



Backing Up Your Statements

How To Perform Literature Searches To Prove Your Points

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(CHEST 2009; 136:1432–1434)

Very often when I am reviewing a manuscript or a regulatory document, I will venture on a statement that I believe requires a reference. More often than not, the answer to my author query is “Everyone knows that . . .” or “The literature shows that . . .” I am reluctant to be argumentative, but I did not know that and would be interested in seeing the literature that shows that!

Whether an author is attempting to validate his/her work in the discussion section of a research paper or is preparing to write a comprehensive review article; or whether a sponsor is attempting to answer questions from a regulatory agency or set the stage for a new product or indication, caution is advised when glibly stating that “current published literature shows that . . .”

When I read this statement, I wonder: (1) Does the literature really show this? (2) Can the author prove it in an unbiased way? And (3) how robust is the “proof” (*ie*, how many published articles back up this statement)? Granted, some things are accepted at face value in science (*eg*, DNA and gravity), but for other statements, particularly ones that are favorable to an author’s or drug sponsor’s work, it is useful to back up the claims with valid literature references. I have discussed references in a previous article¹ and will not repeat caveats on references, except to emphasize that comments concerning, for example, meeting abstracts, posters, and publications in languages one does not read are relevant to literature searches.

Manuscript received July 8, 2009; revision accepted July 17, 2009.

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DOI: 10.1378/chest.09-1615

Many scientists have excellent established protocols, as it were, for conducting literature searches; others may never have considered the need or the process. This article suggests some techniques that I have found to be useful, but certainly other techniques accomplish the same goal. What is important is to have a method that produces the needed results and that it is used consistently.

MAIN POINTS TO CONSIDER

The Basics of Literature Searches

If at all possible, and I would certainly encourage this approach for a document that will be used in support of a regulatory submission, a professional information specialist should be engaged. The author, however, must have a clear idea of the objective of the search and should give some thought to the selection of databases, years of inclusion of the databases, languages to include, and format (*ie*, meeting abstracts, original papers, review articles) before engaging the information specialist and should work with the specialist to refine the search strategy, if necessary. It must be noted, however, that PubMed is a free, online service that is excellent for literature searches for authors who are unable to engage a professional. A tutorial is available at <http://www.nlm.nih.gov/bsd/disted/pubmed.html>.

Process

After the search terms, databases, and date range have been defined and the information specialist or searcher provides a comprehensive list of the found articles in abstract form, the author’s first step is to review the output. Another search will possibly be needed to refine the search terms, databases, or date range. Any article that appears to meet the criteria should be read in full and summarized in a uniform manner (Table 1). Reading the abstract alone will not suffice because the abstract does not provide all

Table 1—Example of a Standard Format for Summarizing Articles Found in a Literature Search

| Format | Citation |
|-----------------------|---|
| Citation | Full citation as it would appear in the published article or regulatory document reference list |
| Objective | As stated in the article |
| Patients | Number and disease state |
| Intervention | Drugs and dosages |
| Study design | As stated in article |
| Results | As stated in article |
| Disease-free survival | |
| Overall survival | |
| Time to progression | |
| Safety | |
| Conclusion | As stated in article |

This table is an example for a chemotherapy indication, in which data on several specific outcomes were required. All information should be condensed to fit on one page.

of the necessary information. By preparing a uniform review of the identified citations, the author is able to ensure that the search both adequately addressed the question and contains all the important information easily accessible for comparison.

It is important that the audience—whether journal readers or regulatory agencies—understand that the author has undertaken a comprehensive literature search for a review article. The information can be added in a methods section or an appendix (for examples, see the studies by Welch and Foote² and Smalling et al³). Table 2 provides one suggested format.

The results of the literature search should be reported, either in the results section or in an appendix. Table 3 shows sample text that explains the number of citations found, read and determined to be relevant, and eventually used in the review article or regulatory submission.

Potential Problems

Literature searches can produce disparate results, particularly when searches are done by different

Table 2—Sample Language To Be Added to Methods Section, Appendix, or Other Section of a Review Article or Regulatory Document To Explain How the Literature Search Was Accomplished

A literature search was done by [information specialists] [hired by or in the library of] [Pharma Co; city, state]. The search was entitled “[add title of search].” The literature databases searched on [day month year] were [list databases (eg, MEDLINE [MEYY and ME95], CANCERLIT [CANC], EMBASE [EMYY and EM950], and EMBASE ALERT [EMBA])]. The publication date coverage was [give starting year] to [ending year], with no language restrictions. The patient population base included men and women [or children < 14 yr or adults > 60 years].

Table 3—Sample Language To Be Added to the Results Section, Appendix, or Other Section of a Review Article or Regulatory Document To Report the Findings of the Literature Search

[Number of citations] were found. The abstracts for all citations were read, and, if relevant, a copy of the entire publication was obtained. We believe that [xx] of the [xx] citations were relevant. [It may be necessary to add a caveat: Some references were found to be laboratory experiments and not clinical studies; these were not summarized]. All remaining articles were read, and the following information was obtained: [customize to required search: objective, study design, and results].

people at different times with different databases. A literature search is considered valid if it is reproducible. Depending on the databases used, the search terms specified, and the date range of the databases, results between 2 literature searches may vary considerably.

The initial search may produce 5000 ‘hits.’ That number of citations rarely is useful, and it certainly would be time consuming to properly read and vet each one. Simply redefining and focusing the search will possibly provide clearer information. Conversely, an initial search of 5 hits may not be useful, unless the topic is rarely reported. Again, refocusing and redefining the search terms may be needed.

Sometimes, despite the skill of the searcher and the inclusion of the appropriate terms and databases, key references will be missed. New literature may be published after the search is completed and the project is underway, but inclusion of subsequently discovered papers is both useful or necessary to provide fair balance or to strengthen the paper or regulatory submission. I certainly encourage their inclusion with a statement to the effect that x number of citations were known to the authors and were included; for complete transparency, I would directly reference these papers in the body of the text (see the study by Welch and Foote² for an example of this technique).

EXPLICATION

It is not feasible to provide results of an actual literature search, but I have provided an example of its reporting.

A literature search was done by information specialists in the Able Acme Pharmaceutical Company (New York, NY) library. The search was entitled “Lipid and glucose values in nonreproducing or non-fertile patients.” The literature databases searched on January 23, 2007, were MEDLINE (MEYY and ME95), CANCERLIT (CANC), EMBASE (EMYY

and EM95), and EMBASE ALERT (EMBA). The publication date coverage was 1989 to 2007, with no language restrictions. The patient population included men and women.

Seventy-two citations were found. The abstracts for all citations were read, and if the abstract was relevant, a full copy of the article was obtained. Fifty-eight articles were considered relevant; however, 43 articles were discovered to be laboratory and nonclinical studies, and these articles were not summarized. The remaining 15 articles were read, and the following information was abstracted: objective; patient population; glucose ranges; lipid range; and conclusion, as stated in the article.

Additionally, the reference sections of these articles were read, and four articles not appearing on the original search were identified.

TAKE-HOME LESSON

A good literature search is invaluable to authors preparing comprehensive review articles and is necessary when attempting to convince regulatory agencies that published literature supports your submission. The hallmarks of a good literature search include the following:

- Documented databases, dates of search, and search terms;
- Careful selection of articles based on abstracts found;

- Accounting of all references found, vetted, and used, as well as accounting of references found outside the search; and
- Uniform abstraction or summation of all articles cited.

By using a few standardized processes, you will be able to confidently back up your statements that indeed “the literature does show” that your statements in a review article, original research article, or a regulatory submission are known to specific scientists, even if not to everyone.

ACKNOWLEDGMENTS

Financial/nonfinancial disclosures: The authors have reported to the ACCP that no significant conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Other contributions: Susan Siefert, Linda Fossati Wood, and Jim Yuen were kind enough to review the manuscript and offer excellent suggestions and comments.

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