a series of “interventions” to assist members in the process of adopting the CPG into clinical practice. This might include (as examples) a) a “how to read/interpret/apply CPGs as a presentation at multiple CSMs; b) regional workshops aimed at clinical managers on assessment of where their practice setting “sits” with regard to the examinations/evaluations, interventions, and outcome measurement strategies recommended in the CPG, with an emphasis on helping managers identify barriers/challenges and potential solutions at their specific institution; or c) consultation services where expert SoN members “visit” an organization interested in adopting the CPG. There are likely many additional creative “interventions” that could be developed to meet member needs (Friedman et al).

In order to monitor the effect and evaluate the outcomes of adoption of a new CPG, it may be helpful for the SoN to create a network of individuals/agencies working to implement the CPG at their own setting. Keeping in touch with persons who have attended Section sponsored “interventions” would provide peer support and networking opportunities, as well as a way to collect information about facilitators/barriers to change across settings (Dulko). Such pooled information would assist future CPG development groups to better understand the process of knowledge translation and build strategies for change into their documents, as well as assist the CPG revision workgroup better understand what might need to be updated/changed as they approach the revision process.

To keep a CPG “alive” over the 5-year-to-revision publication lifetime (i.e., sustain it’s use in the clinic) the SoN might choose to recognize/celebrate successful adoption (including but not limited to the steps/strategies used to incorporate the CPG into practice, changes in documentation, consequences in terms of efficiency and efficacy of care, and outcomes in terms of reimbursement) by highlighting practices/agencies that have made the transition. This might take the form of articles in the e-newsletter, presentations at CSM, or a scholarly article in JNPT. Such efforts would potentially provide incentive as well as a successful model for other practice settings considering adoption of the new CPG.

One of the major challenges faced by groups who develop and disseminate CPGs is to really understand if their work has effectively improved practice (Counts et al; Brusamento et al). By setting up the “infrastructure” described above, the SoN creates for itself an opportunity to “study” the clinical impact of a CPG. For example, a yearly survey sent to those who participated in SoN sponsored interventions as well as to a random sample of members (sorted by setting to which the CPG applies) would provide descriptive data about the impact of the CPG on practice. Such an effort would also serve as a vehicle for ongoing evaluation of member needs with respect to understanding, embracing, and implementing the CPG.

Additional References

- Brusamento S, Legido-Quigley H, Panteli D, et al. Assessing the effectiveness of strategies to implement clinical guidelines for the management of chronic diseases at primary care level in EU Member States: a systematic review. *Health Policy*. 2012 Oct;107(2-3):168-183.
- Counts JM, Astles JR, Lipman HB. Assessing physician utilization of laboratory practice guidelines: barriers and opportunities for improvement. *Clin Biochem*. 2013;46(15):1554-60.
- Dulko D. Audit and feedback as a clinical practice guideline implementation strategy: a model for acute care nurse practitioners. *Worldviews Evid Based Nurs*. 2007;4(4):200-209.
- Friedman L, Engelking C, Wickham R, Harvey C, Read M, Whitlock KB. The EDUCATE Study: a continuing education exemplar for Clinical Practice Guideline Implementation. *Clin J Oncol Nurs*. 2009;13(2):219-230. doi: 10.1188/09.CJON.219-230.
- Hudon A, Gervais MJ, Hunt M. The contribution of conceptual frameworks to knowledge translation in physical therapy. *Phys Ther*. 2014 epub ahead of print
<http://ptjournal.apta.org/content/early/2014/07/23/ptj.20130483>
- Shiffman NR, Dixon J, Brandt C, et al. The Guideline Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline implementation. *BMC Medical Informatics & Decision Making*. 2005;5(1):23-28.