AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

PROCESS PROCEDURE
LIBRARIAN AND RESEARCH ANALYST RESPONSIBILITIES
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1.0 PURPOSE
The purpose of this document is to outline the responsibilities following an introductory guideline meeting. The following duties should be taken as a general overview rather than a step-by-step process as each unique guideline presents unique tactical approaches.

2.0 SCOPE
This procedure applies to all guidelines developed by the American Academy of Orthopaedic Surgeons Guidelines Unit and all research analysts, librarians or research interns developing these documents.

3.0 RESPONSIBILITIES
3.1 The medical librarian is responsible for conducting literature searches, maintaining a unique reference manager database and recalling relevant literature for a guideline topic.

3.2 Research analysts are responsible for requesting and reviewing articles, creation and maintenance of an Access database, data extraction, statistical analyses, guideline draft write-up and PowerPoint presentations for each guideline.

3.3 The CPG Manager is responsible for reviewing completed draft guidelines and PowerPoint presentations.

3.4 The AAOS Director of Research must approve all changes to this procedure. (see section 11.0 Chain of Approval)

4.0 APPLICATION
4.1 The intent of this procedure is to insure that all guidelines follow the appropriate steps of the guideline development process. The steps outlined help ensure guidelines are completed in a timely manner.

4.2 Individuals responsible for each step of the guideline development process are highlighted. Questions pertaining to any step of the guideline development process should be directed to the CPG manager or the appropriate (referenced) individual(s).

5.0 REFERENCES
5.1 Computer Procedure 1: Importing Citations into Reference Manager Databases and/or Using Cite While You Write (.\Computer Procedures\Guideline Computer Procedures 1 RefMan and CWYW (v0.0).doc)


2 8/22/2011
5.3 Computer Procedure 3: Article Requests and Inclusion/Exclusion (..\Computer Procedures\Guideline Computer Procedures 3 Article Requests and Inclusion_Exclusion (v1.0).doc)

6.0 SUMMARY OF METHODS

6.1 Librarian
   6.1.1 Use the preliminary recommendations in creating a search strategy.
   6.1.2 Search all relevant databases and include citations in a Reference Manager database.
   6.1.3 Supply Research Analyst(s) with abstracts for review.
   6.1.4 Run additional searches as necessary (unique and updated).

6.2 Research Analyst(s)
   6.2.1 Review abstracts and request full text articles from the Medical Librarian based on the applicable inclusion criteria.
   6.2.2 Review full text articles for relevancy, assign to appropriate recommendations, and assign a preliminary level of evidence for each outcome.
   6.2.3 Extract all necessary information from included articles into a Microsoft Access database.
   6.2.4 Conduct appropriate statistical analyses using STATA, Excel, etc.
   6.2.5 Draft an initial guideline report to be reviewed by the CPG Manager.
   6.2.6 Create a PowerPoint presentation addressing the available evidence on a recommendation by recommendation level.

7.0 APPLICABLE SOFTWARE

7.1 Microsoft Office (Word, Excel, Access, PowerPoint) 2003

7.2 Reference Manager 12

7.3 STATA 10

7.4 G-Power 3.0

7.5 Adobe Professional

8.0 ESSENTIAL REQUIREMENTS
8.1 Appropriate software must be installed on all Research Analysts’ computers.

8.2 It is essential that all Access databases are properly maintained and updated.

8.3 It is essential that the unique Reference Manager database is clearly identified and maintained. Failure to do so will interfere with the “cite-while-you-write” feature of Reference Manager during the guideline write-up process.

8.4 Research analysts should maintain all files (electronic and hard copies) for auditing purposes including, but not limited to: included/excluded articles with mark-ups, draft guideline documents, correspondence with internal staff and work group members regarding any recommendation or guideline, STATA syntax for each analysis run.

9.0 PRECAUTIONS

9.1 A single Reference Manager database should be created for each guideline and will include updated and additional unique search results. The creation of multiple Reference Manager databases can result in inappropriate article numbering, confusion among analysts for database usage, and error messages while using the “cite-while-you-write” feature of Reference Manager.

9.2 Research Analysts should save all old versions of draft documents (guideline and PowerPoint presentations).

10.0 PROCEDURE

10.1 Literature Search

10.1.1 Using the preliminary recommendations, inclusion/exclusion criteria, and synonyms created at the “Introductory Meeting”, the Medical Librarian creates an initial guideline search strategy. Initial search strategies should be created within one month following the “Introductory Meeting.”

10.1.2 The search strategy (saved as a Microsoft Word document) is posted by the research analysts to the SharePoint portal for the work group to review.

10.1.3 The CPG Manager notifies the work group of the posting and requests input from the work group. The work group has approximately two weeks to review the posted list. If changes are required or requested, the CPG Manager will notify the Medical Librarian who will edit the search terms as needed.

10.1.4 Once the workgroup has reviewed the search strategy, the Medical Librarian searches the following electronic databases:
- MEDLINE
- Embase
- Any other databases as necessary (CINAHL, Cochrane Library etc.)
10.1.5 The Medical Librarian records the search strategy used for each database searched. Appendices of all completed guidelines include the search strategies.

10.1.6 The Medical Librarian provides the research analysts with a complete list of all abstracts found in the search. This list is a result of all searches compiled into a Reference Manager database and “de-duplicated.”

10.1.7 The research analysts, assigned to a guideline topic, review the abstract list and determines, based on the preliminary recommendations and final inclusion criteria for a guideline, what full-text studies to retrieve based on the information in the abstract.

10.1.8 The research analyst retrieves the full-text article for review when the abstract presents insufficient or unclear information or when a clear determination “for-or-against recall” is not clear.

10.1.9 The Medical Librarian is responsible for:
- Tracking all full text studies requested by an analyst
- Ordering all full-text studies requested
- Cataloguing the full-text studies received
- Forwarding all studies to the appropriate research analyst when received.

10.2 Database Update
10.2.1 The research analyst designs a Microsoft Access database specifically for the guideline by modifying an existing database stored on the shared General Drive (G: Drive).

10.2.2 In order to aid the process of reviewing abstracts and recalling full-text articles, the research analyst determines the most effective manner to organize abstracted data using Microsoft Access, Microsoft Excel or both.

10.2.3 The research analyst adds fields to the database that correspond to the specifications requested by the workgroup.

10.2.4 The research analyst enters articles requested, articles retrieved and extracted data into the Access Database. For detailed information regarding this process, see the AAOS Computer Procedure “Importing Citations from Reference Manager to Microsoft Access Databases.”

10.3 Review of Full-Text Articles
10.3.1 The lead guideline research analyst reads the methods section and results section of each full text article.
10.3.2 The research analyst immediately excludes an article if it does not meet the inclusion criteria determined at the “Introductory Meeting” by the Workgroup or is not relevant to any of the preliminary recommendations.

10.3.3 The research analyst records the reason for exclusion in the Microsoft Access database.

10.3.4 The research analyst consults another analyst for consensus when the full-text article presents insufficient or unclear information and if it is unclear if a study is relevant to the guideline.

10.3.5 The research analyst labels included articles with the preliminary recommendation number to which it corresponds.

10.3.6 As research analysts exclude or assign articles to preliminary recommendations, they will update the inclusion status of all articles in Microsoft Access.

10.3.7 The research analyst reviews the bibliographies of included studies for additional articles that were not recalled/identified in the original search. Note: If the lead analyst finds that too many articles were not identified based upon bibliography reviews, the Medical Librarian should be consulted and a new search strategy compiled.

10.3.8 The research analyst will assign a preliminary level of evidence to each included article while reviewing the articles for inclusion in the guideline.

10.3.9 The research analyst creates a reference book of all “Included Articles” for a guideline. The reference book should contain unmarked copies of the studies.

10.3.10 The “Included Articles” reference book contains a hard copy of all included studies for a guideline and should be organized by recommendation. Multiple copies of some studies may need to be made if the study is included to answer more than one recommendation.

10.4 Article Abstraction

10.4.1 The research analyst abstracts data pertaining to any patient-oriented outcome in the study.

10.4.2 The research analyst will abstract data pertaining to other outcomes identified by the workgroup as relevant to the guideline.

10.4.3 The research analyst extracts the relevant data into the Access database or Microsoft Excel.
10.4.4 Data that may be abstracted for all guideline topics include:
- Study design
- Number of patients
- Level of evidence of a study
- Randomization procedure
- Blinding procedure
- Follow-up characteristics
- Adverse events
- Funding information
- Outcome data

10.5 Data Analyses
10.5.1 Data analyses is performed using Stata 10, Microsoft Excel, SPSS, and any other statistical software available to the research analyst.

10.5.2 The methods section of all guidelines includes a list of all statistical software programs used for analysis.

10.6 Generating Evidence Tables
10.6.1 Using Microsoft Access and Excel software, the research analyst creates tables summarizing the statistical data for each recommendation.

10.6.2 The research analyst also creates supporting tables illustrating the Included/Excluded Articles, Quality and Design, Funding Sources and Study Data for applicable guidelines.

10.7 Writing the Evidence Report
10.7.1 As data analysis is completed, the research analyst writes the evidence report using the data analyzed for each simulated recommendation.

10.7.2 The basic format of an AAOS guideline can be found in the most current version of the guideline template.

10.7.3 Research analysts update the methods section, literature search, study selection section, and statistical methods section with specific information relevant to the guideline.

10.7.4 The results section contains the data, analysis, and graphs (created during data analysis) under the preliminary recommendation that the analyses were performed to support.

10.7.5 The results section also contains the level of evidence, descriptive information about the trials, and recommendation grade assigned by the research analyst.
10.7.6 Using the current tools and rules for grading evidence, the research analyst will assign an initial grade of recommendation to each preliminary recommendation.

10.7.7 The first paragraph of a rationale for all recommendations is written in the following order:

- If we make a recommendation, the first paragraph in the rationale should explain why we want to recommend the intervention.
- If the analysis contains several levels of analyses, refer to Level I evidence first, Level II evidence next, etc. The best available evidence should always be described first because it is the evidence we have the most confidence in.
- Report the number of supporting studies, again in order of the best available evidence.
- Report the quality of the supporting studies.
- Explain the reason for downgrading the quality of evidence.

10.7.8 Identify authors on all illustrations, tables and graphs.

10.7.9 Do not use the passive voice.

10.8 Calculations

10.8.1 The type of statistical tests performed depends on the data compiled from the included studies, the study design of the best available evidence and the outcomes considered important by the guideline physician workgroup.

10.8.2 Whenever possible, research analysts evaluate outcomes using the effect size, minimally statistical significant difference (MCID), and the minimum clinically important improvement (MCII).

10.8.3 Effect sizes are calculated using the STATA “metan” command with the “hedges” modifier (specifying a Hedges g calculation).

10.8.4 When an outcome has a known MCII, calculate study power using 80% power and a two-tailed 95% confidence interval (software: G-Power).

10.8.5 Additional statistical tests often include:

- Odds Ratios (OR): to compare the measure of association among treatments
- T-test: to compare the difference between means
- ANOVA: to compare the difference between means
- Meta-analysis

10.9 PowerPoint Presentation
10.9.1 The research analyst creates slides using Microsoft PowerPoint that summarize the findings for each simulated recommendation in the guideline.

10.9.2 The research analyst posts the preliminary presentation to the shared general drive two to four weeks prior to the final meeting for AAOS staff to review.

10.9.3 The AAOS CPG Manager and Director of Research will review the presentation with the research analyst, edit the presentation as necessary and add slides for additional clarification.

10.9.4 Save the final PowerPoint presentation to both the shared general drive and a flash drive for the final recommendation meeting.

11.0 CHAIN OF APPROVAL

Approved By:
Charles M. Turkelson Ph.D.
AAOS Director of Research and Scientific Affairs

Janet L. Wies MPH
AAOS Clinical Practice Guidelines Manager

Signatures available upon request.