

APTA Academy of Aquatic Physical Therapy Manual for Developing Evidenced-based Physical Therapy Clinical Practice Guidelines

INTRODUCTION to the CLINICAL PRACTICE GUIDELINE

An evidence-based clinical practice guideline (CPG) is a collection of action statements based on a systematic review with or without meta-analyses on the topic of choice that reflects current recommended clinical practice intended to optimize patient care, minimize harm and reduce unnecessary variability.¹ The evidence is then weighted using a transparent process of appraisal and recommendation with recommendations made based on the strength of the supporting literature, the expertise of the guideline development group, and stakeholder input which includes patients, families, payers and policy makers.

The following document reflects the processes this committee selected for the development of such guidelines; advice regarding this process; and procedural guidelines to assist future Aquatic Academy (AS) CPG developers. While development of CPG's continues to evolve, the following guidelines parallel international processes with the goal a synthesis of available research making application in clinical practice clearer using graded recommendations. The intent of this document is procedural consistency for future guideline developers, and for this document to serve as a road map to facilitate CPG completion.

The Institute of Medicine (IOM), in 2011, provided specific indices to ensure CPG statements are trustworthy including they should:

- be based on a systematic review of the existing evidence;
- be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- consider important patient subgroups and patient preferences, as appropriate;
- be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest;
- provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations; and
- be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.²

INTENDED AUDIENCE:

The document describes the physical process of Clinical Practice Guideline development for the APTA Aquatic Academy and is intended to be used by the Academy's guideline developer groups. Information contained herein delineates the process adapted by this Academy for the development of CPG's to insure all guidelines produced by this Academy demonstrate consistent procedures.

ABBREVIATIONS: AAPT: Academy of Aquatic Physical Therapy; BoD: Board of Directors, specifically of the Academy, CPG: Clinical Practice Guidelines; GCDC: Guidelines Core Development Committee; SCPGTF: Specific Clinical Practice Guideline Taskforce.

STEPS to CREATING CPG:

1. **DETERMINING CPG AIMS:** Prior to actual topic selection, the AS Board of Directors (BoD) in considering the feasibility of such an endeavor must first explore the significant financial and publication commitment needed to produce a CPG. The BoD must next solicit the guidance of an expert panel which will include the Guidelines Core Development Committee to initiate the discussion of the feasibility as well as the Academy's dedicated interest in moving forward with this arduous task. This Specific Clinical Practice Guideline Taskforce, once appointed, will report directly to the GCDC who will act as an interface to the BoD andl oversee the organization and development of all AAPT CPGs.

2. **TOPIC SELECTION:** CPG's can focus on a diagnosis or condition in its entirety or can be limited to the interventions or the measurements of a condition. The IOM has established eight criteria to assist with topic selection and includes:
 - a. Burden of the disease or condition on the patient, the family or society;
 - b. Existing controversy on the management or measurement of the condition;
 - c. The economic cost of having the condition or its management and interventions;
 - d. The availability of sufficient evidence;
 - e. The availability of new evidence that might change prior recommendations;
 - f. The potential to improve health outcomes;
 - g. Public or provider interest;
 - h. The desire to reduce unwarranted variations in care.¹

Topic proposals can be solicited via membership or recommended by the appointed committee. All proposed topic requests shall be completed on the form provided by the AS, and contain the following requested information:

- a. a brief summary of the rationale discussing the scope and purpose of the proposed CPG;
- b. a literature review including existing guidelines of this topic plus related systematic reviews and primary research;
- c. timetable for completion of this proposal.

These can be submitted to the GCDC at any time, but will be reviewed with a determination requiring one year for BoD budget approval. The schedule will be established by the BoD, and provided to all membership via email notification plus the Academy's website publication in January.

Academy support is based on both availability and applicability of existing guidelines, and the availability of a qualified team leader willing to undertake the task of a specific CPG development. Additionally, both a significant financial commitment and committee support for CPG completion is imperative for success with this endeavor. The AS's BoD will hold responsibility for final topic approval to insure adequate monies exist prior to task onset.

3. **GUIDELINE CORE DEVELOPMENT COMMITTEE (GCDC):** This committee of 3 members, selected and approved by the AS BoD, will review all CPG proposals and present its findings to the BoD for a topic meeting the criteria to proceed with the CPG process. Additionally, the GCDC oversees all active CPG efforts for the AS. The GCDC committee leader holds a non-voting seat on the BoD and will present all CPG findings at an official BoD meeting.

The GCDC leader is appointed by the AS BoD, and once appointed, serves a 3-year term with a possibility for re-appointment, but cannot serve longer than 6 consecutive years, unless a CPG is under development and leadership change will negatively impact conclusion of this process.

4. **CREDENTIALS OF GCDC LEADER:** This individual must possess both content expertise and research experience including research design and synthesis, statistics plus expertise in synthesizing literature, and experience in publication. In addition, the GDC leader must exhibit clinical knowledges related to aquatic therapy. It would likewise be attributable to hold experience in the organizational process of the AS.
5. **SCPGTF: Specific Clinical Practice Guideline Taskforce Members:** This committee should be comprised of both clinicians and scholars with working knowledge of evidence-based practice and research design; experience in synthesizing literature; and clinical expertise related to aquatic interventions. Non-AS members may comprise up to 20% of the SCPGTF if these individuals hold the requisite qualifications. A balance of both research experience and clinical knowledge is critical for the success of this project. The candidates can apply or be selected by the GCDC and additional members will be considered as needed to provide the necessary, competent expertise to move the CPG to completion.

6. **RESPONSIBILITIES:** The ultimate responsibility of the SCPGTF leader is to facilitate completion of a CPG that can withstand the rigors of physical therapy application. To that end it becomes incumbent upon this individual to assign GDC team members tasks based on their strengths and what duties must be completed at various stages of development to insure successful CPG completion. Following is a list of—but limited to-- those task:
- a. Identify/invite team members and reviewers with consideration of clinical experience from other disciplines that can interface with physical therapy. Inter-professional writing groups hold considerable greater validity at the international level.
 - b. Establish the chronology of events to keep the CPG process moving forward, and to benefit the AS BoD with budget planning.
 - c. Determine authorship rules within the GDC.
 - d. Provide administrative management for the project including: setting up of conference calls between committee members; creating a draft; organize internet resources so all GDC membership has free access to as well as preparation of abstract submissions throughout the length of this project; provide membership with timely appraisals of progress.
 - e. Establish/maintain viable communication with the AS BoD either through meeting attendance or scheduled documentation.
 - f. Prepare a working budget for the AS BoD reflective of expenses such as but not limited to: clerical assistance; author meetings at a site (one to two per year for the duration of the CPG); professional librarian and statistician services; literature searches; software purchases; and publications.
 - g. Request financial support from and complete appropriate documentation as required by the AS BoD and other funding sources such as the APTA CPG Committee.
 - h. Manage clerical assistants when available including task delineation, monitoring of assignments, recording keeping for task hours and payment as needed (as in the case of a graduate assistant).
 - i. Set up email communication process with a designated email address, including unique account name. This account should be the designated repository for all communication on the project, and accessible to all SCPGTF members. Once an individual is selected as a SCPGTF member, this information will be provided to insure accurate/timely communication among members.
 - j. Establish a repository for all document drafts with a logical storage format, accessible to all members of the SCPGTF team. This facilitates posting of current editions of manuscript drafts, provides for timely edits and allows for sharing of information throughout the team. Additionally, it is critical to maintain a stamped master copy of all documents to eliminate redundancy.
 - k. Set up an exclusive repository of PDF article files for the SCPGTF team; as per copyright law, these articles must be restricted to exclusive team usage. A variety of software reference manager programs are available that provide for a creation of a virtual library of PDF's that can be accessed as needed by team members. These include MENDELAY DESKTOP (www.mendelay.com); ENDNOTES (www.endnote.com); and ZOTERO (www.zotero.org).
 - l. Set-up of conference calls. Various mechanisms are available through the internet to provide for group interaction that facilitates real-time progress on the project. Using such conference provides not only for group discussion but the ability to share the desktop so documents can be viewed/edited in real time. Online meetings and blackboards include: SKYPE (<http://beta.skype.com>); JOIN ME (<http://join.me/>) or ELLUMINATE LIVE (www.illuminate.com). Some require a modest fee and others are used free of charge.
 - m. Draft letters to literature appraisers and draft reviewers to invite their participation. Such volunteers can be sought through the AS membership and others knowledgeable in aquatics who are willing to devote a significant amount of effort to CPG development. Communication with interested individuals may focus on one aspect or all of the following:
 - Request for ideas on the scope of this CPG;
 - Request for clinician ranking of collected data;
 - Request for critical appraisers;
 - Assignment/follow-up of assigned articles for critical appraisers.

- n. Organize meetings with GDC leader and *Aquatic Physical Therapy Journal* editor to discuss appropriate timeline for publication. Continue to provide the *Journal* editor with CPG progress so that its publication date can be estimated/planned.
 - o. Conduct and combine multiple literature searches with periodic updates so that the CPG is current when published.
 - p. Determine inclusion/exclusion criteria for the body of literature to be reviewed and validate the search process.
 - q. Select criteria appraisal tools to determine the quality of the evidence dependent on the study design. Such tools include Appraisal of Guidelines for Research and Evaluation (AGREE II), or PEDRO.
 - r. Establish the reliability for the critical appraisal process for diagnosis, prognosis, and intervention studies.
 - s. Screen abstracts for relevance of inclusion in the appraisal process. This should be done by small groups of the SCPGTF team, with discrepancies regarding inclusion, being decided by an independent team member and the team leader. It is not necessary for all team members to read all abstracts, but all abstracts that are deemed acceptable must be the result of agreement by a minimum of two team members.
 - t. Provide recommendations regarding how acceptable articles will be distributed throughout the SCPGTF team membership and by what tool(s) evaluations will be finalized.
 - u. Write assigned portion of the CPG and collaborate in the preparation/editing of same.
 - v. Provide timely updates regarding the CPG progress to the AS membership via email or slide presentations at CSM or other APTA events.
 - w. Apply to Guideline.gov
 - x. Submit the completed CPG for publication in *Aquatic Physical Therapy Journal* or another professional journal.
 - y. Assist in any other tasks deemed appropriate for the completion of this project as directed by the GDC team.
7. **REVIEWERS AND STAKEHOLDER CREDENTIALS:** Volunteers with diverse backgrounds should be included in as many development stages as possible. This includes focus groups, consumers from both public and private sectors and interested clinicians. These individuals should assist with content validation, critical appraisals, content validity, and the usefulness of this CPG in practice.
8. **DEVELOPMENT OF CPG GUIDING QUESTIONS:** The GDC will solicit topics and/or questions from as many stakeholders as possible to determine the extent of the CPG. Ranking the importance of the topics can be accomplished by an on-line survey distributed to all identified interested parties. Finally, the scope of the guideline can be delineated through an outline based on the consensus among the SCPGTF clinical experts. Additionally, these experts will determine whether the CPG will include a full range of patient management or whether focus is narrowed to a specific question.
9. **CONDUCTING A COMPREHENSIVE SEARCH AND APPRAISAL OF THE LITERATURE:** A comprehensive literature search is essential to producing quality, evidence-based CPG's. To ensure the scope is accurately addressed, employing the services of a reference librarian is required. It is imperative the optimal hierarchy of search terms and databases are used, and the inclusion/exclusion criteria for searches are recorded for mention in the final document. Additionally, interested stakeholders can be invited to contribute literature searches with mention of specified search terms, databases used, and number of studies excluded.

SCPGTF members likewise conduct searches throughout the CPG process to guarantee newly published research is included. It is important to search those databases not part of a library collection—such as those held by professional organizations and charitable foundations with interests paralleling the CPG topic.

Once all abstracts from those documents deemed appropriate are located, the SCPGTF must collect full-texts for those articles screened for inclusion. These are to be posted into the reference repository and made available to all SCPGTF members. It may also be necessary at this time to secure funding from the AS to purchase relevant full-text copies of those articles not otherwise available.

10. **CREATE A LITERATURE GRID/EVIDENCE TABLE:** A master grid containing all articles, reviewers, critical appraisal scores and relevant variables for guidelines will be created in a spreadsheet to facilitate tracking progress. This grid may include: purpose, sample size and characteristics, special tests and measures, outcomes as well as other variables that the GDC considers pertinent to the guideline. This allows the team to add columns, sort articles based on selected variables and group like articles. Avoid merging cells as this does not allow for sorting of the literature grid based on selected variables.

Evidence tables defined as “...outcome summaries presenting data from a number of related studies...aim to demonstrate overall trends in the evidence and enable the process of making recommendations...”.¹ These tables can be constructed for the final document as appendices or as web-links, but they tend to contain more detail than is feasible to publish and should not be constructed until all the available data is located, assessed, and discussed thoroughly.

11. **CRITICALLY APPRAISING THE LITERATURE:** The basis of a CPG is the critical appraisal of literature; this process must be reliable. The AS can support this process by active solicitation for appraisers conducted both on the website and via membership email blasts.
 - **ESTABLISHING RELIABILITY:** The following steps can facilitate establishing reliability of the critical appraisal volunteers.
 - i. Independently or with other sections and/or APTA annually offer critical appraisal topic (CAT) workshops for interested members or individuals.
 - ii. Create documents describing the critical appraisal process, assignment of articles and follow-up reminders, all with a specified time frame.
 - iii. Determine which categories of literature to be critically appraised based on the CPG scope.
 - iv. Identify the literature appraisers and establish reliability of the organizing team.
 - v. Given the low number of items within each critical appraisal form, authors recommend establishing 90% or greater reliability between appraisers---allowing for a difference of 1 point among appraisers. For those appraisers not meeting the reliability threshold of 90%, the SCPGTF may choose mentorship and or recommend attendance at one of the CAT workshops.
 - **APPRAISAL PROCESS:** Articles are individually sent to randomly paired appraisers who review the article separately, score it, and return it to the SCPGTF leader for reliability assessment (or a designated SCPGTF team member). If the two independent reviewers do not agree they will confer regarding their score discrepancies to achieve consensus. If consensus cannot be reached, appraisers communicate with the SCPGTF leader who will randomly assign another SCPGTF team member to add another article critical assessment score to the original appraiser pair. All final scores are entered on the list grid.

12. **WRITING THE CPG:** The writing of a CPG initiates as the critical appraisal of selected topics is completed. Each document consists of an introduction to the problem, a brief history and relevant issues, and then proceeds with the scope, intended audience, statement of intent and additional content items.

These action statements/recommendations can be written using BRIDGE-WIZ software or other software developed to accommodate definitions of levels of evidence and grades of recommendation. Both levels of evidence and grades of recommendation are previously defined by the SCPGTF.

To insure accuracy of such action statements, the literature grid each specific topic must first be completed. This safeguards that all decisions about the quality of supporting evidence for recommendations occurred and available to all members of the SCPGTF. Additionally, such transparency reduces biases which can occur when only one individual generates the action statement. Following is the summarized weighted evidence that must be provided for each recommendation.

- ACTION STATEMENT: A statement that includes evidence quality and strength of;
- Benefits of the CPG
- Risk, harm, cost of intervention, condition
- Value Judgement
- Intentional vagueness
- Role of patient preference
- Exclusion
- Supporting Evidence and Clinical Interpretation

A list of action statements should be a “stand alone” part of the CPG, usually appearing in the first pages of the document. Detailed rationales for the recommendations follow in the body of the CPG. “Best Practices” considerations can be used when common procedures are recommended but in the absence of supporting literature. Research recommendations are listed under Supporting Evidence and Clinical Interpretation Section of each Action Statement; identifying evidence gaps for which future research is needed.

13. **REVIEW AND DISSEMINATION OF THE CPG:** There are three CPG process phases from writing to public dissemination. These include the following:

- **REVIEW PROCESS:** in which various stakeholders provide critical comment for review. The review by content method experts requires an identification of those individuals—stakeholders—representing multiple clinical and lay groups who will be affected by the CPG, AND solicitation of constructive criticism of the 1st draft. This process includes:
 - i. Establishing a format for receiving feedback on the draft. This should consist of standardized form consisting of guiding questions for reviewer comment.
 - ii. Submitting the draft to 1st line reviewers including the GCDC.
 - iii. Revising the draft on the basis of comments received and then sending out the revised document for 2nd review. This 2nd review should include the Journal editor, a broader base of clinical professionals as well as consumers. Depending on the extent of revisions, a 3rd review may be necessary.
- **PUBLICATION:** Manuscript preparation for publication. Once all revisions are integrated, the manuscript is prepared for journal submission either as an article or a separate addendum to journal. Authorship rules regarding publication are established by the GCDC at the onset of CPG undertaking and process checked to see if workloads matched those originally projected. Additionally, it is suggested the SCPGTF leader be first author with remaining authors listed alphabetically. All literature searchers, critical appraisers and writer reviewers plus funding sources should be acknowledged, usually at the end

of the document. It remains the Journal editor's responsibility to ensure language consistency, format and writing style.

- **POSTING** of the CPG on Guidelines.gov. The SCPGTF leader with support and review from the GDC is tasked with preparing an application for dissemination through guidelines.gov. A Guideline Submission Kit can be downloaded from the National Guideline Clearinghouse website (<http://guidelines.gov/submit/index.aspx>).
- i. Coordination of CPG Reviews- The GDC committee should establish a date of expiration for the guideline, devise a time line for a revision process and recommend a revision leader(s).

CLINICAL PRACTICE GUIDELINE-CONTENT OUTLINE

Following is a recommended starting point for actually writing the CPG.

1. **Title Page**
2. **Abstract**
3. **Tables with Level of Evidence and Grades of Recommendation explanations**
4. **Summary of Action Statement (following is required per action statement)**
5. **INTRODUCTION:** Provides an overview of both the scope and need for this CPG. Included here should be a description of the purpose of the guidelines. There are various ways to accomplish this dependent on the guideline's focus. Additionally, background information regarding challenges leading up to the selection as well as questions that should be answered by this guideline are included here. Lastly, descriptors relative to the population as well as the scope of the literature are discussed here.
6. **STATEMENT of INTEREST:** Something similar to the following statement should be included in the CPG: This guideline is intended for clinicians, family members, educators, researchers, policy makers and payers. This CPG is a summary of the practice recommendations supported by research and reviewed by expert practitioners and stakeholders.
7. **METHODS:**
 - Determining the purpose and scope; outline of content
 - Literature Review: describe search process in-depth
 - Critical Appraisals of all articles including appraisal scores
 - Levels of Evidence
 - Document Structure: defines how the document will be laid out
8. **Topic Headings:**
 - Incidence and progression inclusion of risk factors
 - Initial Referrals
9. **Key Action Statements:** This is the heart of the CPG where statements are presented with appraisal literature. Whenever possible statements should be organized to follow the steps of patient management and integrate the domains of the International Classification of Function, Disability and Health.
10. **Implementation and Audit Recommendations:** Describe strategies for the implementation of this CPG into practice with recommendations for pragmatic application.
11. **Development of Guidelines:** Describe the process that was utilized in the development of this CPG.
12. **Statement of Internal Review:** Describe the evaluation process.
13. **Definitions and Concepts:** Provide definitions of key terms with references; when multiple definitions exist for a key term provide the operational definition as used in the CPG.
14. **Abbreviations Glossary**
15. **ICF Codes:** Identify the relevant ICF (International Classification of Function, Disability and Health) Codes that might imply impairments of the body structures and functions, functional limitations, and participation challenges for the patient. Both ICD-10 and CPT codes should likewise be included.
16. **References:** Provided in the precise medical format that has been deemed appropriate by the GDC team.
17. **Appendices and Tables:** As needed

18. Evidence Tables: Provide a summary table in spreadsheet format of the articles that support each recommendation including authors, dates, level of evidence, subject matter, dependent variables, measures, intention and outcomes. This can be provided as an online document for member use as well as for future CPG revision teams.

19. Quick Reference Guide

20. Documentation Suggestions

REFERENCES:

1. Kaplan SL. Coulter C. Fetters L. Developing evidence-base physical therapy clinical practice guidelines. *Pediatric Physical Therapy*. 2013;257-270.
2. Kaplan SL. Godges JJ. APTA Workshop: Developing Clinical Practice Guidelines: Organization, Methodology and Strategies; July 24-26,2013 Washington, DC.

CPG guideline processes were adapted from those described by the Academy of Pediatric Physical Therapists' document on writing guidelines (Kaplan et al, 2013), and from APTA CPG training sessions and manual.