American Academy of Orthotists & Prosthetists (AAOP)

State-of-the-Science Evidence Report Guidelines

Professionals Advancing Care through Knowledge

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OVERVIEW

The American Academy of Orthotists and Prosthetists (AAOP), with funding from the Department of Education, has developed a program for facilitating State-of-the-Science Conferences (SSCs) on topics related to the provision of orthotic and prosthetic (O&P) care. A SSC is a key activity in the development and assessment of healthcare evidence and policy. The purpose of the AAOP SSC program is to evaluate the available scientific information on an aspect of O&P care and develop statements that advance understanding of specific issues that will be useful to health professionals and the public. Other objectives may include documenting clinical belief systems and standards of O&P care, assessing the existing evidence pertaining to specific clinical decisions and treatments, identifying research priorities and advocating for targeted research funding in areas related to O&P, and developing public statements and policy that serve to promote O&P care. Additional details regarding the development and execution of an Academy SSC may be found in the Academy Grant Master Agenda, located on the Academy's website.[1]

The AAOP SSCs are coordinated by the Academy and chaired by invited conference leaders with the appropriate skills and experience to convene and coordinate a meeting of expert clinicians, academics, and researchers. Each SSC is developed around an "Evidence Report," which consists of a systematic review of the literature and an evaluation of evidence on the conference topic. The Evidence Report author(s), academic experts with appropriate backgrounds in SSC topic areas and the research skills necessary for performing a systematic literature review, are selected by the conference leaders and commissioned by the Academy. The results of the draft Evidence Report are used to select participants, establish the SSC agenda, and provide perspective for invited speakers' presentations and conference discussions. Following the SSC, the Evidence Report will be published along with the conference proceedings and serve to document the existing state-of-the-science on the conference topic.

The purpose of this document is to provide invited authors with guidelines for developing an Evidence Report as part of an Academy sponsored SSC. These guidelines are intended to promote a standardized format for SSC Evidence Report, but to be sufficiently flexible so as to allow individual authors the ability and freedom to develop reviews in a format best suited to the acquired evidence. This process is rigorous, but following these guidelines is expected to yield a greater understanding of the literature than is possible by simply reading the relevant literature and developing a typical literature review.

EVIDENCE REPORT GUIDELINES

The Evidence Report is a key element of a State-of-the-Science Conference and will form the basis for invited speakers, presentations, and subsequent discussions. Therefore, development of the conference should parallel that of the Report. Conference leaders are encouraged to involve the Evidence Report author(s) as early as possible in the development of the SSC. Similarly, authors and conference leaders are encouraged to maintain contact throughout this process in order to best facilitate the conference activities. The development of the Evidence Report includes 12 primary steps (Figure 1).

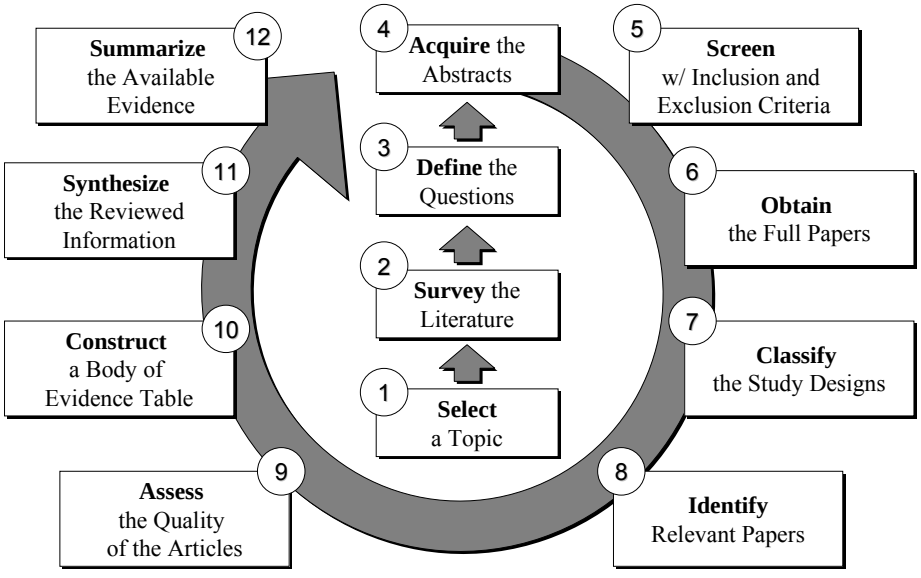

Figure 1 – Development of a SSC Evidence Report

Steps 1–3 direct development of the SSC topic and clinical and/or scientific questions to be answered by the SSC. Steps 4–6 target acquisition of the scientific evidence. Steps 7–9 focus on the classification and evaluation of the available scientific evidence. Steps 10–12 combine the results across the body of literature and summarize the available evidence with respect to the original questions. Specific step-by-step guidelines for Evidence Report authors are provided below. As noted in the figure above, the steps may not be linear, and may require iteration. Therefore, authors are strongly encouraged to document their progress throughout the development of the report so as to modify steps, as needed in this process. (Note: Although conference leaders are not required to commission the Report authors until Step 4, involving them in the initial development of the SSC will serve to ensure the quality and scope of the Evidence Report is appropriate for the conference.)

1. Select a Topic

Topics for a SSC may be recommended by clinicians, educators, researchers or other organizations associated with or engaged in the profession of orthotics and/or prosthetics. Typical sources of suggestions may also include, but are not limited to, health agencies and the public. Final selection of a topic is made when agreement is reached by the Academy's Planning Committee and the Academy Board of Directors. A SSC topic must meet the following criteria:

- The topic should have public health (habilitation or rehabilitation related) importance; it should affect or broadly apply to a significant number of people who possess physical dysfunction that is amenable to prosthetic or orthotic management. The severity of the problem (morbidity and mortality) and the feasibility of prosthetic and orthotic intervention are key considerations.
- Controversy or unresolved issues can be clarified, or a gap between current knowledge and current practice may be narrowed.
- The topic must have an available base of scientific information from which to answer the conference questions and/or resolve controversies. If conference questions and/or controversies cannot be fully addressed with the available evidence, then targeted research priorities may be formulated.
- The topic should be amenable to clarification based upon evidence, and the outcome should not depend primarily on the subjective judgments of Conference Participants.

Additional elements desirable in selecting a conference topic are the impact on health care costs and a high degree of interest in the O&P community. After a topic is judged by the Academy's Planning Committee and the Academy Board of Directors to meet the selection criteria, planning and implementation of the SSC may proceed under direction of the Academy leadership. The primary goal of a State-of-the-Science Conference is to summarize the evidence regarding conference questions and to recommend directions for further research. Where appropriate, the SSC may also identify generally accepted clinical practices based on the existing evidence and/or expert opinion.

A list of topics that have been selected and/or are currently being considered for an Academy SSC is contained in the Academy Grant Master Agenda, located on the Academy's website.[2]

As noted, SSC topics may be submitted by persons interested or involved in the O&P profession. In order to submit a topic for review, the applicant must complete the "Online Topic Suggestion Form" located on the Academy's website.[3] Applicants are asked to consider a number of criteria when submitting a topic for a SSC. These include relevance to current clinical practice, influence on a significant number of patients, importance to improving patient outcomes, controversy or lack of widespread consensus, presence of gaps between knowledge and practice, emerging or evolving concepts, quantity and quality of available peer reviewed literature, and degree of public interest. Applicants are also asked to explain why they feel the topic is relevant to O&P, suggest pertinent literature regarding the topic, and formulate at least three key questions regarding the topic.

In order to develop a topic for an intervention-focused SSC, applicants are encouraged to use the "PICO Method" for developing well-built clinical questions. The PICO method uses a step-by-step approach to develop a clinically relevant question based on four key criteria: (P) Patient or population; (I) Intervention or exposure; (C) Comparison; and (O) Outcome. In order to develop a question using PICO, the applicant is asked to answer the following questions with as much specificity as possible:

- Patient or population
    - What are the characteristics of the patient or population in question?
- Intervention or exposure
    - What is the desired treatment or evaluation?
- Comparison
    - What are the alternatives to the chosen intervention or exposure?
- Outcome
    - What are the potential outcomes to treatment?

For example, consider a 45 year old below-knee amputee who lost his leg in a motorcycle accident in 2004. Despite the use of massage, he suffers daily episodes of phantom limb pain (PLP) that severely impact his ability to work. Amputees in local support groups have informed him of techniques that may reduce the pain associated with these episodes (i.e., silver liners, electrical stimulation, drugs, etc.) and he wants to know if other treatments may be more effective than his current solution. Using PICO, you would note the following:

Patient:	Traumatic transtibial amputee
Intervention:	Metallic textiles, pharmacologic or transcutaneous electrical nerve stimulation (TENS) treatments
Comparison:	Mechanical stimulus
Outcome:	Reduce frequency and intensity of PLP

Given those results, a clinical question would be formed that says, "Are silver-infused textiles, pharmacologic, or TENS treatments more effective than massage at reducing the frequency or intensity of phantom limb pain in traumatic, transtibial amputees?"

Ultimately, as the question is developed through the steps below, it may be broadened to include a larger body of evidence. For example, the final clinical question derived from the PICO example above may read, "What treatments have been shown to be more effective than massage at reducing the frequency or intensity of phantom limb pain in traumatic amputees?"

It is important to note that the conference topic (and/or population) may be redefined, limited, or expanded based upon the results of the literature survey (see Section 2, below).

2. Survey the Literature

A preliminary search of the literature should be conducted to assess the relative quantity of literature available on the selected conference topic. This preliminary survey should be conducted by those individuals responsible for selecting the SSC topic. The purpose of the survey is to assess the magnitude of articles that are likely to be included in the Evidence Report and to expand or limit the topic based upon that result. As those individuals responsible for selecting the topic may not have access to library resources, the initial survey of the literature is best conducted with the freely-available PubMed (i.e., MEDLINE) database[4]. If a more comprehensive assessment of the O&P literature is desired, the RECAL Legacy database may also be used for the survey.[5] Additionally, authors may consider other databases such as the Cumulative Index to Nursing & Allied Health Literature (CINAHL) for topics that would index journals related to the social science, psychology, or nursing literature. While no single database provides comprehensive coverage of all O&P-related activities, a survey of these databases may provide sufficient coverage to approximate the relative number of scientific articles that will be expected in the full search (see Section 4, below).

The results of the literature survey may be used to either expand or limit the conference topic. For example, if the conference topic is selected to be "lower extremity orthotics," a preliminary review of the literature using the words "lower limb" or "lower extremity" combined with "orthotics" or "orthoses" produces over 1200 articles in the PubMed database. This is likely to be too broad of a topic for an effective literature review. Conversely, if the topic is "lower extremity orthoses used in patients with poliomyelitis," a similar preliminary review reveals only 20 articles. In this case, the topic is likely too narrow and should potentially be expanded to include other, related conditions. All search parameters (including date, keywords, database, etc.) and corresponding results should be documented so as to avoid redundancy and aid in question development.

The topic should be refined until an adequate and reasonable number of results are obtained from a targeted keyword search. This determination should be made in regards to the selected topic and to the available resources. For example, systematic review of 200 articles may not be feasible in a three-week period of time, but review of 200 articles may be appropriate if sufficient time is available to the author(s) to perform the review. Once the final topic has been selected, results of the initial survey may be used to define the SSC questions and keywords (see Sections 3 and 4, below). It is important to note that this literature survey is used primarily to develop a proper SSC topic and questions. Evidence Report authors are encouraged to perform their own survey of the literature in order to acquire the needed abstracts (see Section 4, below).

3. Define the Questions

One of the critical steps of developing the Evidence Report is to define the questions for the SSC. The questions developed for the SSC will be used to focus the Evidence Report search process and selection of search terms (see Section 4, below). Typically, the SSC questions will be a variation on the following themes:

- What is existing evidence?
- What are the relationships between the available evidence and current clinical practice?
- What are the research priorities?

The first question is intended to be addressed by the Evidence Report. Answering the second and third questions is commonly reserved for discussions at the SSC. The results of those papers, presentations, and discussions may be included in the Evidence Report, or they may be added to the conference proceedings as part of the conference leaders' summary of the SSC.

Recruited Evidence Report authors are typically provided with the conference topic, initial survey results, and questions. Report authors are then asked to review steps 1 – 3 and complete steps 4 – 12 in order to draft an Evidence Report in advance of the SSC. Upon review of steps 1 – 3, Evidence Report authors may elect to reassess the literature and revise the questions under direction of the Academy leadership before beginning the systematic search to acquire relevant abstracts (see Step 4, below).

4. Acquire Abstracts

Once the clinical and/or research questions relevant to the SSC are defined, specific search terms (and/or combinations of terms) must be identified and selected for the *systematic* literature search. This step differs from the literature survey (see Step 2, above) in that the Step 4 literature search is conducted to systematically locate and obtain the literature (*i.e.*, articles) relevant to the SSC topic and questions and not just to survey the approximate quantity of available literature.

Terms used for the systematic search are to be selected by the Evidence Report authors and may include Medical Subject Headings (MeSH).[6] MeSH terms are a list of more than 22,000 descriptors developed by the National Library of Medicine to index scientific articles in the MEDLINE database. Search terms for the Evidence Report should initially be selected from these descriptors, but may include other search terms as well. (Note: select databases, such as RECAL do not index via MeSH descriptors and may have their own list of indexed terms). MeSH descriptors may be identified using the National Library of Medicine's MeSH Browser.[7] Other terms may be identified through articles, abstracts, or titles of collected manuscripts. It is also important that authors consider acronyms and synonyms as part of the search strategy (e.g., both "Syme's amputation" and "ankle disarticulation" should be targeted in a systematic search). The search terms ultimately selected for the review should be explicitly documented in the Evidence Report (see Section 6, below).

Based upon the search terms selected, a systematic review of the literature should be performed. It is recommended that the Evidence Report authors begin the literature search by seeking systematic review articles or meta-analyses on the topic of interest. These types of publications offer the Evidence Report author a source for relevant articles and/or search terms, and may provide a foundation for the Evidence Report by allowing them to update an existing review, if appropriate, rather than replicating one that has already been performed. The Cochrane Library is an example of a source for such reviews and meta-analyses.[8]

The Cochrane Library is a quarterly publication dedicated to disseminating evidence that informs healthcare decisions. The Library contains systematic reviews of published scientific evidence (*i.e.,* the Cochrane Database of Systematic Reviews), technology assessments, economic evaluations, and reports of clinical trials in a variety of healthcare topics. It is published by the Cochrane Collaboration, an international, non-profit organization that performs and disseminates systematic reviews of healthcare interventions. The Cochrane Library is indexed from the mid 1990's to present.

It is next recommended that the literature search be extended to include several different healthcare databases. An official affiliation with a university or hospital may be needed to access selected databases, so it may be appropriate to contact the Academy for an academic partner if such access is unavailable. Examples of scientific, biomedical, and clinical databases that index O&P journals include the following:

MEDLINE: The MEDLINE database is an open-access biomedical database managed by the National Library of Medicine and the National Institute of Health and commonly accessed through the PubMed interface.[4] MEDLINE indexes over 5000 biomedicine journals, covering such topics as medicine, nursing, dentistry, veterinary medicine, the health care system, and the preclinical sciences. The MEDLINE database spans publication dates from the 1950's to the present. MEDLINE may also be accessed through other interfaces, including the Ovid[9] internet-based interface or through management software such as Thomson Endnote[10].

EMBASE: The EMBASE database is a subscription-based biomedical database managed by Elsevier Publishing.[11] EMBASE indexes biomedical publications and scientific publications specific to drugs and pharmacology, including the effects and use of drugs, clinical and experimental aspects of pharmacokinetics and pharmacodynamics, and side and adverse effects. Only 3000 of the 4800 indexed titles overlap with the PubMed database. The EMBASE database spans publication dates from 1980 to the present.

CINAHL: The Cumulative Index to Nursing & Allied Health Literature (CINAHL) database is a subscription-based allied health database managed by CINAHL Information Systems.[12] CINAHL indexes over 700 journals related to nursing, allied health, biomedicine and healthcare. The CINAHL database spans publication dates from 1982 to the present.

Web-of-Science: The Web-of-Science is a subscription-based science database managed by Thomson Scientific.[13] Web-of-Science includes the Science Citation Index (Expanded) and indexes over 8700 scientific journals. Unlike many other databases, Web-of-Science allows for cited-reference searching (*i.e.,* reverse citation lookup). This is a key feature of this database that allows the user to find papers that have cited specific publications. This feature can be useful for finding related publications that may not reveal themselves in a standard keyword or MeSH search. The Web-of-Science database spans publication dates from 1965 to the present.

RECAL: The RECAL Legacy bibliographic database* is a free historical database managed by the National Centre for Training and Education in Prosthetics and Orthotics at the University of Strathclyde, Scotland (UK).[5] This database is specific to prosthetics, orthotics and O&P related physical medicine and engineering publications. The RECAL database spans publication dates from the early 1900's to 2007. (Note: As the RECAL Legacy database is not indexed after 2007, authors should use the RECAL database only to augment other keyword/MeSH searches).

Because no single database covers the entire spectrum of published scientific evidence (Table 1), it is recommended that the Evidence Report search include a minimum of two databases. This comprehensive search strategy will help increase the likelihood that all relevant information is included in the review.

Table 1 – Selected rehabilitation related journals indexed by healthcare databases

Journal Title	MEDLINE	EMBASE	CINAHL	Web-of-Science	RECAL
Advances in Clinical Rehabilitation	•		•		•
American Journal of Physical Medicine Rehabilitation	•	•	•	•	•
Archives of Physical Medicine and Rehabilitation	•	•	•	•	•
Assistive Technology	•	•	•	•	•
Bulletin of Prosthetics Research	•				•
Clinical Rehabilitation	•	•	•	•	•
Disability and Rehabilitation	•	•	•	•	•
Expert Review of Medical Devices	•	•		•	
IEEE Transactions on Rehabilitation Engineering	•	•		•	•
Journal of Bone and Joint Surgery	•	•	•	•	•
Journal of Prosthetics and Orthotics			•	•	•
Journal of Rehabilitation Research and Development	•	•	•	•	•
Orthotics and Prosthetics				•	•
Clinics in Podiatric Medicine and Surgery	•	•	•		•
Prosthetics and Orthotics International	•	•		•	•

Use of a reference manager, such as Endnote® can be used to manage the list of references and remove duplicate items obtained from searching multiple databases.

Abstracts of articles that meet the search criteria should be obtained directly from the database search (when available). If the full author-written abstract is unavailable from a database, it is recommended to try searching via other means to acquire it. Authors are reminded to document all search terms and results for inclusion in the Evidence Report. Once all the abstracts have been collected, they will be screened using the appropriate inclusion/exclusion criteria (see Section 5, below).

* Note: Indexed RECAL articles include a summary written by the RECAL staff and do not include the journal-provided abstract. Therefore, it will be necessary to acquire the abstract from another source prior to screening (See Step 5, below).

5. Screen with Inclusion/Exclusion Criteria

Abstracts obtained from the selected databases should next be screened against inclusion and exclusion criteria. These criteria may be defined prior to the systematic search (see Step 4, above) or they may be refined during the development of the SSC Evidence Report and used for final screening upon completion of the search. Evidence Report authors are encouraged to clearly and explicitly define the criteria used to select abstracts for full review. Inclusion and exclusion criteria may include language, study design, population, intervention, or outcome measures. Examples of selection criteria are shown in Table 2.

Table 2 – Examples of potential selection criteria

Language	Study Design	Population	Intervention	Outcome Measures
English • Translations Foreign • German • Spanish • Etc.	By category • Experimental trial • Observational study • Etc. By specific level • Before-and-after trial • Cohort study • Etc. By threshold • Controlled trial or better • Case study/series only • Etc.	By age • Pediatric • Geriatric • < 5 years • Etc. By (degree of) disability • Amputation (level) • Plagiocephaly • Muscular dystrophy • Etc. By etiology • Traumatic • Oncologic • Etc. By experience • > 2 years amputee • 6+ months on AFO • Etc. By activity • < K-level 3 • Active walker • Etc.	By component • Energy-storing foot • HKAFO and RGO • Etc. By treatment • Physical therapy • Pharmaceuticals • Surgery • Etc.	By type • Objective • Subjective • Professional report • Self-report • Etc. By category • Temporal-spatial • Kinetics • Kinematics • Etc. By specific measure • Range-of-motion • Time of hospital stay • Reported pain level • Etc.

Eligibility for the inclusion of abstracts should be screened by more than one reviewer and consensus should be achieved through discussion, if necessary. If inclusion is in doubt, the article should be acquired and re-assessed once the full paper is obtained (see Section 6, below). Authors are encouraged to document why articles were excluded from the review and note which inclusion/exclusion criteria were not met in a figure (See Section 8, below) or in an Appendix of the Evidence Report.

6. Obtain the Full Papers

Papers that meet the inclusion criteria, are in question, or are relevant for the introduction/discussion material should be acquired in either digital or hard copy. If either option is available, an electronic copy is preferred as it may more easily be part of the package of reading materials that are disseminated to SSC participants prior to the conference. Questionable papers should be re-screened using the inclusion/exclusion criteria (See Section 5, above) to determine candidacy for the review.

The process of collecting those papers selected for inclusion will vary by topic and by the resources available to the Evidence Report author(s). Those authors with a university or hospital affiliation will likely have access to a wide variety of scientific journals and texts through their university or hospital library. For authors without such access, or for papers that are not available through these resources, there are several alternatives for locating and obtaining scientific papers.

> **Free publications:** Selected journals offer free electronic access to their published manuscripts. Some journals offer unrestricted access to all published work. The *Journal of Rehabilitation Research and Development* is an example of a journal that offers unrestricted access to its entire library of published articles. Other journals may offer free access, but may include a "restricted period" in which only members or subscribers have access to the most recent publications. For example, the *Journal of Prosthetics and Orthotics* offers free access to all publications older than two years. Those articles published more recently than two years are only available to members of the American Academy of Orthotists and Prosthetists.

Subscription publications: Many professional memberships include a complementary subscription to the organization's professional journal. With current membership, individuals may have access to these publications. For example, *Prosthetics & Orthotics International* is available to persons with membership in the International Society for Prosthetics and Orthotics (ISPO). When seeking a publication from such journals, contacting a member of the professional organization may be an efficient way to obtain these papers.

Database services: Select databases offer services for obtaining scientific articles. For example, RECAL will acquire any article indexed by their database and fax a copy of the article to a registered user for a fee of £0.15 (~$0.30 USD) per page. These services offer a cost-effective method for obtaining articles.

Fee-based publications: Many publishers offer the ability to purchase single articles directly without the need for a full journal subscription. For example, Elsevier offers its library of over 2000 scientific journals through ScienceDirect. ScienceDirect users can search for articles and purchase individual papers for $30.00 per article. Due to the expense, it is not recommended that all articles needed for review be acquired in this manner. However, if a small number of articles cannot be acquired through other means, this may offer an alternative for obtaining those manuscripts.

It is important to note that authors should make every attempt to locate articles that meet the screening criteria. If articles cannot be located via the above means, it is recommended that the Evidence Report author(s) contact the Academy, as additional resources for obtaining the needed papers may be available. The titles of references included in the reviewed articles should be briefly inspected for other relevant articles that may not have been identified through the database search. If appropriate, abstracts of these references should be obtained and screened with the established inclusion/exclusion criteria and full papers obtained for review. Once all the papers have been obtained, each study should then be classified by study design (see Section 7, below).

7. Classify the Study Designs

Evidence Report authors are expected to classify the designs of all studies included in the final review. Two or more reviewers should examine the *Methods* or *Methodology* section of all studies and identify each study type using a consistent format. Any discrepancies should be resolved by discussion among the reviewers. The following classification scale (Table 3) is provided for classifying study *type* in the Evidence Report. Detailed descriptions of the listed study types are provided in Appendix A.

Table 3 – Study Design Classification Scale (adapted[14])

Category	Rating	Type of Study
Structured Review	**S1**	Meta-analysis
	S2	Systematic review
(Quasi)Experimental Trial	**E1**	Randomized controlled trial
	E2	Controlled trial
	E3	Interrupted time series trial
	E4	Single subject experimental trial
	E5	Controlled before-and-after trial
Observational Study	**O1**	Cohort study
	O2	Case-control study
	O3	Cross-sectional study
	O4	Qualitative study
	O5	Case series
	O6	Case study
Expert Opinion	**X1**	Group consensus
	X2	Individual opinion

It is important to note that the study design classification scale, while adhering to a general hierarchy of evidence established for healthcare research, does not necessarily indicate the appropriateness or quality of the study. The classification of study design is performed in order to assess the types of studies commonly used to investigate or research the SSC topic. Evidence Report authors are asked to keep this in mind when describing the results of the classification.

8. Identify Relevant Papers

Once all of the full papers have been collected and classified, the Evidence Report authors should identify papers for inclusion into the report based on the established inclusion/exclusion criteria, study design classification, and/or relevance to the established topic and questions posed for the SSC. The Evidence Report authors should remember to document the search strategies used to obtain the resultant articles. It is critical that the Evidence Report describe, in detail, the search process and the resultant articles. One method for documenting this process is a search flowchart (See Appendix B). The search flowchart is not necessary, but is a convenient way to present readers with an overview of the search strategy used by the Evidence Report author(s). The author(s) should, at a minimum, identify all key elements of the search and selection strategy, including database names (and relevant dates), the keywords or phrases used to perform the search, the applied inclusion/exclusion criteria, and key details of the final selection process. It may also be appropriate for the authors to list those articles that were excluded from the search process, and the reasons for the exclusion (See Appendix C).

Authors may elect to note demographics of those articles identified by the systematic search and/or selected for review. Characteristics such as dates of publication or source journals may be presented in tabular or graphical format (Figure 2 and Figure 3) in order to provide background knowledge to SSC participants, to note trends in published research, and/or to identify research priorities. Once this process has been documented, individual papers selected for review should then be assessed for methodological quality (see Section 9, below).

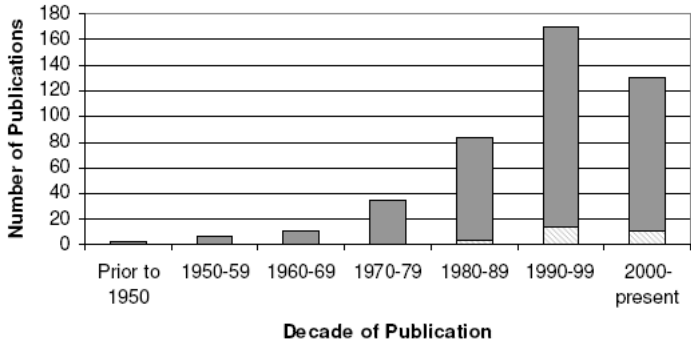

Figure 2 – Example of article demographics (*i.e.*, number of publications by decade identified in the systematic search) from an Evidence Report[15]

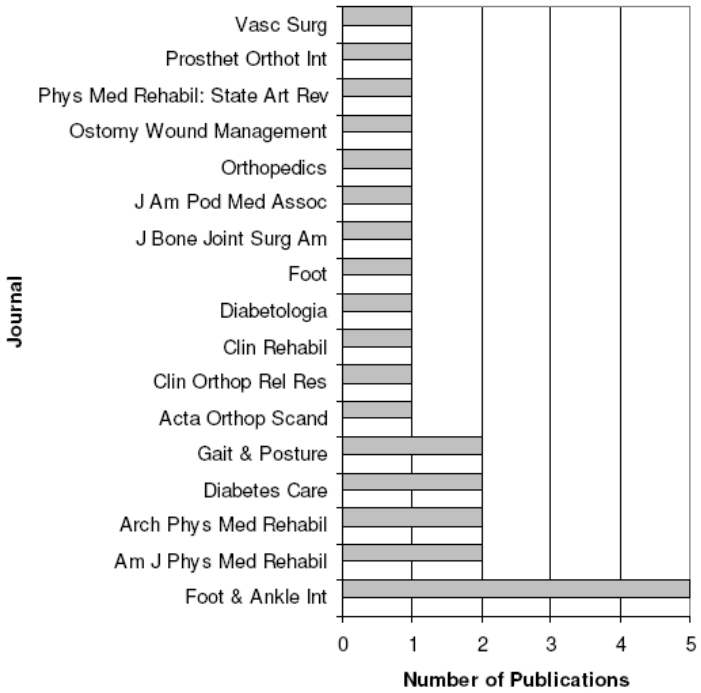

Figure 3 – Example of article demographics (*i.e.*, number of publications selected for review by journal) from an Evidence Report[15]

9. Assess the Quality of the Articles

Research studies in those articles selected for final review should be evaluated by two or more authors for methodological quality. Quality assessment should be performed using an established, standardized format and technique to ensure consistency among reviewers and among SSC Evidence Reports. Experimental and quasi-experimental trials and observational studies should be subjected to a full methodological quality review. Structured reviews and expert opinion articles are not subject to the standardized format, but should be weighed appropriately by the Evidence Report authors.

The Academy has developed a standardized form (Appendix D) to assist reviewers in evaluating the internal and external validity of experimental, quasi-experimental, and observational research. The form indicates 18 potential threats to internal validity (noted as IV-1 through IV-18) and eight potential threats to external validity (noted as EV-1 through EV-8) that must be assessed for each article. Reviewers are asked expand, compress, or modify this list, as needed, to address the topic of interest. The authors should clearly articulate the quality criteria they selected. Once the form has been modified for the topic of interest, the authors are asked to complete the form for each (quasi) experimental trial or observational study included in the Evidence Report. Each criterion listed in the quality assessment form indicates a threat to internal and/or external validity and should be evaluated by the reviewers. Reviewers should also comment on each criterion in the spaces provided in order to best assess the study's overall internal and external validity.

Not all threats apply to all study designs and where appropriate, reviewers should indicate these as non-applicable, "N/A.". For example, experimental group designs should have comparable groups, whereas experimental within-subject designs address this same threat by using a subject as his or her own control. Examples of threats that are "not applicable" to individual study designs are shown in Table 4. This list does not address all possible situations, and therefore reviewers should use their judgment when noting a criterion as "N/A."

Table 4 – Examples of quality threats that are not applicable (N/A) in specific study designs

Study Category	Study Classification	Non-applicable Criteria
(Quasi)Experimental Trials	Group Designs ($E_1 – E_2$)	IV-5
(Quasi)Experimental Trials	Within-Subject Designs ($E_3 – E_5$)	I V-1, I V-2, I V-3, I V-4
Observational Studies	Correlational or Predictive ($O_1 – O_2$)	I V-1, I V-2, I V-3, I V-4, I V-5
Observational Studies	Normative or Longitudinal ($O_3 – O_6$)	I V-1, I V-2, I V-3, I V-4, I V-5

Quality Assessment Form: The quality assessment form contains a list of quality criteria that are to be examined and evaluated by the reviewer. Each listed criterion indicates a threat to internal and/or external validity that should be evaluated by the reviewer. Reviewers should check "Yes" if the threat is adequately addressed, "No" if it is not adequately addressed, and "N/A" if it is not applicable to the study (based on study design). Reviewers should note comments for all threats marked "Yes" or "No" and note the total number of identified threats in the form. It is important to consider that not all threats to internal or external validity carry the same weight. Therefore, the total number of identified threats should not directly infer an overall level of validity. Instead, Evidence Report authors are asked to appropriately weigh the tallied threats when assigning the overall validity of the reviewed articles. Overall internal and external validity should be assessed based upon the number *and* type of threats and correspondingly noted as "High," "Moderate," or "Low" (see below).

- **High** – Indicates that the reviewer has strong confidence in the design (when reviewing internal validity) or applicability (when reviewing external validity) of the reviewed article and that bias introduced by threats to validity identified in the quality evaluation does not compromise this confidence.
- **Moderate** – Designates that the reviewer has confidence in the design/applicability of the reviewed article, but that bias introduced by threats to validity identified in the quality evaluation may limit the confidence in the study design and/or results.
- **Low** – Denotes that the reviewer has little-to-no confidence in the design/applicability of the reviewed article due to strong bias introduced by the threats to validity identified in the quality evaluation.

(Note: It should be noted that the process of quality evaluation is a subjective task, and may vary based upon the experience and background of the Evidence Report authors. Authors are strongly encouraged to review articles independently and then achieve consensus where differences in assessed quality exist.)

Once all of the studies have been evaluated by individual reviewers, a consensus of the quality criteria and the validity assessments should be determined by the lead Evidence Report author. The results may then be combined in tabular form for the Evidence Report (see Section 10, below).

10. Construct a Body of Evidence Table

The consensus results of the study classification and quality assessment should next be combined into a body of evidence table(s). The goal of the body of evidence table(s) is to provide readers with an overview of the quality of the collected literature (See Section 9, above). Because of specific differences in quality criteria between experimental trials and observational studies, an Evidence Report that includes reviewed studies of both types may have more than one body of evidence table. Content and style of the tables is ultimately up to the author(s), but should include all criteria that are critical to assessing the overall quality of the body of evidence (Table 5).

Table 5 – Example of a body of evidence table from a Cochrane Review[16] (Note: Criteria shown were selected by the Cochrane Authors. AAOP Evidence Reports should use the quality criteria IV1-IV18 and EV1-EV8 listed in Appendix C.

Author	Parameters	Subjects (Reason & Level of Amputation, & Age [yr] [Range or Mean ± SD])	Selection					Intervention						Statistical Validity				Total Score	Level of Evidence
			A1	A2	A3	A4	A	B5	B6	B7	B8	B9	B	C10	C11	C13	C		
Barth et al. [13]	Walking speed, step length, cadence, VO_2 (mL/kg/min, mL/kg/m), joint motion (°), time-related variables	3 traumatic TT, 39 ± 10; 3 vascular TT, 64 ± 5	1	1	1	1	4	1	1	0	1	1	4	1	0	0	1	8	B
Boonstra et al. [16]	Walking speed, joint motion (°), time-related variables	9 TT, 20–70	1	0	1	0	2	1	1	0	1	1	4	0	1	1	2	8	B
Casillas et al. [20]	VO_2 (mL/kg/min, mL/kg/m), satisfaction (0–100), walking speed	12 traumatic TT, 50 ± 14; 12 vascular TT, 73 ± 7	1	1	1	0	3	1	1	0	1	1	4	1	1	1	3	10	B
Cortes et al. [3]	Kinetic, kinematic, and time-related variables	8 traumatic TT, 19–49	1	1	1	1	4	1	1	0	1	1	4	0	1	1	2	10	B
Culham et al. [22]	Walking speed, stride length, cadence, time-related variables, knee motion (°)	10 TT (9 vascular, 1 traumatic), 32–79	1	0	1	1	3	1	1	0	1	1	4	1	1	1	3	10	B

Individual articles in the body of evidence table may be listed by date of publication or categorized by other means appropriate for illustrating the overall quality of the body of evidence. Authors may elect to also create additional tables to assist in the synthesis of the available evidence (see Section 11, below).

11. Synthesize the Reviewed Information

Traditionally, synthesis of the reviewed information in a systematic literature review includes an objective evaluation through a meta-analysis, a statistical analysis of data from different studies or sources. Properly conducted meta-analyses require consistency in the acquired data, including such things as sample population, experimental methods, and outcome measures. Given the wide range of such elements in published O&P research, a meta-analysis is often unsuited for synthesis of the data in a SSC Evidence Report. Instead, authors are encouraged to combine data in a format appropriate to the reviewed literature.

Synthesis of the literature is accomplished through the Evidence Report narrative (i.e., main body of the Evidence Report). It is the goal of the narrative to condense the collected, reviewed, and assessed literature into a focused report on the SSC topic. The narrative is often written around (or supported by) additional tables or figures. These items should build upon the body of evidence table(s) and emphasize important aspects of the systematic review. Key elements of the reviewed studies, such as population demographic information, outcome measures, and/or key results (*i.e.*, evidence statements) may be included in the tables (Table 6).

Table 6 – Example of an evidence table from an AAOP State-of-the-Science Conference[17]

Author	Aim	Primary outcome(s) measure	Comparison	Sample selection	Number of subjects (≥20) Nb. "?" means unclear. [Total eligible/total accepting/total providing data]	Mean age (y)	Etiology	Level of amputation	Time from amputation or other milestone (mean unless stated otherwise)
Miller et al., 2001	Comparison of reliability and validity of Houghton, LCI and PEQ mobility subscale	LCI	2 Min TWT, TUG and ABC scale	Single center, consecutive, O/P	For reliability study (Study 1), 55 of 76; for validity study (Study 2), 329 of 427	Study 1 = 58 Study 2 = 60	Study 1: Vascular, 55% Other, 45%; Study 2: Vascular, 53% Other, 47%	Study 1: TTA, 72% TFA, 28%; Study 2: TTA, 74% TFA, 26%; Bilat excluded	Study 1: 7 y (mean); Study 2: 16 y (mean)
Franchignoni et al., 2004	Reliability, validity and responsiveness of LCI	LCI 5	RMI, 10 m TWT, FIM	Prospective, consecutive, 3 center, I/P	50 included, 50 participated	51	Vascular, 32% Trauma, 58% Other, 10%	TTA, 40% TFA, 60% No bilat	Median months from surgery, 7
Treweek and Condie, 1998	To compare BI, Russek's classification, and LCI	Russek's classification	BI and LCI	Convenience, multicenter, O/P	?/938/938	67	Vascular, 87% Trauma, 5% Tumor, 2%	TTA, 74% TFA, 26% Bilat excluded	At d/c
Ryall et al., 2003	To develop a valid measure of mobility suitable for routine use, including monitoring change	SIGAM mobility grades	RMI and TWT	Prospective, single center, O/P	For reliability study, /?/?/62; for validity study, ?/?/200. Data from a sensitivity study were excluded because it involved only 20 patients.	57	For reliability study, Vascular, 32% Trauma, 39% Tumor, 6% Other, 23%; for validity study, Vascular, 32% Trauma, 40% Tumor, 8% Other, 20%	For reliability study: TTA, 56% TFA, 47%; For validity study, TTA, 57% TFA, 41%; Bilat included in both studies	Mean of 5 y post-fitting for reliability study; mean of 18 y for validity study

Similarly, tables can be used to list Evidence Statements that summarize the synthesized information into specific clinical assertions based upon the available evidence (Table 7). These statements may be developed by the Evidence Report author, or by the SSC participants. Such tables are useful for documenting the types and quantities of studies that support a particular clinical observation.

Table 7 – Example of an evidence table that lists outcome statements[15]

#	Statement	Number of rated studies	Level of confidence in outcomes	Relevant section in review
1	PFA affects the temporal and spatial features of gait.	1 x E2 2 x E3 1 x E4 7 x O2 3 x O3	High	4.3
2	PFA with a history of diabetes and vascular disease walk slowly – about 2/3 the speed of healthy control subjects.	2 x E3 5 x O2 3 x O3	High	4.3.3.1
2a	PFA with a history of diabetes and vascular disease walk at a similar velocity to appropriately matched controls.	1 x O2 1 x O3	Moderate	4.3.3.1
2b	PFAs without diabetes or vascular disease walk at a similar velocity to healthy controls.	1 x E2 1 x E4 2 x O2	Moderate	4.3.3.1
2c	PFA walk more slowly as a result of reductions in stride length and/or cadence.	1 x E2 1 x E4 2 x O2 1 x O3	Low	4.3.3.2

Authors may elect to assign confidence ratings to the Evidence Statements, as shown here, in order to provide the reader with an assessment of the overall evidence in support of each statement. Such ratings should only be performed when all the evidence has been gathered and reviewed in the previous steps. While the ratings may be subjective, they should be based upon the knowledge gained by developing (or reading) the Evidence Report.

It is important to recognize that evidence tables and figures may vary. The use, content, and/or format of these are at the discretion of the Evidence Report author(s). Recall, the goal of the Evidence Report narrative and associated evidence figures/tables is to provide conference attendees with a concise overview of the body of literature with respect to the questions proposed (see Section 3, above). Authors are strongly encouraged to review previous AAOP Evidence Reports in order to see how other authors have presented synthesized evidence on other O&P topics.[18] To conclude the Evidence Report narrative, the author(s) are expected to apprise the overall body of evidence and provide a summary of the findings (see Section 12, below).

12. Summarize the Available Evidence

To finalize the Evidence Report, author(s) should strive to summarize the overall body of knowledge examined in the literature review. Authors are encouraged to emphasize those results most applicable to the proposed SSC topic (see Section 1, above) and the SSC questions (see Section 3, above). The format, length, and content of this summary are left to the discretion of the authors, but should, at a minimum, address each of the scientific and clinical questions posed to the SSC panelists.

Once a draft of the Evidence Report is complete, it will be circulated to the SSC participants in advance of the meeting, and will serve to establish the conference agenda, provide background information for the invited presentations, and promote subsequent discussions. Evidence Report authors are required to attend the SSC so as to present their findings from the literature review and to address questions from the participants. Evidence Report authors are encouraged to then incorporate any relevant information discussed at the SSC into the Evidence Report prior to finalizing the document for publication. The finalized Evidence Report will be published as part of the SSC proceedings and will serve as the official literature review of the conference.

SUMMARY

Developing the Evidence Report is a key activity in conducting a State-of-the-Science Conference (SSC) under direction of the American Academy of Orthotists and Prosthetists. Commissioned authors are encouraged to review these Evidence Report Guidelines before initiating this process. Although ultimately, the Evidence Report will be a product of the commissioned author(s), these guidelines serve to ensure a thorough and consistent report is developed for each SSC topic. It should also be noted that preparing the Evidence Report requires a serious investment of time and effort on behalf of the Academy and the selected author(s), as proper development of the report is vital to the success of the conference.

The Evidence Report is a critical component for the facilitation of an American Academy of Orthotists and Prosthetists (AAOP) SSC. It not only serves to provide a comprehensive, systematic review of the scientific literature on a relevant O&P topic, but also helps conference leaders establish the agenda, speakers, and presentations for the conference. The Evidence Report is intended drive pertinent discussions among conference attendees and stand as a documented review of the evidence in support of clinical care, methods, and/or interventions in O&P.

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APPENDIX A – SSC Classification Definitions

AAOP State-of-the-Science Evidence Report
- SSC Classification Definitions -

Identifying and classifying the design of a published study is a critical component in the systematic review of literature. To standardize this process for Academy-sponsored State-of-the-Science Conferences (SSCs), the following study design classification scale (Table 1) and associated descriptions are recommended to classify the study *type* when performing a literature review. Please read the descriptions carefully so as to appreciate the subtle differences among the noted classification levels.

Table 8 – Study Design Classification Scale

Category	Rating	Type of Study
Structured Review	**S_1**	Meta-analysis
	S_2	Systematic review
(Quasi)Experimental Trial	**E_1**	Randomized controlled trial
	E_2	Controlled trial
	E_3	Interrupted time series trial
	E_4	Single subject experimental trial
	E_5	Before-and-after trial
Observational Study	**O_1**	Cohort study
	O_2	Case-control study
	O_3	Cross-sectional study
	O_4	Qualitative study
	O_5	Case series
	O_6	Case study
Expert Opinion	**X_1**	Group consensus
	X_2	Individual opinion

STRUCTURED REVIEWS

Structured reviews are the methodological collection, analysis, and presentation of information from multiple sources. The analysis of the collected information may be statistical or descriptive in nature, which will identify the structured review as a meta-analysis (R_1) or a systematic review (R_2).

Meta-analysis **(S_1):** A statistical analysis that combines the results from multiple studies. Meta-analyses adhere to a structured and appropriate procedure for identifying, including, and analyzing data found in a body of literature.

Systematic review **(S_2):** A comprehensive methodological review and critical appraisal of literature obtained from multiple sources. Systematic reviews adhere to a structured and appropriate procedure for gathering, selecting, evaluating and reporting the evidence found in a body of literature.

EXPERIMENTAL TRIALS

Experimental or quasi-experimental trials are prospective research studies that include one or more subjects, a control or comparison condition, one or more interventions, and data collected at known times. In experimental and quasi-experimental trials, interventions are applied by the researchers. The number of subjects, random assignment of the subject(s) and control(s), and the frequency of data collection will identify a trial as a randomized control trial (E_1), controlled trial (E_2), interrupted time series trial (E_3), single subject experimental trial (E_4), or a controlled before-and-after trial (E_5).

Randomized controlled trial **(E_1):** A prospective experimental study in which subjects are *randomly* assigned to either a control or intervention group. Outcome measures are assessed after an appropriate follow-up time and results are compared between the control and intervention groups.

***Controlled trial* (E_2):** A prospective experimental study in which subjects are *non-randomly* assigned to either a control or intervention group. Outcome measures are assessed after an appropriate follow-up time and results are compared between the control and intervention groups.

***Interrupted time series trial* (E_3)**: A prospective experimental study in which multiple subjects are assigned only to an intervention group. No control group is formed; instead subjects serve as their own control. Subjects are evaluated multiple times before and multiple times after one or more interventions. Outcome measures are assessed at known pre/post intervals and results are compared between the studied conditions.

***Single subject experimental trial* (E_4):** A prospective experimental study in which one subject is given one or more interventions. The subject serves as his/her own control. The subject is evaluated multiple times before and after each intervention. Repeated outcome measures are assessed at known intervals and results are compared between the studied conditions.

***Controlled before-and-after trial* (E_5):** A prospective experimental study in which one or more subjects are assigned to an intervention group. No control group is formed; instead subjects serve as their own control. Subjects are evaluated once before and once after one or more interventions. Outcome measures are assessed after an appropriate follow-up time and results are compared between the studied conditions.

OBSERVATIONAL STUDIES

Observational studies include one or more subjects evaluated at a moment in or over a period of time. In observational studies, interventions are not applied by the researchers. Instead, outcomes and influencing factors are observed in order to draw correlations between them. The timing of the measurement(s), number of subjects, frequency of data collection, and type of data collected will identify an observational study as a cohort study (O_1), case-controlled study (O_2), cross-sectional study (O_3), qualitative method study (O_4), case series (O_5), or case study (O_6).

***Cohort study* (O_1):** A prospective, observational study of subjects that may develop a specific condition. Subjects without the condition at baseline are classified based on exposure to factors that may influence occurrence of the condition. Incidence of the condition is assessed after an appropriate follow-up time (typically long-term). The incidence of the condition in the exposed and unexposed subjects is compared to identify factors that affect the risk of developing the condition.

***Case-controlled study* (O_2):** A retrospective, observational study in which a subject group with an existing condition is compared to a similar subject group that does not have that condition. Information on possible casual factors are obtained from subject histories and used to evaluate the relationships between those factors and the risk of developing the condition of interest.

***Cross-sectional study* (O_3):** A descriptive, observational study in which one or more subject groups are evaluated at one point in time to describe the population(s) of interest, assess the prevalence of a condition of interest, or evaluate the correlations between possible risk factors and a condition of interest.

***Qualitative study* (O_4):** A descriptive, observational study in which a subject group is evaluated through subjective, open-ended questions and interview techniques.

***Case series* (O_5):** A descriptive, observational study of the diagnosis, prognosis, treatment, and/or outcome of a subject group with the same (or similar aspects of a) condition.

***Case study* (O_6):** A descriptive, observational study of the diagnosis, prognosis, treatment, and/or outcome of a single subject.

EXPERT OPINIONS

Expert opinions are peer-reviewed descriptive documents by acknowledged experts. The extent of agreement and synthesis of results will identify an expert opinion as a group consensus (X_1) or an individual opinion (X_2).

***Group consensus* (X_1):** A peer-reviewed, descriptive synthesis of the results from a conference with multiple experts in a particular topic area. This may also include unstructured literature reviews that were not conducted with a comprehensive methodology consistent with a systematic review (R_2).

***Individual opinion* (X_2):** A peer-reviewed descriptive document by one or more recognized experts in a particular topic area.

APPENDIX B – Example of a Systematic Review Methodology

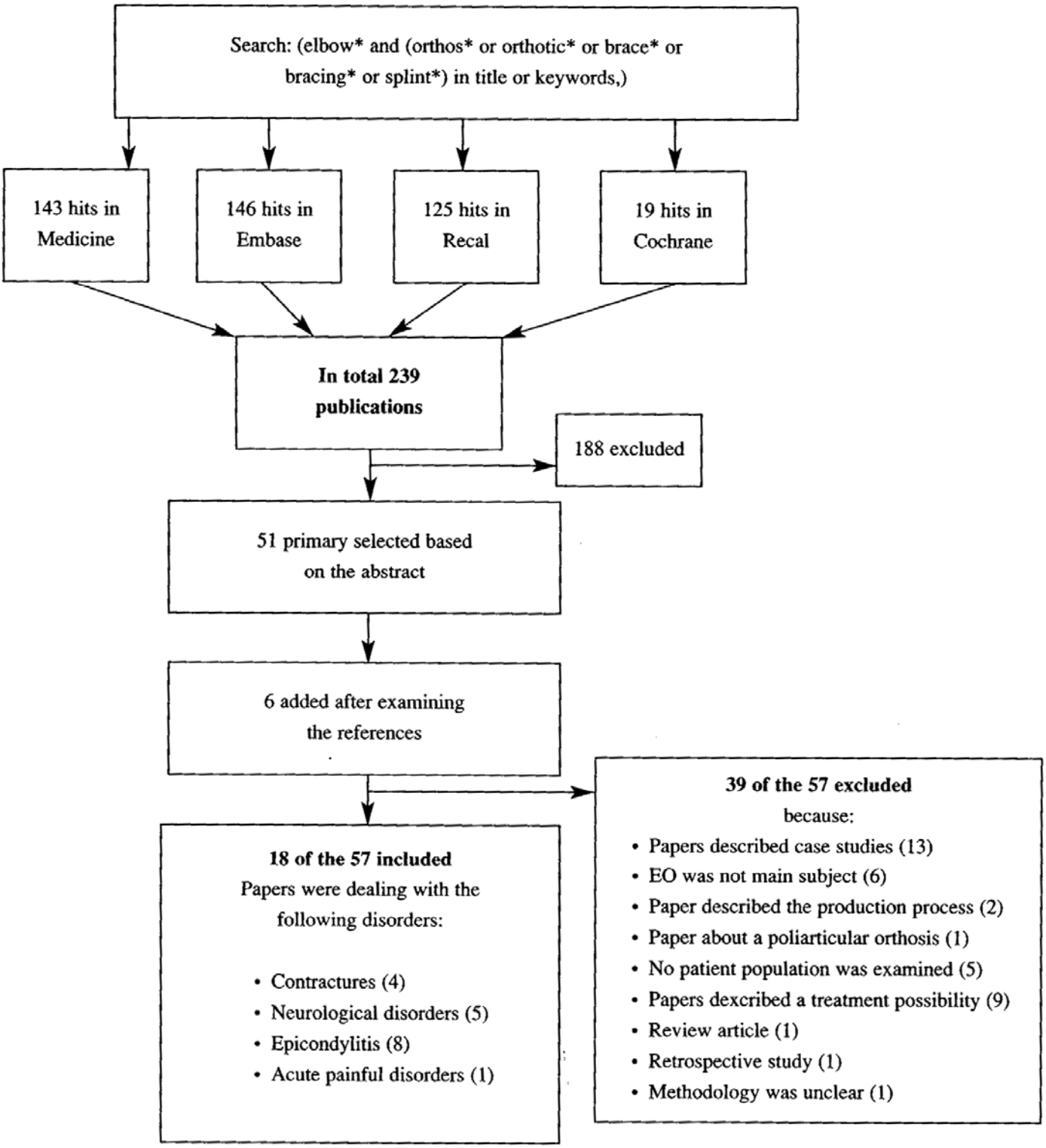

Figure B1 – Example of a systematic review methodology[19]

APPENDIX C – Example of an Exclusion List

Here is an example of an exclusion list. Similar tables may be included in the Evidence Report to note those studies that were obtained in the search, but were ultimately not included in the review and report findings.

Table C1 – Excluded studies and reason for exclusion[17]

Excluded Studies	Reason for Exclusion
Atkinson, 2002	Newsletter, predictive
Burton and Saunders, 2002	Newsletter
Campbell and Ridler, 1996	Survey
Cyril et al., 2002	Poster
Davies and Datta, 2003	Survey
Demet et al., 2003	Mixed UL and LL amputees
Donovan-Hall et al., 2002	Cosmesis, $n < 20$
Gallagher and Maclachlan, 2000	QOL relative to amputation not prosthetic use
Gardiner et al., 2002	$n < 20$
Gauthier–Gagnon and Grise, 1994	Pre-1995
Gauthier–Gagnon et al., 1999	Survey, predictive
Gauthier–Gagnon et al., 1998	Survey, predictive
Geertzen et al., 2001	Nonsystematic literature review
Grieve and Lankhorst, 1996	Survey (SIP)
Hagberg and Branemark, 2001	Survey (SF-36)
Hanspal and Fisher, 1991	Cognitive and psychomotor, pre-1995
Hoffman et al., 2002	Survey (SF-36)
Hoogendoom and Van der Werken, 2001	Mixed groups
Horgan and MacLachlan, 2004	OM not primary focus
Kent and Fyfe, 1999	Narrative review
Legro et al., 1999	Survey (PEQ, SF-36)
Linn et al., 1998	$n < 20$, mixed group, survey
Melchiorre et al., 1996	Survey
Muecke et al., 1992	Pre-1995
Munin et al., 2001	No OM, predictive
Neumann et al., 1998	Survey
Peters et al., 2001	Survey, $n < 20$
Rommers et al., 2001	Systematic review
Rushton and Miller, 2002	Goal attainment scaling, $n < 20$
Schoppen et al., 2003	Predictive
Turney et al., 2001	Survey
Williams et al., 1999	Newsletter

UL = upper limb; LL = lower limb; QOL = quality of life; Pre1995 = published before 1995; SIP = Sickness Impact Profile; SF-36 = Short Form 36; OM = outcome measure; PEQ = Prosthesis Evaluation Questionnaire.

APPENDIX D – SSC Quality Assessment Form

AAOP State-of-the-Science Evidence Report
- SSC Quality Assessment Form -

Instructions: Reviewers are asked to complete the following form for each experimental trial or observational study included in the Evidence Report. Each of the listed criterion indicate a threat to internal and/or external validity that should be evaluated by the reviewer. Reviewers should check "**Yes**" if the threat is adequately addressed, "**No**" if it is not adequately addressed, and "**N/A**" if it is not applicable to the study (based on study design). Reviewers should note comments for all threats marked "Yes" or "No" and note the total number of identified threats. Overall internal and external validity should be assessed based upon the number and type of tallied threats and correspondingly noted as "**High**," "**Moderate**," or "**Low**."

Internal Validity is the degree to which a study demonstrates a causal relationship between the independent and dependent variable(s). This assessment evaluates the likelihood that the experimental treatment was responsible for the observed change(s) reported in the study and that extraneous factors are not responsible for the results. Threats to internal validity vary by study design, and therefore not all threats are applicable to all studies. Reviewers are asked to assess overall internal validity using the checklist below.

Criterion – Internal Validity	**Yes**	**No**	**N/A**	**Comments**
IV-1. Comparison or control group used				
IV-2. Groups formed by random assignment				
IV-3. Groups comparable at baseline				
IV-4. Groups handled the same way				
IV-5. Control/comparison group appropriate				
IV-6. Intervention(s) blinded				
IV-7. Inclusion criteria appropriate				
IV-8. Exclusion criteria appropriate				
IV-9. Protocol addresses fatigue and learning				
IV-10. Protocol addresses accommodation and washout				
IV-11. Attrition explained and less than 20%				
IV-12. Attrition equal between groups				
IV-13. Outcome measures reliable				
IV-14. Statistical analysis appropriate				
IV-15. Effect size reported				
IV-16. Statistical significance reported				
IV-17. Statistical power adequate				
IV-18. Free from conflicts of interest				
Total number of threats identified				
Overall assessment of internal validity (circle one)	High		Moderate	Low

External Validity is the degree to which the study results can be generalized to persons, settings, and/or times outside of the situation measured in the experimental trial. This assessment evaluates the likelihood that the same results would be achieved for other patients, in other locations, and/or at different times than those measured by the study. Threats to external validity are common for most experimental study designs. Reviewers are asked to assess overall external validity using the checklist below.

Criterion – External Validity	**Yes**	**No**	**N/A**	**Comments**
EV-1. Sample characteristics adequately described				
EV-2. Sample representative of the target population				
EV-3. Outcome measures adequately described				
EV-4. Outcome measures valid for this study				
EV-5. Intervention adequately described				
EV-6. Findings clinically significant/relevant				
EV-7. Conclusions placed in context of existing literature				
EV-8. Conclusions supported by findings				
Total number of threats identified				
Overall assessment of external validity (circle one)	High		Moderate	Low

Additional Notes