Guidelines for Effective Literature Analyses: An Agency Perspective

Doug Taylor, Nipa Patel, Cindy Busch, Gina Mushrock, Monica Salvadore, and Philip Sjostedt

The Medicine Group, 41 N. Main Street, New Hope, PA 18938

Abstract

OBJECTIVE

To create a uniform approach to the development of a scientific literature analysis, incorporating the best practices of professional organizations, scientific literature, and evidence-based medicine.

RESEARCH DESIGN AND METHODS

A search of PubMed, EMBASE, CINAHL, and other scientific literature databases for protocols and methods in the literature, combined with a search for guidance documents from organizations including the American Medical Writers Association, Cochrane Collaboration, the American Medical Association, government agencies, and universities, revealed a preliminary list of procedures for conducting scientific literature analyses. These results were examined by internal medical information specialists and then combined into a suite of guidelines that were distributed to medical writers for feedback and approval. A second round of review, from scientific and medical experts, preceded the final process guidelines, which were circulated to industry professionals.

RESULTS

The result is a guidance document that provides all medical writing personnel with a step-by-step method to organize and complete a scientific literature analysis. The guidelines provide staff with a standardized operating procedure for:

1. Conducting preliminary MeSH searches
2. Focusing searches on a specific therapeutic area or audience
3. Completing qualitative and quantitative analysis on publication type, frequency, and global distribution
4. Incorporating reviewer comments after multiple draft reviews
5. Delivering a focused, scientifically sound product

CONCLUSIONS

Guidelines for conducting scientific literature analyses vary among organizations, resulting in incomplete or inconsistent reports. Developing a standardized approach for internal and external stakeholders provides a global template for scientific literature analyses that is applicable to all parties.

Background

- Conducting a scientific literature review is a critical step in the research process. There is considerable variability in guidelines for searches and analyses of biomedical literature, with no widely used systematic template. In many cases, guidance documents are exclusive to specific organizations or companies and do not translate successfully to other groups
- Scientific literature reviews can represent a large portion of a medical communication agency's workload, and creating a scientifically rigorous, peer-reviewed, and reproducible process saves time, resources, and minimizes research bias, considered a weakness of poorly conceived analyses[1,2]
- Different types of analyses – systematic versus non-systematic, qualitative versus quantitative, and narrative reviews – require different sets of guidance based on best practices across the industry (**Table 1**)[3]

Table 1. Systematic Reviews Versus Traditional Narrative Reviews

	Good Quality Systematic Reviews	Traditional Narrative Reviews
Deciding on review question	Start with clear question to be answered or hypothesis to be tested	May also start with clear question to be answered, but they more often involve general discussion of subject with no stated hypothesis
Searching for relevant studies	Strive to locate all relevant published and unpublished studies to limit impact of publication and other biases	Do not usually attempt to locate all relevant literature
Deciding which studies to include and exclude	Involve explicit description of what types of studies are to be included to limit selection bias on behalf of reviewer	Usually do not describe why certain studies are included and others excluded
Assessing study quality	Examine in systematic manner methods used in primary studies, and investigate potential biases in those studies and sources of heterogeneity between study results	Often do not consider differences in study methods or study quality
Synthesizing study results	Base their conclusions on those studies which are most methodologically sound	Often do not differentiate between methodologically sound and unsound studies

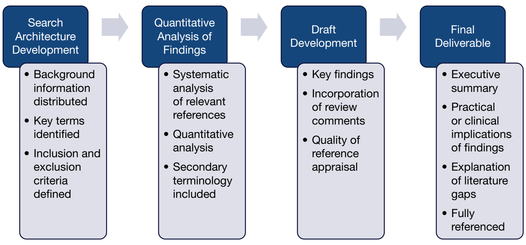
Adapted from Petticrew M. Systematic reviews from astronomy to zoology: myths and misconceptions. *BMJ*. 2011;322(7278):98–101.

- The Cochrane Handbook for Systematic Reviews of Interventions details the hallmarks of a successful systematic review, including *"a clearly stated set of objectives with pre-defined eligibility criteria for studies; an explicit reproducible methodology; a systematic search that attempts to identify all studies that would meet the eligibility criteria."*[1]
- The need for a clearly defined, peer-reviewed, reproducible protocol for conducting a scientific literature analysis is apparent due to considerable variability in project scope, research architecture, research staff experience, and overall search hypothesis

Purpose

- The medical and editorial teams at The Medicine Group sought to combine peer-reviewed guidance documents from MEDLINE®, EMBASE, CINAHL, and other scientific and medical literature databases with current industry standards to create and implement a company-wide standard operating procedure (SOP) for all literature search and analysis activities
- In order for the guidance document to be effective, it was determined that the following criteria must be satisfied:
  - The SOP must be reviewed by medical writers, medical strategists, information specialists, and editorial contributors to ensure a comprehensive guide for each department is available at every step (**Figure 1**)

Figure 1. The Medicine Group's Literature Analysis Process



  - The SOP must define the roles of individual cohorts throughout the literature review process (**Figure 2**)
  - The SOP must incorporate input from all internal and external stakeholders throughout the literature analysis development process

Figure 2. Role of Each Department Throughout the Literature Review Process

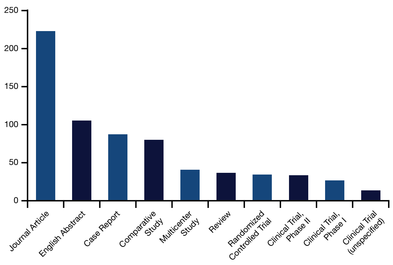
Methods

- The authors conducted a search of PubMed, MEDLINE®, CINAHL, and EMBASE for guidance documents published in peer-reviewed scientific journals in order to capture all relevant guidelines published in the last 15 years
- The following search terms were utilized:
  - **Keywords:** systematic review; literature review; guidelines; literature search; literature analysis
  - **Language:** English
  - **Date range:** 1998 to 2013
  - **Article type:** Guideline; Practice Guideline; Review; Scientific Integrity Review; Systematic Review; Technical Report
- Further searches of professional organizations such as the American Medical Writer's Association (AMWA), the American Medical Association (AMA), International Society for Medical Publication Professionals (ISMPP), European Medical Writer's Association (EMWA), and Board of Editors in the Life Sciences (BELS) revealed a variety of industry protocols that feature key elements of literature analyses
- An in-depth analysis of methods employed by the Cochrane Collaboration and other academic organizations focusing on evidence-based care (such as the University of York Centre for Reviews and Dissemination) formed the basis for the protocol
- These findings were analyzed by personnel in the Publications, Medical Information, Medical Writing, and Medical Strataegy departments, who identified the necessary practices to form the SOP template
- The protocol's first draft was circulated to yield feedback across all internal departments
  - Medical Strategy identified the overall scope and scale of the process
  - Medical Information set the limits, MeSH or EMTREE search terms, and recorded all search architecture information
  - Medical Writing reviewed preliminary search results for each topic and identified which articles, guidelines, and reports should be included for in-depth analysis
  - Publications determined a process that most accurately reflects the industry standard in terms of timelines, deliverables, and costs

Procedures

1. Search Hypothesis
   a. A comprehensive search hypothesis is developed and agreed on by all key stakeholders prior to initial search to ensure complete alignment of the analysis objectives
   b. Key questions to be answered by the results of the scientific literature search are developed in tandem with the study hypothesis
2. Search Architecture
   a. Scope, time frame, parameters, key MeSH terms, and general inclusion and exclusion criteria for the analysis are discussed with all key stakeholders before any search is conducted to ensure appropriateness of the search
   b. Background information on the subject is gathered and read before any search is undertaken, providing an introduction of the material to all stakeholders[4]
   c. The complete range of key search terms for each concept is identified, including acronyms, synonyms, and differences in terminology and spelling[5]
   d. Search strings are created by Medical Information staff and circulated to Medical Strategy and Medical Writing team members for approval prior to conducting initial searches
   e. The reference identification process incorporates two distinct and intentionally overlapping methods:
      i. A protocol-driven search, defined at the outset of the study; and
      ii. "Snowballing," whereby relevant articles are selected from reference lists of articles identified during protocol-driven searches[6]
   f. Abstracts of results are presented to medical writers, who identify relevant articles warranting comprehensive analysis
   g. Search strings are refined after initial results are distributed to medical writers to capture any additional salient information not included in the preliminary search[7]
   h. Key MEDLINE® indicators for each identified publication are cataloged in a centralized database to enable analysis of publication type, frequency, top journals, MeSH/EMTREE terms, and authorship
3. Quantitative Analysis of Findings
   a. Articles identified by members of the Medical Writing and Strategy teams as being informative and relevant to the overall goal of the literature search are quantitatively analyzed, including:
      i. Publication Month/Year
      ii. Journal
      iii. Publication Type
      iv. First Author
      v. Country of First Author
      vi. Supporting Author(s)
      vii. Country of Supporting Author(s)
      viii. Keywords
   b. Search string is evaluated and refined, based on the initial quantitative assessment
   c. Additional secondary inclusion and exclusion criteria are incorporated to further refine the search, based on the relative volume or paucity of data, and to include terminology not previously apparent

Figure 3. Quantitative Analysis of Preliminary Findings



4. Qualitative Assessment
   a. A comprehensive qualitative analysis is undertaken by the Medical Information department, with the results based on the overall study hypothesis, key questions, and search architecture
   b. Evidence is evaluated for its scientific and clinical rigor, using the GRADE standardized evaluation criteria[8–10]*
   c. A cross-comparative assessment of key scientific and medical claims is conducted to assess consensus or conflict in evidence
   d. Conclusions and key scientific/medical claims for each article are written and incorporated into a centralized database (See 2.h above)
   e. Based on stakeholder input, assessment of key scientific and medical claims may be reviewed by an external, third-party expert
5. Draft Development
   a. The executive summary is an essential part of the report, although a structured framework throughout draft development is critical[11]
   b. An appraisal of the quality and quantity of the references studied and an analysis of the strengths and weaknesses of the evidence, including paucity and bias, are included in the summary[11]
   c. The practical implications of the review's findings are outlined in detail
   d. Comments from key stakeholders and reviewers are incorporated through each stage of draft development
6. Final Delivery
   a. The scope and specifics of the final deliverable are established before any literature analysis is started, with the mutual understanding that such projects are necessarily fluid and will change depending on early findings
   b. Qualitative data analysis is accompanied by an executive summary stating the major findings of the review and identifying potential message gaps in the current literature
   c. All references included in the analysis are accurately cited and made available to all stakeholders upon request

*Sources: (1) The GRADE working group. Grading quality of evidence and strength of recommendations.[8] (2) The GRADE working group. Systems for grading the quality of evidence and the strength of recommendations I: Critical appraisal of existing approaches.[9] (3) The GRADE working group. Systems for grading the quality of evidence and the strength of recommendations II: A pilot study of a new system for grading the quality of evidence and the strength of recommendations.[10]

Conclusions

- Successful literature analyses represent the culmination of a carefully designed and meticulously implemented process
- Although significant variability exists among academic and industry guidance documents, a reliable framework for literature analysis emerges with a focus on accurate and dynamic search architecture, explicit inclusion and exclusion criteria, and a consistent, easily reproduced methodology
- The goal of any literature search is to provide stakeholders with the most current evidence; hence, occasional updates are warranted. Although there is no standard timeframe for revisions to literature analyses, Shojania *et al.*, cited the median survival for relevance as 5.5 years and called for incorporating more recent data within 1 year of completion[12]

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- All authors reviewed the primary data and contributed equally to the development of The Medicine Group's literature analysis protocol and this poster

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