

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.

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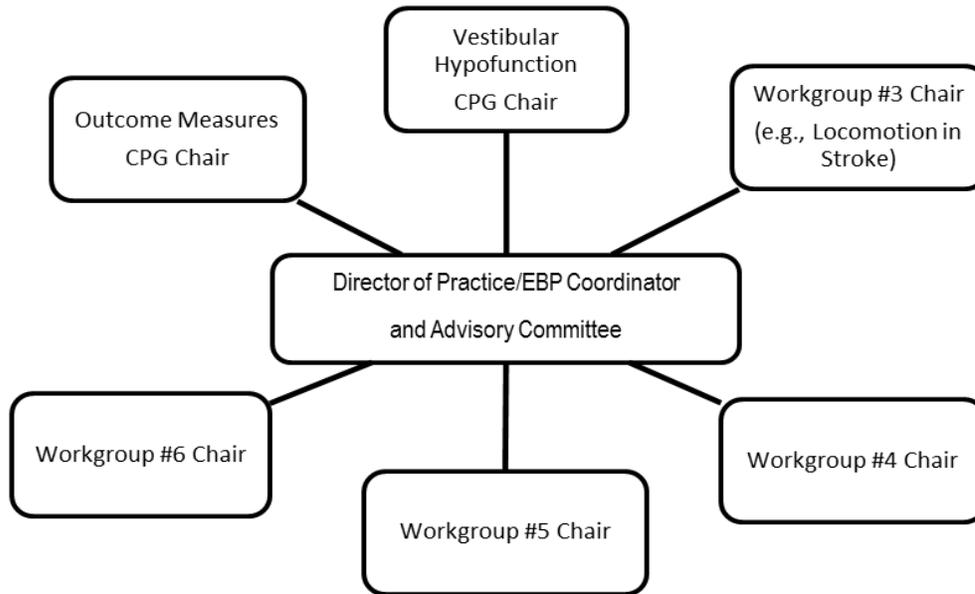
Pocket guide Pocket guides are short summary statements in a portable tool. A pocket guide could be derived from any of the above documents. When pocket guides are developed independent of another document, they are intended to be based on best available evidence and expert consensus and are referenced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

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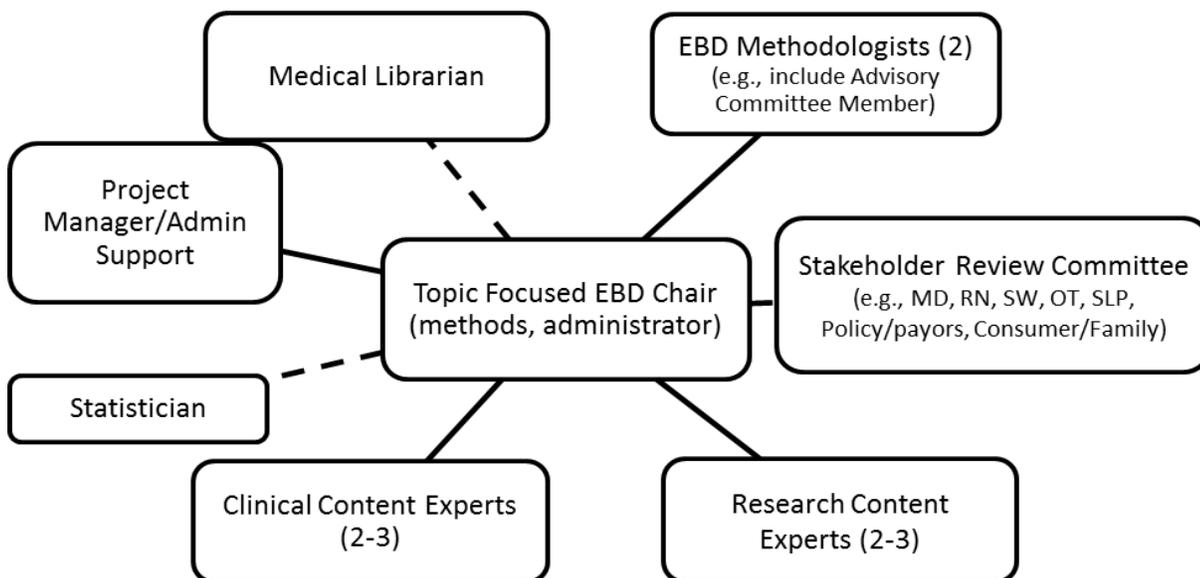
II. Structure and People Needed to Develop Evidence Based Documents (EBDs)

The Neurology Section complete 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 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.



III. Roles and Responsibilities

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 a 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

- 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 5-7 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.

IV. Honorarium

The section will follow the section honorarium policy for the determination of honoraria for members involved with the development of EBDs.

V. 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).

VI. SCOPE

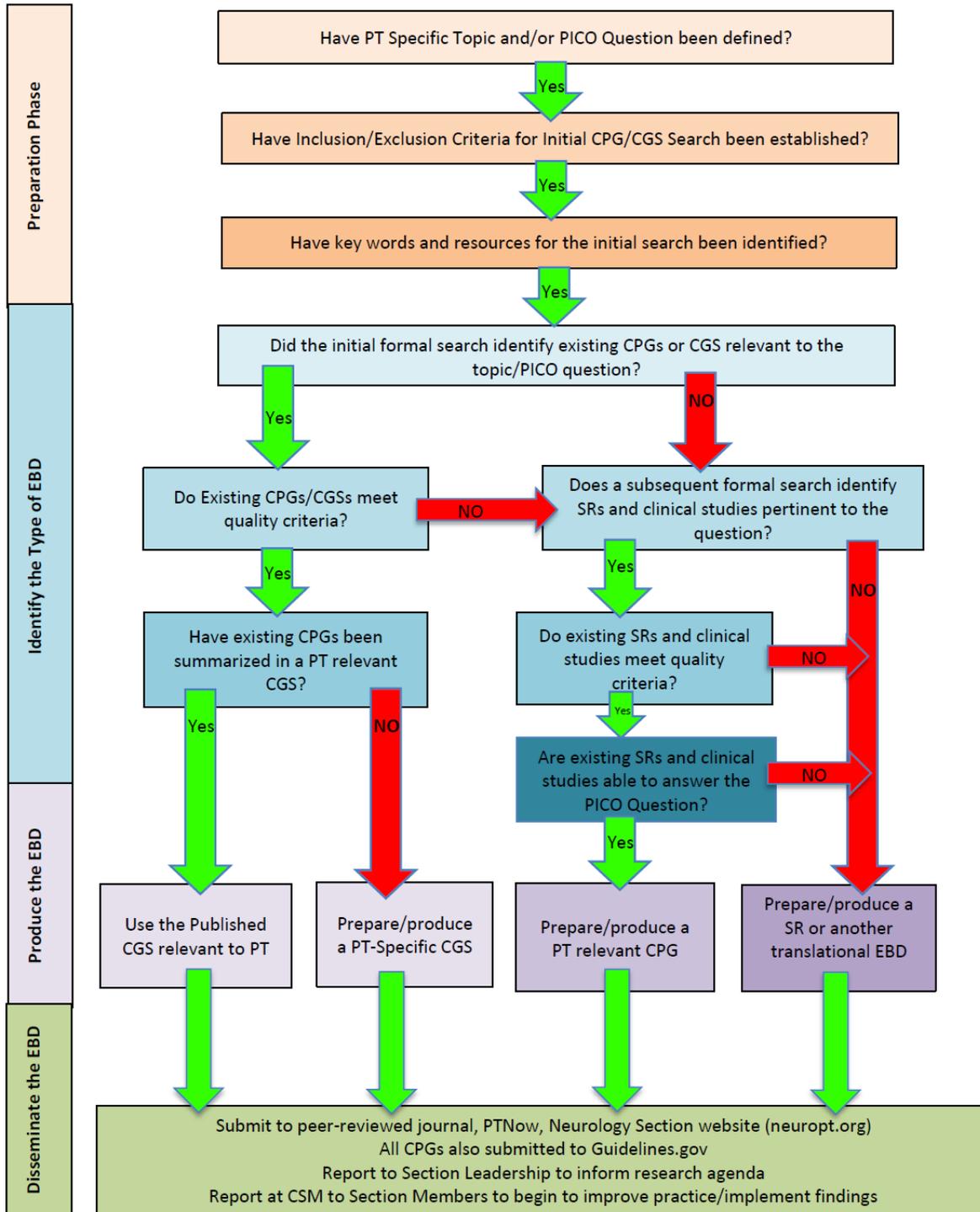
The scope of the EBD is dependent upon two things: The breadth and depth of the EBD and the type of EBD. Depending on the degree of development of the topic and question(s) these steps are complementary.

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 MDD 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**.

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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.

VII. 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.”

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