ASPS Evidence-Based Clinical Practice Guideline Methodology

A. INTRODUCTION & OVERVIEW

Evidence-based medicine (EBM) is an approach to the practice of medicine using a combination of clinical expertise, patient values and the best scientific evidence. Using the Medline (PubMed) Trend database, the number of randomized controlled trials (RCTs) published in MEDLINE has increased from 39 RCTs in 1965 to over 32,300 in 2015.[1] Physicians are increasingly unable to keep up with the stream of new published evidence, and likewise do not have the time to assess the quality and potential biases of each study. Clinical practice guidelines have become a fundamental component of clinical practice since they contain recommendations for practice based on quality-appraised, synthesized scientific evidence. Clinical practice guidelines are developed to provide physicians and other healthcare professionals with recommendation statements "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."[2]

In 2016, the Quality and Performance Measurement Committee (QPMC) of ASPS voted to change the methodology used for the development of clinical practice guidelines to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. From 2011-2016, ASPS utilized a methodology based on criteria from Critical Skills Appraisal Program and the Centre for Evidence Based Medicine. GRADE is the leading methodology and current standard for the development of clinical practice guidelines, utilized by over 50 organizations such as The World Health Organization, Kaiser Permanente, the American College of Physicians, the Cochrane Collaboration, the Agency for Healthcare Research and Quality (AHRQ), and the American College of Surgeons. Potential advantages of the GRADE methodology over the previous ASPS method include:

- Stronger and more transparent methodology
  - Utilizes an objective numerical scorning system for quality assessment
- Alignment with the majority of published clinical practice guidelines
  - Increases understanding/interpretation of recommendations across readers
- More robust recommendation statements
  - Recommendations made across outcome rather than individual studies
  - Includes consideration of benefits/harms and patient values and preferences
  - Includes statistical comparison of quantitative outcomes data
- Ability to perform meta-analysis when possible (≥ 3 related studies)
- Significant reduction in production time
- Reduction in staff needed per guideline project

The use of the GRADE methodology for ASPS clinical practice guidelines began in late 2016.

B. GUIDELINE TOPIC SELECTION & TIMING OF PROJECTS

The QPMC is charged with selecting the topics for clinical practice guideline (CPG) projects. Each CPG will contain approximately five clinical questions with a limited maximum of seven clinical questions, as recommended by GRADE. The average time frame for each CPG project is approximately 18-24 months.

C. WORK GROUP COMPOSITION

- 10 ASPS members (including 2 Chairpersons)
- 1 Executive Committee or Board of Directors Advisor
- 4-5 representatives from stakeholder organizations (1 per organization)
- 1-2 patient representatives
    - Obtained through Consumers United for Evidence-Based Healthcare (CUE) or a relevant patient network
- 1 ASPS staff methodologist
- 1 medical librarian
- Optional (as needed):
    - 1 statistician

Work Group Member Criteria

Experience developing and/or knowledge of guideline development, evidence-based medicine, systematic reviews, epidemiology, statistics, research is desirable, but not required.

Work Group Member Responsibilities

Each Work Group member serves as an active participant in the development of the guideline and is responsible for determining the project scope, clinical questions, and literature search criteria. The Work Group collectively develops evidence-based recommendation statements and drafts supporting text for the guideline.

Chairpersons, Work Group Responsibilities

In addition to the responsibilities outlined above, the Work Group Chairpersons are responsible for managing the Work Group meetings, facilitating discussion and arbitration among differing opinions, enforcing adherence to the clinical practice guideline development scope and process, and facilitating the guideline development process.

Expected Time Commitment

Work Group members are expected to participate in quarterly conference calls, email discussions, individual assignments, and attend the in-person Introductory Meeting.

Managing Conflict of Interest

The Work Group Chairpersons should not have a conflict of interest. If a leading expert with a relevant conflict of interest is determined to be the best person to chair the Work Group, a co-Chair with no relevant conflict of interest will also be appointed. No more than 50% of Work Group members can have a relevant conflict of interest.

Each member applicant must accept all terms of the following:

1. No outside funding used for CPG development.
2. Work Group member COIs to be reviewed by QPMC, and ASPS COI Committee (for applicants with potential conflicts).
3. Work Group Chairpersons to be free of conflicts.

4. Per the Institute of Medicine (IOM) standards[2], Work Group members with COIs shall represent less than half the composition of the Work Group.
5. Per the Council for Medical Specialty Societies (CMSS) principles[3], the period in which COI disclosures must be obtained and managed is one year prior to initiation of the project through publication.
6. Per CMSS principles, Work Group members should decline offers from industry to speak about the content of the guidelines related to the industry products while in development.
7. Work Group members with relevant COIs will not participate in discussion, drafting or voting on recommendations specific to the conflict topic.
8. Per ASPS policy, the staff methodologist will add the COI disclosure report, which includes the disclosure statements of all Work Group members to each meeting agenda. The staff methodologist will review the Work Group's COI disclosures based on the agenda; the Chair will manage the discussion.

Conflicts of interest (COI) will be renewed, disclosed, and managed according to the ASPS Conflict of Interest Policy.

The Work Group Chair may request the Work Group Member to:

1. remain in the room, participating fully in the discussion involving the conflict but not vote;
2. remain in the room while the matter is being discussed but not speak or vote;
3. provide his or her opinion and leave the room while the matter is considered and voted upon;
4. remain out of the room while the matter is being considered and voted upon.

The Work Group Chair may also make other determinations related to the matter, including insulating the Work Group Members from documents that might be related to the conflict.

The ASPS COI Policy can be found at: www.plasticsurgery.org/COI.

D. WORK GROUP FORMATION

Work Group members are solicited through an online application process. A "Call for Experts" email will be sent to all ASPS members (US and Canada) on behalf of the Board Vice President (VP) of Research and the QPMC Chair. The online application for the CPG Work Group will include:

- Work Group Member descriptions
- Tentative Introductory Meeting date/location
- Anticipated duration of CPG project
- Information related to expected time commitment (conference calls, email discussions, in-person meetings, individual Work Group member assignments)
- Questions related to clinical interests, experience related to guideline topic, CPG development experience at ASPS or elsewhere, knowledge of EBM, quality, epidemiology, statistics, or research
- Conflict of Interest (COI) disclosure

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8. Per ASPS policy, the staff methodologist will add the COI disclosure report, which includes the disclosure statements of all Work Group members to each meeting agenda. The staff methodologist will review the Work Group's COI disclosures based on the agenda; the Chair will manage the discussion.

The Work Group Chairpersons will be selected by the QPMC Chair based on the applicants' content expertise and experience in guideline development/evidence-based medicine. Staff will reach out to the selected candidates to confirm interest in the Co-Chair position, answer any questions about the role/project, and obtain CVs. The selected Work Group Chairpersons will need to gain approval from the Board VP of Research, followed by the ASPS President and President-Elect. Final Co-Chair approvals are sought from the ASPS Conflict of Interest Committee via a memo with CV and COI information. Formal invitations will be sent to selected Co-Chairs on behalf of the QPMC Chair and Board VP of Research.

Staff works with the newly appointed Work Group Chairs and QPMC Chair to select the top eight potential Work Group members. Considerations should be made according to experience with topic content, guideline development, evidence-based medicine, quality improvement, research, epidemiology/statistics, as well as a balance of practice type and size, geographic location, gender, and potential COIs.

A memo with the selected Work Group members will be sent on behalf of the QPMC Chair to the Board VP of Research, ASPS President, and President-Elect for final approval. The memo should contain a summary of the process used to identify the proposed Work Group members, as well as the selected stakeholder groups.

Formal invitations will be sent to selected Work Group members on behalf of the QPMC Chair and Board VP of Research. Pertaining to the ASPS/PSF Guideline for Committee Appointments, ad hoc Work Groups for clinical practice guideline and performance measure development do not count against the 5-committee maximum for ASPS members.

Formal invitations will be sent to the selected stakeholder organizations and the patient representative on behalf of the ASPS President (stakeholder organization asked to nominate one representative), noting that the stakeholder organization will be responsible for their representative's travel/lodging costs.

To maintain the credibility of the final guideline publication, the composition of the Work Group cannot be altered. Should a Work Group member resign during development, a new member shall not be appointed in their place.

E. INTRODUCTORY MEETING

Work Group members are asked to submit potential clinical questions or subtopic ideas via email prior to the introductory meeting.

The main objectives of the introductory meeting are to educate the Work Group members in EBM and CPG methodology, discuss clinical question development, discuss literature search terms and inclusion/exclusion criteria, and identify potential peer reviewer organizations.

F. SYSTEMATIC REVIEW PROCESS

Clinical Questions (PICO Questions)

Selected clinical questions will be converted into the PICO question format. The PICO model defines the clinical question by identifying the specific components of (P) patient population; (I) intervention; (C) comparison; and (O) outcomes of interest. PICO questions are drafted *a priori* to target the questions focused on the important clinical questions and avoid the development of questions around available data.

Inclusion/Exclusion Criteria

Study inclusion criteria are determined *a priori* by the Work Group. Articles that do not meet the established criteria are not considered as evidence for the CPG. Universal inclusion/exclusion criteria for all CPGs include:

Study Inclusion Criteria

- Relevance to disease/condition
- Publication date range (e.g., past 10 years)
- Minimum number of patients per study and/or per arm of study (e.g., minimum 50 patients)
- Clinical study
- English language
- Human subjects
- Publication types: RCTs, clinical trials, comparative studies, observational studies, cohort studies, case-control studies, case series

Exclude

- Animal subjects
- Cadaver subjects
- Publication types: systematic reviews*, meta-analyses*, validation studies**, case reports, review articles, consensus statements, position statements, medical records review, meeting abstracts, historical articles, editorials, letters, news, commentaries

*The reference lists for relevant systematic reviews and meta-analyses are reviewed to serve as a spot check to ensure inclusion of all potential evidence.
**Validation studies will be included for diagnostic PICO questions

Literature Searches

Literature search strategies for each individual PICO question will be developed and performed by the medical librarian, which will include a search tailored to procedural resource use (cost, availability). The

librarian will perform the searches in the MEDLINE (PubMed), EMBASE, TRIP, Cochrane Central Register of Controlled Trials databases, National Guideline Clearinghouse, and the G-I-N CPG Library.

Abstract review

ASPS uses the internet-based CPG software program, "Presentation and Evaluation of Evidence-Based Research" (PEER) to manage guideline projects. During abstract review, a first pass of the literature search results are reviewed by the title and/or abstracts for potential relevance to the CPG topic. A reason(s) for rejection will be noted for each excluded article.

Appraisal of study quality

ASPS uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. GRADE is the leading methodology and current standard for the development of clinical practice guidelines.

Drafting of recommendations

The following factors are considered when developing recommendation statements:

1. Level of evidence (assessment of study quality)

2. Benefits vs. Harms—based upon an analysis of any harms/side effects, the Work Group assesses whether:
    a. Benefits outweighed harms
    b. Benefits equaled harms
    c. Harms outweighed benefits
    d. The balance between benefits and harms was unclear

3. Patient values and preferences—based on the clinical expertise of the Work Group and discussion in the referenced papers (e.g., tolerability, compliance, and patients' experiences with the treatments in question), the Work Group judges whether:
    a. The vast majority of well-informed patients (> 90%) would most likely use this patient-care strategy, compared to alternative patient-care strategies or no treatment
    b. The majority of well-informed patients would most likely use this patient-care strategy, compared to alternative patient-care strategies or no treatment
    c. The majority of well-informed patients would most likely NOT use this patient-care strategy, compared to alternative patient-care strategies or no treatment
    d. The vast majority of patients (> 90%) would most likely NOT use this patient-care strategy, compared to alternative patient-care strategies or no treatment

4. Resource use (when available)- based on monetary cost and availability of procedure

Strength and Grading of Recommendations

The grade assigned to drafted recommendations is determined by the quality of evidence, benefits vs harms assessment, and patient values and preferences.

Strength	Overall Strength of Evidence	Description
Strong	Strong	Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention. Benefit or harm predominates. The vast majority of well-informed patients (> 90%) would most likely *use or not use* this patient-care strategy, compared to alternative patient-care strategies or no treatment.
Moderate	Moderate	Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention. Benefit or harm predominates. The majority of well-informed patients would most likely *use or not use* this patient-care strategy, compared to alternative patient-care strategies or no treatment.
Weak	Low Strength Evidence or Inconsistent Evidence	Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Benefit or harm predominates or is unclear. The majority of well-informed patients would most likely *use or not use* this patient-care strategy, compared to alternative patient-care strategies or no treatment.
Option	Very Low Strength Evidence or Inconsistent Evidence	Evidence from one or more "Very Low" quality studies with consistent findings or evidence from a single "Weak" quality study recommending for or against the intervention. Potential benefits are harms are balanced. The majority of well-informed patients would most likely *use or not use* this patient-care strategy, compared to alternative patient-care strategies or no treatment.

All members of the Work Group participate in discussion and voting on the recommendation statements, as well as drafting the various sections of the manuscript.

Wording of Recommendation Statements

Recommendation wording per IOM and CMSS standards:

- Strong Recommendation: The Work Group *recommends* that clinicians *should*…
- Moderate Recommendation: The Work Group *recommends* that clinicians *could*…
- Weak Recommendation: The Work Group *suggests* that clinicians *may*…
- Option: When potential benefits and harms are balanced, an Option can be presented (e.g., "It is an Option to prescribe medication X or Y.")

G. RECOMMENDATION VOTING

A second one-day in-person meeting will be held to draft and finalize the guideline recommendation statements.

H. PEER REVIEW & PUBLIC COMMENT

The draft manuscript is reviewed by the multiple ASPS Committees and selected peer reviewers. The manuscript is posted to the ASPS website for a 30-day public comment period.

I. APPROVAL PROCESS

The CPG manuscript is sent to the ASPS Executive Committee for final review and approval.

J. JOURNAL SUBMISSION

The approved and finalized guideline is submitted to *Plastic and Reconstructive Surgery* (PRS), where it undergoes an additional round of peer review through the journal's required submission process.

K. NGC AND G.I.N. SUBMISSION

The guideline is submitted and posted to the National Guidelines Clearinghouse and Guidelines International Network.

L. QUALITY MEASURES WORK GROUP

Clinical practice guidelines are preferred to be used as a scientific evidence base for the development of quality metrics. A subsequent Work Group is formed to develop quality measures.

M. PLAN FOR UPDATING GUIDELINE

In accordance with the inclusion criteria of the National Guideline Clearinghouse, each guideline will be updated within five years to reflect changes in scientific evidence, practice parameters, and treatment options.

REFERENCES

1. Corlan AD. Medline Trend: Automated Yearly Statistics of PubMed Results for Any Query. http://dan.corlan.net/cgi-bin/medline-trend?Q=randomized+and+controlled+and+trial. Accessed August 9, 2016.
2. IOM (Institute of Medicine). *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press; 2011.
3. Council of Medical Specialty Societies. *Principles for the Development of Specialty Society Clinical Guidelines.* 2016.