American Academy of Orthotists & Prosthetists (AAOP)

Process for the Establishment of Clinical Practice Guidelines

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Introduction and background

The development of clinical practice guidelines (CPGs) is a common objective for a wide range of health care disciplines. Considering the realities of competing priorities for the busy clinician, large gaps may exist between what may be considered best evidence and practice.[1] CPGs are intended to help close that gap to reduce inappropriate practice variation, enhance translation of research into practice, and improve healthcare quality and safety.[2] Recognizing the need to determine the present state of peer-reviewed evidence for a range of salient clinical topic of interest,[3,4] our Academy convened a series of thirteen State of the Science Conferences (SSCs) over a fifteen-year period, from 2002 to 2017.[5] The development of CPGs is therefore viewed as a natural progression of translating knowledge, as gleaned through the SSC process, to practice by guiding clinical decision-making aimed at achieving optimal patient outcomes.

In pursuing the establishment of clinical practice guidelines, considerable effort was placed in two specific areas: determining methodologies considered optimal for the orthotic and prosthetic (O&P) profession to establish consensus while also developing a CPG product that could withstand a high level of academic scrutiny. Two of the more common methods in formulating consensus in healthcare are the nominal group technique and the Delphi technique.[6-9] The nominal group technique[7,10] was deemed most appropriate to determine which areas of O&P practice are most suitable for the pursuit of a CPG effort. Recognizing the most trustworthy CPGs are based on high-quality systematic reviews of the literature,[2] the modified Delphi process[11] was determined to be the method of choice for clinical consensus. The Delphi technique is recognized as a multi-step process where a panel of experts offer their informed and anonymous opinions aimed at establishing levels of consensus on a specific field of study.[12] To avoid the risk of a range of factors that may undermine the quality and trustworthiness of a CPG,[2] the use of the AGREE II instrument was determined to be the most useful guide to ensure the most appropriate level of academic rigor was employed in this process.[13,14] Each of these elements were considered important in recommending the following guidelines for the establishment of CPGs for the O&P profession.

Process for the Establishment of Clinical Practice Guidelines (CPG)

The State-of-the-Science Program Committee (SSPC) shall serve as an oversight committee for all steps in the CPG development process.

Process (Steps)	Key Process Elements	Rules of Engagement /Recommendations (Best Practice)
Determine the CPG Topic  [Recommended Duration: 2 months]	• The SSPC recommends the topic to the Academy Research Council (RC) for final approval and funding by the Academy Board • In the case where a new Systematic/Scoping Review (SR) is needed, funding should be requested for Academy Board consideration at the same time as topic approval.	• For the Modified Delphi process, the clearer the objectives of the CPG, the higher the likelihood that meaningful agreement will be achieved. • Topics may be selected from a variety of inputs as outlined in the State-of-the-Science Program guidelines.[4,11] • The development of a CPG should be based on stronger evidence than is typically needed for a State-of-the-Science Conference (SSC), which balances expert opinion with evidence.
Systematic/Scoping Review (SR)  [Recommended Duration – 18 months]	• A SR serves as the primary basis from which a series of postulates can be developed by the GDG to be used in the Modified Delphi Rounds for building consensus. • The SSPC oversees the SR process and approves the final document.	• The Academy's Systematic Review Guidelines:[15] - For new SR development, these guidelines should be used for the process of determining authors and then provided to the authors to follow for new SR development - For existing SR use, these guidelines should be used to assess if the SR aligns well with those current standards • SR authors may later serve as a resource to the Guideline Development Group (GDG) early on in their process to answer questions related to their findings. However, to avoid potential bias, they should not be part of the development of the survey postulates used in the Modified Delphi process. • SR authors may also eventually be asked to serve on the Panel of Experts (POE)
Establish a Guideline Development Group (GDG) 	• The role of the GDG is to develop questions, evaluate consensus for each Modified Delphi Round, and draft CPG recommendations and final report. •The GDG is composed of a Chair, a Vice-Chair, and 4-6 Subject-Matter Experts for the clinical topic of interest • A Request for Proposal (RFP) shall be utilized to solicit qualified candidates interested in serving as the GDG Chair and Vice-Chair as a team. • The SSPC will review the applications and make a recommendation to the RC for Academy Board approval of the most qualified candidates to serve as GDG Chair and Vice-Chair. • Subject Matter Experts shall be recommended by the GDG Chair/Vice-Chair to the SSPC for approval with input from Academy staff	• The GDG Chair and Vice-Chair positions are not volunteers; each are paid stipends of set amounts upon the completion of key milestones throughout the CPG development process. • GDG Chair and Vice-Chair: - Both must have leadership experience, an understanding of (and possibly experience using) a Modified Delphi process, and knowledge in the use of AGREEII instrument (www.agreetrust.org);[14] - At least one of them must have: ◦ Knowledge/experience in topic area; ◦ Project management experience; - Both must declare all potential Conflicts of Interest (COI) for the SSPC to determine whether they are problematic for leading the CPG process; - Upon request, they are expected to provide updates on the CPG development to the SSPC. • Subject Matter Experts should: - Have a working knowledge of research in and strong ability to review and apply research findings in the CPG topic area; - As a group, represent multi-disciplinary team with varying opinions that balance each other in the topic area; - Preferably have experience with CPG development and/or use

[Recommended Duration: 3 Months]		- Preferably have a working knowledge of the Modified Delphi technique for achieving consensus; - Declare all potential COIs for review and approval by the GDG Chair and Vice-Chair, as well as the SSPC, to determine ability to serve as a Subject Matter Expert.
Establish the Panel of Experts (POE)  [Recommended Duration: 2 months]	• POE will be selected by the GDG Chair and Vice-Chair • Due to possible attrition, the panel should start with at least 20 individuals to participate in the Modified Delphi Rounds.	• POE participants should: - As a group represent a broad range of multi-disciplinary expertise,[16] with varying opinions, to enhance the quality and credibility of the process, and ideally include the following general categories: ◦ Health Professionals: Those who use the technology or techniques, including orthotists, prosthetists, physicians, therapists, psychologists, nurses, or other healthcare providers; ◦ Research Investigators: Those who remain active in the field and may include the SR authors; - Be able to discuss the scientific and clinical material presented during the Modified Delphi rounds; - Frequently engage in clinical treatment and/or research of this topic area; - Be objective, thoughtful, and capable of collaborative work; - Declare all potential COIs for review by GDG Chair and Vice-Chair and confirmation by the SSPC to determine eligibility to serve on POE; - Remain anonymous throughout the Modified Delphi process in order to remove effects of status, personalities and group pressures that can otherwise arise in meeting settings.[11,17] To mitigate attrition, it is recommended that the GDG Chair or Vice-Chair personally contact each individual approved to serve on the POE to ensure they will have the time and interest to participate in the entire Modified Delphi process.
Conduct Modified Delphi Process 	• Considering the stated objectives aligned with the establishment of a CPG, the GDG determines the initial questionnaires and subsequent series of postulates for POE consideration throughout the Modified Delphi process. These postulates will be further refined for clarity, or discarded altogether, during the Modified Delphi Round process.	• The Modified Delphi Technique uses a SR of literature on a specific topic to develop a series of postulates, with supporting citations, which are reviewed by the POE in the series of Modified Delphi rounds. • The Modified Delphi process typically uses 2 to 3 rounds. • To aid in assuring a series of practice guidelines that would be viewed as high quality, the six Domains referenced in the AGREE II Instrument (www.agreetrust.org) should be reviewed by the GDG at the start of the CPG development process.[14] • **Drafting preliminary postulates:** The GDG is responsible for drafting the postulates based on the SR (evidence-based) and the information obtained during the pre-survey interviews. These postulates will be used for the Modified Delphi Round 1. GDG may wish to contact the authors of the SR for clarification on key aspects of the SR content, but not for aid in developing the postulates so that the authors maintain the ability to participate on the POE

		without influencing process. The mindset for developing postulates should be to avoid bland generalities that may represent the lowest common denominator of any clinical debate. There is risk in achieving consensus only on points where any thinking clinician would agree, and thus little progress is made in determining levels of consensus on more cutting-edge questions. [*4 Weeks Duration*] • **Postulate testing/revision:** Preliminary postulates will be tested with 3-5 GDG members to ensure that they are clear, clinically meaningful, and sufficiently comprehensive prior to use in the Delphi rounds.[12] Ideally, each discipline should have one representative participating in this part of the process. These should be conducted as individual conversations versus a single group meeting whenever possible to maintain individual anonymity. One or more members of the GDG will review preliminary postulates derived from the initial systematic/scoping review with 3-5 members of the POE. POEs will be asked to comment on the content and format of existing postulates, and to identify any potential gaps in the preliminary postulates. GDG members will take field notes during the conversation with each individual POE member, and notes will be collated across POEs for each individual postulate. Based on POE feedback, postulates will be revised or removed. [*3-4 Weeks Duration*] • **Round 1:** The POE's are sent a list of postulates for which they indicate their level of agreement for each via a 5-point Likert scale. Participants are afforded the opportunity to provide commentary on their selection for each postulate. This may include citing literature or making a compelling clinical argument to support their position, especially in areas where they disagree with the postulate. At least 75% agreement (a median score of 3.75 or higher) is required to be recognized as "consensus;" a reasonable level of agreement to support a statement or a recommended clinical action. In cases of 60-75% agreement, the postulates can be modified by the GDG and sent back for Round 2 to gain a higher level of consensus. Postulates with no or minor agreement (<60%) may be eliminated or modified more significantly for Round 2 inclusion by GDG. In the case of low agreement, it may also be worth reaching out to a few POE members to determine whether the verbiage of the question made sense. Other measures of central tendency may be beneficial in assessing levels of agreement for each postulate being scored by the POE's. For example, making use of mean, median and mode, and levels of dispersion, such as standard deviation and inter-quartile ranges, are advisable in informing both levels of agreement and determining areas where further refinement of stated postulates should be considered.[11] [*4 Weeks Duration:* 2 Weeks for POE responses; 2 Weeks for GDG synthesis and revisions to be sent out for another Delphi Round]

[Recommended Duration: 4.5 months]		• **Round 2:** The postulates are further refined by the GDG and subsequently scored by the POE's to gain acceptable levels of consensus on the range of deliverables aligned with the stated objectives of the CPG. The same process as described for Round 1 is used. [*4 Weeks Duration:* 2 Weeks for POE responses; 2 Weeks for GDG synthesis and revisions to be sent out for another Delphi Round] • **Round 3:** If greater consensus is sought, each panelist receives the Round 2 postulates with POE ratings and feedback as summarized by the GDG. For those instances where an individual panelist's score varies greatly from the consensus of the POE, as a group, they are asked to reconsider their judgement or specify their reason for their remaining outside of consensus. This may include citing literature and/or providing a compelling clinical argument. This affords each panelist the opportunity to further clarify their position of disagreement or increase their degree of consensus. A list of questions where less than 60% agreement persist, a.k.a. equipoise statements, should be listed separately in the final CPG report. These statements could bring clarity to future research priorities. [*2 Weeks Duration:* Obtain POE responses to this round.] • **Recommended Levels of Consensus:**[8,18] (Based on median scores of each postulate) • Consensus: ≥75% agreement (a median score of 3.75 or higher) • Near Consensus: 60-74% agreement (median score of 3-3.74) • Equipoise: 30-59% agreement; sufficient levels of disagreement, supported by peer-reviewed evidence or a lack thereof, suggesting further research is required to recommend clinical guidance and standardize treatment strategies. Note: In the event a postulate receives less than 30% agreement, and if it is determined the reason for this lack of consensus may reflect agreement that its level of importance for clinical consideration is low, this too should be reported. To inform the reader of more granular levels of consensus, or lack thereof, stating the % agreement median score for each postulate is recommended within each of the three levels of consensus.[19] • **Face-to-Face Meeting**: In very rare cases it may be beneficial to convene a (virtual versus in-person) meeting with all of the POE's to help refine the consensus being sought in the development of a given CPG. Considering the strength of the anonymity of the Modified Delphi Process and the interest to avoid the "power of personalities," care should be taken on the level of refinement being sought for the final production of a given CPG. This may be used in situations where the opinions of the POE diverge significantly at the conclusion of the Modified Delphi Rounds. Every effort should be made during the modified Delphi rounds process to avoid this outcome. Therefore, in these

		rare instances, it would be the GDG Chair's responsibility to submit a proposal to the SSPC with substantial justification for seeking such means for achieving consensus.
Generate a Final Report: CPG Publication	• The CPG report should describe the stated objectives and the methods employed in reaching the varying levels of consensus achieved. • The GDG Chair is ultimately responsible for the submission of this manuscript to the Academy for adoption and permission to submit for publication in the Journal of Prosthetics and Orthotics (JPO). • The GDG submits the final CPG review to the SSPC for feedback and review. The SSPC advises the Academy Board, via the Research Council Chair, as to decision-making for endorsement/rejection of CPG report and dissemination of the information to Academy membership and the public.	• The AGREE II Instrument (www.agreetrust.org) should be reviewed by the GDG prior to writing the final CPG report as it will be used by the SSPC when providing feedback on the final document.[14] • The experiences and expectations of the target population (patients, public, etc.) should inform the development of recommended guidelines. • The use of a Systematic Review and its role in informing the CPG process should be stated. • A description of the GDG and POE membership should be included. This should include how participants were selected or excluded, the professions represented, years of experience, qualifications, or expertise in the topic area, as applicable to the development of the CPG. Additionally, any notable attrition for POE participation throughout the Modified Delphi process should be reported (without making specific reference to individual participants).[9] • A description of the entire process (pre-survey work and Modified Delphi Rounds) should be described in detail. This should include how consensus is defined, and the methodology employed for the scoring of postulates that were modified for further consideration vs. removed. • All postulates, in their final form with their respective ratings of consensus and equipoise statements should be concisely reported, including the exact percentage of consensus and other statistical information. • The development of Figures that may be viewed as instructive to promote best-practice, based on the levels of consensus achieved, should be encouraged. • To help inform the SSPC in its review of the CPG produced prior to advising the Academy Board as to whether to publish the document, two initiatives should be strongly considered: 1) The SSPC should convene an independent multi-disciplinary panel of professionals, having no affiliation with the CPG process, for the purpose of offering their assessment of the CPG document utilizing the AGREE II instrument.[20] [*8 Weeks Duration*] 2) Facilitate a Public Comment Period for the CPG prior to publication. This feedback would be provided to the GDG, who can offer a response to the SSPC for further consideration. [*4 Weeks Duration*] • Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. To be *trustworthy*, guidelines should: • be based on a SR of the existing evidence[2]

[Recommended Duration: 6 months]		• 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.[21]

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